



Environmental Health & Safety
 100 EHS
 Iowa City, IA 52242 – 1000
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Date: January 3, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of January 3, 2013

Members Present: Drs. Adam Clore, Paul Cooper, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, Michael Pentella and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Leonard Duncan and Jeffery Meier

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on December 20 2012**
 No suggestions for changes in the circulated minutes were made. Dr. Clore made a motion, seconded by Ms. McGhan, to approve the minutes of the December 20, 2012, meeting. The members voted unanimously for approval.
2. **rDNARDS under review:**
 The rDNARDS being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARDS and reviewed them prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following nine rDNARDS were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	N. Spencer	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

rDNA#	PI	rDNA Registration Document Title
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[REDACTED]	M. Wilson	[REDACTED]
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- The [REDACTED] rDNA [REDACTED] the [REDACTED] will occur [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA#	PI	rDNA Registration Document Title
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[REDACTED]	A. Lee	[REDACTED]
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- The goal of this project [REDACTED] the function of [REDACTED] channels
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

Voters approved [REDACTED] abstained [REDACTED]

rDNA#	PI	rDNA Registration Document Title
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[REDACTED]	J. Meier	[REDACTED]
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- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

Voters approved [REDACTED] abstained [REDACTED]

rDNA#	PI	rDNA Registration Document Title
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[REDACTED]	D. Lubaroff	[REDACTED]
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- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

Voters approved [REDACTED] abstained [REDACTED]

3. Old Business

- a) Additional information was provided to the committee by Dr. White regarding the request of Dr. Ibrahim Ozobolat (Department of Mechanical and Industrial Engineering) to use a bioprinter in a vertical laminar flow clean bench rather than in a biosafety cabinet (BSC). The PI has proposed that he move the printer into the BSC when human cells are used and subsequently decontaminate the outer portion of the printer with UV light and ethanol. The syringes and inner tubing are disposable and would be disposed of in a biohazardous waste container. Following decontamination of the printer and disposal of the syringes and inner tubing, the printer will be moved from the BSC to the clean bench for use with animal cells. The preparation of all cell samples and loading of syringes will be done in the BSC.

The committee asked about the size of the printer and if it likely will affect the airflow in the BSC adversely. Prior to the meeting Dr. White attempted to contact the technical manager at ENV to address this question but was unable to obtain a response. The printer is not a solid piece of equipment, but rather has an open structure which likely would allow ample airflow around it and not interfere with the containment provided by the cabinet. Dr. White will work with the PI to ensure that, prior to use of the printer with human cells inside the BSC, airflow testing is performed by the ENV technician to establish that when the printer is inside the BSC airflows are not affected adversely. The PI is aware of the annual certification requirement of the BSC.

No further concerns were raised by committee members regarding the use of the bioprinter in the BSC when human cells are used assuming that it is established that the airflow of the BSC provides appropriate containment and the PI follows the procedures outlined here.

4. New Business

- a) Dr. Sinn reported on one amendment to a previously-approved rDNARD that was approved by Dr. Dr. Sinn since the last meeting.
- Dr. Lentz, #120262 was amended to include an additional staff member.
- b) Dr. Sinn informed the committee that [REDACTED] was completed at the [REDACTED] [REDACTED] last month and that the report will be sent out to committee members following this meeting.
- c) Dr. Kirchhoff reported on his recent efforts to ensure that all non-exempt rDNA research being conducted at the UI is reviewed and approved by the IBC as required under the *NIH Guidelines*. Currently, the University has a two-tier system under which research involving rDNA is either registered and approved by the IBC or deemed exempt from registration under the *NIH Guidelines*. Prompted by a PI's recent uninformed and baseless claim that his rDNA research was exempt from registration, Dr. Kirchhoff conducted telephone interviews with six PIs whose claims for exemptions from the requirement for registration had been accepted by EHS in the past and who did not have active IBC-approved rDNARDS. Only one of the six PIs interviewed was able to provide appropriate justification for the exemption based on the narrow provisions in the *NIH Guidelines* that relate to exemptions and thus appeared to be in compliance. The other five PIs were unable to provide justification for their exemptions based on the relevant provisions in the *NIH Guidelines* and thus appeared to be non-compliant either in the past or currently.

Subsequent to Dr. Kirchhoff's telephone interviews with the PIs, Dr. Walker held a meeting with Drs. Sinn, White, and Kirchhoff, as well as Ms. McGhan, to discuss how best to eliminate instances of non-compliance resulting from inappropriate claims for exemptions from the requirement for registration. A basic problem in the current process for exemptions is the conflict of interest inherent in allowing PIs to make the determinations that their rDNA research is exempt. The possibility of developing a more rigorous administrative procedure for processing requests for exemptions that would ensure compliance was discussed at length. The group concluded that a procedure for processing and monitoring exemptions that would ensure compliance with the *NIH*

Guidelines would require as much, if not more, work for both the PIs and EHS staff as would registering the proposed rDNA experiments through the usual process. Having reached this conclusion, and also considering the fact that requests for exemptions from the requirement for registration are quite rare, it was decided unanimously that the option of obtaining exemptions from registration of proposed experiments involving rDNA should be eliminated. The group felt that moving to a single-tier system under which PIs would have to register all proposed rDNA research through the smoothly-functioning electronic system maintained by EHS would be administratively less onerous for all parties involved and at the same time ensure compliance with the *NIH Guidelines*

Committee members were asked to consider this proposal for further discussion at our next meeting. Any questions should be addressed to Dr. Kirchhoff or Biosafety Staff.

The next meeting will be held at 3:30 p.m. on January 17, 2013.

The meeting adjourned at 4:05 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: January 17, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of January 17, 2013

Members Present: Drs. Adam Clore, Paul Cooper, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Jeffery Meier, Michael Pentella and Ms. Carol McGhan

Members Absent: Drs. Leonard Duncan, Maria Martino-Cardona and Haley Sinn

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:35 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on January 3 2013**
 No suggestions for changes in the circulated minutes were made. Dr. Clore made a motion, seconded by Ms. McGhan, to approve the minutes of the January 3, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDS under review:**
 The rDNARDS being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARDS and reviewed them prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following nine rDNARDS were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	R. Weigel	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

rDNA# PI rDNA Registration Document Title
[redacted] D. Spitz [redacted]

- [redacted] of glucose metabolic differences and [redacted] leading to develop [redacted] and [redacted] nodules, [redacted] of heat, head and neck [redacted]
 - [redacted]
 - [redacted]
 - [redacted]
 - [redacted] that the above listed [redacted] have been met
- [redacted]

rDNA# PI rDNA Registration Document Title
[redacted] M. Wilson [redacted]

- [redacted]
 - [redacted]
 - [redacted]
 - [redacted]
 - [redacted]
 - [redacted]
 - [redacted]
 - [redacted]
- [redacted]

rDNA# PI rDNA Registration Document Title
[redacted] D. Lubaroff [redacted]

- [redacted]
 - [redacted]
 - [redacted]
 - [redacted]
 - [redacted]
 - [redacted]
- [redacted]

Dr. Jones joined the meeting at this time.

rDNA# PI rDNA Registration Document Title
[redacted] E. Fuentes [redacted]

- [redacted]
 - [redacted]
 - [redacted]
- [redacted]

[REDACTED]

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	S. Russell	[REDACTED]

[REDACTED]

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	B. Davidson	[REDACTED]

[REDACTED]

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	B. Amendt	[REDACTED]

[REDACTED]

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	A. Burnett	[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

The second part of the meeting was open to the public.

3. Old Business

- a) Dr. Kirchhoff summarized the issues relating to the proposal he presented to the IBC at its last meeting, under which all experiments involving rDNA, including experiments exempt from registration under the *NIH Guidelines*, would have to go through the IBC's registration and approval process. Dr. Jones voiced his general concern about the increasing amount of time PIs have to spend dealing with regulatory requirements and also stated his expectation that the adoption of the proposed single-tier system would further increase this burden for PIs doing exempt rDNA work. In response, Dr. Kirchhoff explained that since almost all of the PIs he contacted who had obtained exemptions from registration currently were or had been noncompliant with the *NIH Guidelines*, a more rigorous procedure for processing PI requests for exemptions would have to be developed to ensure compliance. He further stated that such an expanded process for review of requests for exemptions would involve more administrative time on the part of the PIs and also would involve an increased burden for EHS staff. Ms. McGhan stated her agreement with this latter perspective and mentioned that information presented at meetings of the American Biological Safety Association (ABSA) and discussions with counterparts at other academic institutions indicate that roughly half of them have single-tier systems such as that proposed. She and Dr. Kirchhoff reiterated the fact that only a very small number of PIs currently are doing exempt rDNA research. Ms. McGhan then further explained that EHS staff expect that moving to a single-tier system under which PIs would have to register all proposed rDNA research through the electronic system maintained by EHS would be administratively simpler for PIs and at the same time ensure compliance with the *NIH Guidelines*.

Dr. Kirchhoff summarized the changes in the UI's processes and documents that would have to be made following the IBC's approval of the single-tier proposal:

- Revision of the routing form to remove the question that asks if the proposed rDNA work is exempt from the *NIH Guidelines*, in addition to revision of the letter that is generated in response to an indication that the proposed work involves rDNA or synthetic nucleic acids;
- Revision the annual EHS audit form;
- Notification through email to all PIs of this change, explaining that it will ensure compliance with the *NIH Guidelines* and reduce the time required for PIs to obtain approval for their proposed rDNA work;
- Publishing an article in the *EHS LabNews* that explains the change in procedure;
- Revision of the rDNA training course;
- Revision of the rDNA manual; and
- Revision of the IBC SOP

Dr. Clore made a motion, seconded by Dr. Meier, to require that all work with rDNA and synthetic nucleic acids be registered with the IBC, even that which is considered exempt from registration under the *NIH Guidelines*.

- b) Ms. Kratz provided additional information or clarification that was received from the PI regarding the following rDNARDs and was judged to be satisfactory:
- Dr. Sigmund, #120318, clarified that AAV work is not part of this protocol.
 - Dr. Legge, #120319 provided his staffs' experience working with the virus and rDNA, added vaccinia and listeria as hosts to the table and removed vaccinia strain PPL-2.
 - Dr. Domann, #120329, confirmed that Ad-CMV is a shuttle plasmid, not a viral vector and also that this work will be done in *E coli* at BSL1.
 - Dr. Lee, #120341, added the suggested antibiotic gene blasticidin.

4. New Business

- a) Ms. McGhan reported on five amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff since the last meeting.
- Dr. Perlman, #110088 was amended to include an additional staff member additional inserts to the SARS-CoV work he's doing in BSL3 (which includes monkey cell lines and mice), and added work with vaccinia virus (WR) strain in rabbit cell lines and mice.
 - Dr. Erives, #130102 was amended to add addition vectors, e.g., pBluescript and similar vectors into *Drosophila* – all at BSL1.
 - Dr. Lalumière, #100138 was amended to include additional inserts (ASIC 1a and GFP) for his approved work with AAV in rats.
 - Dr. Davidson, #100173, was amended to include the Rheb gene as an insert to her extensive list of inserts used with plasmid and viral work that is done in cell lines, animals, and *E coli*.
 - Dr. Kirby, #110067 was amended to include inserts from *Staphylococcus aureus* and *S. aureus* as a host, along with adding staff.
- b) Registration of rDNA projects at the Transgenic and Genome Manipulation Core (combined Transgenic and Knockout cores)

Dr. Phillip Sanford, director of the new Transgenic and Genome Manipulation Core would like to have blanket approval to perform specific work in the core. He provided Dr. White with a list of four types of projects that he would like to have included under such blanket approval, and Dr. White summarized the projects for the IBC. Dr. Kirchhoff requested that Dr. White work with Dr. Sanford to refine his proposal such that it is a formal request that succinctly states what his proposal is and what work would be excluded. Dr. White will present Dr. Sanford's revised proposal at a future IBC meeting.

The next meeting will be held at 3:30 p.m. on January 31, 2013.

The meeting adjourned at 4:27 p.m.

Minutes submitted by: Carol McGhan, MPH, CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



Environmental Health & Safety
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Date: January 31, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of January 31, 2013

Members Present: Drs. Paul Cooper, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, Michael Pentella, Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Adam Clore and Jeffery Meier

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:36 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

- Approval of minutes from meetings on January 17, 2013**
 No suggestions for changes in the circulated minutes were made. Dr. Martino-Cardona made a motion, seconded by Dr. Jones, to approve the minutes of the January 17, 2013, meeting. The members voted unanimously for approval.
- rDNARDs under review:**
 The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following ten rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	M. Milhem	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED] that the above listed criteria, drawn from the [REDACTED] [REDACTED] have been [REDACTED]

rDNA# **PI** **rDNA Registration Document Title**
[REDACTED] S. Gopishetty [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] DGL 1 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] I-0 obtained

rDNA# **PI** **rDNA Registration Document Title**
[REDACTED] D. Soll [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] DGL 1 [REDACTED]
[REDACTED] H.D. 4
[REDACTED]
[REDACTED]
[REDACTED] I-0 obtained

rDNA# **PI** **rDNA Registration Document Title**
[REDACTED] D. Soll [REDACTED]

[REDACTED] may be to determine [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] at DGL 1 due to [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] I-0 obtained

rDNA# **PI** **rDNA Registration Document Title**
[REDACTED] S. Janz [REDACTED]

[REDACTED] gene function as it relates to development and growth [REDACTED]
[REDACTED]
[REDACTED] DGL 1 [REDACTED]
[REDACTED] H.D. 3
[REDACTED]
[REDACTED] I-0 obtained

Dr. Pentella joined the meeting at this time.

rDNA# PI rDNA Registration Document Title
[REDACTED] M. Blumberg [REDACTED] of cerebellar activity in human

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] S. Janz [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] A. Mark [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] L-S. Song [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]



Environmental Health & Safety
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Date: February 14, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of February 14, 2013

Members Present: Drs. Adam Clore, Paul Cooper, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Maria Martino-Cardona, Jeffery Meier and Michael Pentella

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:36 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. Approval of minutes from meetings on January 31, 2013

No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Duncan, to approve the minutes of the January 31, 2013, meeting. The members voted unanimously for approval.

2. rDNARDS under review:

The rDNARDS being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARDS; however, Dr. Cooper indicated that he had not had time to review the rDNARDS prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following fifteen rDNARDS were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	R. Smith	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED], 0 opposed, 0 abstained

rDNA# PI rDNA Registration Document Title
12002 B. Amendt [REDACTED] during [REDACTED] at

[REDACTED] learn more [REDACTED] [REDACTED]
[REDACTED]
Discussion [REDACTED]
[REDACTED]
[REDACTED]
By its majority vote, the committee [REDACTED] [REDACTED]
[REDACTED] have been met.
[REDACTED] 0 approved, 0 opposed, 0 abstained

Dr. Clore joined the meeting at this time.

rDNA# PI rDNA Registration Document Title
[REDACTED] P. Brophy [REDACTED] and [REDACTED] [REDACTED]
[REDACTED]

[REDACTED] [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] et.
[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] M. Anderson [REDACTED]

[REDACTED] [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] J. Fairley [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] A. Naderi [REDACTED]

cancer in the brain (Brain Expressed Transmembrane Signaling Protein).
 [Redacted]
 [Redacted]
 [Redacted]
 [Redacted]

rDNA#	PI	rDNA Registration Document Title
[Redacted]	S. Perlman	[Redacted]

This project is to use a [Redacted] [Redacted] [Redacted]
 [Redacted]
 [Redacted]
 [Redacted]
 [Redacted]

rDNA#	PI	rDNA Registration Document Title
[Redacted]	D. Rutkowski	[Redacted]

[Redacted]
 [Redacted]
 [Redacted]
 [Redacted]
 [Redacted]
 [Redacted]

rDNA#	PI	rDNA Registration Document Title
[Redacted]	R. Cornell	[Redacted]

[Redacted]
 [Redacted]
 [Redacted]
 [Redacted]
 [Redacted]
 [Redacted]

rDNA#	PI	rDNA Registration Document Title
[Redacted]	A. Dupuy	[Redacted]

[Redacted]
 [Redacted]
 [Redacted]
 [Redacted]

[REDACTED] affirmed that the above listed study, [REDACTED] NIH Guidelines, have been met.
[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] W. Moye-Rowley [REDACTED]

- [REDACTED] of this project is to study the oncogene specific folding of [REDACTED].
- [REDACTED] the committee requested that a statement be added [REDACTED] [REDACTED] genes or oncogenes will be [REDACTED], [REDACTED] staff will [REDACTED] [REDACTED] [REDACTED] of the revision.
- [REDACTED]
- [REDACTED]
- [REDACTED] the committee affirmed that the above listed study, [REDACTED] NIH Guidelines, have been met.
[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] A. Dupuy [REDACTED]

- [REDACTED] of this project is to identify cancer genes in [REDACTED].
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED] the committee affirmed that the above listed study, [REDACTED] NIH Guidelines, have been met.
[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] A. Russo [REDACTED]

- [REDACTED] of this project is to understand the control of gene expression in the mammalian nervous system in response to [REDACTED].
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED] the committee affirmed that the above listed study, [REDACTED] NIH Guidelines, have been met.
[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] R. Smith [REDACTED]

- [REDACTED] of this project is to produce recombinant GEL and GELP-CPHS protein from yeast and [REDACTED].
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED] the committee affirmed that the above listed study, [REDACTED] NIH Guidelines, have been met.
[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] W. Johnson [REDACTED]

Prior to today's IBC meeting, Dr. Walker was informed of the non-compliance and met with Drs. Kirchhoff, Sinn, and White and Ms. McGhan to discuss the issue. After careful review of the history of containment levels used for the HSV-1-injected mice, the group concluded that this constitutes non-compliance that must be reported to NIH/OBA as a violation. The committee discussed the event and the details of both ABSL2a and ABSL2c housing containment. Dr. Cooper made a motion, seconded by Dr. Jarosinski, to report the non-compliance event to NIH/OBA. The members voted unanimously for approval. Drs. Kirchhoff and Sinn will draft a report using the NIH reporting template; the draft report will be sent to committee members prior to the next meeting for final review and approval. Dr. Kirchhoff will inform the PI that this event will be reported to NIH/OBA.

Subsequent to the initial meeting with Dr. Sinn, the PI submitted an amendment request to house HSV-1-injected mice at ABSL1 containment. The request was sent to all committee members prior to the meeting. Dr. Kirchhoff gave a brief overview of how other institutions are housing HSV infected animals and also an overview of the PI's statement that the vector is replication defective due to an interruption of the TK gene.

The committee further discussed the shedding experiments performed by the laboratory and concluded that additional information is required before the amendment can be considered further. Drs. Kirchhoff and Sinn will draft a letter requesting additional information on both the experiments performed to evaluate shedding of the vector and the detailed maps of the recombinant HSV-1 strains Dr. Sluka uses in her experiments.

The next meeting will be held at 3:30 p.m. on February 28, 2013.

The meeting adjourned at 4:37 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



Environmental Health & Safety
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 Fax 319-335-7564

Date: February 28, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of February 28, 2013

Members Present: Drs. Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Jeffery Meier, Maria Martino-Cardona and Ms. Carol McGhan

Members Absent: Drs. Adam Clore, Paul Cooper, Leonard Duncan, Michael Pentella, and Haley Sinn

Guest Present: Mrs. Deborah Kratz

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:34 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

- Approval of minutes from meetings on February 14, 2013**
 No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Meier, to approve the minutes of the February 14, 2013, meeting. The members voted unanimously for approval.
- rDNARDS under review:**
 The rDNARDS being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDS prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following five rDNARDS were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	F. Sutterwala	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

rDNA# **PI** **rDNA Registration Document Title**
130048 F. Sutterwala ~~High mammalian signaling in human responses to Gamma~~
~~Heroin~~

- The goal of this study is to provide molecular understanding of how G-proteins activates the ~~MAP3~~
~~kinase~~ which will be potentially augmented based on the immune system cells
signal pathway.
- ~~Discovered that~~
- ~~A mammalian containment: DDE and TDE~~
- ~~GI-15~~
- ~~By using jerry vote, the committee affirmed that the above listed criteria, drawn from the~~
~~containing, have been met.~~
- Vote: 6 opposed, 0 abstained

rDNA# **PI** **rDNA Registration Document Title**
130049 B. Davidson ~~Production of antibodies to~~

- The goal of this study is to ~~provide molecular understanding of~~
- ~~Discovered that~~
- ~~It was noted that the above listed criteria, drawn from the~~
~~Davidson's~~
~~broader~~
~~containing, have been met.~~
- ~~A mammalian containment: DDE~~
- ~~GI-15~~
- ~~By using jerry vote, the committee affirmed that the above listed criteria, drawn from the~~
~~containing, have been met.~~
- Vote: 6 opposed, 0 abstained

rDNA# **PI** **rDNA Registration Document Title**
130052 C. Grueter ~~Production of antibodies to~~

- ~~The goal of this study is to~~
- ~~Discovered that~~
- ~~By using jerry vote, the committee affirmed that the above listed criteria, drawn from the~~
~~containing, have been met.~~
- Vote: 11 opposed, 0 abstained

rDNA# **PI** **rDNA Registration Document Title**
130053 D. Bonthuis ~~Production of antibodies to~~

- ~~The goal of this study is to~~
- ~~Discovered that~~
- ~~By using jerry vote, the committee affirmed that the above listed criteria, drawn from the~~
~~containing, have been met.~~
- Vote: 11 opposed, 0 abstained

The second part of the meeting was open to the public.

3. Old Business

- a) The draft report to NIH/OBA detailing Dr. Sluka's non-compliance event was sent to committee members prior to the meeting.

Dr. Kirchhoff discussed the report and asked for comments. Ms. McGhan noted a couple of minor editing changes that she would send Dr. Kirchhoff; Dr. Martino-Cardona noted that changes to the ACURF that were mentioned in the report are not finalized, as the online form is being beta-tested prior to implementation and it could be mid-year before the form is finalized. Dr. Kirchhoff will revise the report to reflect this.

Dr. Jarosinski made a motion, seconded by Dr. Martino-Cardona to send the revised report to NIH/OBA.

Vote: 6 approved, 0 opposed, 0 abstained

- b) Additional information requested from Dr. Sluka regarding her amendment request to house HSV-1 infected mice at ABSL1 was sent to committee members prior to the meeting.

Dr. Kirchhoff discussed at length Dr. Sluka's response. Just prior to the meeting, additional information had been sent to Drs. Kirchhoff and Sinn by Dr. Sluka in an email stating that a collaborator had provided information regarding the virulence of the HSV vector and that it was 10,000 times less neurovirulent than the wild type; however, neither the collaborator's name nor any scientific data were provided. Regarding Dr. Sluka's assertion that no leakage or shedding of the virus occurred after the mouse was injected with the rHSV-1, data were not provided to support that claim. After an extensive discussion about the lack of scientific data, it was decided to table this request until more information could be obtained about the projected number of animals that would need to be potentially housed at ABSL2c, and for what period of time they would need to remain in ABSL2c containment before allowing them to move into ABSL1.

Dr. Jones made a motion, seconded by Ms. McGhan, to table this amendment request.

Vote: 6 tabled, 0 opposed, 0 abstained

- c) Dr. Kirchhoff discussed the new requirement to register all rDNA work that is exempt under the *NIH Guidelines* and whether or not this should include the cross-breeding of transgenic/knockout rodents that can be maintained at ABSL1 containment. After a brief discussion, the committee agreed that because the issue of cross-breeding of such rodents is not ambiguous and does not present the same concerns as other types of rDNA research, the cross breeding of transgenic/knockout rodents contained at ABSL1 will not require registration with the IBC.

Dr. Meier made a motion, seconded by Dr. Jones, to exempt this work from IBC registration.

Vote: 6 approved, 0 opposed, 0 abstained

4. New Business

- a) Ms. McGhan reported on five amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
- Dr. Legge, #120319 was amended to include IP and IV as routes of administration.
 - Dr. Moore, #110082 was amended to include a research assistant.
 - Dr. Salem, #120069 was amended to include a lentiviral vector and GMCSF as an insert.
 - Dr. Welsh, #110077, was amended to include siRNA for the inserts listed within his protocol.

- Dr. Henry, #100145, was amended to include Cre-AAV and new staff members.
- b) One IRB reportable event related to an approved rDNARD was sent to committee members prior to the meeting. Dr. Lubaroff had submitted this report for an administrative reason, and not one related to an adverse event or patient illness. The committee had no concerns about the reported change to the protocol.

The next meeting will be held at 3:30 p.m. on March 14, 2013.

The meeting adjourned at 4:11 p.m.

Minutes submitted by: Carol McGhan, MPH, CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



Environmental Health & Safety
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Date: March 14, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of March 14, 2013

Members Present: Drs. Adam Clore, Keith Jarosinski, Louis Kirchhoff, Jeffery Meier, Maria Martino-Cardona and Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Paul Cooper, Leonard Duncan and Bradley Jones

Guest Present: Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:32 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on February 28, 2013**
 No suggestions for changes in the circulated minutes were made. Dr. Martino-Cardona made a motion, seconded by Dr. Meier, to approve the minutes of the February 28, 2013, meeting. The members voted unanimously for approval.
2. **rDNARDS under review:**
 The rDNARDS being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDS prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following seven rDNARDS were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	G. Lal	[REDACTED]

- [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
- Vote: 7 approved, 0 opposed, 0 abstain

- The goal of this project is to understand the expression pattern and physiological role of [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	K. Campbell	[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

The second part of the meeting was open to the public.

3. Old Business

- a) Dr. Sinn informed the committee that Dr. Sluka has not provided any data to support her statements that there is no shedding of HSV-1 2-4 weeks after the initial injection of the rodents used in her studies. Dr. Sluka will review old files in an attempt to find such data but at this time the committee's request for additional information has not been fulfilled.

Ms. McGhan made a motion, seconded by Dr. Martino-Cardona, to disapprove Dr. Sluka's request for an amendment to lower containment of HSV-1 infected animals from ABSL2a to ABSL1.
 Vote: 7 approved, 0 opposed, 0 abstained

Dr. Sluka has inquired as to what data the committee would find acceptable to re-review her amendment request to lower containment of her animals to ABSL1. The committee stated that samples should be taken at the surgical site in a short time frame after injection, including 6 hours, 2 and 5 days and then longer time frames of 2 and 4 weeks. PCR testing was also requested by the committee. Drs. Kirchhoff and Sinn will prepare an email to send to Dr. Sluka describing possible experiments that she can perform.

4. New Business

- a) Dr. Sinn reported on five amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
 - Dr. Stapleton, #120021 was amended to an infectious clone of HCV and GBV-C viruses.
 - Dr. Potthoff, #120140 was amended to include a FGF21 co-receptor insert and additional staff.
 - Dr. Wu, #120029 was amended to include DH5 α *E.coli* and HEK293 cells as hosts.
 - Dr. Hammond, #120179, was amended to include AAV as a vector, opsin and marker inserts additional routes of administration to animals and additional staff.
 - Dr. Johnson, #110062, was amended to include additional staff.

- b) One IRB reportable event related to an approved rDNARD was sent to committee members prior to the meeting. This report covers similar protocol deviations previously submitted by Dr. Lubaroff;

the report does not involve an event related to the recombinant vector. The committee had no concerns about the reported change to the protocol.

The next meeting will be held at 3:30 p.m. on March 28, 2013.

The meeting adjourned at 4:00 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: March 28, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of March 28, 2013

Members Present: Drs. Paul Cooper, Leonard Duncan, Bradley Jones, Louis Kirchhoff, and Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Adam Clore, Keith Jarosinski, Maria Martino-Cardona and Jeffery Meier

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:40 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

- Approval of minutes from meetings on March 14, 2013**
 No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Cooper, to approve the minutes of the March 14, 2013, meeting. The members voted unanimously for approval.
- rDNARDs under review:**
 The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDs prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following eight rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
15005	P. Sanford	[REDACTED]
		<ul style="list-style-type: none"> The goals of this project are to... Dr. Cooper informed the committee that Dr. Sanford is listed as PI on the annual... Dr. Cooper is listed as the PI there. While... ...

- Dr. Dupuy, #120181 was amended to include a replication defective AAV vector.
 - Dr. Smith, #120320 was amended to include several additional inserts from the mouse.
 - Dr. Maury, #120060, was amended to include guinea pigs as a host.
 - Dr. Comellas, #120002 and 120212, was amended to include an additional staff member.
- b) Dr. Sinn discussed an amendment request submitted by Dr. Maury, rDNARD #120057, and forwarded to the committee prior to the meeting. Dr. Maury's request to add guinea pigs to her pseudovirion protocol (#120060) was approved as noted above. She also requested that the containment be reduced from ABSL2a to ABSL1 following VSV pseudovirion administration since the virions are replication defective. The committee agreed with the administration of the pseudovirions and inclusion of additional glycoproteins in the protocol but did not reduce the animal biocontainment level for VSV pseudovirions. Dr. Sinn will contact Dr. Maury's collaborators at Texas Biomedical Research Institute (TBRI) to obtain more information on the replication defective nature of the pseudovirions. An additional concern was raised in that Dr. Maury will ship the immunized animals to TBRI and the committee requested assurance that the animals are not considered infectious following immunization.

The next meeting will be held at 3:30 p.m. on April 11, 2013.

The meeting adjourned at 4:12 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: April 11, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of April 11, 2013

Members Present: Drs. Adam Clore, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Paul Cooper, Bradley Jones, and Jeffery Meier

Guest Present: Mrs. Deborah Kratz

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on March 28, 2013**
 No suggestions for changes in the circulated minutes were made. Ms. McGhan made a motion, seconded by Dr. Martino-Cardona, to approve the minutes of the March 28, 2013, meeting. The members voted unanimously for approval.
2. **rDNARDS under review:**
 The rDNARDS being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDS prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following five rDNARDS were considered:

rDNA#	PI	rDNA Registration Document Title
10001	X. Zhu	[REDACTED]
		[REDACTED]
		[REDACTED]
		[REDACTED]
		[REDACTED]

[REDACTED]

rDNA# **PI** **rDNA Registration Document Title**
[REDACTED] M. Anderson A [REDACTED] mouse [REDACTED]

[REDACTED] mouse [REDACTED] laboratory staff with [REDACTED] safety staff
[REDACTED] Anderson and [REDACTED] necessary
[REDACTED] containment [REDACTED]
[REDACTED] that the above [REDACTED] from the [REDACTED]
[REDACTED] approved, 0 opposed, 0 abstained

rDNA# **PI** **rDNA Registration Document Title**
[REDACTED] M. Wilson [REDACTED] Macrophage-Activating [REDACTED]

[REDACTED] trigger(s) determining [REDACTED]
[REDACTED] will occur after [REDACTED]
[REDACTED] Assays of [REDACTED] and [REDACTED]
[REDACTED] that the above listed criteria drawn from the [REDACTED]
[REDACTED] 7 approved, 0 opposed, 0 abstained

rDNA# **PI** **rDNA Registration Document Title**
[REDACTED] D. Mohapatra [REDACTED] laboratory [REDACTED] on
[REDACTED] TRP, [REDACTED] by [REDACTED] and [REDACTED] E
[REDACTED] proteins by diverse [REDACTED] signaling

[REDACTED] voltage-gated [REDACTED] channels
[REDACTED] neurons
[REDACTED] signaling [REDACTED]
[REDACTED] receptors [REDACTED]
[REDACTED] of [REDACTED]
[REDACTED] of [REDACTED]
[REDACTED] of [REDACTED]
[REDACTED] of [REDACTED] from the [REDACTED]
[REDACTED] approved, 0 opposed, 0 abstained

rDNA# **PI** **rDNA Registration Document Title**
[REDACTED] R. Lalumiere [REDACTED]

[REDACTED] project is [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

The second part of the meeting was open to the public.

3. Old Business

a) Dr. Sinn provided additional information or clarification that was received from the PI regarding the following rDNARDs and was judged to be satisfactory:

- Dr. Sanford, #130039, clarified that he has assumed the role of Facility Director of the Transgenic Animals and Genome Manipulation Facility.
- Dr. McCarter, #130059 provided information regarding the tetracycline resistance gene used in *V. parahaemolyticus*. Dr. Kirchhoff provided an overview of the information; the gene is tetA which is widely distributed in nature and has been shown to be present in a substantial portion of isolates of *V. parahaemolyticus*. Therefore, this insertion is not a major action.

b) Dr. Sinn contacted Dr. Maury's collaborators at Texas Biomedical Research Institute (TBR) in an effort to obtain more information on the replication defective nature of the VSV pseudovirions. TBR staff has not worked with this system prior and therefore was unable to provide additional information. Dr. Figler, IACUC Director, contacted colleagues at Pfizer where pseudovirion work has been done and they stated that they would house the animals at ABSL2 out of an abundance of precaution but not because they were worried about shedding.

Dr. Sinn also reported she has contacted USAMRIID and Biosafety staff at Yale but has yet to directly speak with anyone who can provide additional information.

4. New Business

a) Dr. Sinn reported on four amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.

- Dr. McCray, #120062 was amended to include several additional inserts as well as common protein tags.
- Dr. Van Daele, #120263 was amended to include a red fluorescent protein insert.
- Dr. Welsh, #110077 was amended to include stereotaxic injections in to the mouse brain.
- Dr. Giangrande, #120010, was amended to include EphA2 aptamer siRNA chimeras with or without IR dye conjugation.

b) Dr. Sinn informed the committee of a possible reportable event regarding Dr. Maury's housing of VSV pseudovirion infected mice at ABSL1. She will meet with Dr. Maury tomorrow and begin the draft report for NIH/OBA; the report and additional information will be shared with the committee at the next meeting.

c) Dr. Sinn reported that NIH/OBA responded to our last reportable event on Dr. Sluka and no additional actions or information was requested.

d) Dr. Sinn discussed the need to review the BSL3 manuals as stated in the IBC Charter. Ms. McGhan and Dr. Sinn provided information on the recent CDC inspection of our select agent program and stated that the manuals will likely undergo further revision. These revisions will be in addition to those previously made as a result of the regulatory changes in October. The committee requested that the manual review occur after the inspection report is received and all requested changes are incorporated into the manuals.

The next meeting will be held at 3:30 p.m. on April 25, 2013.

The meeting adjourned at 4:02 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: April 25, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of April 25, 2013

Members Present: Drs. Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Adam Clore, Paul Cooper, Leonard Duncan, and Jeffery Meier

Guest Present: Mrs. Deborah Kratz

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:37 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. Approval of minutes from meetings on April 11, 2013

No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Martino-Cardona, to approve the minutes of the April 11, 2013, meeting. The members voted unanimously for approval.

2. rDNARDs under review:

The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDs prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following eight rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	M. O'Donnell	[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	A. Klingelutz	[REDACTED]

■ The goal of this project is to determine how human keratinocytes become immortal
■ some after infection by human papillomavirus (HPV) type 16 (HPV-16)
■ Discussion:
■ Assessment of commercial potential:
■ By its majority vote, the committee has decided that the above information is
■ sufficient to support the registration of this project.
■ Approved by the committee on [redacted]

rDNA# PI rDNA Registration Document Title
[redacted] J. McNamara [redacted]

■ The goal of this project is to develop a novel approach for delivering the recombinant molecule
■ Discussion:
■ Assessment of commercial potential:
■ By its majority vote, the committee has decided that the above information is
■ sufficient to support the registration of this project.
■ Approved by the committee on [redacted]

rDNA# PI rDNA Registration Document Title
[redacted] S. Gopishetty [redacted] Fermentation of Glucose

■ The goal of this project is to [redacted] above
■ Discussion:
■ Assessment of commercial potential:
■ By its majority vote, the committee has decided that the above information is
■ sufficient to support the registration of this project.
■ Approved by the committee on [redacted]

rDNA# PI rDNA Registration Document Title
[redacted] S. Gopishetty [redacted]

■ The goal of this project is to [redacted]
■ Discussion:
■ Assessment of commercial potential:
■ By its majority vote, the committee has decided that the above information is
■ sufficient to support the registration of this project.
■ Approved by the committee on [redacted]

rDNA# PI rDNA Registration Document Title
[redacted] M. Henry [redacted] Glucose Proc

■ The goal of this project is to [redacted] of product
■ Discussion:
■ Assessment of commercial potential:
■ By its majority vote, the committee has decided that the above information is
■ sufficient to support the registration of this project.
■ Approved by the committee on [redacted]

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	S. Strack	[REDACTED] Neuroprotective

- [REDACTED] to identify the mechanism by which [REDACTED] impacts neuronal ability to stroke [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED] affirmed that [REDACTED]
- [REDACTED] has not
- [REDACTED] opposed [REDACTED]

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	C. Frank	[REDACTED] [REDACTED]

- [REDACTED] opportunity.
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED] affirmed that the [REDACTED]
- [REDACTED] has not
- [REDACTED]

The second part of the meeting was open to the public.

3. Old Business

a) Regarding Dr. Maury's work with recombinant VSV pseudovirions, Dr. Sinn related that she contacted the Biosafety Officer at Yale University to investigate further the replication defective nature of the VSV pseudovirions. Yale researchers do not use pseudovirions but the BSO stated that with Dr. Maury's data we can determine when shedding ceases and with a risk assessment, which is provided under IATA and DOT, we can select the appropriate classification for shipping. Under the regulations in the State of Connecticut, the ability to lower containment levels at Yale is hindered under the human pathogen regulation; once animals are infected with a pathogen, the animals, waste and bedding are considered infectious for the duration of the study, regardless of risk.

Dr. Sinn also stated that she spoke with a veterinarian at the Texas Biomedical Research Institute, where some of Dr. Maury's collaborators work, who in turn spoke with their IBC Chair. The Chair thought that as long as the VSV pseudovirions to which guinea pigs were exposed were replication defective they could be shipped through the usual commercial channels.

Dr. Maury previously stated that she would perform shedding experiments, if requested. The committee requested that Dr. Maury propose experimental methods to examine the animals for shedding; the committee will review the proposal and provide feedback as necessary. After shedding data are reviewed by the committee, an opinion on the proper containment of the VSV pseudovirion work will be rendered.

b) Dr. Kirchhoff discussed the draft report to NIH/OBA regarding Dr. Maury's lack of compliance with the ABSL specified in her rDNARD approved by the IBC that was distributed to committee members prior to the meeting. Minor wording changes were suggested. Dr. Kirchhoff will revise the document as suggested and send the report to NIH/OBA prior to the 30 day deadline.

4. New Business

- a) Dr. Sinn reported on six amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
- Dr. Baker, #100134 was amended to include several additional inserts.
 - Dr. Okeoma, #100257 was amended to include an adenoviral-cre recombinase vector.
 - Dr. Zhu, #120331 was amended to include additional plasmids such as pcDNA3.1, pBluescript and the antibiotic resistance gene, zeocin.
 - Dr. Rutkowski, #110203, was amended to include additional inserts related to lipid metabolism and shRNA to silence these genes.
 - Dr. Perlman, #110088 and #120125, were amended to include epitopes and structural proteins from MHV and several open reading frames from MERS-CoV.
 - Dr. Artemyev, #110150, was amended to include an additional staff member.
- b) Dr. Sinn discussed an Animal Protocol recently submitted by Dr. Engelhardt covering the infection of CF ferrets with various bacterial species. The bacterial species are not pathogenic in immunocompetent persons. Dr. Engelhardt proposed ABSL2a housing for the CF ferrets involved in these experiments. Mice in similar experiments have been approved at ABSL1. Dr. Sinn asked for input from the committee as to whether ABSL2a containment is necessary, considering the fact that the corresponding ABSL1 mice are housed in closed cages and the CF ferrets will be housed in open cages.

The committee requested that Dr. Engelhardt indicate if the ABSL2a containment was proposed to reduce the risk of cross contamination of the various bacterial strains among the CF ferrets. If this is the basis for proposing ABSL2a containment, then the CF ferrets can be housed at ABSL2a without further input from the committee. If on the other hand if cross contamination is not the issue, the committee requested that Dr. Engelhardt submit a proposed containment protocol to the IACUC and the IBC for review.

The next meeting will be held at 3:30 p.m. on May 9, 2013.

The meeting adjourned at 4:15 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



Environmental Health & Safety
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Date: May 9, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of May 9, 2013

Members Present: Drs. Adam Clore, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Paul Cooper, Bradley Jones, and Jeffery Meier

Guest Present: Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:34 p.m.

The first part of the meeting was closed because it included discussion of proprietary research information.

Business Agenda

- Approval of minutes from meetings on April 25, 2013**
 No suggestions for changes in the circulated minutes were made. Ms. McGhan made a motion, seconded by Dr. Martino-Cardona, to approve the minutes of the April 25, 2013, meeting. The members voted unanimously for approval.
- rDNARDs under review:**
 The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDs prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following six rDNARDs were considered:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
[REDACTED]	M. Spies	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
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<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
[REDACTED]	S. Polyak	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The second part of the meeting was open to the public.

3. Old Business

Committee members received a containment proposal from Dr. Engelhardt’s lab, requesting ABSL1 housing for ferrets infected with bacterial strains that are non-pathogenic in the absence of immunosuppression. The committee discussed the bacterial strains and concluded that the strains were a benign group of agents for humans but could cause a health issue for the CF ferrets; however, the ferrets in this study would be susceptible to any agent that a wild-type animal, housed in the same room, might carry. The committee concluded that ABSL1 housing would be appropriate as these bacteria strains are not pathogenic for humans and the researcher is not concerned with the organisms passing among the co-housed ferrets.

Dr. Martino-Cardona made a motion, seconded by Dr. Clore, to approve the request to house ferrets infected with the indicated bacterial strains at ABSL1. The members voted unanimously for approval.

Dr. Sinn will communicate the approval with the IACUC office and inform them that a containment protocol is not necessary. Dr. Sinn will also communicate the approved containment level to Dr. Engelhardt and request that he amend his rDNARD to include *E. coli* strain EC838, as this is a recombinant strain.

4. New Business

Dr. Sinn reported on four amendments to previously-approved rDNARDs that were approved by Dr. Kirchoff or Dr. Sinn in the case of staff additions, since the last meeting.

- Dr. Dupuy, #120181 was amended to include several additional inserts expressed in adenovirus, some of which included oncogenes. Dr. Dupuy detailed additional biosafety features that were designed into these adenoviral vectors; including Cre-dependent expression of the oncogene and through sequence design, rendering shRNA non-functional against human p53.
- Dr. Shchelochkov, #120123 was amended to include additional sources of cDNA, morpholinos and an updated staff roster.
- Dr. Polyak, #120098 was amended to include administration of aptamers into mice.
- Dr. Fisher, #120093, was amended to include additional inserts involved in RGS6 signaling and shRNA.

The next meeting will be held at 3:30 p.m. on May 23, 2013.

The meeting adjourned at 3:46 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: May 28, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of May 28, 2013

Members Present: Drs. Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, Jeffery Meier and Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Adam Clore, Paul Cooper, Leonard Duncan, and Keith Jarosinski

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 4:05 p.m.

The meeting was closed because it included discussion of proprietary research information and work with select agents.

Business Agenda

1. Approval of minutes from meetings on May 9, 2013

No suggestions for changes in the circulated minutes were made. Dr. Martino-Cardona made a motion, seconded by Dr. Jones, to approve the minutes of the May 9, 2013, meeting. The members voted unanimously for approval.

2. rDNARDS under review:

The rDNARDS being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDS prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following five rDNARDS were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	M. Stamnes	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

There was no old business.

4. New Business

- a) Dr. Sinn reported on four amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
- Dr. Lee, #120116 was amended to include two shRNA expressing plasmids.
 - Dr. Wright, #120103 was amended to include siRNA inserts.
 - Dr. Engelhardt, #120019 was amended to include a recombinant E.coli to be administered to ferrets.
 - Dr. Perlman, #110079 and #110088, were amended to include an adenoviral vector expressing Dpp4 mouse protease and VEE replicon bearing the coding sequence for the MERS-CoV spike protein, respectively.
- b) Dr. Sinn briefly discussed the [REDACTED] report and the facility response sent to committee members on May 22nd, 2013. Overall, the inspection went well. Issues identified included improper signing of the log book, equipment not maintained properly, and failure to autoclave waste and remove it from the BSL3 laboratory on a daily basis. A factor possibly contributing to the identified deficiencies is the fee structure used by CCOM Administration, under which users are charged for the time they actually spend in the BSL3 laboratory. This may have the effect of causing users to rush to get out of the laboratory at the expense of their completing all tasks required by protocol. The Faculty Director and Assoc. Director of the facility are currently in discussion with CCOM Administration regarding the fee structure.

Dr. Jones made a motion, seconded by Dr. Martino-Cardona, to approve the inspection report; all members voted unanimously for approval.

- c) Dr. Sinn reported that NIH/OBA responded to our last reportable event on Dr. Maury and no additional actions or information was requested.
- d) Dr. Sinn informed the committee of an incident involving recombinant *Francisella tularensis* that occurred in the BSL3 laboratory on April 10, 2013. The risk assessment for the incident determined that no exposure resulted from the release and thus the incident was reported to CDC simply as a release of a select agent. After reviewing the report, CDC responded that the incident should be viewed as a potential exposure, regardless of PPE worn, and that as such it had to be reported to NIH/OBA. A draft report of the incident written on the NIH/OBA incident reporting template will be sent by Dr. Kirchhoff to committee members for suggestions for revision and approval. He requested that committee members respond to him by E-mail by the close of business on Thursday, May 30th, since he would like to send the report to NIH/OBA on Friday, May 31st.
- e) Dr. Sinn informed the committee of an incident involving bedding from mice that had been exposed to wild type and recombinant SARS-CoV that occurred in the BSL3 laboratory on April 18, 2013. As in the case of the incident described above involving *F. tularensis*, risk assessment for this incident determined that no exposure resulted from the release and thus the incident also was reported to CDC as a release of a select agent. In view of CDC's response to the report of the *F. tularensis* incident, however, a draft report of the incident written on the NIH/OBA incident reporting template will be sent by Dr. Kirchhoff to committee members for suggestions for revision and approval. He requested that committee members respond to him by E-mail by the close of business on Thursday, May 30th, since he would like to send this and the report mentioned above to NIH/OBA on Friday, May 31st.

As a result of these incidents and communication with CDC, Drs. Sinn and White will meet with Ms. McGhan to review our procedures regarding spills in the BSL3 laboratory. Based on CDC's

interpretation, spills will be treated as potential exposures and the relevant procedures specified in the BSL3 manuals will be modified to be consistent with this interpretation.

- f) Ms. McGhan informed the committee of an incident on May 23rd, 2013, involving the BSL3 facility. A leak from the BSL3 shower drain damaged a ceiling light in the BSL2 laboratory below. The leak was due to corrosion at metal connectors of an acid resistant pipe. The corrosion was due to weekly charging the drain with bleach. This resistant pipe was installed a year ago following leaks from the sinks in the BSL3 facility. The sink drains were never restored to their original configuration, but rather the pipes were capped and the sinks currently drain into carboys which are autoclaved out of the facility. The shower is no longer used routinely and serves as an emergency shower only. Both CCOM and FM are working to resolve the issue.

The next meeting will be held at 3:30 p.m. on June 6, 2013.

The meeting adjourned at 4:35 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: June 6, 2013
To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject: Minutes of the IBC Meeting of June 6, 2013
Members Present: Drs. Adam Clore, Paul Cooper, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, Jeffery Meier and Haley Sinn and Ms. Carol McGhan
Members Absent: No one
Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

- 1. Approval of minutes from meetings on May 28, 2013
No suggestions for changes in the circulated minutes were made. Dr. Cooper made a motion, seconded by Dr. Martino-Cardona, to approve the minutes of the May 28, 2013, meeting. The members voted unanimously for approval.
2. rDNARDs under review:
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDs prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following one rDNARD was considered:

Table with 2 columns: rDNA# PI and rDNA Registration Document Title. Row 1: [redacted] D. Quelle [redacted]

- List of bullet points describing the rDNA registration document, including details about protocols, containment, and personnel training. Most text is redacted.

[REDACTED]

Dr. Jones joined the meeting at this time.

The second part of the meeting was open to the public.

3. Old Business

Dr. Kirchhoff discussed the processing of the reports of the BSL3 incidents involving *Francisella tularensis* and SARS-CoV that were discussed at the last meeting. Final versions of the two reports were sent to committee members shortly after the last meeting for review and approval. In both cases a majority of committee members voted for approval and submission to NIH/OBA., which was done on May 29th.

4. New Business

- a) Ms. McGhan reported on six amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
 - Dr. Welsh, #110077 was amended to include an insert (Cas 9 and mutants).
 - Dr. Levasseur, #120170 was amended to include inserting Cre recombinase into an adenoviral vector for use in human and animal cells.
 - Dr. Fassler, #130080 was amended to add new hosts (*S. cerevisiae*, TOP10, and HB101) and new plasmid vectors and Topo2.1, and a new staff member.
 - Dr. Adams, #120119 was amended to add mouse inserts and a plasmid vector.
 - Dr. Colgan, #130109 was amended to add plasmid vectors, *S. cerevisiae* and inserts.
 - Dr. Cheng, #100252 was amended to add staff.

- b) Drs. Kirchhoff and Sinn discussed the issue of the appropriate containment level for mice in experiments involving recombinant methicillin-sensitive *Staphylococcus aureus* (MSSA), which currently is ABSL2. It was decided that Dr. Sinn and Ms. McGhan will contact NIH/OBA staff to discuss the possibility of housing mice exposed to MSSA strains at ABSL1. Information obtained from that conversation will be reported at a subsequent IBC meeting.

- c) Dr. White described a recent incident in which a Baker SGIII 603TX, which is a class II B2 biological safety cabinet (BSC), located in one of the BSL3 laboratories, was opened to replace the motor but was not decontaminated before the work was started. The Director of the BSL3 laboratory escorted a contractor's technician into the area where the BSC was located. The technician stated that BSCs of the type in question were designed so that they could be opened for such repairs without creating a risk of exposure to potentially contaminated areas, and thus prior decontamination was not required. Nonetheless, when the front access panel was removed to replace the motor, it was immediately evident that the area containing contaminated surfaces had been breached. The technician and the Director were both wearing the appropriate PPE (including scrubs, gown, PAPR, double gloves, dedicated shoes and shoe covers). Exposed surfaces on the inside and outside of the BSC, as well as those in the room were all disinfected as a precaution.

Since relevant personnel are currently unavailable, it is not certain exactly what procedures involving SARS-CoV had been performed in the BSC, but we know that the agent was last used in the BSC on May 11, 2013.

When contacted the following day after the incident, staff of the company that manufactured the BSC agreed to revise their manual for this BSC model to ensure that the information regarding the need for decontamination is accurate. In addition, the company servicing BSCs at the UI will revise

its procedures to ensure that all BSCs are decontaminated prior to performing the type of repair described herein.

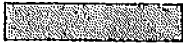
Dr. White has notified the CDC, NIH/OBA, the Iowa Department of Public Health, and the Johnson County Department of Public Health. The required follow-up reports will be sent to CDC and NIH/OBA in a timely manner and copies will be sent to the other two agencies.

The next meeting will be held at 3:30 p.m. on June 20, 2013.

The meeting adjourned at 4:04 p.m.

Minutes submitted by: Carol McGhan, MPH, CBSP

Minutes approved by: Louis V. Kirchoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: June 20, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of June 20, 2013

Members Present: Drs. Adam Clore, Paul Cooper, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn and Ms. Carol McGhan

Members Absent: Dr. Jeffery Meier

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:34 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on June 6, 2013**
 No suggestions for changes in the circulated minutes were made. Dr. Duncan made a motion, seconded by Dr. Clore, to approve the minutes of the June 6, 2013, meeting. The members voted unanimously for approval.
2. **rDNARDS under review:**
 The rDNARDS being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDS prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following five rDNARDS were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	J. Radley	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] V. Sheffield [REDACTED]

[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] S. Baker [REDACTED]

[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] W. Talman [REDACTED]

[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] G. Bishop [REDACTED]

[REDACTED]

■ [REDACTED]
■ [REDACTED]
■ [REDACTED]
[REDACTED]
[REDACTED]

The second part of the meeting was open to the public.

3. Old Business

Dr. Kirchhoff briefly discussed the draft NIH/OBA report involving the potential exposure to the BSC exhaust HEPA filter which was sent to committee members prior to this meeting. This event was reported to CDC on a Form 3 as a potential exposure, although the potential for exposure was extremely low. The root cause for this incident was the incorrect information in the manual provided by The Baker Company, the manufacturer of the BSC. Staff at The Baker Company stated that the manual for the BSC involved in the incident will be revised and that the company undercontract to service the BSCs at the UI, ENV Services, will make it standard protocol to decontaminate all cabinets on campus prior to the removal of access panels.

Dr. Jones made a motion, seconded by Dr. Duncan, to approve the report and its being sent to NIH/OBA. The members voted unanimously for approval. Dr. Kirchhoff will send an electronic version of the report to all appropriate University staff and NIH/OBA.

4. New Business

- a) Ms. McGhan reported on four amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
 - Dr. Milhem, #130008 was amended to change the dosing schedule of the adenovirus-hIL-12 vector administered to patients.
 - Dr. Potthoff, #120140 was amended to include a novel rat insert and additional staff.
 - Dr. Felder, #110012 was amended to add shRNA and a scrambled control expressed from a replication defective lentivirus also expressing GFP.
 - Dr. Campbell, #120159 was amended to include a subunit of the dihydropyridine receptor and additional staff and remove staff.
- b) Dr. Sinn reported that NIH/OBA responded to our last reportable event on the spill of medium from a cell culture plate. Apart from the delay in reporting, OBA staff opined that the event was handled appropriately.
- c) The next committee meeting will fall on July 4th; Dr. Sinn will send out a Doodle poll to determine the most convenient time to reschedule.

The meeting adjourned at 3:53 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: July 9, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of July 9, 2013

Members Present: Drs. Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Jeffery Meier and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Adam Clore, Paul Cooper, Maria Martino-Cardona,

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:34 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Introduction of new IBC member**
 Dr. Kirchhoff introduced Dr. Lucy DesJardin as a new member of the committee. Dr. DesJardin is currently a program manager at the State Hygienic Laboratory at the University of Iowa.
2. **Approval of minutes from meetings on June 20, 2013**
 No suggestions for changes in the circulated minutes were made. Ms. McGhan made a motion, seconded by Dr. Jones, to approve the minutes of the June 20, 2013, meeting. The members voted unanimously for approval.
3. **rDNARDS under review:**
 The rDNARDS being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDS prior to the meeting. Members were asked to report any conflict with the protocols under review. Dr. Jarosinski reported a conflict of interest with his protocol and will recuse himself from the voting. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following eight rDNARDS were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	F. Zhan	[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] K. Jarosinski [REDACTED] ... disease ...

- The goal of this project is to test the hypothesis that certain proteins ...
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] P. Giangrande [REDACTED] ... A17 Aptamers for ...

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] A. Horswill [REDACTED] ... signal transduction in ...

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

The second part of the meeting was open to the public.

4. Old Business

- a) rDNARDs approved at a previous IBC meeting contingent upon receipt from the PI of additional information or clarification.

Additional information or clarification was received from the PIs regarding the following rDNARDs and was judged to be satisfactory:

- Dr. Radley, rDNARD #130113, specified AAV2 and AAV5 serotypes that will be used in the project.

- b) Dr. Sinn reported that NIH/OBA responded to our last two reportable events on the spill of animal bedding and the potential exposure to the BSC exhaust HEPA filter. Apart from the delay in reporting the animal bedding incident, OBA staff opined that the event was handled appropriately.

5. New Business

- a) Dr. Sinn reported on six amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
- Dr. Adams, #120119 was amended to include a pcDNA vector and siRNA.
 - Dr. Bishop, #130133 was amended to include additional retroviral vectors, marker inserts, siRNA and micro RNAs and additional staff.
 - Dr. Zhang, #120180 was amended to include additional staff.
 - Dr. London, #120187 was amended to replace the Co-PI and add adenoviral expression of already approved inserts.
 - Dr. Xue, #120173 was amended to include additional transcription factor inserts and demethylase inserts.
 - Dr. Welsh, #110077 was amended to include additional GFP variants and mucin inserts.
- b) Dr. Kirchhoff discussed the completed form for a reportable event associated with Dr. Milhem's human gene transfer protocols that had been sent to the committee previously. The event described involved the use over five years of U.S.-sourced bovine serum in the production of the recombinant product administered to study subjects. Since U.S.-sourced bovine serum may be contaminated with the prion that causes bovine spongiform encephalopathy its use might affect the process of obtaining informed consent from study subjects. No concerns or questions regarding the issue were raised by committee members.
- c) Dr. Sinn discussed a request from Dr. Campbell to lower the animal housing containment requirements for mice exposed to mouse-adapted influenza (PR8). As the veterinarians were unable to attend this meeting, the committee requested that additional information be provided regarding Dr. Campbell's claims that PR8 cannot infect humans or be transmitted among cage-mate mice following administration. Dr. Sinn will work with both the veterinarians and Dr. Campbell to obtain additional information prior to the next meeting.

The next meeting will be held at 3:30 p.m. on July 18, 2013.

The meeting adjourned at 4:03 p.m.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: July 18, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of July 18, 2013

Members Present: Drs. Adam Clore, Lucy DesJardin, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, and Haley Sinn and Ms. Carol McGhan

Members Absent: Dr. Paul Cooper, Leonard Duncan, Maria Martino-Cardona, Jeffrey Meier

Guest Present: Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

- Approval of minutes from meetings on July 9, 2013**
 No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Ms. McGhan, to approve the minutes of the July 9, 2013, meeting. The members voted unanimously for approval.
- rDNARDs under review:**
 The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARD had time to review the rDNARDs prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following seven rDNARDs were considered:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
[REDACTED]	K. Rice	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
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[REDACTED]

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	B. Davidson	[REDACTED]

[REDACTED]

The second part of the meeting was open to the public.

3. Old Business

- a) Dr. Sinn reported that Dr. Campbell's request to house mice infected with a mouse adapted influenza virus, PR8, at ABSL1 has been withdrawn. Dr. Campbell's group will be performing parallel experiments involving a Coxsackie virus in mice that must be housed at ABSL2a and he simply prefers house all the mice in one room.
- b) Dr. Sinn reported that NIH/OBA responded to her request for information on proper containment housing for animal experiments. The following containment issues were commented on:
 - Dr. Sluka's administration of a replication defective recombinant HSV-1 to mice in muscle or joint tissue. NIH/OBA responded that moving mice from ABSL2 to ABSL1 after shedding has stopped is acceptable. Dr. Sinn will inform Dr. Sluka of NIH/OBA's response and request that if she plans to conduct shedding experiments that a detailed plan of the methodology be reviewed by the IBC prior to initiating the work. Dr. Sinn will also remind her of the obligation to obtain specific approval for such experiments from the IACUC and the IBC through the usual registration forms.
 - Dr. Maury's administration of replication defective pseudovirions to immunize mice. NIH/OBA responded that moving mice from ABSL2 to ABSL1 after shedding has stopped is acceptable. Dr. Sinn will inform Dr. Maury of NIH/OBA's response and request that if she plans to conduct shedding experiments that a detailed plan of the methodology be reviewed by the IBC prior to initiating the work. Dr. Sinn will also remind her of the obligation to obtain specific approval for such experiments from the IACUC and the IBC through the usual registration forms.
 - Challenging rodents with methicillin-sensitive *Staphylococcus aureus* (MSSA). NIH/OBA responded that housing mice at ABSL1 is acceptable provided that the

OAR staff follow the ABSL1 procedures and housing conditions specified in Dr. Sinn's letter.

4. New Business

- a) Dr. Sinn reported on three amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
- Dr. Morita, #110016 and #110072 were amended to change the location of his laboratory and office as he has now moved to the VA Medical Center.
 - Dr. Smith, #110005 was amended to include a new staff member, remove staff and add IV as a route of administration.
 - Dr. Felder, #110012 was amended to add human and mouse cell lines for the purpose of generating a replication defective lentiviral vector and testing the efficacy of the vector. An additional room was added for the use of a BSC and training for viral vector production.

The meeting adjourned at 3:50 p.m.

The next meeting will be held at 3:30 p.m. on August 1, 2013.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



Environmental Health & Safety
 100 EHS
 Iowa City, IA 52242 – 1000
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 Fax 319-335-7564

Date: August 1, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of August 1, 2013

Members Present: Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, Jeffery Meier, and Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Paul Cooper and Bradley Jones

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. Approval of minutes from meetings on July 18, 2013

No suggestions for changes in the circulated minutes were made. Dr. Clore made a motion, seconded by Ms. McGhan, to approve the minutes of the July 18, 2013, meeting. The members voted unanimously for approval.

2. rDNARDs under review:

The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and had time to review them prior to the meeting. Members were asked to report any conflict with the protocols under review. Dr. Duncan reported a conflict with rDNARD # 130162 and stated that he would recuse himself from the voting. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following six rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	M. Niki	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

The second part of the meeting was open to the public.

3. Old Business

There was no old business.

4. New Business

- a) Dr. Sinn reported on three amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
 - Dr. Maury, #120057 and #120060 were amended to remove staff, add new staff and include IM and IP as additional routes of administration.
 - Dr. Nauseef, #130134 was amended to include several additional sources of inserts, a replication defective lentivirus, additional plasmid vectors and several inserts from humans, *Drosophila*, yeast and *E.coli*.
 - Dr. Holstein, # 100333 and #110263 were amended to include additional staff.
- b) Dr. Kirchhoff introduced a conflict of interest policy for IBC members that was previously sent to committee members. The committee discussed the circumstances under which a recusal would be appropriate. Dr. Martino-Cardona made a motion, seconded by Dr. Duncan, to approve the policy as an amendment to the IBC Charter. The members voted unanimously for approval.
- c) Dr. Sinn discussed an amendment request from Dr. Perlman to rDNARD #120125 that would involve housing MHV-infected mice at ABSL1. The committee questioned Dr. Perlman's statement of his use of wild-type MHV at ABSL1 as the virus is known to be highly contagious. It was unclear if Dr. Perlman is using a variant, such as MHV-1, that is attenuated and is not transmitted to cagemates. The committee requested that additional information be provided such as the specific strain to be used in the proposed experiments and the meaning of "wild type" and "recombinant versions of the lab strain." Dr. Sinn will contact Dr. Perlman and request the additional information.

By unanimous vote, the committee tabled this amendment request.

- d) Dr. Sinn discussed a request from Dr. Gopishetty regarding a proposed project to ferment *Streptococcus oralis* at BSL2-large scale. Dr. Gopishetty was concerned with PPE and handling recommendations for the large scale fermentations. The committee did not have specific concerns with the use of *S. oralis* and asked how Dr. Gopishetty determined that this was a RG2 organism. Dr. Kirchhoff requested that an rDNARD be submitted for consideration. Dr. Sinn will inform Dr. Gopishetty of the discussion.

The meeting adjourned at 4:05 p.m.

The next meeting will be held at 3:30 p.m. on August 15, 2013.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: August 15, 2013
To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject: Minutes of the IBC Meeting of August 15, 2013
Members Present: Drs. Paul Cooper, Louis Kirchhoff, Maria Martino-Cardona, Jeffery Meier, and Haley Sinn and Ms. Carol McGhan
Members Absent: Dr. Adam Clore, Leonard Duncan, Lucy DesJardin, Keith Jarosinski, and Bradley Jones
Guest Present: Drs. James Sheets and Rachel White and Mrs. Deborah Kratz

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:39 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. Approval of minutes from meetings on August 1, 2013

No suggestions for changes in the circulated minutes were made. Dr. Martino-Cardona made a motion, seconded by Dr. Cooper, to approve the minutes of the August 1, 2013, meeting. The members voted unanimously for approval.

2. rDNARDS under review:

The rDNARDS being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the rDNARDS and had time to review them prior to the meeting. Members were asked to report any conflict with the protocols under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following seven rDNARDS were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	C-L. Cheng	[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] S. Seo [REDACTED]

- The [REDACTED] of the Rbs protein [REDACTED] physiological mechanisms [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] C. Stipp [REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] C. Thomas [REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] S. Gopishetty [REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title

- b) Dr. Sinn discussed an amendment request from Dr. McCray to rDNARD #120060 to add RSV (A2 strain) as a new vector. RSV A2 strain is a replication competent virus that has been attenuated for laboratory use. Dr. Kirchhoff explained that he had decided to send this amendment request to the full committee because RSV a major human pathogen that kills more than 10,000 persons annually in the U.S. The committee members focused on the fact that Dr. McCray had not presented any information on the transmissibility and pathogenicity of RSV A2 strain beyond to say that it is attenuated. While they felt that BSL2 containment is likely to be appropriate, they requested references and/or data relating to Dr. McCray's claim that the A2 strain is attenuated. Dr. Sinn will contact Dr. McCray and request such information.

Dr. Cooper made a motion, seconded by Dr. Martino-Cardona, to approve Dr. McCray's request to amendment rDNARD #120060 to include experiments involving RSV A2 strain as a vector for transfecting cells in culture at BSL2, pending the receipt of acceptable information regarding the attenuation of the strain. The members voted unanimously for approval.

The meeting adjourned at 4:09 p.m.

The next meeting will be held at 3:30 p.m. on August 29, 2013.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

4. New Business

- a) Dr. Sinn reported on three amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
- Dr. Jarosinski, #110215 and #130139 were amended to add and remove staff.
 - Dr. Sigmund, #120318 was amended to include protein kinase C-alpha subunit as an insert.
 - Dr. Salem, #120069, was amended to include miRNAs as an insert and new staff.

The meeting adjourned at 4:00 p.m.

The next meeting will be held at 3:30 p.m. on September 12, 2013.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: September 12, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of September 12, 2013

Members Present: Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn

Members Absent: Drs. Paul Cooper and Jeffery Meier and Ms. Carol McGhan

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on August 29, 2013**
 No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Duncan, to approve the minutes of the August 29, 2013, meeting. The members voted unanimously for approval.
2. **rDNARDS under review:**
 The rDNARDS being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the one pending rDNARD and reviewed it prior to the meeting. Members were asked to report any conflict with the rDNARD under review. No conflicts were reported. The review of the proposed research project involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following rDNARD was considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	M. Schultz	[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

- By its majority vote, the committee affirmed that the above listed criteria, drawn from the *NIH Guidelines*, have been met.

Vote: 8 approved, 0 opposed, 0 abstained

The second part of the meeting was open to the public.

3. Old Business

The committee reviewed additional information provided by Dr. Perlman in an E-mail message to Dr. Kirchhoff regarding the issue of cage-mate transmission of MHV-JHM strain. Dr. Perlman responded that the unchallenged suckling mice that were cage mates were monitored for symptoms for 10-14 days. Dr. Perlman noted that suckling mice are very sensitive to the virus. The LD50 after intracranial inoculation is less than 1 PFU so that if even 1 PFU entered the brain, the mice would die quickly. Most importantly, this virus does not infect the gut so does not have the properties of the highly-transmissible MHV strains that are the scourges of animal colonies. The committee accepted the response and no further questions were raised.

4. New Business

- a) Dr. Sinn reported on two amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions, since the last meeting.
 - Dr. Leslie, #130165 was amended to add additional inserts and staff.
 - Dr. Carter, #120129 was amended to include another replication defective lentiviral vector and additional inserts.

The meeting adjourned at 3:44 p.m.

The next meeting will be held at 3:30 p.m. on September 26, 2013.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: September 26, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of September 26, 2013

Members Present: Drs. Adam Clore, Paul Cooper, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Lucy DesJardin, Leonard Duncan, Bradley Jones, and Jeffery Meier

Guest Present: Dr. James Sheets

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:35 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

- Approval of minutes from meetings on September 12, 2013**
 No suggestions for changes in the circulated minutes were made. Dr. Martino-Cardona made a motion, seconded by Dr. Clore, to approve the minutes of the September 12, 2013, meeting. The members voted unanimously for approval.
- rDNARDS under review:**
 The rDNARDS being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the one pending rDNARD and reviewed it prior to the meeting. Members were asked to report any conflict with the rDNARD under review. No conflicts were reported. The review of the proposed research project involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following seven rDNARDS were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	M. Ascoli	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	J. Wemmie	[REDACTED]

[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] J. Mezhir [REDACTED]

[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] S. Gopishetty [REDACTED]

[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] S. Gopishetty [REDACTED]

[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] S. Gopishetty [REDACTED]

[REDACTED]

[REDACTED]

The second part of the meeting was open to the public.

3. Old Business

Dr. Sinn reported on responses she received from other Universities regarding registration of siRNA or DNA restriction fragments. Half the responses required registration with an expedited review of the research, often by the Biosafety Officer and IBC Chair only. The other half did not require registration with the reasoning that the *NIH Guidelines* did not apply to these types of experiments as these molecules do not meet the definition of rDNA, particularly in that they cannot replicate.

The committee discussed the various criteria of synthetic DNA outlined in the *Guidelines*: >100 base pairs, integration, replication, and transcription/translation. Ultimately the committee discussed requiring registration of all synthetic nucleic acid molecules that would be introduced into a biological system, such as an animal or tissue culture cells, regardless of whether it meets the criteria listed above. As members of the IBC will be meeting soon with a group of faculty to discuss the requirement to register exempt rDNA research, announcement of this registration requirement will be postponed until after that meeting in order to allow for further discussion with the researchers.

4. New Business

- a) Dr. Sinn reported on four amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff since the last meeting.
 - Dr. Lee, #120341 was amended to add Cav1.4, a calcium channel, as an insert and include mouse as a host in additional rows of the table.
 - Dr. Sigmund, #120061, is approved to use any mouse gene identified in a microarray or high throughput sequencing study and amended the protocol to include any human gene identified in the same manner.
 - Dr. Lee, #120341 was amended to include retinal injection as a route of administration.
 - Dr. McCray, #120062 was amended to include alpha-fetoprotein as an insert.
- b) Dr. Kirchhoff discussed an amendment request associated with Dr. Milhem's human gene transfer protocol that had been sent to the committee previously. No changes were made to the study drug or route of administration. No concerns or questions regarding the amendment were raised by committee members.
- c) Dr. Sinn discussed the July 2013 [REDACTED] and subsequent response from the Faculty and Associate Directors that also had been sent to committee members prior to the meeting. No concerns or questions regarding the report were raised by committee members. Ms. McGhan made a motion, seconded by Dr. Jarosinski, to approve the inspection report and subsequent response. The members voted unanimously for approval.
- d) Dr. Sinn notified the committee of a possible exposure of a staff member to a recombinant lentiviral vector. A staff member received a needlstick after she had injected pigs with mouse cells transduced with a replication defective lentiviral vector expressing GFP. Dr. Hartley at UEHC was immediately contacted by the staff member and forwarded information about the incident to Dr. Sinn. Drs. Sinn and White will be meeting with the PI and the staff member tomorrow to investigate the incident further. Furthermore, during initial discussion with the PI, it was determined that IBC approval for use of the lentiviral vector in pigs had not been obtained; the PI is currently working on a new rDNARD and this will be reviewed during the discussion tomorrow. NIH/OBA was notified through email of the potential exposure and the failure to receive IBC approval.

The meeting adjourned at 4:05 p.m.

The next meeting will be held at 3:30 p.m. on October 24, 2013.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: October 24, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of October 24, 2013

Members Present: Drs. Maria Martino-Cardona, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, James Sheets, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Adam Clore, Lucy DesJardin, Bradley Jones, and Jeffery Meier

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on October 10, 2013**
 No suggestions for changes in the circulated minutes were made. Dr. Duncan made a motion, seconded by Dr. Jarosinski, to approve the minutes of the October 10, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
 The sole rDNARD being considered was made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARD and reviewed it prior to the meeting. Members were asked to report any conflict with the rDNARD under review. No conflicts were reported. The review of the proposed research project involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following five rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	J. Weiner	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	[REDACTED]	[REDACTED]

12000 C. Ellermeier [redacted]

- The goal of this project is to identify [redacted] factors in [redacted] envelope stress of [redacted].
 - [redacted]
 - [redacted]
 - [redacted]
 - [redacted]
- By its majority vote, the committee affirmed that the above listed criteria drawn from the [redacted] [redacted] have been [redacted].
- Voted: approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
12000	W. Maury	[redacted]

- The goal of this project is to identify [redacted] cell targets important for [redacted].
- By its majority vote, the committee affirmed that the above listed criteria drawn from the [redacted] [redacted] have been [redacted].
- Voted: approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
12001	B. Davidson	[redacted]

- The goal of this project is to [redacted] [redacted] [redacted].
- By its majority vote, the committee affirmed that the above listed criteria drawn from the [redacted] [redacted] have been [redacted].
- Voted: approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
120215	A. Bassuk	[redacted]

- The goal of this project is to identify [redacted] to be involved in [redacted] [redacted] these mutations may play in disease [redacted].
- By its majority vote, the committee affirmed that the above listed criteria drawn from the [redacted] [redacted] have been [redacted].
- Voted: approved, 0 opposed, 0 abstained

The second part of the meeting was open to the public.

3. Old Business

The IBC reviewed a draft report destined for NIH/OBA of the incident involving a potential exposure to a recombinant lentivirus, the PI's failure to receive IBC approval for administration of recombinant cells to pigs, and the PI's failure to list all personnel conducting the experiments involving rDNA.

During the investigation of this incident, it was determined that the assistant who received a puncture from a used cannula was not exposed to a lentivirus, as the cannula contained a control saline solution. However, in addition to using improper procedures for disposing of sharp needles, two issues regarding the rDNARD were found: 1) the approved protocol did not list all personnel working on this project, and 2) although mice were listed as a host, the pigs involved in the experiment were not.

Dr. White explained that she has instructed the PI and staff regarding proper sharps disposal methods. Regarding revising the protocol to include all staff and animal hosts, the current rDNARD expires in October 2013, hence the PI will submit a new rDNARD, and include all the necessary revisions.

A motion to submit the report to NIH/OBA was made by Dr. Sinn and seconded by Dr. Duncan. The motion was approved unanimously.

4. New Business

- a) Ms. McGhan reported on three amendments to previously-approved rDNARDs that were approved by Dr. Sinn or Dr. Kirchhoff since the last meeting.
 - Dr. Clegg, #120270, was amended to add a new staff member and a graduate student to his protocol.
 - Dr. Jones, #1100126, was amended to add Dr. Lee-Ann Allen as co-PI and also to add 5 of her staff.
 - Dr. Stanford, #130039, was amended to include the use of the GTVC to make the vectors listed in his protocol, as the transgenic core will not be able to make these.
- b) Prior to the meeting Dr. Sohn sent to the IBC for review a copy of a revised informed consent form for his approved rDNARD #130094. The committee discussed the revisions and had no concerns. Biosafety staff will add a note in this rDNARD stating that the IBC has reviewed and discussed the revised informed consent document.
- c) Dr. Kirchhoff brought a question to the committee for discussion regarding whether co-PIs should be allowed to amend a PI's protocol. Currently only PIs can submit a request for an amendment. Following a brief discussion, it was decided to allow co-PIs to apply for amendments of currently approved rDNARDs. PIs can add laboratory managers or other staff as co-PI, thus allowing these persons to submit requests for amendments. Dr. Duncan made a motion, seconded by Dr. Sinn, to allow this change in the IBC's amendment process.

The meeting adjourned at 3:54 p.m.

The next meeting will be held at 3:30 p.m. on November 7, 2013.

Minutes submitted by: Carol McGhan, MPH, CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: November 7, 2013
To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject: Minutes of the IBC Meeting of November 7, 2013
Members Present: Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, James Sheets, and Haley Sinn, and Ms. Carol McGhan
Members Absent: Drs. Bradley Jones, Maria Martino-Cardona, and Jeffery Meier
Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:34 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

- Approval of minutes from meetings on October 24, 2013**
No suggestions for changes in the circulated minutes were made. Dr. Sheets made a motion, seconded by Ms. McGhan, to approve the minutes of the October 24, 2013, meeting. The members voted unanimously for approval.
- rDNARDS under review:**
The rDNARDS being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDS and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDS under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following four rDNARDS were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	M. Hansen	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

- a) Dr. Sinn reported on five amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions since the last meeting.
- Dr. Clegg, #120270 was amended to add staff.
 - Dr. Jones, #110126, was amended to add Dr. Lee-Ann Allen as a Co-PI and add Dr. Allen's staff.
 - Dr. Sanford, #130039 was amended to include the Gene Transfer Vector Core for the production of already approved vectors.
 - Dr. Johnson, #110062 was amended to include additional staff and chitosan nanoparticles as a vector.
 - Dr. Lutter, #120120, was amended to add staff.
- b) Dr. Sinn discussed the recent announcement in the Federal Register regarding the addition of *P. aeruginosa* as a Risk group 2 bacterial agent and MERS as a Risk group 3 virus to Appendix B of the *NIH Guidelines*. The committee requested that Biosafety staff generate a report that lists which labs currently work with *P. aeruginosa*; Biosafety staff will provide the information to the committee prior to the next meeting for further discussion.

The meeting adjourned at 4:02 p.m.

The next meeting will be held at 3:30 p.m. on November 21, 2013.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



Environmental Health & Safety
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 Iowa City, IA 52242 – 1000
 Ph. 319-335-8501
 Fax 319-335-7564

Date: November 21, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of November 21, 2013

Members Present: Drs. Adam Clore, Lucy DesJardin, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, James Sheets, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Leonard Duncan and Jeffery Meier

Guest Present: Drs. Nancy Figler, James Walker and Rachel White and Mrs. Deborah Kratz

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on November 7, 2013**
 No suggestions for changes in the circulated minutes were made. Ms. McGhan made a motion, seconded by Dr. Sheets, to approve the minutes of the November 7, 2013, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
 The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review. No conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following eight rDNARDs were considered:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
[REDACTED]	V. Sheffield	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

science department heads. At that meeting the policy change and the impact of its implementation were explained in detail and questions posed by the three faculty members were answered.

Dr. Walker requested that EHS delay the implementation of the newly-approved policy requiring the registration of all exempt work until additional data can be gathered to determine how many PIs would be affected by the policy. Committee members expressed the opinion that the burden is on the PI to determine whether or not proposed rDNA research is exempt and discussed ways to train PIs regarding the definitions of exempt rDNA research and gather data on the numbers of PIs doing exempt research. EHS staff will work with Drs. Kirchhoff and Walker to develop a process to gather the requested information which will be presented to the committee at a future meeting.

- b) Following the recent assignment of RG2 to *Pseudomonas aeruginosa*, a report was sent to committee members prior to the meeting listing the PIs currently working with this organism. The committee discussed proper containment for animal experiments involving *P. aeruginosa* and determined that the University's ABSL1 housing conditions would be sufficient for rodents. However, additional information regarding strain and administration routes was requested for the large animal work (e.g., ferrets, pigs). Biosafety staff will work with the veterinarians to gather the information regarding this issue and present it to the committee at the next meeting.
- c) rDNARDs approved at a previous IBC meeting contingent upon receipt from the PI of additional information or clarification.
Additional information or clarification was received from the PIs regarding the following rDNARDs and was judged to be satisfactory:
 - Dr. Tucker, rDNARD #130224, responded that he will test the transduced cells to ensure the absence of Sendai virus prior to inoculating animals, as described in the literature attached to his rDNARD.

4. New Business

- a) Dr. Sinn reported on four amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions since the last meeting.
 - Dr. McCray, #120062, was amended to include four additional inserts, a surfactant protein, an immune regulatory protein, the spike protein from MERS, and a transmembrane protein.
 - Dr. Legge, #120319, was amended to remove staff and add the NP142t-response marker from influenza.
 - Dr. Qi, #120031 was amended to include siRNA.
 - Dr. Rodriguez, #1000272 was amended to include crispr regulatory RNAs originating from *S. pyogenes* and *S. aureus* and the Cas9 nuclease insert.
- b) Dr. Figler, IACUC Director, discussed the current practice to approve an Animal Protocol (AP) when the rDNARD is pending approval; this is considered a conditional approval and not allowed by regulators. The IACUC office proposed to educate the PIs that an approved rDNARD is required prior to AP approval or to request that all rDNA work be amended into the AP following rDNARD approval. The IACUC office will work with Biosafety staff to more closely tie the rDNARD approval to the AP approval.
- c) Dr. Kirchhoff discussed a recent reportable event associated with Dr. Berg's rDNARD, previously sent to committee members. No concerns were raised by the committee.

The meeting adjourned at 4:36 p.m.

The next meeting will be held at 3:30 p.m. on December 5, 2013.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



Environmental Health & Safety
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Date: December 5, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of December 5, 2013

Members Present: Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, Jeffery Meier, James Sheets, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Bradley Jones and Maria Martino-Cardona

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on November 21, 2013**
 No suggestions for changes in the circulated minutes were made. Dr. Sheets made a motion, seconded by Ms. McGhan, to approve the minutes of the November 21, 2013, meeting. The members voted unanimously for approval.
2. **rDNARDs under review:**
 The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review. Dr. Sinn recused herself from consideration of rDNARD #130231 (Dr. Maury) because a family member is a co-investigator on the project. No other conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following six rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	M. Feiss	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

impact of such implementation. After the information is collected it will be provided to the IBC to inform the implementation or revision of the new policy.

- b) Dr. Sinn received a response from laboratories administering *P. aeruginosa* to pigs and ferrets. Both labs utilize strain PA01 which may be wild-type or recombinant; the various routes of administration were also discussed. The committee requested that additional information be provided regarding the required changes to housing procedures to move this research from an ABSL1 to ABSL2 containment. Dr. Martino-Cardona, Sheets, and Sinn will meet and draft a containment procedure to be presented to the committee at their earliest convenience.

4. New Business

- a) Dr. Sinn reported on two amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions since the last meeting.
 - Dr. Zhang, #120180, was amended to include pTraffic as a plasmid vector, CD177 and ROR1 inserts, and use of the Transgenic Animal and Genome Manipulation facility to create transgenic mice.
 - Dr. Salem, #120069, was amended to include rat as a host model.
- b) Ms. McGhan requested input from committee members on information that should be included in the IBC annual report submitted by Biosafety staff. The committee discussed the possibility of including the pounds of biohazard waste collected annually but felt that an article to the research community addressing proper waste disposal and awareness of the cost of disposing of biohazard waste would be more valuable.

Reporting on previous lab inspections for each PI with an rDNARD under consideration was also discussed. As the lab audit encompasses chemical, radiation and biological review the committee felt that this information would be better addressed by a laboratory safety committee. Any issues directly involving rDNA are brought to the Chair's or committee's attention and this practice should continue. A laboratory utilizing rDNA with persistent issues could be brought to the IBC's attention at the time of rDNARD review; however, a general comment on the status of each lab's previous lab inspection is not necessary.

- c) Dr. Sheets requested input on the standard housing conditions for lentivirus vectors as he will be meeting with a faculty recruit. Ms. McGhan stated that common, commercially available lentiviruses utilizing a triple transfection process to generate the replication defective vector are typically housed at ABSL1.

The meeting adjourned at 4:30 p.m.

The next meeting will be held at 3:30 p.m. on December 19, 2013.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: December 19, 2013

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of December 5, 2013

Members Present: Drs. Adam Clore, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, Jeffery Meier, James Sheets, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Lucy DesJardin, Bradley Jones, and Maria Martino-Cardona

Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on December 5, 2013**
 No suggestions for changes in the circulated minutes were made. Dr. Clore made a motion, seconded by Dr. Sheets, to approve the minutes of the December 5, 2013, meeting. The members voted unanimously for approval.
2. **rDNARDs under review:**
 The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following six rDNARDs were considered:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
[REDACTED]	B. Davidson	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

rDNA# **PI** **rDNA Registration Document Title**
[REDACTED] S. Holstein [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

rDNA# **PI** **rDNA Registration Document Title**
[REDACTED] C. Grose [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

rDNA# **PI** **rDNA Registration Document Title**
[REDACTED] J. Mezhir [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

rDNA# **PI** **rDNA Registration Document Title**
[REDACTED] R. Boudreau [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

rDNA# **PI** **rDNA Registration Document Title**
[REDACTED] B. Davidson [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

The second part of the meeting was open to the public.

3. Old Business

- a) rDNARDs approved at a previous IBC meeting contingent upon receipt from the PI of additional information or clarification.

Additional information or clarification was received from the PIs regarding the following rDNARD and was judged to be satisfactory:

- Dr. Maury, rDNARD #130231, clarified that the plasmid vectors would not be used in animals; therefore, mice were removed from the host column and the ABSL designation was deleted.
- b) Several days before the meeting Dr. Sinn forwarded to committee members Dr. Engelhardt's response to her request for additional information on the EIAV replication defective vector that was the focus of his request for an amendment to approved rDNARD #120019 sent to EHS on 12/3/2013. The committee discussed whether or not to require Dr. Engelhardt to test for replication competent lentivirus. The members felt that such testing was not necessary. The committee voted to approve the new information, including that related to the use of the EIAV vector as an amendment to rDNARD #120019.

Vote: 8 approved, 0 opposed, 0 abstained

4. New Business

- a) Dr. Sinn reported on three amendments to previously-approved rDNARDs that were approved by Dr. Kirchhoff or Dr. Sinn in the case of staff additions since the last meeting.
 - Dr. Zode, #130199, was amended to include the human myocilin sgrRNA as an insert.
 - Dr. Irani, #130158, was amended to include a modified oxidative protein as an insert and adenoviral vectors of already approved inserts.
 - Dr. Barker, #130063, was amended to include Dr. Jerrold Weiss as staff.
- b) Several days prior to the meeting Dr. Sinn forwarded to the committee the annual IBC report. The committee discussed the report and had no concerns or comments. Ms. McGhan stated that if there are additional items the committee would like to see in future reports to please inform Biosafety Staff. Dr. Sinn requested that the annual report be submitted in September/October next year to better coincide with the end of the fiscal year. The committee had no concerns with the change in submission date.

Dr. Sheets made a motion, seconded by Dr. Meier, to approve the annual report. The members voted unanimously for approval.

The meeting adjourned at 3:55 p.m.

The next meeting will be held at 3:30 p.m. on January 2, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: January 2, 2014
To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject: Minutes of the IBC Meeting of January 2, 2014
Members Present: Drs. Adam Clore, Leonard Duncan, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn, and Ms. Carol McGhan
Members Absent: Drs. Lucy DesJardin, Keith Jarosinski, Bradley Jones, Jeffery Meier, and James Sheets
Guest Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:36 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

- Approval of minutes from meetings on December 19, 2013**
No suggestions for changes in the circulated minutes were made. Dr. Clore made a motion, seconded by Dr. Duncan, to approve the minutes of the December 19, 2013, meeting. The members voted unanimously for approval.
- rDNARDs under review:**
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following three rDNARDs were considered:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
[REDACTED]	M. Wold	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
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was forwarded to committee members prior to the meeting, along with a draft of an approval letter from Dr. Kirchhoff.

The following items were discussed: (1) the standard referenced on page 52 should read "NSF"; (2) inquire as to whether the facility is still waiting for clarification from FM on the ventilation systems; (3) confirm that a respirator program is in place; and (4) general editing is needed regarding the references to the particular agents (misspellings and such). Biosafety staff will work with Mr. Fishbaugh to address the committee's comments and revise the containment plan, as necessary. There were no further concerns raised by committee members.

Dr. Jones made a motion, seconded by Dr. DesJardin, to approve the containment plan following revision and Dr. Kirchhoff's approval letter. The members voted unanimously for approval.

The meeting adjourned at 4:05 p.m.

The next meeting will be held at 3:30 p.m. on January 30, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: January 30, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of January 30, 2014

Members Present: Drs. Adam Clore, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, Jeffery Meier, James Sheets, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Lucy DesJardin and Bradley Jones

Guest Present: Mrs. Deborah Kratz

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:31 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

- Approval of minutes from meetings on January 16, 2014**
 No suggestions for changes in the circulated minutes were made. Dr. Duncan made a motion, seconded by Dr. Martino-Cardona, to approve the minutes of the January 16, 2014, meeting. The members voted unanimously for approval.
- rDNARDs under review:**
 The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following seven rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	P. Ferguson	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Dr. Clore joined the meeting at this time.

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	S. Gopishetty	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	O. Shchelochkov	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The second part of the meeting was open to the public.

3. Old Business

rDNARDs approved at a previous IBC meeting contingent upon receipt from the PI of additional information or clarification.

Additional information or clarification was received from the PIs regarding the following rDNARDs and was judged to be satisfactory:

- Dr. Badovinac rDNARD #130280, clarified the statement “mouse without any transfer of cells” referred to mice which did not receive a transfer of T-cells prior to agent administration. Dr. Badovinac also clarified that plasmid pPL2 was used to create recombinant *Listeria* carrying the LCMV epitope and chicken ovalbumin.

4. New Business

- Dr. Sinn reported on three amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff.
 - Dr. Lin, #120198, was amended to include markers as inserts.
 - Dr. Maury, #120057 and 120060, were amended to include additional cell lines and glycoprotein genes from various viruses.
 - Dr. Stipp, #120045, was amended to include additional cell proliferation inserts.
- Dr. Sinn reported on the receipt of several trial documents following the continual review of Dr. Russell’s human gene transfer rDNARD, #120350. Minor changes were made to the trial, including a Sponsor change, transfer of responsibility for the Interim Medical Monitor Instruction, and the informed consent which involved revising the sponsor and increasing the mobility testing from 45 to 90 minutes. There were no changes that affected the rDNA vector or administration to patients.

Dr. Kirchhoff also reviewed the trial documents and stated that no changes affected the information reviewed by the IBC. Interested committee members can contact Dr. Sinn for a full copy of the trial documents. No concerns were raised by committee members.

The meeting adjourned at 3:45 p.m.

The next meeting will be held at 3:30 p.m. on February 13, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchoff, MD, MPH, Chair, Institutional Biosafety Committee



Date: February 13, 2014
To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject: Minutes of the IBC Meeting of February 13, 2014
Members Present: Drs. Adam Clore, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, Jeffery Meier, and Haley Sinn, and Ms. Carol McGhan
Members Absent: Drs. Lucy DesJardin and James Sheets
Guests Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

- Approval of minutes from meetings on January 30, 2014**
No suggestions for changes in the circulated minutes were made. Dr. Martino-Cardona made a motion, seconded by Dr. Jones, to approve the minutes of the January 30, 2014, meeting. The members voted unanimously for approval.
- rDNARDs under review:**
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following nine rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	B. Davidson	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

The second part of the meeting was open to the public.

3. Old Business

Proposed revised ABSL2n containment forms for use with ferrets and pigs exposed to recombinant *P. aeruginosa* were developed by Drs. Martino-Cardona, Sheets, and Sinn and sent to the members of the committee for review prior to the meeting. These forms were developed following conversations Drs. Martino-Cardona, Sheets, and Sinn had with staff members in Dr. Engelhardt's and Dr. Zabner's group who foresee working with ferrets and pigs exposed to recombinant *P. aeruginosa*. At today's meeting the question arose as to whether ABSL1 containment level would be appropriate for ferret dams whose pups had been exposed to recombinant *P. aeruginosa* and euthanized some time later. No decision was reached regarding this issue and the members agreed that it should be addressed at a later meeting when specific experimental details are in hand and possibly with input from NIH/OBA.

No additional concerns or comments regarding revised ABSL2n containment forms were made by committee members. Dr. Jones made a motion, seconded by Dr. Meier, to approve the containment forms as submitted. The members voted unanimously for approval.

4. New Business

- a) Dr. Sinn reported on three amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff.
 - Dr. Felder, #140002, was amended to include additional inserts, such as protein kinases and signaling proteins in the inflammatory cytokine pathways.
 - Dr. Engelhardt, #120019, was amended to include a replication defective MMLV vector which will be administered to mice and ferrets.
 - Dr. McCray, #120062, was amended to include PR8 influenza expressing GFP for use in *E.coli* and cell lines only.
- b) Dr. Kirchhoff discussed a reportable event associated with Dr. Russell's rDNARD #120350. This event was result of a purely administrative issue and unrelated to the rDNA administered to study subjects. No concerns were raised by the committee.
- c) Dr. Kirchhoff discussed at some length the draft of an incident report for NIH/OBA that was sent to committee members prior to the meeting. The report deals with a violation of the *NIH Guidelines* involving experiments with recombinant MERS-CoV in the laboratory of Dr. Stanley Perlman that had not been approved by the IBC. The committee requested clarification regarding which of the experiments involving the MERS-CoV BAC and viral clones had been performed in Dr. Perlman's laboratory under BSL2 containment vs. the BSL3 facility. Considerable discussion was had regarding the latter issue and other elements of the report, during which several revisions were suggested. The possible implementation of monitoring and corrective actions to prevent the recurrence of violations of this type were also discussed at length. Dr. Kirchhoff will make the suggested changes in the report and send the revised version to the committee for further review. The committee agreed to hold a special meeting to discuss the revisions and subsequent submission of the report to NIH/OBA.

The meeting adjourned at 4:42 p.m.

A special meeting will be held at 3:30 pm on February 17, 2014

The next regularly scheduled meeting will be held at 3:30 p.m. on February 27, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP.

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



Environmental Health & Safety
100 EHS
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Ph. 319-335-8501
Fax 319-335-7564

Date: February 17, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of February 17, 2014

Members Present: Drs. Adam Clore, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, Jeffery Meier, James Sheets, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Lucy DesJardin

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:32 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on February 13, 2014**
No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Ms. McGhan, to approve the minutes of the February 13, 2014, meeting. The members voted unanimously for approval.
2. **Old Business**
 - a) Dr. Kirchhoff discussed two amendments to previously-approved rDNARDs, submitted by Dr. Stanley Perlman and sent to committee members prior to the meeting.
 - rDNARD, #120125, has been amended to include additional MHV inserts and two additional staff members. All required training has been completed by the new staff. The committee requested clarification on the difference between MHV wild type strain and MHV-A59 strain, the latter of which is included in the new information. Biosafety staff will contact Dr. Perlman and revise the document as appropriate.
 - rDNARD, #110079, was amended to include the N-protein from MERS-CoV.

Dr. Duncan made a motion, seconded by Dr. Jones, to approve the amendment requests; however, approval of #110079 is contingent upon obtaining a satisfactory response from the PI regarding the information requested by EHS's Biosafety staff. The members voted unanimously for approval.
 - b) Dr. Kirchhoff discussed the revised draft of the rMERS-CoV incident report that was sent to committee members prior to the meeting. Minor edit requests were requested by members but no concerns were raised with the revisions. Dr. Jones made a motion, seconded by Dr. Duncan, to approve the circulated version of the report and submit it to NIH/OBA. The members voted unanimously for approval.

The meeting adjourned at 3:47 p.m.

The next meeting will be held at 3:30 p.m. on February 27, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

[REDACTED]

The second part of the meeting was open to the public.

3. **Old Business**

- a) rDNARDs approved at a previous IBC meeting contingent upon receipt from the PI of additional information or clarification.

Additional information or clarification was received from the PIs regarding the following rDNARDs and was judged to be satisfactory:

- Dr. Perlman rDNARD #120125, stated that MHV-A59 is a strain of MHV that is 95% similar to the JHM strains at the nucleotide level. It is both hepatotropic and neurotropic, whereas the JHM strains are just neurotropic. It also tends to grow to higher titers in cell culture than does the JHM strain, thus making it highly useful to study MHV in cell culture.
- Dr. Haim rDNARD #140022, stated that he was previously a post-doc at Harvard and while there was unaware of the *NIH Guidelines*, since the PI handled all such administrative issues. Prior to submitting the rDNARD he was carrying out the research described in the protocol. He did not receive any information regarding the *NIH Guidelines* and associated registration requirements at the University of Iowa and submitted the protocol as soon as he was informed of the requirements. Following further investigation, it was determined that Dr. Haim was not listed on the new hire list provided by the Provost's office; the reason for his not being on the list is under review by EHS staff.

4. **New Business**

- a) Dr. Sinn reported on six amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff, or in the case of staff changes, approved by Dr. Sinn.
- Dr. Engelhardt, #140005 and #120019, were amended to include the jugular vein as an additional route of administration in ferrets.
 - Dr. Habelhah, #110232, was amended to include an additional cell line and the replication defective MMLV vector, pQCXIH.
 - Dr. Legge, #110319, was amended to include an additional staff member and incorporate rDNARD #110204; there were no changes necessary in the insert/host/vector table.
 - Dr. Henry, #130093, was amended to include additional staff, remove staff, and add transcription factor inserts and an additional replication defective lentiviral vector.
 - Dr. Goel, #110121, was amended to add and remove staff.
- b) Dr. Sinn discussed the December 2013 inspection of the [REDACTED] and the [REDACTED]'s subsequent response, which was previously sent to committee members. There were no major concerns identified during the audit and the response was deemed acceptable. Dr. Jones made a motion, seconded by Dr. Duncan, to approve the inspection report and subsequent response. The members voted unanimously for approval.
- c) Dr. Kirchhoff discussed a reportable event associated with Dr. Russell's rDNARD #120350, a copy of which was sent to committee members prior to this meeting. This event was unlikely related to the rDNA vector administered. No concerns were raised by the committee.
- d) Drs. Martino-Cardona, Sheets, and Sinn modified waste handling procedures for ABSL1 small animal housing involving recombinant agents. The revised procedures were sent to committee members prior to the meeting. The committee determined that the waste should be disposed of as biohazardous for the life of the animals exposed to rDNA and therefore the revised procedure will so indicate. The most effective ways to communicate this change to the research community were

discussed. EHS's LabNews and annual audits will be utilized in addition to providing the information during Animal Protocol and amendment approvals involving ABSL1 recombinant agents. Possible use of the Animal Resource's listserv will also be reviewed.

- e) Dr. Maury submitted a protocol for testing for shedding following VSV-pseudovirion administration with the intent to reduce the containment of mice from ABSL-2 to ABSL-1 housing, as previously approved by NIH/OBA. The protocol was sent to committee members prior to the meeting. The committee requested further information on the sensitivity of the assay and why the animals must be euthanized for the sample collection when nasal instillation is the route of administration. Dr. Sinn will contact Dr. Maury and report the additional information at the next IBC meeting.
- f) Dr. Sinn discussed the need for the IBC to review the BSL3 manuals for the ~~_____ of _____~~ and the ~~_____ of _____~~. The manuals have undergone significant review and revision as a result of the April 2013 CDC inspection and 2014 registration renewal. The manuals are now in the final form although a response from the CDC inspection is still outstanding. A hard copy of the manuals will be available for review from 2:30-3:30pm in room ~~_____~~ 1189 on March 13, just prior to the next IBC meeting. Please contact Haley to arrange an alternative time to review the manuals if conflicts arise. The room is reserved through 4:30 pm and starting at 3:30 pm the meeting will be held here.

The meeting adjourned at 4:30 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on March 13, 2014 in room MERF 1189.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: March 13, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of March 13, 2014

Members Present: Drs. Lucy DesJardin, Leonard Duncan, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Adam Cløre, Keith Jarosinski, Jeffery Meier, and James Sheets,

Guests Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 1189 MERF, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

- Approval of minutes from meetings on February 27, 2014**
 No suggestions for changes in the circulated minutes were made. Dr. Duncan made a motion, seconded by Dr. Martino-Cardona, to approve the minutes of the February 27, 2014, meeting. The members voted unanimously for approval.
- rDNARDs under review:**
 The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following ten rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	R. Hohl	[REDACTED] Inhibition on Expression and Localization of GFP

- [REDACTED] GFP [REDACTED] GFP [REDACTED] GFP
- [REDACTED] GFP [REDACTED] GFP [REDACTED] GFP
- [REDACTED] GFP [REDACTED] GFP [REDACTED] GFP
- [REDACTED] GFP [REDACTED] GFP [REDACTED] GFP
- [REDACTED] GFP [REDACTED] GFP [REDACTED] GFP
- [REDACTED] GFP [REDACTED] GFP [REDACTED] GFP
- [REDACTED] GFP [REDACTED] GFP [REDACTED] GFP
- [REDACTED] GFP [REDACTED] GFP [REDACTED] GFP
- [REDACTED] GFP [REDACTED] GFP [REDACTED] GFP
- [REDACTED] GFP [REDACTED] GFP [REDACTED] GFP

- [REDACTED] correlate genetic mutations in [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI **rDNA Registration Document Title**
 [REDACTED] C. Ahern [REDACTED]

- The goal of this project is to virally express [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI **rDNA Registration Document Title**
 [REDACTED] J. Cullen [REDACTED]

- [REDACTED] project is to examine the role of glutathione reductase in hydrogen peroxide [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI **rDNA Registration Document Title**
 [REDACTED] C. Morita [REDACTED]

- The goal of this project is to develop new vaccines for [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI **rDNA Registration Document Title**
 [REDACTED] C. Morita [REDACTED]

[REDACTED]

The second part of the meeting was open to the public.

3. Old Business

Dr. Kirchhoff informed the committee of NIH/OBA's response to the incident report involving the unapproved generation of recombinant MERS-CoV in Dr. Stanley Perlman's laboratory. Dr. Kirchhoff and Biosafety staff will review the monitoring program that was instituted several years ago for another laboratory that had violated the *NIH Guidelines* and will design a program for monitoring rDNA work in Dr. Perlman's laboratory. Information will be brought back to the committee at the next meeting for discussion and subsequent implementation.

4. New Business

- a) Dr. Sinn reported on two amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff, or in the case of staff changes, approved by Dr. Sinn.
 - Dr. Leslie, #130165, was amended to include additional lentiviral vectors and inserts, including markers, a kinase, repair gene and oncogenes.
 - Dr. Wilson, #130083, was amended to add additional staff.
- b) Dr. Kirchhoff discussed an amendment request from Dr. Haim, previously sent to the committee for review. There were no concerns raised by the amendment request and the committee voted unanimously for approval.
- c) Dr. Sinn provided copies of the [REDACTED] and [REDACTED] manuals to the committee members prior to the meeting. The committee provided minor comments regarding revisions which will be distributed to the appropriate program administration. Dr. DesJardin made a motion, seconded by Dr. Martino-Cardona, to approve the [REDACTED] manuals. The members voted unanimously for approval.

The meeting adjourned at 4:15 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on March 27, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: April 10, 2014
To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject: Minutes of the IBC Meeting of April 10, 2014
Members Present: Drs. Adam Clore, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, James Sheets, and Haley Sinn, and Ms. Carol McGhan
Members Absent: Drs. Lucy DesJardin, Bradley Jones, Maria Martino-Cardona, and Jeffery Meier
Guests Present: Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

- Approval of minutes from meetings on March 27, 2014**
No suggestions for changes in the circulated minutes were made. Dr. Sheets made a motion, seconded by Ms. McGhan, to approve the minutes of the March 27, 2014, meeting. The members voted unanimously for approval.
- rDNARDs under review:**
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following seven rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	E. Abel	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] B. Davidson [REDACTED]

- [REDACTED] to produce, concentrate, and in [REDACTED]
- [REDACTED]
- [REDACTED] the gene and [REDACTED] and request for the committee [REDACTED] and local BSC approval [REDACTED] has been tabled and only will [REDACTED] from NIH/ODAP [REDACTED] team gene [REDACTED] by unanimous vote, the committee [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] B. Davidson [REDACTED]

- [REDACTED] to produce, concentrate and [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED] committee affirmed that the above [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] N. Harata [REDACTED]

- [REDACTED]
- [REDACTED] The committee [REDACTED] Harata and revise the rDNA [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED] committee affirmed that the above [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] S. Gopishetty [REDACTED]

- [REDACTED] to produce [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED] committee affirmed that the above [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] J. Houtman [REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] J. Martin [REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

The second part of the meeting was open to the public.

3. Old Business

a) Prior to today's meeting Dr. Maury sent to EHS staff and the committee a PowerPoint presentation depicting her work involving the vaccination of mice with VSV-pseudovirions and the Ebola virus glycoprotein gene. Dr. Maury attended today's meeting via phone and reviewed the content of her slides in detail with the committee members, after which they asked several questions. They requested that she try to increase the sensitivity of the detection assay and also raised issues relating to the handling of the mice after vaccination, IACUC approvals, and USDA permits. Dr. Maury stated that she will request an amendment to her USDA permit that will cover shipment of the vaccinated mice.

Dr. Maury agreed to attend the next IBC meeting and present at that time data relating to post-vaccination shedding of VSV pseudovirions and the sensitivity of her assay.

4. New Business

- a) Dr. Sinn reported on two amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff, or in the case of staff changes, approved by Dr. Sinn.
- Dr. Chen, #110103, was amended to update the laboratory personnel, include the generation of a transgenic mouse, update the antibiotic resistance genes and update the Animal Protocol number.
 - Dr. Sluka, #130160, was amended to add additional staff.
- b) Dr. Kirchhoff discussed his revisions of the informed consent form that is part of Dr. Russell's rDNARD, #120350, which previously was sent to the committee for review. In his view the revisions were not related to the rDNA administered to the study subjects but rather involved the mechanics of administration. The consent document was expanded to include language addressing a lifting of the retina after rDNA injection. Dr. Kirchhoff provided an edited version of the

document which Dr. Sinn will send to the IRB. No further concerns were raised by the members of the committee.

- c) Dr. Sinn discussed changing the date of the next IBC meeting due to a conflict with the CDC Select Agent inspection. A doodle poll will be sent around to determine member availability on alternative dates for the meeting.

The meeting adjourned at 4:30 p.m.

The next regularly scheduled meeting will be determined.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: April 28, 2014
To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject: Minutes of the IBC Meeting of April 28, 2014
Members Present: Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Louis Kirchhoff, Jeffery Meier, James Sheets, and Haley Sinn, and Ms. Carol McGhan
Members Absent: Drs. Keith Jarosinski, Bradley Jones, and Maria Martino-Cardona,
Guests Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

- 1. Approval of minutes from meetings on April 10, 2014
No suggestions for changes in the circulated minutes were made. Dr. Duncan made a motion, seconded by Dr. Sheets, to approve the minutes of the April 10, 2014, meeting. The members voted unanimously for approval.
2. rDNARDs under review:
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; Dr. Sinn reported a conflict with 3 rDNARDs and will abstain during the votes. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following seven rDNARDs were considered:

Table with 2 columns: rDNA# PI and rDNA Registration Document Title. The content is heavily redacted with black bars.

- Dr. Engelhardt, #140005, was amended to include recombinant E. coli (EC838) which will be administered to ferrets and additional routes of administration.
- b) Dr. Sinn discussed a revised procedure to register the Gene Transfer Vector Core's broad approval rDNARDs. The committee agreed to the revised procedure; Dr. Sinn will work with Ms. Scheel to submit the broad approval request and subsequent quarterly reports in a manner that is consistent with the revised procedure..

The meeting adjourned at 4:48 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on May 8, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: May 8, 2014
To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject: Minutes of the IBC Meeting of May 8, 2014
Members Present: Drs. Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, James Sheets, and Haley Sinn, and Ms. Carol McGhan
Members Absent: Drs. Adam Clore, Lucy DesJardin, and Jeffery Meier
Guests Present: Mrs. Deborah Kratz and Dr. Rachel White

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

- 1. Approval of minutes from meetings on April 28, 2014
No suggestions for changes in the circulated minutes were made. Dr. Duncan made a motion, seconded by Dr. Sheets, to approve the minutes of the April 28, 2014, meeting. The members voted unanimously for approval.
2. rDNARDs under review:
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; Dr. Sinn reported a conflict with 3 rDNARDs and will abstain during the votes. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following fourteen rDNARDs were considered:

Table with 2 columns: rDNA# PI and rDNA Registration Document Title. The content is heavily redacted with black bars.

The goals of this project are to (1) determine if particulate matter (PM) induces [redacted] LFC [redacted] plasma membrane and [redacted] cell [redacted] by endocytosis [redacted] PM [redacted] inflammation and (2) determine whether PM-induced [redacted] including [redacted] PKC phosphorylation of the occludin C-terminal domain and whether inhibition of PKC prevents [redacted] induced [redacted] inflammation.

- [redacted]
 - Assessment of containment BSL [redacted] and [redacted]
 - Classification [redacted]
 - [redacted] the committee affirmed that the above listed criteria, drawn from the [redacted] [redacted] have [redacted]
- Vote: [redacted] approved, 0 opposed, 0 abstained.

rDNA#	PI	rDNA Registration Document Title
[redacted]	T. Tootle	[redacted] and [redacted] interactions in cancer cells

The goal of this project is to determine how manipulating COX2 and PaeA in [redacted] NSCLC [redacted] cell growth, cell migration, and remodeling, and invasion.

- [redacted]
 - Assessment of containment BSL 2 [redacted]
 - Classification [redacted]
 - [redacted] the committee affirmed that the above listed criteria, drawn from the [redacted] [redacted] have [redacted]
- Vote: 8 approved, 0 opposed, 0 abstained.

The second part of the meeting was open to the public.

3. Old Business

Dr. Kirchhoff provided revised language to replace the BSL2* footnote in the table attached to Dr. Perlman's pending rDNARD, #140083 prior to today's meeting. The committee discussed the language and had no concerns. Dr. Sinn will contact Dr. Perlman to discuss the revision and update the rDNARD as necessary.

4. New Business

- a) Dr. Sinn reported on two amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff.
 - Dr. Taylor, #130110, was amended to include retro-orbital sinus as a route of administration.
 - Dr. Harty, #120163, was amended to include MHV-JHM and a replication defective lentivirus as vectors and shRNA against apoptosis regulating genes, VSVG and gag/pol as inserts.
- b) Prior to today's meeting, Dr. Sinn forwarded to committee members Dr. Wu's amendment request to rDNARD #120029. The committee discussed the use of the replication defective rabies virus and determined that ABSL2a was the appropriate containment. However, the source and function columns are incorrect. Mrs. Kratz stated that additional inserts need to be added in order to cover the work entered in the AP as an amendment. Biosafety staff will work with Dr. Wu to ensure the table is complete and accurate. The committee unanimously approved the amendment request pending the addition of this information.

The meeting adjourned at 4:24 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on May 22, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: May 22, 2014
To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject: Minutes of the IBC Meeting of May 22, 2014
Members Present: Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, James Sheets, and Haley Sinn, and Ms. Carol McGhan
Members Absent: Dr. Jeffery Meier
Guests Present: Mrs. Deborah Kratz

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. Approval of minutes from meetings on May 8, 2014
No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Sheets, to approve the minutes of the May 8, 2014, meeting. The members voted unanimously for approval.

2. rDNARDs under review:
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; Dr. Sinn reported a conflict with 1 rDNARD and will abstain during the vote. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following four rDNARDs were considered:

Table with 2 columns: rDNA# PI and rDNA Registration Document Title. The content is heavily redacted with black bars.

The second part of the meeting was open to the public.

3. Old Business
None

4. New Business

- a) Dr. Sinn reported on three amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff.
- Dr. Welsh, #110077, was amended to include several inserts, additional staff and the intracranial route of administration.
 - Dr. Okeoma, #130218, was amended to include mutations of already approved inserts, the Cas9 nuclease from *S. pyogenes* and an additional plasmid vector.
 - Dr. McCray, #120062, was amended to remove Iowa State University as a collaborating institution with PIV5 research in pigs; no pig work with PIV5 will be performed at the University of Iowa and therefore pig has been removed as a host from the table. Any animal work with this plasmid will have to be approved by the appropriate committees at the collaborating site.
- b) Dr. Sinn reported that she, Dr. Jarosinski, and Mrs. Kratz met with Dr. Perlman and his staff members involved in rDNA research as part of the monitoring program imposed as a result of the laboratory's violation outlined in the recent report to NIH/OBA. At that meeting ongoing rDNA research was reviewed and it was determined that human cell lines must be added as a host to both approved rDNARDs (#s 120125 and 140083) In addition, Perlman staff member J. Athmer needed to be added to rDNARD #140083 by amendment and this was done subsequently by Dr. Perlman and approved by Dr. Kirchhoff. The next monitoring meeting will take place in August.
- c) Prior to today's meeting, Dr. Sinn forwarded a document describing a reportable event associated with Dr. Lubaroff's rDNARD #120345. Dr. Kirchhoff discussed the event and no additional concerns were raised by the committee.
- d) Prior to today's meeting, Drs. Martino-Cardona and Sheets provided proposed language to add to the rDNARD approval letters regarding animal work approved in the rDNARD but not the Animal Protocol (AP). IACUC staff are currently contacting PIs with non-congruent approvals and informing them of the need to amend their AP; however, as some animal experiments may be planned for the distant future, PIs are requesting to amend the AP at a later date. IACUC administers must inform Biosafety Staff that the language is to be added into the approval letter; otherwise, the language will not be included.

The following language will be included when appropriate: "Please be aware that your approved rDNA Registration Document (rDNARD) lists the use of additional species or procedures that are not listed/approved in the associated Animal Protocol/s. Only procedures approved by the Institutional Animal Care and Use Committee (IACUC) may be conducted under this approved rDNARD. You must amend your Animal Protocol and receive IACUC approval prior to conducting any currently unapproved procedures or utilizing a currently unapproved species."

- e) Mrs. Kratz discussed the review of the rDNARDs by the committee and requested feedback prior to the meeting in order to expedite processing of the rDNARD following the meeting. The AP approvals are now withheld until all rDNA work has been approved and PIs are frustrated at the delay in approvals. Dr. Martino-Cardona stated that previous reviews of APs involved frequent communication with the PIs who then became frustrated at the multiple emails/phone calls from the IACUC. The committee decided that our current process of collecting concerns/questions at the time of the meeting is appropriate and will result in minimal interruptions to the PI. The average time for AP approval is 4-6 weeks and PIs should have no issues receiving rDNA approval within the time frame of the AP review if the rDNARD is submitted simultaneously with the AP.

The meeting adjourned at 4:19 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on June 5, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchoff, MD, MPH, Chair, Institutional Biosafety Committee



Environmental Health & Safety
 100 EHS
 Iowa City, IA 52242 - 1000
 Ph. 319-335-8501
 Fax 319-335-7564

Date: June 5, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of June 5, 2014

Members Present: Drs. Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, James Sheets, and Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Adam Clore, Lucy DesJardin, and Jeffery Meier

Guests Present: Mrs. Deborah Kratz

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:32 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

- Approval of minutes from meetings on May 22, 2014**
 No suggestions for changes in the circulated minutes were made. Dr. Martino-Cardona made a motion, seconded by Dr. Jones, to approve the minutes of the May 22, 2014, meeting. The members voted unanimously for approval.
- rDNARDs under review:**
 The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following three rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	J. Kirby	[REDACTED]

- [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
- Guidelines based on [REDACTED]
- [REDACTED]

- b) Prior to today's meeting, Dr. Sinn forwarded to committee members Ms. Scheel's request to amend rDNARD #140118 which lists in a table inserts that fall outside the GVTC's broad approval. The committee requested that a footnote be added to the vector column of the table that refers the reader back to the replication-defective description of all the vectors listed in the approved rDNARD. The committee also discussed how to handle future amendment requests from the GVTC and decided that the process currently being utilized is appropriate. In this process, Dr. Kirchhoff reviews the substance of each amendment request and either approves the request or sends it to the committee for full review.

Ms. McGhan made a motion, seconded by Dr. Sheets, to approve the amendment request. The members voted unanimously for approval.

The meeting adjourned at 4:00 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on June 19, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

3. Old Business

None

4. New Business

- a) Dr. Sinn reported on five amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff or in the case of staff additions, approved by Dr. Sinn.
- Dr. Weiss, #130173, was amended to include an insert involved in cellulose binding, a pET vector and additional staff.
 - Dr. Banfi, #120191, was amended to include microRNA inserts and a gene involved in transcriptional regulation and the pBS vector.
 - Dr. Janz, #130015 and 130019, were amended to include additional staff.
 - Dr. Engelhardt, #130148, was amended to include injection of ASPM1 mRNA (mitotic spindle function) into a ferret embryo and additional routes of administration for ferrets.
 - Dr. Rutkowski, #110203, was amended to include additional genes related to peripheral metabolism and ER stress in an AAV vector.
- b) Prior to today's meeting, Dr. Sinn forwarded to committee members Dr. Berg's annual report to OBA, associated with rDNARD #140031. Dr. Kirchhoff briefly discussed the report, noting that no SAEs were related to the rDNA administered and that the project is closed to new enrollment at the University of Iowa. There were no concerns regarding the report were raised by the committee members.
- c) Dr. Sinn will send an email to all committee members to determine their availability for the next regularly scheduled meeting on July 3 and based on the responses will determine if the meeting should be rescheduled.

The meeting adjourned at 3:54 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on July 3rd.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: July 3, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of July 3, 2014

Members Present: Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, Jeffery Meier, James Sheets and Ms. Carol McGhan

Members Absent: Drs. Bradley Jones and Haley Sinn

Guests Present: Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:32 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. Approval of minutes from meetings on June 19, 2014

No suggestions for changes in the circulated minutes were made. Dr. DesJardin made a motion, seconded by Dr. Clore, to approve the minutes of the June 19, 2014, meeting. The members voted unanimously for approval.

2. rDNARDs under review:

The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following three rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	A. Comellas	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Dr. [redacted] affirmed that the above listed criteria, drawn from the NIH Guidelines, have been met, however, approval is contingent upon obtaining satisfactory responses from the PI regarding the information requested by EHS's Biosafety staff. [redacted] approved, 0 opposed, 0 abstained.

rDNA#	PI	rDNA Registration Document Title
[redacted]	P. McCray	[redacted] host cell interactions and transgene development

The goal of this project is to determine the route of infection for [redacted] CAPS G, V, and MPB G, V in the [redacted] [redacted] which cell types are being infected. We are also interested in the [redacted] [redacted] in mouse models [redacted] [redacted]

Dr. [redacted] affirmed that the above listed criteria, drawn from the NIH Guidelines, have been met, however, approval is contingent upon obtaining satisfactory responses from the PI regarding the information requested by EHS's Biosafety staff. [redacted] approved, 0 opposed, 0 abstained.

rDNA#	PI	rDNA Registration Document Title
140149	S. Chen	[redacted] for [redacted] migration and tumor metastasis by [redacted]

The goal of this project is to determine how [redacted] to migration and [redacted] is regulated by G protein signaling.

Dr. [redacted] affirmed that the above listed criteria, drawn from the NIH Guidelines, have been met, however, approval is contingent upon obtaining satisfactory responses from the PI regarding the information requested by EHS's Biosafety staff. [redacted] approved, 0 opposed, 0 abstained.

The second part of the meeting was open to the public.

- 3. Old Business
None
- 4. New Business

- a) Ms. McGhan reported on three amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchoff or in the case of staff additions, approved by Dr. Sinn.
 - Dr. Jarosinski, #130139, was amended to include additional hosts, vectors and animals, e.g., full Marek's disease virus genome, modified endogenous vial telomerase RNA, MDV UL44 glycoprotein C, an ILTV (infectious laryngotracheitis virus) glycoprotein and a turkey herpesvirus glycoprotein.
 - Dr. Anderson, #130079, was amended to add a new staff member in the lab, and additional strains of non-pathogenic *E. coli*.

- Dr. Lal, #130037, was amended to add an insert (shRNA to ECM1) and pLKO.1 vector (Lentivirus), another cell line, SCID or NOG mice and a new route of infection.
- Ms. Scheel, #140118, added a mouse insert for use with an AAV vector and hosts consisting of E coli, Sf9 and HT 1080 cells.

The meeting adjourned at 3:45 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on July 17th.

Minutes submitted by: Carol McGhan, MPH, CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: July 17, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of July 17, 2014

Members Present: Drs. Lucy DesJardin, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Adam Clore, Leonard Duncan, Jeffery Meier, and James Sheets

Guests Present: Ms. Wendie Dockstader and Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:32 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. Approval of minutes from meetings on July 3, 2014

No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Martino-Cardona, to approve the minutes of the July 3, 2014, meeting. The members voted unanimously for approval.

2. rDNARDs under review:

The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following ten rDNARDs were considered:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
[REDACTED]	F. Sutterwala	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

rDNA# PI

rDNA Registration Document Title

[REDACTED] Y. Vyas

[REDACTED] Regulation of WASP gene transcription

- The goal of this project is to define, at the level of chromatin regulation, a novel nuclear role of Wiskott-Aldrich syndrome protein (WASP) in the molecular and transcriptional pathways leading to CD4 T cell (Th1) differentiation and the development of type 1 pathogen-specific immunity.
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI

rDNA Registration Document Title

[REDACTED] C. Thomas

[REDACTED] RNA and its function in the glomerular basement membrane

- The goal of this project is to identify the mechanisms that regulate the increased expression of the *hprt* gene in glomerular mesangial cells and determine the effect of *hprt* isoforms on gene expression.
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI

rDNA Registration Document Title

[REDACTED] R. Smith

[REDACTED] Study of Membranoproliferative Glomerulonephritis Type II

- The goal of this project is to identify an effective treatment for Membranoproliferative Glomerulonephritis Type II (MPGN II) in patients.
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI

rDNA Registration Document Title

[REDACTED] A. Horswill

[REDACTED] Signaling pathways in *Staphylococcus aureus*

- The goal of this project is to identify regulatory cascades in *Staphylococcus aureus*.
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title

[REDACTED] S. Moore [REDACTED]

- The goal of this project is to determine the mechanism of [REDACTED]
- [REDACTED]
- Assessment of containment: BSL-2
- Classification: H-D-1
- By a majority vote, the committee affirmed that the above listed criteria, drawn from the NIH Guidelines, have been [REDACTED]

[REDACTED] approved, 0 opposed, 0 abstained

rDNA# PI rDNA Registration Document Title

[REDACTED] H. Habelhah [REDACTED]

- The goal of this project is to define the role of RFL cleavage in TRAIL-induced [REDACTED] activation and its implication in cancer cell resistance to TRAIL-induced [REDACTED].
- [REDACTED]
- Assessment of containment: [REDACTED]
- Classification: H-D-3
- By a majority vote, the committee affirmed that the above listed criteria, drawn from the NIH Guidelines, have been [REDACTED]

[REDACTED] approved, 0 opposed, 0 abstained

rDNA# PI rDNA Registration Document Title

[REDACTED] M. Wilson [REDACTED]

- The goal of this project is to identify the white blood cells that contribute to the [REDACTED]
- [REDACTED]
- Assessment of containment: BSL-1, BSL-2 and ABSL-2
- Classification: H-D-1
- By a majority vote, the committee affirmed that the above listed criteria, drawn from the NIH Guidelines, have been [REDACTED]

[REDACTED] approved, 0 opposed, 0 abstained

rDNA# PI rDNA Registration Document Title

[REDACTED] L. Norian [REDACTED]

- The goal of this project is to identify the mechanisms responsible for [REDACTED]
- [REDACTED]
- Assessment of containment: BSL-2, ABSL-1 and ABSL-2
- Classification: H-D-1
- By a majority vote, the committee affirmed that the above listed criteria, drawn from the NIH Guidelines, have been [REDACTED]

[REDACTED] approved, 0 opposed, 0 abstained

rDNA# PI rDNA Registration Document Title

[REDACTED] K. DeMali [REDACTED]

- The goal of this project is to understand [REDACTED] in promoting cell stiffness [REDACTED]
- [REDACTED]
- Assessment of containment: BSL-2 and ABSL-1

[REDACTED]

The second part of the meeting was open to the public.

3. Old Business

- a) rDNARDs approved at a previous IBC meeting contingent upon receipt from the PI of additional information or clarification.

Additional information or clarification was received from the PIs regarding the following rDNARDs and was judged to be satisfactory:

- Dr. McCray rDNARD #140143, stated that SARS-CoV is in the title because it is the title of the associated grant. The strain of MERS-CoV is wild-type MERS-CoV.

- b) Prior to today's meeting, Dr. Sinn forwarded to committee members Dr. Maury's most recent results regarding post-vaccination shedding by mice vaccinated with VSV pseudovirions bearing the glycoproteins of Ebola and Marburg viruses. Dr. Kirchhoff discussed the results and asked the committee members if they had concerns with the experiments performed or the results. There were no concerns raised and members felt the data reasonably demonstrated that there was no shedding following the vaccinations. Dr. Maury also submitted a request to lower the containment level for the VSV pseudovirion vaccinated mice from ABSL2 to ABL1 as an amendment to rDNARD #140095.

The committee voted unanimously to approve Dr. Maury's amendment request.

4. New Business

- a) Dr. Sinn reported on two amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff or in the case of staff additions, approved by Dr. Sinn.
- Dr. Parekh, #130267, was amended to include additional staff.
 - Dr. Perlman, #120125, was amended to include additional routes of administration to animals.

The meeting adjourned at 3:50 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on July 31st.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



Environmental Health & Safety
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 Ph. 319-335-8501
 Fax 319-335-7564

Date: July 31, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of July 31, 2014

Members Present: Drs. Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Adam Clore, Lucy DesJardin, Bradley Jones, Jeffery Meier, and James Sheets

Guests Present: Ms. Wendie Dockstader and Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:32 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

- Approval of minutes from meetings on July 17, 2014**
 No suggestions for changes in the circulated minutes were made. Dr. Duncan made a motion, seconded by Dr. Martino-Cardona, to approve the minutes of the July 17, 2014, meeting. The members voted unanimously for approval.
- rDNARDs under review:**
 The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following ten rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	O. Shchelochkov	[REDACTED]
		<ul style="list-style-type: none"> The goal of this project is to investigate the function of genes in metabolic pathways. Discussions Containment level: BSL-1 Classification The committee affirmed that the above listed items had been reviewed and approved, if opposed, it is submitted.

rDNA#	PI	rDNA Registration Document Title
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[REDACTED] L. Zingman [REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title
 [REDACTED] C. Zhao [REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title
 [REDACTED] D. Lubaroff [REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title
 [REDACTED] C. Benson [REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title
 [REDACTED] B. Boles [REDACTED]

- [REDACTED]
- [REDACTED]

- Discussed. During the meeting a committee member requested additional information on the source that will be listed in the project description. This information will be listed at the bottom of the table. The committee also requested clarification on whether the single vector listed in the application carries all five antibiotic resistances. It is an additional vector that is used. Biosafety staff will contact Dr. Boles and amend the rDNA RD.
- Assessment of containment: BSL-2
- Classification: II-B
- By majority vote, the committee affirmed that the above listed criteria, drawn from the NIH Guidelines, have been met, however, approval is contingent upon obtaining satisfactory responses regarding the information requested by EHS's Biosafety staff.
- Vote: 6 approved, 0 opposed, 0 abstained.

rDNA#	PI	rDNA Registration Document Title
10164	S. Gopishetty	[REDACTED]

- The goal of this project is to ferment *Pichia pastoris* at various scales starting from 10-L to 1000-L and supply them with cells.
- Discussed.
- Assessment of containment: BSL-1 Large scale
- Classification: III-D-G
- By majority vote, the committee affirmed that the above listed criteria, drawn from the NIH Guidelines, have been met.
- Vote: 6 approved, 0 opposed, 0 abstained.

rDNA#	PI	rDNA Registration Document Title
10165	S. Gopishetty	[REDACTED]

- The goal of this project is the production of cell paste for purification of enzyme.
- The committee requested that the vector listed in the text box under the table be added to the vector column of the table. Biosafety staff will make the requested change.
- Assessment of containment: BSL-1 Large scale
- Classification: II-B
- By majority vote, the committee affirmed that the above listed criteria, drawn from the NIH Guidelines, have been met.
- Vote: 6 approved, 0 opposed, 0 abstained.

rDNA#	PI	rDNA Registration Document Title
1017	N. Karankikar	[REDACTED]

- The goal of this project is to examine whether CD8+ T cells generated in EMI Cx36 people with mice are regulatory in nature.
- Discussed.
- Assessment of containment: BSL-2, ABSL 2a
- Classification: II-B
- By majority vote, the committee affirmed that the above listed criteria, drawn from the NIH Guidelines, have been met.
- Vote: 6 approved, 0 opposed, 0 abstained.

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	D. Price	[REDACTED]

- [REDACTED] project is to study the role of transcription factors in regulating gene expression at the level of [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED] majority vote, the committee affirmed that the above listed criteria drawn from the *NIH Guidelines* have been [REDACTED]
- [REDACTED] 0 approved, 0 opposed, 0 abstained

The second part of the meeting was open to the public.

3. Old Business

There was no old business.

4. New Business

- a) Dr. Sinn reported on five amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff or in the case of staff additions, approved by Dr. Sinn.
 - Dr. Salem, #120069, was amended to include additional inserts, a cmRNA vector and administration to animals via implantation in calvarial defects.
 - Dr. Salgado-Pabon, #140017, was amended to include subcutaneous as an additional routes of administration to animals.
 - Dr. Welsh, #140122, was amended to include the FOXJ1 promoter as an insert.
 - Ms. Scheel, #140118, was amended to include lactate dehydrogenase A as an insert.
 - Dr. Vyas, #140129, was amended to include an additional replication-defective lentiviral vector and microRNA for HMGN1, a nucleosomal binding protein, as an insert.
- b) Prior to today's meeting, Dr. Sinn forwarded to committee members the Gene Transfer Vector Core's second quarter report for 2014. There were no concerns raised by the committee. Dr. Duncan made a motion, seconded by Ms. McGhan, to approve the report; the members voted unanimously for approval. Dr. Sinn will attach this report to the GTVC's broad approval rDNARD, #140118.

The meeting adjourned at 3:50 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on August 14th.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: August 14, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of August 14, 2014

Members Present: Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, James Sheets, and Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Bradley Jones and Jeffery Meier

Guests Present: Ms. Wendie Dockstader and Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

- Approval of minutes from meetings on July 31, 2014**
 No suggestions for changes in the circulated minutes were made. Dr. Sheets made a motion, seconded by Dr. Desjardin, to approve the minutes of the July 31, 2014, meeting. The members voted unanimously for approval.
- rDNARDS under review:**
 The rDNARDS being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDS and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDS under review; Dr. Jarosinski reported a conflict with rDNARD #140175 (P. Schlievert) and will abstain on that vote. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following nine rDNARDS were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	S. Hunter	[REDACTED]

- The goal of this project is to develop a treatment for [REDACTED]
- [REDACTED]
- [REDACTED] of containment: BSL1, BSL2 and ABSL1
- [REDACTED]
- [REDACTED] of the committee affirmed that the above listed criteria drawn from [REDACTED]
- [REDACTED]
- [REDACTED] proposed [REDACTED]

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	P. Schlievert	[REDACTED] Pathogens-Cytarabine Endocarditis

- [redacted] to determine if the new superantigens and cytotoxins in [redacted] ability to cause infective endocarditis and skin diseases in [redacted]
- [redacted]
- [redacted] of containment: BSL2 and ABSL2
- Classification: HEP
- [redacted] vote, the committee affirmed that the above listed criteria drawn from the [redacted]
- [redacted] approved, 0 opposed, 1 abstained

rDNA# PI rDNA Registration Document Title

[redacted] F. Abboud [redacted] Genetically Modified Sensory Transduction by rDNA Sensing Channels

- The goal of this project is to develop better treatment strategies for human with high blood [redacted] at normal [redacted] generation
- [redacted]
- [redacted]
- Classification: HEP
- [redacted] vote, the committee affirmed that the above listed criteria drawn from the [redacted]
- [redacted] met.
- [redacted]

rDNA# PI rDNA Registration Document Title

[redacted] J. Sieren [redacted] [redacted] Animal Cancer Model

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA# PI rDNA Registration Document Title

[redacted] M. Tanas [redacted] [redacted] [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

rDNA# PI rDNA Registration Document Title

[redacted] W. Paradee [redacted] [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] S. Gopishetty [REDACTED]

[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] S. Gopishetty [REDACTED]

[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] M. Wilson [REDACTED]

[REDACTED]

The second part of the meeting was open to the public.

3. Old Business

There was no old business.

4. New Business

- a) Dr. Sinn reported on three amendments to previously-approved rDNARDS that were recently approved by Dr. Kirchhoff.
 - Dr. Banfi, #120191, was amended to include microRNA inserts and a replication defective AAV vector.
 - Dr. Harty, #110264, was amended to include RSV attachment and membrane proteins as inserts and a replication defective adenoviral vector.

- Dr. Perlman, #140083, was amended to include additional plasmid constructs.
- b) Prior to today's meeting, Dr. Sinn forwarded to committee members a reportable event associated with Dr. Russell's rDNARD, #120350. The study protocol required reporting any hospitalization as a severe adverse event even though the investigators indicated that the event was definitely not related to the study drug. The committee members had no concerns with the report.

The meeting adjourned at 3:50 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on August 28th.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchoff, MD, MPH, Chair, Institutional Biosafety Committee



Environmental Health & Safety
 100 EHS
 Iowa City, IA 52242 – 1000
 Ph. 319-335-8501
 Fax 319-335-7564

Date: August 28, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of August 28, 2014

Members Present: Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, James Sheets, and Haley Sinn and Ms. Carol McGhan

Members Absent: Dr. Jeffery Meier

Guests Present: Ms. Wendie Dockstader and Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:32 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

- Approval of minutes from meetings on August 14, 2014**
 No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Ms. McGhan, to approve the minutes of the August 14, 2014, meeting. The members voted unanimously for approval.
- rDNARDS under review:**
 The rDNARDS being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDS and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDS under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following ten rDNARDS were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	J. Klesney-Tait	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] M.S. O'Dorisio [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] R. Mullins [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

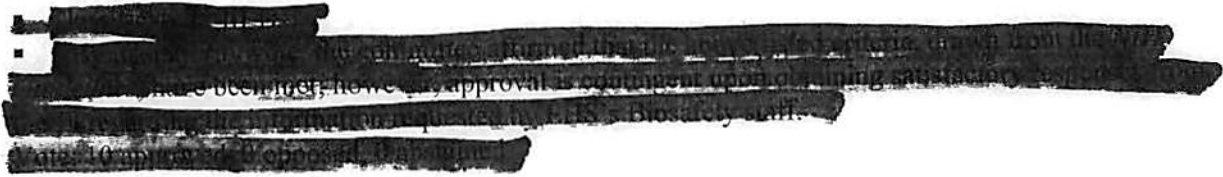
rDNA# PI rDNA Registration Document Title
[REDACTED] X. Meng [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] D. Rutkowski [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] V. Mahajan [REDACTED]



The second part of the meeting was open to the public.

3. Old Business

There was no old business.

4. New Business

- a) Dr. Sinn reported on four amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff.
- Dr. Spies, #120082, was amended to include the High Throughput Screening Facility, new staff and a new funding source.
 - Dr. Tucker, #130224, was amended to include a transgenic Pro23His rhodopsin pig.
 - Dr. Weiss, #130173, was amended to include additional plasmid vectors and a Keio collection of E. coli K-12 knockout mutants.
 - Dr. Chapleau, #130173, was amended to include an additional shRNA-AT1Ra insert.
- b) Dr. Sinn reported that she, Dr. Jarosinski, and Mrs. Dockstader met with Dr. Perlman and his staff members involved in rDNA research as part of the monitoring program imposed by the committee as a result of the laboratory's violation outlined in the recent report to NIH/OBA. At that meeting ongoing rDNA research was reviewed and it was determined that plasmid vectors must be added for cloning of the MHV nsp3 and nsp15 inserts by amendment. This was done subsequently by Dr. Perlman and approved by Dr. Kirchhoff as an amendment to approved rDNARD #120125.

In addition, Dr. Perlman added an MHV-JHM vector carrying Cre-recombinase to rDNARD #120125 and a Bac clone and infectious MERS-CoV vector carrying a mutated S protein of MERS-CoV to rDNARD #140083.

The next monitoring meeting with Dr. Perlman and his staff will take place in November.

- c) Prior to today's meeting, Dr. Sinn informed committee members regarding Dr. Maury's request to the IACUC to remove mice infected with recombinant infectious VSV from the ABSL2a housing for imaging purposes. Prior to this meeting Dr. Sinn forwarded to all committee members Dr. Maury's relevant rDNARD and a protocol previously developed by OAR for removing mice infected with recombinant replication deficient VSV. After considerable discussion, the committee decided to request additional information and clarification from USDA regarding this issue. The latter approach was taken because Dr. Maury's USDA permit does not contain restrictions on where the work involving mice exposed to recombinant infectious VSV may be carried out, but a prior USDA permit for Dr. Goel did restrict the work with similar mice to her laboratory and the ABSL2a room. Dr. Sinn will contact the USDA for clarification and inform Dr. Maury of the committee's decision.
- d) Ms. McGhan discussed the Biosafety Stand-down and National Biosafety Stewardship Month (September 2014) established by OSTP and NIH. In the early 2000s, and again some years later when the Select Agent Program was established at UI, EHS asked all PIs to review their freezer inventories of biological materials. In addition, laboratories currently are required by EHS to provide a copy of their biological agent inventories at the time of the annual laboratory review. These inventories are required to include agents actively being used as well as those in storage.

Consistent with the goals of the Biosafety Stand-down and National Biosafety Stewardship Month Ms. McGhan and Drs. Sinn and Walker will meet to review the biosafety programs currently in place and determine what, if any, efforts need be made to strengthen the oversight at the University.

The meeting adjourned at 4:10 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on September 11th.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: September 11, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of September 11, 2014

Members Present: Drs. Adam Clore, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn and Ms. Carol McGhan

Members Absent: Drs. Lucy DesJardin, Leonard Duncan, Bradley Jones, James Sheets, and Jeffery Meier

Guests Present: Ms. Wendie Dockstader and Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:32 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on August 28, 2014**
 No suggestions for changes in the circulated minutes were made. Dr. Martino-Cardona made a motion, seconded by Dr. Clore, to approve the minutes of the August 28, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
 The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following six rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	M. Pufall	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

rDNA# PI rDNA Registration Document Title
[REDACTED] B. Boles [REDACTED]

[REDACTED] provides the conditions of S. aureus bio-film development
[REDACTED] informed the committee that the new Annual Protocol (AP) will
[REDACTED] be added as a route of administration to [REDACTED]
[REDACTED] was added into the approval letter, informing Dr. Boles that IACUC
[REDACTED] is
[REDACTED] of containment: BSL2, ABSL1, and ABSL2a
[REDACTED]
[REDACTED] the committee affirmed that the above listed criteria drawn from the
[REDACTED]
[REDACTED] approved 0 opposed 0 abstained

rDNA# PI rDNA Registration Document Title
[REDACTED] S. Gopishetty [REDACTED]

[REDACTED] produce cell paste to purify recombinant protein
[REDACTED] Large Scale
[REDACTED]
[REDACTED] the committee affirmed that the above listed criteria drawn from the
[REDACTED] have been
[REDACTED] approved 0 opposed 0 abstained

rDNA# PI rDNA Registration Document Title
[REDACTED] S. Gopishetty [REDACTED]

[REDACTED] for the expression of GFP protein
[REDACTED]
[REDACTED] Large Scale
[REDACTED]
[REDACTED] the committee affirmed that the above listed criteria drawn from the
[REDACTED]
[REDACTED] approved 0 opposed 0 abstained

rDNA# PI rDNA Registration Document Title
[REDACTED] S. Gopishetty [REDACTED]

[REDACTED] the fermentation for the expression of GFP protein
[REDACTED]
[REDACTED] Large Scale
[REDACTED]
[REDACTED] the committee affirmed that the above listed criteria drawn from the
[REDACTED]
[REDACTED] approved 0 opposed 0 abstained

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



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Date: September 25, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of September 25, 2014

Members Present: Drs. Adam Clore, Lucy DesJardin, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, and Ms. Carol McGhan

Members Absent: Drs. James Sheets, Jeffery Meier, and Haley Sinn

Guests Present: Ms. Wendie Dockstader and Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:34 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meetings on September 11, 2014**
 No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Martino-Cardona, to approve the minutes of the September 11, 2014, meeting. The members voted unanimously for approval.

2. **rDNARDs under review:**
 The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following eight rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	C. Stein	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

rDNA# PI rDNA Registration Document Title
140223 G. Richerson ~~SEDER Research Alliance: Respiratory and Tissue Mechanisms~~

- ~~The goal of this project is to define how seizures cause stroke and persistent cognitive deficits. We will use genetic strategies, identify the markers, and aid in forensic diagnosis through mouse models.~~
- ~~Discussion: Dr. Desjardins requested clarification of whether the constructs will be made at the University of North Carolina. Dr. Richerson will obtain the requested information if necessary. Ms. Deckstader informed the committee that the PI will include and mutants to the inserts listed in the table. So the rDNA matches what is listed in the table.~~
- ~~Assessment of containment: BSL2 and ABSL2~~
- ~~Classification: III-D-1~~
- ~~As a majority vote, the committee affirmed that the above listed criteria, drawn from the NIH Guidelines, have been met.~~
- ~~0 approved, 0 opposed, 0 abstained~~

rDNA# PI rDNA Registration Document Title
140224 A. Horswill ~~Measuring ribonuclease activity of Staphylococcus aureus~~

- ~~The goal of this project is to use the RNase RNA degrading activity associated with Staphylococcus aureus.~~
- ~~Discussion: Ms. Deckstader stated the PI would like to add the IN name of administrative rDNA. Dr. Desjardins will match the rDNA.~~
- ~~Assessment of containment: BSL2 and ABSL2~~
- ~~Classification: III-D-1~~
- ~~As a majority vote, the committee affirmed that the above listed criteria, drawn from the NIH Guidelines, have been met.~~
- ~~0 approved, 0 opposed, 0 abstained~~

rDNA# PI rDNA Registration Document Title
140225 H. Habelhah ~~Characterize the role of RSKAP in NF-kB activation~~

- ~~The goal of this project is to shed new light on the role of RSK2 phosphorylation in NF-kB activation and cancer cell resistance to stress-induced apoptosis.~~
- ~~Assessment of containment: BSL2 and ABSL2~~
- ~~Classification: III-D-1~~
- ~~As a majority vote, the committee affirmed that the above listed criteria, drawn from the NIH Guidelines, have been met.~~
- ~~0 approved, 0 opposed, 0 abstained~~

rDNA# PI rDNA Registration Document Title
140226 S. Baker ~~Role of retinoic acid receptors in retinoic acid-induced gene expression~~

- ~~The goal of this project is to test the efficacy of transactivating retinoic acid receptors with retinoic acid in the regulation of gene expression. The PI will include and mutants to the inserts listed in the table. So the rDNA matches what is listed in the table.~~
- ~~Assessment of containment: BSL2 and ABSL2~~
- ~~Classification: III-D-1~~
- ~~As a majority vote, the committee affirmed that the above listed criteria, drawn from the NIH Guidelines, have been met.~~
- ~~0 approved, 0 opposed, 0 abstained~~

- Dr. Quelle, #130122, was amended to add new lab staff, a new AP number, and new route of administration.
- Dr. Chapleau, #140068, was amended to add two new synthetic inserts.
- Dr. Stapleton, #120021, was amended to include new vectors and inserts.
- Dr. Rutkowski, #140194, was amended to include a new host and use of naked plasmid rDNA.
- Dr. Abel, #140069, was amended to add new vectors, inserts and hosts, in addition to a Co-PI.

The meeting adjourned at 3:57 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on October 9th.

Minutes submitted by: Carol McGhan, MPH, CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



Environmental Health & Safety
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Date: October 9, 2014

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of October 9, 2014

Members Present: Drs. Lucy DesJardin, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, James Sheets, Haley Sinn, and Ms. Carol McGhan

Members Absent: Drs. Adam Clore, Leonard Duncan, Bradley Jones, and Jeffery Meier

EHS Staff Members Present: Ms. Wendie Dockstader and Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:40 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

- Approval of minutes from meetings on September 25, 2014**
 No suggestions for changes in the circulated minutes were made. Ms. McGhan made a motion, seconded by Dr. Sheets, to approve the minutes of the September 25, 2014, meeting. The members voted unanimously for approval.
- rDNARDs under review:**
 The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; Dr. Sinn reported a conflict with #140242 and #140245 rDNARDs and will abstain during the votes. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following ten rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	B. Jones	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

rDNA# PI rDNA Registration Document Title

[REDACTED] S. Gopishetty [REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title

[REDACTED] J. Freeman [REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title

[REDACTED] P. Sinn [REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

rDNA# PI rDNA Registration Document Title

[REDACTED] P. Sinn [REDACTED]

- [redacted] including the [redacted] chain
- [redacted] into a shuttle plasmid for a new [redacted] investigation
- Discussion: As with the previous rDNA, the goal of this submission is to transfer the [redacted] [redacted] [redacted] to Dr. Singh. There are no other changes to this document, other than the change in [redacted]
- [redacted] of containment: BSL2
- Classification: II
- [redacted] vote, the committee affirmed that the above listed criteria, drawn from [redacted] Guidelines, have been met
- [redacted] approved, 0 opposed, 0 abstained

rDNA# **PI** **rDNA Registration Document Title**
 [redacted] A. Horswill [redacted]

- The goal of this project is to determine the [redacted]
- Discussion: None
- [redacted] of containment: BSL1 and BSL2
- Classification: II
- [redacted] vote, the committee affirmed that the above listed criteria, drawn from the NIH [redacted] Guidelines, have been met
- [redacted] approved, 0 opposed, 0 abstained

rDNA# **PI** **rDNA Registration Document Title**
 [redacted] S. McGowan [redacted]

- [redacted] mechanisms responsible for regulating [redacted] capillary formation in the developing [redacted]
- Discussion: The committee requested clarification on the labeling of "rDNA" as a vector in table. Biosafety staff will contact Dr. McGowan and update the list and [redacted]
- [redacted] of containment: BSL1, BSL2, and ABSL2
- Classification: II
- [redacted] vote, the committee affirmed that the above listed criteria, drawn from the NIH [redacted] Guidelines, have been met
- [redacted] approved, 0 opposed, 0 abstained

rDNA# **PI** **rDNA Registration Document Title**
 [redacted] A. Kwitek [redacted]

- [redacted] project is to identify novel genes and pathways causing Metabolic Syndrome [redacted]
- [redacted]
- [redacted] of containment: BSL2
- Classification: III-D-1
- [redacted] vote, the committee affirmed that the above listed criteria, drawn from the [redacted] Guidelines, have been met
- [redacted] approved, 0 opposed, 0 abstained

rDNA# **PI** **rDNA Registration Document Title**
 [redacted] S. Gopishetty [redacted]

- The goal of this project is the production of cell [redacted]
- Discussion: None
- [redacted] of containment: BSL1 large scale

[REDACTED]

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	S. Gopishetty	[REDACTED]

[REDACTED]

The second part of the meeting was open to the public.

3. Old Business

There was no old business.

4. New Business

- a) Prior to today's meeting, Dr. Maes forwarded to committee members a document describing UI's response to NIH's stand down request. Biosafety staff described the measures taken to ensure training and programs are up-to-date and inclusive of all relevant information, as well as the activities that will be undertaken to ensure the biological agent inventories collected annually by the safety advisors are accurate. The committee members had no concerns with the draft.
- b) Dr. Kirchhoff discussed the membership of the committee and whether or not members preferred a formal or informal process of rotating off the committee. At this time no members responded that they would like to be rotated off the committee.

The meeting adjourned at 4:09 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on October 23rd.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



Environmental Health & Safety
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Date: October 23, 2014
To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject: Minutes of the IBC Meeting of October 23, 2014
Members Present: Drs. Adam Clore, Leonard Duncan, Keith Jarosinski, Bradley Jones, Louis Kirchhoff, Maria Martino-Cardona, James Sheets, and Haley Sinn, and Ms. Carol McGhan
Members Absent: Drs. Lucy DesJardin and Jeffery Meier
EHS Staff Members Present: Ms. Wendie Dockstader and Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:35 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

- Approval of minutes from meetings on October 9, 2014**
No suggestions for changes in the circulated minutes were made. Dr. Jones made a motion, seconded by Dr. Clore, to approve the minutes of the October 9, 2014, meeting. The members voted unanimously for approval.
- rDNARDs under review:**
The rDNARDs being considered were made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARDs and reviewed them prior to the meeting. Members were asked to report any conflict with the rDNARDs under review; no conflicts were reported. The review of the proposed research projects involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following four rDNARDs were considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	J. Sebag	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

rDNA# PI rDNA Registration Document Title

[REDACTED] K. Glenn [REDACTED] Secretory and Aging

- The project is to examine the autophagy pathways to determine 1) which components are important in aging tissue and organs, and 2) which components are important in the process of autophagy.
- During the meeting, the committee requested clarification on the use of BGE and anti-BECLIN1. Whether or not these are shRNA insertions. In addition, the committee requested that the table be clarified that the insertions are cloned in the commercially produced vectors.
- Biosafety staff will contact Dr. Glenn and revise the rDNA RD.
- Assessment of containment: BSL1 and BSL2
- Classification: H.D.
- By a majority vote, the committee affirmed that the above listed criteria, drawn from the NIH Guidelines, have been met.

Votes: 0 approved, 0 opposed, 0 abstained

rDNA# PI rDNA Registration Document Title

[REDACTED] V. Lira [REDACTED] Secretory and Aging

- The project is to examine the GSK3 and GSK2 protein kinases and their effects on the heart and muscle function.
- During the meeting, the committee requested that the proposal be revised to include the staff's experience with the use of adenovirus. The committee requested that the proposal be revised to include the use of adenovirus in the lungs. The proposal #12 as a consistency review with the Animal Protocol. Biosafety staff will contact the PI and the committee to revise the proposal.
- Assessment of containment: BSL2, ADBS1, and ADBS2
- Classification: H.D.
- By a majority vote, the committee affirmed that the above listed criteria, drawn from the NIH Guidelines, have been met.

Votes: 0 approved, 0 opposed, 0 abstained

rDNA# PI rDNA Registration Document Title

[REDACTED] R. Fisher [REDACTED] Secretory and Aging

- The project is to examine the role of the kinases GSK3 and GSK2 in the regulation of insulin signaling.
- Classification: H.D.
- Assessment of containment: BSL2, ADBS1, ADBS2
- Classification: H.D.
- By a majority vote, the committee affirmed that the above listed criteria, drawn from the NIH Guidelines, have been met.

Votes: 0 approved, 0 opposed, 0 abstained

The second part of the meeting was open to the public.

3. Old Business

Dr. Kirchhoff discussed the membership of the committee and asked if a specific term limit is appropriate. In the past, a term limit was established but members were difficult to find and subsequently train and the term limit was discarded. Since then members have been replaced as necessary. The committee determined that an informal process is preferable under which Dr. Kirchhoff will review the membership occasionally and contact members who do not participate in order to determine if they should be replaced.

4. New Business

- a) Dr. Sinn reported on seven amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff.
- Dr. Campbell, #120159, was amended to include two new inserts, furin and DOK7.
 - Dr. Weiss, #130162, was amended to include new promoters, use of the Flow Cytometry Facility and additional shuttle vectors.
 - Dr. McCray, #120062, was amended to update staff and include a Co-PI.
 - Dr. Harty, #110264, was amended to add additional vectors, including an MSCV vector.
 - Dr. Irani, #130158, was amended to include new inserts and TALEN vectors, additional staff and the creation of knockout mice.
 - Dr. Wilson, #140201, was amended to include additional routes of administration.
 - Dr. Banfi, #120191, was amended to include a microRNA as an insert.
- b) Prior to today's meeting, Dr. Sinn forwarded to committee members the third quarter report from the Gene Transfer Vector Core. The committee had no concerns and voted unanimously for approval.
- c) Dr. Sinn requested feedback from committee members on how to report required changes to the rDNARDs following consistency review by the IACUC administrator. The committee requested additional time to review new information in the rDNARD and determined that no changes should be made to the protocols after the Tuesday prior to the meeting. Ms. Dockstader will note all changes that are made to the rDNARDs after they are sent to members and send this worksheet to members on Tuesday before end of day; no subsequent changes to the rDNARDs will be made. Any outstanding issues that are not addressed in the worksheet will be discussed at the IBC meeting.
- d) Ms. McGhan requested feedback from committee members on their preference for the new URL for the upcoming rDNA submission protocol. There were no concerns with using eIBC. Biosafety staff will inform RIS of the discussion.

The meeting adjourned at 4:10 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on November 6, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee



Environmental Health & Safety
100 EHS
Iowa City, IA 52242 - 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: November 6, 2014
To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)
Subject: Minutes of the IBC Meeting of November 6, 2014
Members Present: Drs. Adam Clore, Lucy DesJardin, Keith Jarosinski, Louis Kirchhoff, Maria Martino-Cardona, and Haley Sinn, and Ms. Carol McGhan
Members Absent: Drs. Leonard Duncan, Bradley Jones, Jeffery Meier, and James Sheets
EHS Staff Members Present: Ms. Wendie Dockstader and Dr. Nyree Maes

The meeting was held in 126 GAC, and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

- 1. Approval of minutes from meetings on October 23, 2014**
No suggestions for changes in the circulated minutes were made. Dr. Martino-Cardona made a motion, seconded by Dr. DesJardin, to approve the minutes of the October 23, 2014, meeting. The members voted unanimously for approval.
- 2. rDNARDs under review:**
The rDNARD being considered was made available electronically to all IBC members one week prior to this meeting. All members present indicated that they had access to the pending rDNARD and reviewed it prior to the meeting. Members were asked to report any conflict with the rDNARD under review; no conflicts were reported. The review of the proposed research project involved the consideration of containment level, facilities, procedures, practices, and the experience of personnel involved in the rDNA research.

The following one rDNARD was considered:

rDNA#	PI	rDNA Registration Document Title
[REDACTED]	M. Tanas	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

The second part of the meeting was open to the public.

3. Old Business
None

4. New Business

- a) Dr. Sinn reported on five amendments to previously-approved rDNARDs that were recently approved by Dr. Kirchhoff.
- Dr. Perlman, #120125, was amended to include a tagged nucleocapsid protein from MHV as an insert.
 - Dr. Mahajan, #140058, was amended to include a Co-PI and add the E.coli strain, BL21.
 - Dr. Martin, #140082, was amended to include cell culture work with a replication defective MLV vector.
 - Dr. Campbell, #120159, was amended to update staff and include jugular as a route of administration.
 - Dr. Fisher, #140262, was amended to include additional inserts that will be administered to animals.
- b) Prior to today's meeting, Dr. Sinn forwarded to committee members the report covering last July's ~~inspection of the~~ facility and their responses. Dr. Sinn and Ms. McGhan discussed the inspection report and the committee had no concerns with the report or the responses. Ms. McGhan made a motion, seconded by Dr. Clore, to approve the report. The members voted unanimously for approval.

The meeting adjourned at 3:40 p.m.

The next regularly scheduled meeting will be held at 3:30 p.m. on November 20, 2014.

Minutes submitted by: Haley Sinn, Ph.D., CBSP

Minutes approved by: Louis V. Kirchhoff, MD, MPH, Chair, Institutional Biosafety Committee

NIH OBA Incident Report

For reporting Human Gene Transfer Adverse Events a separate template is available at:
http://www4.od.nih.gov/oba/RAC/Adverse_Event_Template.doc

Does this incident involve research subject to the <i>NIH Guidelines</i> ?	Yes If no, this incident does not have to be reported to OBA
Institution name:	University of Iowa
Date of report:	February 17, 2012
Reporter name and position:	Louis Kirchhoff, MD, MPH; IBC Chair
Reporter telephone:	319-356-7227
Reporter email:	louis-kirchhoff@uiowa.edu
Date of incident:	1/17/2012
Name of principal investigator:	Alexander R. Horswill, PhD
Is this an NIH funded project?	No
If yes, please provide:	NIH grant or contract number: N/A
	NIH funding institute or center: N/A
	NIH program officer contact information (name, email etc): N/A
What was the <u>nature</u> of incident?	Possible personnel exposure to a recombinant strain of <i>Staphylococcus aureus</i>

Did the Institutional Biosafety Committee (IBC) approve this research	Yes
If yes, please provide:	Approval date: 9/29/2011
	Approved biosafety level for the research: BSL2
	Additional approval requirements: None
What section(s) of the <i>NIH Guidelines</i> is the research subject to?	III-D-1
Has a report of this incident been made to other federal or local agencies? If so please indicate by checking the appropriate box.	No

DESCRIPTION OF INCIDENT: (continued)

Introduction:

On January 18, 2012, the University of Iowa's Biosafety Officer (BSO) became aware that an incident resulting in injury of a graduate student the previous day involved a recombinant strain of *S. aureus*. That injury is described in the First Report of Injury form. This incident constitutes a violation of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (Appendix G-II-B-2-k) and therefore must be reported to the Office of Biotechnology Activities at the National Institutes of Health (NIH/OBA). This report, which follows our initial notification of NIH/OBA on January 18, 2012, provides a description of the investigation of this incident, an analysis of the factors underlying the incident, and the University's planned remedial measures intended to prevent the occurrence of incidents of this type in the future.

Description of incident:

This incident involved a graduate student in the laboratory of Dr. Alexander Horswill, a principal investigator in the Department of Microbiology who has an approved rDNA Registration Document that covers work with recombinant *S. aureus*. The student was working with a recombinant *S. aureus* which carries a targeted mutation in a regulator gene. As the student removed the cap from a glass test tube containing the bacteria, the tube broke and cut his finger. The student reported to the University Employee Health Clinic and was sent to the Emergency Room where he received two stitches and tetanus vaccination. He also given a prescription for a three-day course of trimethoprim/sulfamethoxazole. On the day following the incident the BSO met with the student and the principal investigator to obtain additional information regarding the incident. Importantly, the principal investigator explained that although possible, it was highly unlikely that there would have been any *S. aureus* on the neck of the glass tube that broke and cut the student's finger. The student took the antibiotic as prescribed. No local evidence of infection developed at the site of the cut and subsequently it has healed completely.

As of the time of the incident, the student had completed all online training required by the University, which includes Basic Biological Safety; Lab Chemical Safety; PPE Awareness for Labs; and rDNA Research, *NIH Guidelines*.

Laboratory issues uncovered by the investigation:

- At the time the incident occurred the student was not wearing any PPE. It was emphasized during the meeting that disposal gloves and a laboratory coat are required for BSL2 work with hazardous agents.
- Glass tubes are used for frozen storage of the *S. aureus* strains used in the project. The principal investigator stated that they use glass tubes instead of plastic simply because his Department supplies them free of charge.

Has the IBC reviewed this incident?

Yes

If yes, please provide a copy the minutes of the IBC meeting in which the incident was reviewed.

Has a root cause for this incident

Yes

been identified?

If yes please describe: The use of glass tubes to store frozen *S. aureus* strains.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation: (use additional space as necessary)

- The student assured the BSO that the required PPE will be worn while he works with hazardous materials in the laboratory.
- At the request of the IBC, the principal investigator will encourage a culture of safety in his laboratory by emphasizing that laboratory coats and appropriate disposable gloves must be worn when working with hazardous materials, and then will ensure that such PPE is always worn when required.
- The principal investigator will look into the possible use of plastic instead of glass tubes and report to the BSO within one month.

- **Please provide copies of any documents referenced in this report.**
- **Additional information may be requested by OBA after review of this report depending on the nature of the incident.**

NIH OBA Incident Report

**For reporting Human Gene Transfer Adverse Events a separate template is available at:
http://www4.od.nih.gov/oba/RAC/Adverse_Event_Template.doc**

Does this incident involve research subject to the <i>NIH Guidelines</i> ?	Yes If no, this incident does not have to be reported to OBA
Institution name:	University of Iowa
Date of report:	5/30/2012
Reporter name and position:	Louis V. Kirchhoff, MD, MPH; IBC Chair
Reporter telephone:	319-356-7227
Reporter email:	louis-kirchhoff@uiowa.edu
Date of incident:	5/1/2012
Name of principal investigator:	Jeffery L. Meier, MD
Is this an NIH funded project?	Yes
If yes, please provide:	NIH grant or contract number: 5T32AI007533-12
	NIH funding institute or center: NIAID
	NIH program officer contact information (name, email etc): Ed McSweegan, phone: 301-402-8370, mcsweegan@nih.gov
What was the <u>nature</u> of incident?	Possible personnel exposure to a recombinant strain of human CMV (rhCMV)

Did the Institutional Biosafety Committee (IBC) approve this research	Yes
If yes, please provide:	Approval date: 11/24/2009
	Approved biosafety level for the research: BSL2
	Additional approval requirements: None
What section(s) of the <i>NIH Guidelines</i> is the research subject to?	III-D-2
Has a report of this incident been made to other federal or local agencies? If so please indicate by checking the appropriate box.	Other: Iowa City Department of Veterans Affairs Medical Center Oversight Committee

DESCRIPTION OF INCIDENT: (continued)

Introduction:

On May 2, 2012, the University of Iowa's Biosafety Officer (BSO) became aware that an incident resulting in injury of a graduate student the previous day involved a recombinant strain of human cytomegalovirus (rhCMV). This incident constitutes a violation of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (Appendix G-II-B-2-k) and therefore must be reported to the Office of Biotechnology Activities at the National Institutes of Health (NIH/OBA). This report, which follows our initial notification to NIH/OBA on May 2, 2012, provides a description of the investigation of this incident, an analysis of the factors underlying the incident, and the University's planned remedial measures intended to prevent the occurrence of incidents of this type in the future.

Description of incident:

This incident involved a graduate student in the laboratory of Dr. Jeffery Meier, a principal investigator with appointments in the Department of Internal Medicine, University of Iowa, and at the Iowa City Department of Veterans Affairs Medical Center. The student was working with an attenuated recombinant strain of human cytomegalovirus (rhCMV; Towne vaccine strain) that carries an origin of replication for a bacterial artificial chromosome, a gene that encodes a green fluorescent protein, and genes that confer resistance to chloramphenicol and kanamycin. This rhCMV strain is not known to cause disease in humans and has been used in human vaccine trials in the past. Moreover, there is no evidence from the vaccine trials that the Towne strain can establish latent infection in persons exposed to it. The student was working in a biological safety cabinet and was infecting mammalian cells in culture with the rhCMV. As the student disposed of a glass pipette into a sharps container, another pipette used just previously in her work was sticking out of the container, penetrated the glove she was wearing, stuck her finger, and resulted in a superficial puncture evidenced by a dot of blood at the site. The student squeezed additional blood from the site, washed the area two times with soap and water and rinsed it with 70% ethanol.

Subsequent to the incident, the student contacted the principal investigator, filed a First Report of Injury form, and reported to the University Employee Health Clinic (UEHC). Blood was drawn at UEHC for pregnancy testing (negative), anti-CMV IgM (negative), and anti-CMV IgG (positive).

Three days after the incident was reported, the BSO met with the student and the principal investigator to obtain additional information regarding the incident. There was no deviation from the laboratory's SOP for working with rhCMV. The student was wearing gloves and a lab coat and the biological safety cabinet in which she had been working was certified. Occupational health requirements for personnel working with this virus restrict pregnant women from working with high titer hCMV.

As of the time of the incident, the student had completed all online training required by the University, which includes Basic Biological Safety; Lab Chemical Safety; Bloodborne Pathogens for Labs, PPE Awareness for Labs; and rDNA Research, *NIH Guidelines*. The student had completed additional training in the Veterans Administration system that included Biological Safety, Lab Chemical Safety and Bloodborne Pathogen training.

The student did not develop any signs or symptoms of infection subsequent to the incident, and thus there is no indication that she has

become infected with the rhCMV strain with which she was working. The fact that she had anti-CMV IgG shortly after the incident is indicative of prior infection.

Laboratory issues uncovered by the investigation:

- At the time the incident occurred, the sharps container was over-filled and a pipette sticking out of the container punctured her finger.

Has the IBC reviewed this incident?

Yes

If yes, please provide a copy the minutes of the IBC meeting in which the incident was reviewed.

Has a root cause for this incident been identified?

Yes

If yes please describe: The over-filled sharps container.

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation: (use additional space as necessary)

- The student was cautioned not to fill the sharps containers above the fill line. Basic Biological Safety and Bloodborne Pathogen training courses instruct laboratory staff to replace sharps containers when they become 2/3 full, and the student was instructed to follow this directive.
- The principal investigator was encouraged to switch from glass to plastic pipettes for all work in his laboratory involving hazardous materials. Links to the web pages of several vendors that market sterile plastic pipettes that are appropriate for cell culture work of the type performed in the principal investigator's laboratory were given to him.

- **Please provide copies of any documents referenced in this report.**
- **Additional information may be requested by OBA after review of this report depending on the nature of the incident.**

NIH OBA Incident Reporting Template

**For reporting Human Gene Transfer Adverse Events a separate template is available at:
http://www4.od.nih.gov/oba/RAC/Adverse_Event_Template.doc**

Does this incident involve research subject to the <i>NIH Guidelines</i> ?	YES If no, this incident does not have to be reported to OBA
Institution name:	University of Iowa
Date of report:	March 1, 2013
Reporter name and position:	Louis Kirchhoff, MD, MPH; IBC Chair
Reporter telephone:	319-356-7227
Reporter email:	louis-kirchhoff@uiowa.edu
Date of incident:	Identified February 1, 2013
Name of principal investigator:	Kathleen A. Sluka, PT, PhD
Is this an NIH funded project?	Yes
If yes, please provide:	NIH grant or contract number: RO1 AR061371
	NIH funding institute or center: NIAMS
	NIH program officer contact information: William P. Tonkins; 301-594-5032; william.tonkins@nih.hhs.gov
What was the <u>nature</u> of incident?	Other - please describe: Mice injected with recombinant herpes simplex virus-1 (rHSV-1) were housed at animal biosafety level 1 (ABSL1) rather than at ABSL2, as approved by the IBC

<p>Did the Institutional Biosafety Committee (IBC) approve this research</p>	<p>YES If yes, on what date? Most current rDNA protocol was approved on 8/5/2010</p>
<p>If yes, please provide:</p>	<p>Approval date: 8/5/2010 Approved animal biosafety level for the research: ABSL2 Additional approval requirements: None</p>
<p>What section(s) of the <i>NIH Guidelines</i> is the research subject to?</p>	<p>III-D-1</p>
<p>Has a report of this incident been made to other federal or local agencies? If so please indicate by checking the appropriate box.</p>	<p>No</p>

DESCRIPTION OF INCIDENT:

Introduction:

On February 1, 2013, the University of Iowa's Biosafety Officer (BSO) became aware that a principal investigator (PI) was housing mice injected with rHSV-1 in ABSL1, despite the fact that the work had been approved by the IBC at ABSL2. This incident constitutes a violation of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (Appendix G-II-B-2-k) and therefore must be reported to the Office of Biotechnology Activities at the National Institutes of Health (NIH/OBA). This report provides a description of the investigation of this incident, an analysis of the factors underlying the incident, and the University's planned remedial measures intended to prevent the occurrence of incidents of this type in the future.

Description of incident:

This incident involved the laboratory of Dr. Kathleen Sluka, PI in the Department of Physical Therapy, who has an approved rDNA Registration Document that covers work with rHSV-1 in mice. Dr. Sluka has had IBC approval for this project since 2004 and the work has consistently been approved at ABSL2. Most recently, in July 2012, Dr. Sluka submitted a request for an amendment to the approved rDNA registration document and the work was again assigned ABSL2 containment. Despite this consistent record of ABSL2 approval from the IBC, Dr. Sluka's laboratory staff has always housed the mice injected with rHSV-1 at ABSL1. This non-compliance was identified during a routine visit by a post-approval monitor from the office of the Institutional Animal Care and Use Committee (IACUC).

Shortly after being made aware of this non-compliance, the BSO held a meeting with the IACUC Director, the Clinical Veterinarian from the Office of Animal Resources (OAR) and Dr. Sluka. Dr. Sluka stated that many years ago a staff member from OAR or the Environmental Health & Safety Office (EHS) had stated to her that ABSL1 housing was appropriate for the mice injected with rHSV-1. Dr. Sluka could not provide any documentation of this discussion, however, and could not recall the name of the staff member who made the latter statement. Moreover, all submitted rDNA Registration Documents as well as the recent amendment submitted by Dr. Sluka and approved by the IBC from 2004 to the present have specified that ABSL2 containment was required for the mice injected with rHSV-1.

At the meeting Dr. Sluka agreed to immediately stop her experiments involving rHSV-1 and mice.

As of the time of the non-compliance was discovered, laboratory staff listed on Dr. Sluka's rDNA Registration Document had completed all online training required by the University, which includes Basic Biological Safety; Lab Chemical Safety; PPE Awareness for Labs; and rDNA Research- *NIH Guidelines*. Dr. Sluka had completed rDNA Research- *NIH Guidelines*

training.

<p>Has the IBC reviewed this incident?</p>	<p>YES If yes, please provide copies of the minutes of the IBC meetings in which the incident was reviewed. February 14 and 28, 2013</p>
<p>Has a root cause for this incident been identified?</p>	<p>YES If yes please describe: Dr. Sluka stated that she assigned responsibility for administration and implementation of her rDNA Registration Documents and the related amendment to a member of her laboratory staff and did not read the documents before she signed them and submitted them to the IBC.</p>
<p>Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation: (use additional space as necessary)</p> <p>For many years the IBC has had a process in place for registering proposed work involving rDNA in which only a PI can sign and submit to the IBC a completed rDNA Registration Document, which includes an attestation regarding compliance with the framework for the research approved by the IBC. Similarly, a request for an amendment to an approved rDNA Registration Document can only be submitted to the IBC by a PI. This process only breaks down, as in the case at hand, if the PI does not properly supervise subordinate personnel in the administration and implementation of the rDNA Registration Documents. To reduce the likelihood in the future of incidents similar to that described herein, the importance of carefully supervising subordinate personnel who deal with the administration and implementation of regulatory processes as well as the need for detailed review of regulatory documents before signing and submitting them will be reiterated with Dr. Sluka. Moreover, a brief reminder along these lines will be inserted in the next issue of <i>LabNews</i>, which is published by EHS staff and circulated throughout the research community at the University.</p> <p>Finally, the University's Animal Protocol currently is undergoing extensive revision. One of the goals of the revision is to ensure that the ABSL listed on the Animal Protocol is the same as that approved by the IBC. To that end the revised Animal Protocol will include a question that asks PIs whose proposed work involves rDNA to indicate what ABSL was approved by the IBC, and if it is not ABSL1 the PI will be required to complete a containment form. Administrative reviewers of the rDNA Registration Document will then check the PI's Animal Protocol to verify that the ABSL approved by the IBC has been entered.</p>	

NIH OBA Incident Reporting Template

For reporting Human Gene Transfer Adverse Events a separate template is available at:
http://www4.od.nih.gov/oba/RAC/Adverse_Event_Template.doc

Does this incident involve research subject to the <i>NIH Guidelines</i> ?	YES If no, this incident does not have to be reported to OBA
Institution name:	University of Iowa
Date of report:	May 2, 2013
Reporter name and position:	Louis V. Kirchhoff, MD, MPH; IBC Chair
Reporter telephone:	319-356-7227
Reporter email:	louis-kirchhoff@uiowa.edu
Date of incident:	Identified April 5, 2013
Name of principal investigator:	Wendy Maury, PhD
Is this an NIH funded project?	YES
If yes, please provide:	NIH grant or contract number: AI 077519
	NIH funding institute or center: NIAID
	NIH program officer contact information: Pat Repik, prepik@niaid.nih.gov
What was the nature of incident?	Other - please describe: Mice injected with recombinant vesicular stomatitis virus (VSV) pseudovirions were housed at animal biosafety level 1 (ABSL1) rather than at ABSL2, as approved by the IBC

<p>Did the Institutional Biosafety Committee (IBC) approve this research</p>	<p>YES If yes, on what date? The most recent rDNA Registration document was approved on 3/29/2012</p>
<p>If yes, please provide:</p>	<p>Approval date: 3/29/2012 Approved animal biosafety level for the research: ABSL2 Additional approval requirements: None</p>
<p>What section(s) of the <i>NIH Guidelines</i> is the research subject to?</p>	<p>III-D-1</p>
<p>Has a report of this incident been made to other federal or local agencies? If so please indicate by checking the appropriate box.</p>	<p>No</p>

DESCRIPTION OF INCIDENT:

Introduction:

On April 5, 2013, the University of Iowa's Biosafety Officer (BSO) became aware that a principal investigator (PI) had housed mice injected with VSV pseudovirions at ABSL1, despite the fact that the work had been approved by the IBC at ABSL2. This incident constitutes a violation of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (Appendix G-II-B-2-k) and therefore must be reported to the Office of Biotechnology Activities at the National Institutes of Health (NIH/OBA). This report provides a description of the investigation of this incident, an analysis of the factors underlying the incident, and the University's planned remedial measures intended to prevent the occurrence of incidents of this type in the future.

Description of incident:

This incident involved the laboratory of Dr. Wendy Maury, a PI in the Department of Microbiology, who has an approved rDNA Registration document that covers work with VSV pseudovirions in mice. Dr. Maury's animal work with VSV pseudovirions was approved at ABSL2. After injection of the mice with the rDNA, however, they were housed at ABSL1. This non-compliance was identified through an email communication with the office of the Institutional Animal Care and Use Committee (IACUC).

Shortly after being made aware of this non-compliance, the BSO held a meeting with Dr. Maury. Dr. Maury stated that no experiments involving VSV pseudovirions in animals are being done currently. She further stated that when such experiments are resumed the animals will be housed at the approved containment of ABSL2.

At the time the non-compliance was discovered, laboratory staff listed on Dr. Maury's rDNA Registration Document had completed all online training required by the University, which includes Basic Biological Safety; Lab Chemical Safety; PPE Awareness for Labs; and rDNA Research- *NIH Guidelines*. Dr. Maury had completed the rDNA Research- *NIH Guidelines* training as required.

Has the IBC reviewed this incident?	<p>YES</p> <p>If yes, please provide copies of the minutes of the IBC meetings in which the incident was reviewed. April 11 and 25, 2013</p>
Has a root cause for this incident been identified?	<p>YES</p> <p>If yes please describe: Dr. Maury assumed that the rDNA containment assignment for the VSV pseudovirions would be ABSL1 as it is for replication defective recombinant lentiviral systems. With this mindset, Dr. Maury did not take note that the rDNA Registration Document indicated that the work with recombinant VSV virions should be at ABSL2.</p>
<p>Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation: (use additional space as necessary)</p> <p>The University's Animal Protocol currently is undergoing extensive revision. One of the goals of the revision is to ensure that the ABSL listed on the Animal Protocol is the same as that approved by the IBC. To that end the revised Animal Protocol will include a question that asks PIs whose proposed work involves rDNA to indicate the ABSL approved by the IBC, and if it is not ABSL1 the PI will be required to complete a containment form. Administrative reviewers of the rDNA Registration Document will then check the PI's Animal Protocol to verify that the ABSL approved by the IBC has been entered. We expect that the consistency between the rDNA Registration Document and the Animal Protocol will eliminate ambiguity as to what containment level is required for the proposed research.</p>	

- **Please provide copies of any documents referenced in this report.**
- **Additional information may be requested by OBA after review of this report depending on the nature of the incident.**

NIH OBA Incident Reporting Template

**For reporting Human Gene Transfer Adverse Events a separate template is available at:
http://www4.od.nih.gov/oba/RAC/Adverse_Event_Template.doc**

Does this incident involve research subject to the <i>NIH Guidelines</i> ?	YES If no, this incident does not have to be reported to OBA
Institution name:	The University of Iowa
Date of report:	May 31, 2013
Reporter name and position:	Louis V. Kirchhoff, MD, MPH; IBC Chair
Reporter telephone:	319-356-7227
Reporter email:	louis-kirchhoff@uiowa.edu
Date of incident:	April 18 th , 2013
Name of principal investigator:	Stanley Perlman, MD, PhD
Is this an NIH funded project?	YES
If yes, please provide:	NIH grant or contract number: AI060699-07
	NIH funding institute or center: NIH NIAID
	NIH program officer contact information (name, email etc): Dr. Rachelle Salomon Influenza, SARS, & Related Viral Respiratory Diseases Section Respiratory Diseases Branch Division of Microbiology and Infectious Diseases NIAID/NIH/DHHS Room 3213 6610 Rockledge Dr. Bethesda, MD 20817 Phone: 301-402-2202 Fax: 301-496-8030 Email: salomonra@niaid.nih.gov
What was the <u>nature</u> of incident?	Personnel exposure Spill

<p>Did the Institutional Biosafety Committee (IBC) approve this research</p>	<p>YES If yes, on what date? 5/26/2011</p>
<p>If yes, please provide:</p>	<p>Approval date: 5/26/2011</p>
	<p>Approved biosafety level for the research: BSL3</p>
	<p>Additional approval requirements: None</p>
<p>What section(s) of the <i>NIH Guidelines</i> is the research subject to?</p>	<p>Section III-D-1</p>
<p>Has a report of this incident been made to other federal or local agencies? If so please indicate by checking the appropriate box.</p>	<p>CDC</p>

DESCRIPTION OF INCIDENT:

At 1:00 PM on April 18, 2013, an incident occurred in the autoclave room of a UI BSL3 laboratory that involved animal bedding from mice infected with wild-type and recombinant strains of SARS-CoV (Risk Group 3 organism). A laboratorian was loading the autoclave with animal cages containing bedding from infected animals. Cages were stacked on top of one another inside an autoclave bag which was loosely tied at the neck. As the bag was loaded into the autoclave, the top cage tilted sideways and tore a portion of the bag. Bedding spilled out of the cage, and a small amount spilled through the tear and onto the floor in front of the autoclave. The spill was not noticed by the laboratorian because the bedding fell behind bags of waste that were waiting to be autoclaved. The laboratorian then closed the autoclave door, started autoclave cycle, removed his PPE, and exited the facility according to protocol.

At 9:30 AM the following morning, the Associate Director of the BSL3 laboratory entered the autoclave room to load the remaining bagged waste into the autoclave. After loading and closing the door, she noticed the spilled bedding on the floor, which covered a circular area approximately 15 cm in diameter. She then gently sprayed the bedding with 10% bleach, covered it with 2 cloth diaper pads soaked in 10% bleach, and allowed it to soak for more than 30 minutes. During this period the Associate Director notified the ARO about the incident. Three other users of the BSL3 laboratory assisted in the clean-up. During entry the users donned standard PPE: scrubs, wrap-around gown, PAPR, double pair of gloves with initial pair taped to cuff of gown, as well as dedicated shoes, socks, and shoe covers. The walls, floor and ceiling of the autoclave room where the bedding was spilled were wiped down with 10% bleach, followed by a wipe-down with Spor-Klenz to remove the bleach film. The floor of the entire BSL3 facility was also wiped down with 10% bleach. All clean-up material was disposed of as biohazardous waste per protocol and was autoclaved prior to removal from the BSL3 laboratory.

Following the cleanup, an incident evaluation and risk assessment were performed by the ARO/ABSO, the Associate Director, and the laboratorian. The risk assessment determined that there was no potential exposure, as supported by the following evidence:

- The laboratorian was wearing the following PPE: scrubs, PAPR, double gloves with the initial gloves taped over the cuff of the gown, facility-dedicated shoes, socks and shoe covers. The Associate Director was wearing: scrubs, wrap-around gown, PAPR, double gloves with the initial gloves taped over the cuff of the gown, as well as facility-dedicated shoes, socks and shoe covers.
- All PPE that was worn was in good condition. PPE is inspected by each user upon donning and doffing to confirm that there are no tears and it was determined that the PAPR was intact and functioning properly.
- The autoclave is located inside the BSL3 laboratory and thus is under negative airflow.
- Although this spill was not immediately noticed, other laboratorians who entered the BSL3 facility between the time of the spill and the clean-up the following morning, including those who entered the autoclave room, were all wearing proper PPE, including a PAPR. The laboratorians who entered the BSL3 laboratory subsequent to the spill but before it was noticed by the Associate Director did not enter until nearly 2 hours after the spill had occurred, during which time several room air exchanges occurred (The times of the entries of other laboratorians were established by review of video surveillance).
- Because the PAPR was functioning properly it was determined that there was no potential exposure to the individual; therefore, no medical surveillance after the incident was required. It merits mention that all persons who work in the BSL3 laboratory are fully aware that they should report any signs or symptoms of illness any time they occur.

During this evaluation it was noted that proper reporting procedures were followed (ARO and PI) as well as proper clean-up of the spill once it was

discovered. One action item that resulted from this evaluation was that the laboratorian needed to be re-trained on proper loading of the autoclave, which includes use of the autoclave cart. Since this incident occurred, all BSL3 users were reminded to use the autoclave cart and autoclave discard pans on a daily basis for removal from the BSL3 laboratory, and they also were instructed on the proper bagging of cages to prevent them from toppling over and tearing the autoclave bag. Mock incidents are routinely conducted with all users of the BSL3 laboratory during annual refresher training. It should be noted that a mock hands-on drill to simulate a spill outside of primary containment was conducted in 2011 and reviewed during refresher training in 2012. After the incident described herein the laboratorian was instructed as to what he should have done and will be further retrained as part of the annual refresher training that is required for all BSL3-registered persons.

At the time of the incident the laboratorian was performing experiments classified as III-D-1 that were described in a rDNA Registration Document approved by the IBC on 5/26/2011. The recombinant SARS-CoV strains had E, C1 or F2 gene deletions. This spill was not reported to NIH/OBA per the reporting requirements outlined in Appendix G-II-C-2-q, again, since a determination was made that there was no potential for exposure. Presently, reporting spills to the IBC is not standard procedure. However we will make this part of our reporting process. As previously stated, it is our understanding that an overt exposure would be an incident that involves direct contact of an organism to the mucus membrane of an individual or a needle-stick. A potential exposure would be an incident that involves a spill outside of the BSC, if people working in the room were not using a functioning PAPR or other respiratory protection. The incident described herein was reported to CDC as a release only, because the evidence from the internal evaluation of the incident and risk assessment did not support the view that the incident was either an overt or potential exposure.

Has the IBC reviewed this incident?	<p>YES</p> <p>If yes, please provide a copy the minutes of the IBC meeting in which the incident was reviewed.</p>
Has a root cause for this incident been identified?	<p>YES</p> <p>If yes please describe: The autoclave bag that contained the animal cages was not secured properly and the autoclave cart was not used for loading the waste into the autoclave.</p>
<p>Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation: (use additional space as necessary)</p> <p>All BSL3 users have been reminded to use the autoclave cart and autoclave discard pans on a daily basis for processing and removal of biohazardous materials from the BSL3 laboratory. Users were also instructed on the proper bagging of cages to prevent them from toppling over and tearing the autoclave bag.</p> <p>In addition, as a result of the CDC's Select Agent Program response to our Form 3 report of a release of agent, our BSL3 manuals will be revised to state that any release will be viewed as a potential exposure and subsequent medical evaluation and required reporting will be carried out. Within the next two months the relevant procedure manuals will be revised to reflect these procedural changes and then will be sent to the appropriate committees for review and approval.</p>	

- **Please provide copies of any documents referenced in this report.**
- **Additional information may be requested by OBA after review of this report depending on the nature of the incident.**

NIH OBA Incident Reporting Template

For reporting Human Gene Transfer Adverse Events a separate template is available at:
[http://www4.od.nih.gov/oba/RAC/Adverse Event Template.doc](http://www4.od.nih.gov/oba/RAC/Adverse%20Event%20Template.doc)

Does this incident involve research subject to the <i>NIH Guidelines</i> ?	YES If no, this incident does not have to be reported to OBA
Institution name:	The University of Iowa
Date of report:	May 31, 2013
Reporter name and position:	Louis V. Kirchhoff, MD, MPH; IBC Chair
Reporter telephone:	319-356-7227
Reporter email:	louis-kirchhoff@uiowa.edu
Date of incident:	April 10, 2013
Name of principal investigator:	Bradley Jones, PhD
Is this an NIH funded project?	YES
If yes, please provide:	NIH grant or contract number: 2PO1AI044642 534 and 2U54AI057160
	NIH funding institute or center: NIH NIAID
	NIH program officer contact information (name, email etc): Michael Schaefer, MSchaefer@niaid.nih.gov
What was the <u>nature</u> of incident?	Personnel exposure Spill

<p>Did the Institutional Biosafety Committee (IBC) approve this research</p>	<p>YES If yes, on what date? 8/4/2011</p>
<p>If yes, please provide:</p>	<p>Approval date: 8/4/2011</p>
	<p>Approved biosafety level for the research: BSL3</p>
	<p>Additional approval requirements: None</p>
<p>What section(s) of the <i>NIH Guidelines</i> is the research subject to?</p>	<p>III-D-1</p>
<p>Has a report of this incident been made to other federal or local agencies? If so please indicate by checking the appropriate box.</p>	<p>CDC</p>

DESCRIPTION OF INCIDENT:

On April 10, 2013, an incident occurred in a University of Iowa BSL3 laboratory that involved a recombinant strain of *Francisella tularensis*, Schu S4 (Risk Group 3 organism). A laboratorian was removing supernatant from a 24-well plate which contained cells that had been infected with the bacteria 16 hours prior to the incident. While preparing to remove supernatant from the final well (approximately 1 ml), the plate slipped out of his hands and hit the diaper that covered the work surface inside the BSC; supernatant spilled out of the well onto the diaper and also onto the uncovered BSC surface. While no drops were observed to have fallen onto the laboratorian's gloved hands or gown, approximately 3 drops of the media dropped onto the lower part of the PAPR bib that he was wearing. As previously instructed, the laboratorian sprayed his gloved hands with disinfectant prior to removing them from the BSC. He then used a bleach wipe to wipe down his PAPR followed by spraying the PAPR hood with Sporklenz and waiting 30 minutes. During the 30 minute wait, the laboratorian contained and treated the spill inside the BSC by covering the area with CiDecon-soaked paper towels. The 24-well plate was disposed of as biohazard waste. The laboratorian removed his exterior PPE, exited the BSL3 laboratory, and reported the spill to the Associate Director, the RO, and the PI, as per protocol.

After an additional 30 minute wait, the Associate Director entered the BSL3 laboratory with the laboratorian to finish cleaning up the spill. Entry included donning standard PPE: scrubs, wrap-around gown, PAPR, double pair of gloves with initial pair taped to cuff of gown, dedicated shoes, socks and shoe covers. Following protocol, the spill was cleaned up in the following manner: the paper towels covering the spill were disposed of in biohazardous waste and the entire interior of the BSC and its contents, including the grill after removal, were sprayed down with 10% bleach, allowed to sit for 30 minutes, and then wiped down with 70% ethanol. As a precaution, the floor outside of the cabinet, the front of the BSC, and the support mechanism were also sprayed with 10% bleach followed by wipe down with 70% ethanol. All clean-up material was disposed of as biohazardous waste that ultimately was autoclaved prior to removal from the BSL3 laboratory.

After the spill was cleaned up, an incident evaluation and risk assessment were performed by the RO/BSO, ARO/ABSO, Associate Director, and the laboratorian. The risk assessment determined there was no potential exposure, as supported by the following evidence:

- The laboratorian was wearing all required PPE: scrubs, wrap-around outer gown, PAPR, and double gloves with the initial gloves taped over the cuff of the gown, in addition to facility-dedicated shoes, socks, and shoe covers.
- All PPE that was worn was in good condition; PPE is inspected by each laboratorian upon donning and doffing to confirm that there are no rips or tears and it was determined that the PAPR was intact and functioning properly.
- A majority of the liquid from the spill was contained in the biosafety cabinet, with only 3 drops found on the lower part of the PAPR bib.
- Because the PAPR was functioning properly it was determined that there was no potential exposure to the individual; therefore, no medical surveillance after the incident was required. It merits mention that all persons who work in the BSL3 laboratory are fully aware that they should report any signs or symptoms of illness any time they occur.

During this evaluation it was noted that proper reporting procedures were followed (RO, Associate Director, and PI) as well as proper clean-up of the spill. Mock incidents are routinely conducted with all users of the BSL3 laboratory during annual refresher training; a mock hands-on drill to simulate a spill outside of primary containment was conducted in 2011 and reviewed during refresher training in 2012. The laboratorian was immediately instructed again as to what he should have done and will be re-trained as part of the annual refresher training required for all registered individuals.

The laboratorian was working under a protocol that had been approved by the University of Iowa's IBC and is classified as III-D-1. This work is funded by NIH grants: 2PO1AI044642 534 and 2U54 AI057160, Project 14, awarded to the PI. The recombinant bacterial strain was designed by disrupting the function of FTT_1236 by inserting non-coding DNA; no antibiotic resistance markers were used. This release was not reported to NIH/OBA per the reporting requirements as outlined in Appendix G-II-C-2-q, again, as a determination had been made that there was no potential for exposure. At this time, reporting spills to the IBC is not standard procedure; however this will be made part of the reporting process. It is our understanding that an overt exposure would be an incident that involves direct contact of an organism to the mucus membrane of an laboratorian or a needle-stick; a potential exposure could be an incident that involves a spill outside of the BSC, if people working in the room did not employ the use of a functioning PAPR or respiratory protection. The incident described herein was reported to CDC as a release only, because the evidence from the internal evaluation of the incident and risk assessment did not support the view that the incident was either an overt or potential exposure.

Has the IBC reviewed this incident?	<p>YES</p> <p>If yes, please provide a copy the minutes of the IBC meeting in which the incident was reviewed.</p>
Has a root cause for this incident been identified?	<p>YES</p> <p>If yes please describe: Gloved hands are routinely sprayed with disinfectant while working in the biosafety cabinet. The laboratorian's gloves were wet while he was handling the plate which caused it to slip out of his hands.</p>
<p>Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation: (use additional space as necessary)</p> <p>All users will avoid handling cultures or plates while gloved hands are wet with disinfectant.</p> <p>In addition, as a result of the CDC's Select Agent Program response to our Form 3 report of a release of agent, our BSL3 manuals will be revised to state that any release will be viewed as a potential exposure and subsequent medical evaluation and required reporting will be carried out. Within the next two months the relevant procedure manuals will be revised to reflect these procedural changes and then will be sent to the appropriate committees for review and approval.</p>	

- **Please provide copies of any documents referenced in this report.**
- **Additional information may be requested by OBA after review of this report depending on the nature of the incident.**

NIH OBA Incident Reporting Template

For reporting Human Gene Transfer Adverse Events a separate template is available at:
http://www4.od.nih.gov/oba/RAC/Adverse_Event_Template.doc

Does this incident involve research subject to the <i>NIH Guidelines</i> ?	YES If no, this incident does not have to be reported to OBA
Institution name:	The University of Iowa
Date of report:	6/22/2013
Reporter name and position:	Louis V. Kirchhoff, MD, MPH; IBC Chair
Reporter telephone:	319-356-7227
Reporter email:	louis-kirchhoff@uiowa.edu
Date of incident:	6/4/2013
Name of principal investigators:	Drs. Paul McCray and Stanley Perlman
Is this an NIH funded project?	YES
If yes, please provide:	NIH grant or contract number: 5P01AI060699-07
	NIH funding institute or center: NIAID
	NIH program officer contact information (name, email etc): Dr. Rachelle Salomon Influenza, SARS, & Related Viral Respiratory Diseases Section Respiratory Diseases Branch Division of Microbiology and Infectious Diseases NIAID/NIH/DHHS Room 3213 6610 Rockledge Dr. Bethesda, MD 20817 Phone: 301-402-2202 Fax: 301-496-8030 Email: salomonra@niaid.nih.gov
What was the nature of incident?	Other - please describe: Biosafety cabinet (BSC) manual error resulted in possible exposure to potentially contaminated HEPA filter during motor replacement.

<p>Did the Institutional Biosafety Committee (IBC) approve this research</p>	<p>YES If yes, on what date? 5/26/2011 (Perlman)</p>
<p>If yes, please provide:</p>	<p>Approval date: 5/26/2011 (Perlman); Work with non-recombinant SARS-CoV MA15 attenuated strain was approved by the Carver College of Medicine BSL3 Oversight Committee (McCray)</p> <p>Approved biosafety level for the research: BSL3</p> <p>Additional approval requirements: none</p>
<p>What section(s) of the <i>NIH Guidelines</i> is the research subject to?</p>	<p>III-D-1</p>
<p>Has a report of this incident been made to other federal or local agencies? If so please indicate by checking the appropriate box.</p>	<p>CDC State/Local Public Health</p>

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

INFORMATION ON FACILITY, AGENT, AND THOSE INVOLVED IN THE INCIDENT:

This incident occurred in a BSL3 facility that is comprised of several procedure rooms in which experiments involving viral Risk Group 3 organisms are performed. The Class II B2 biosafety cabinet (BSC)(The Baker Company, Sanford, Maine) involved in the incident is located in a procedure room used by research assistants who work for Drs. Paul McCray and Stanley Perlman. Experiments involving wild type and recombinant strains of SARS-CoV (Perlman) and the non-recombinant MA15 attenuated strain of SARS-CoV (McCray) are performed in the BSC. The MA15 strain of SARS-CoV is a mouse-adapted attenuated strain that was generated by serial passage of SARS-CoV Urbani strain in mice. Servicing of the BSCs at the University of Iowa is done under a contract with an outside company that provides NSF-certified technicians for the work (ENV Services, San Antonio, Texas). The contractor is responsible for training its technicians and relies on information provided by the manufacturers of the BSCs to develop standard protocols for certifications, repairs, etc. The contractor sent a technician to service the BSC in the BSL3 facility. The technician underwent required visitor training prior to entering the BSL3 facility, was escorted by the Associate Director, and was servicing the BSC when the incident occurred.

DESCRIPTION OF INCIDENT:

Although experiments with the above-mentioned strains of SARS-CoV had been performed in the BSC for approximately eight years, no experiments of this type had been done in it since 5/11/2013. The blower supply motor stopped working on 5/28/2013 and replacement was scheduled for 6/4/2013. While it is standard University of Iowa protocol to decontaminate BSCs prior to accessing potentially contaminated areas in the interior housing, the BSC technician stated that such decontamination is not required prior to servicing a Class II B2 BSC because the motor is self-contained and is adjacent to the air supply plenum, both of which are sealed off from potentially contaminated areas.

The Associate Director escorted the technician to the BSL3 facility on 6/4/2013 where they donned standard PPE prior to entry. Standard PPE includes: PAPR, disposable scrubs, wrap-around gown, two pairs of gloves with the initial pair taped to the cuff of the gown, dedicated shoes and socks, and shoe covers. The technician did not perform vaporized hydrogen peroxide decontamination prior to beginning the service because as noted it was his view that it was not needed for a Class II B2 BSC. Once he removed the access panel of the BSC to start the repair, it was clear that in this BSC the air supply plenum

and motor housing are not segregated from the potentially contaminated side of the exhaust filter and plenum. Thus his removal of the access panel of the BSC resulted in the possible exposure of the procedure room and the two persons in it to potentially contaminated areas inside the BSC. However, the building's HVAC system maintains a negative air pressure, which in each procedure room exhausts continuously through the BSC's exhaust filter. Once the two persons present realized the exhaust filter was exposed and the motor could not be removed in a self-contained fashion, Spor-Klenz was used to spray down all exposed parts of the BSC interior housing. The motor and casing were removed and placed on the floor on top of diaper pads/chucks. The motor was removed from its case and autoclaved prior to removal from the facility. The new motor was placed into the casing that had been wiped down with Spor-Klenz and then placed back into the BSC housing, which had also been wiped down with Spor-Klenz. After the new motor was tested to confirm it was operational, the access panel was put back in place. During this repair process, both the Associate Director and technician removed their outer gloves and replaced them in case there were tears or loss of integrity. When the two persons left the procedure room they each removed their outer pair of gloves, tape, and gown and placed them into a biohazard waste container. The technician followed proper PPE doffing procedure for exiting and temporarily left the BSL3 facility.

After escorting the technician out of the facility, the Associate Director returned to the procedure room and wiped down the outside of the BSC, the floor, chair and wall nearest the BSC with Spor-Klenz. After doing this the Associate Director notified the Alternate Responsible Official that vaporized hydrogen peroxide decontamination had not been done prior to removal of the BSC access panel and the discovery of exposed exhaust filter upon removal of the access panel during the repair.

The technician then was escorted back into the facility, ~~doffing~~ donning standard PPE, in order to certify the cabinet. During the certification the technician's tools were placed on a diaper pad/chuck and wiped down with Spor-Klenz before removal. Once the certification was complete, the technician doffed his PPE and was escorted out of the BSL3 facility by the Associate Director. The Associate Director wiped down the hallway of the BSL3 suite with 10% bleach prior to doffing PPE and exited. All waste generated during this incident was placed in biohazard waste containers for autoclaving prior to removal from the BSL3 facility.

To gain more information regarding the interior design of this Class II B2 BSC, the Alternate Responsible Official spoke with technical managers at the company that manufactured the BSC and also with technical managers at the company contracted to service the BSCs. The managers at both companies indicated that Class II B2 BSC decontamination prior to motor replacement on a Class II B2 is not standard procedure. However, in further discussion it became clear that what the technician saw after removal of the access panel as well as the procedure to remove the motor itself was inconsistent with what is shown in manual provided with this Class II B2 BSC. The manufacturer has agreed to revise the manual based on this

experience and the service company will make it a standard procedure on our campus to perform vaporized hydrogen peroxide decontamination prior to removal of the access panel of any model of BSC in order to access the motor housing.

Throughout this incident standard PPE was worn (including a PAPR) by the two persons involved and the facility's HVAC system was fully functioning and under negative pressure. Thus there was very little potential for exposure. However, because the repair exposed the potentially contaminated exhaust filter, this is being reported as a potential exposure. The Alternate Responsible Official reviewed the signs and symptoms of SARS with the Associate Director and the technician on 6/5/2013, and reminded them to report any symptoms of illness. This action was determined by the Alternate Responsible Official, in consultation with the University Employee Health Clinic physician.

The Alternate Responsible Official alerted users of the [REDACTED] BSL3 facility to not enter this procedure room until it had been surface decontaminated. Surface decontamination of the room was accomplished using 10% bleach on 6/6/2013. All waste generated during the surface decontamination was placed in biohazardous waste containers and was autoclaved prior to removal from the BSL3 facility.

Has the IBC reviewed this incident?	<p>YES</p> <p>If yes, please provide a copy the minutes of the IBC meeting in which the incident was reviewed.</p>
Has a root cause for this incident been identified?	<p>YES</p> <p>If yes please describe: Access to the motor housing was not as outlined in the manufacturer's manual.</p>
<p>Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation: (use additional space as necessary)</p> <p>As noted, the manufacturer of the BSC as well as the company contracted to service BSCs at the University were contacted regarding this occurrence. The manufacturer will revise the manual for this BSC model, since access to the motor is not accurately described in the manual. The company that services the BSCs will make it standard protocol to decontaminate all BSCs at the University prior to removal of an access panel and exposure of any interior housing of a BSC.</p>	

- **Please provide copies of any documents referenced in this report.**
- **Additional information may be requested by OBA after review of this report depending on the nature of the incident.**

NIH OBA Incident Reporting Template

**For reporting Human Gene Transfer Adverse Events a separate template is available at:
http://oba.od.nih.gov/oba/rac/Adverse_Event_Template.pdf**

Does this incident involve research subject to the <i>NIH Guidelines</i> ?	YES
Institution name:	University of Iowa
Date of report:	November 2, 2013
Reporter name and position:	Louis Kirchhoff, MD, MPH; IBC Chair
Reporter telephone:	319-356-7227
Reporter email:	louis-kirchhoff@uiowa.edu
Reporter mailing address:	UIHC – SW54 GH Dept of Internal Medicine Iowa City, IA 52242
Date of incident:	October 4, 2013
Name of principal investigator:	Budd Tucker, Ph.D.
Is this an NIH funded project?	YES
If yes, please provide:	NIH grant or contract number: 1DP2OD007483
	NIH funding institute or center: NIH Director's Award
	NIH program officer contact information (name, email etc): Rochelle Galbraith, rochelle-galbraith@uiowa.edu
What was the <u>nature</u> of incident?	Personnel exposure Failure to obtain IBC approval

Did the Institutional Biosafety Committee (IBC) approve this research	The use of the viral vector and cell lines was approved by the IBC on 10/14/2010; however, subsequent injection of transfected cells into the pig animal model was not approved.
If yes, please provide:	Approval date: 10/14/2010
	Approved biosafety level(s) for the research: BSL2
	Additional approval requirements: None
What section(s) of the <i>NIH Guidelines</i> is the research subject to?	III-D-1
Has a report of this incident been made to other federal or local agencies? If so please indicate by checking the appropriate box.	No
Description of recombinant or synthetic agent or material involved (please indicate strain, attenuation etc. as relevant.)	<p>Replication defective lentivirus expressing green fluorescent protein (GFP). The vector was purchased from Addgene and is an FIV backbone and contains a CMV promotor. This lentivirus was gag/pol deleted.</p> <p>Mouse cells were transduced with the recombinant lentivirus vector bearing the GFP gene and then injected into the pig via sub-retinal administration.</p>
<p>Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. Include the following information as applicable.</p> <p>DESCRIPTION OF INCIDENT: (use additional space as necessary)</p>	

Introduction:

On October 4, 2013, the University of Iowa's Biosafety Officer (BSO) became aware of a puncture wound incident resulting in injury of a research assistant. On October 10, 2013 it was determined that the syringe may have contained mouse cells transduced with a replication defective lentivirus expressing GFP. In addition, following discussion with the Principal Investigator (PI), it was determined that IBC approval had not been obtained for administration of these recombinant cells into pigs. This incident constitutes a violation of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (Appendix G-II-B-2-k) and therefore must be reported to the Office of Biotechnology Activities at the National Institutes of Health (NIH/OBA). This report, which follows our initial notification of NIH/OBA on October 10, 2013, provides a description of the investigation of this incident, an analysis of the factors underlying the incident, and the University's planned remedial measures intended to prevent the recurrence of incidents of this type.

Description of incident:

This incident involved a research assistant in the laboratory of Dr. Budd Tucker, a PI in the Department of Ophthalmology who has an approved rDNA Registration Document that covers work with replication defective vectors and cell lines. The assistant, along with two surgeons, was administering a recombinant mouse cell line which had been transfected with a lentiviral vector expressing GFP into a pig via sub-retinal injection. The experiment was a blind study such that the assistant was unaware which syringe held the recombinant cells or control saline. PPE worn at the time of administration included a gown, gloves and mask.

Following injection of the cells or saline, the syringe with cannula attachment was placed on a table for the duration of the surgery. During clean-up of the area, the assistant received a puncture to her right index finger. The assistant contacted a physician at the University Employee Health Clinic and discussed the incident. The physician instructed the assistant to monitor her health for symptoms suggestive of a viral infection, including fever or enlarged lymph nodes.

On the day after being informed about the incident the BSO met with the assistant and the PI to obtain additional information. Importantly, the PI explained that he had decoded the experiment and determined that the assistant had received a puncture wound from the control syringe containing saline. At that time no local or systemic evidence of infection was present.

As of the time of the incident, the assistant had completed all online training required by the University for general lab work, which includes Basic Biological Safety; Lab Chemical Safety; and PPE Awareness for Labs. However, the assistant did not complete the online training requirement for work with rDNA, and will be required to complete the rDNA Research - *NIH Guidelines* course.

Laboratory issues uncovered by the investigation:

- Following administration to the animal, the syringe with cannula attachment was not placed directly into a sharps container.
- The surgeons and research assistant were not listed on the approved recombinant DNA registration document.
- The administration of recombinant material into pigs was not listed on the approved rDNA registration document.

Has the IBC reviewed this incident?	YES	NO
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	<p>If yes, please provide a copy the minutes of the IBC meeting in which the incident was reviewed. October 10 and 24, 2013</p>
<p>Has a root cause for this incident been identified?</p>	<p>YES</p> <p>If yes please describe: Following administration to the animal, the syringe with cannula attachment was not placed directly into a sharps container.</p>
<p>Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation: (use additional space as necessary)</p> <p>The administration procedure will be modified such that following administration to the animal, any needles or cannulas will be placed directly into a sharps container.</p> <p>The BSO met with the PI and reviewed the requirements for rDNA registration, including the registration of all staff involved in rDNA experiments as well as the listing of all animal species that will be exposed to rDNA. The PI will formally request that his approved rDNARD be amended to include the three staff members in question and the injection of the recombinant material into pigs.</p>	

- **Please provide copies of any documents referenced in this report.**
- **Additional information may be requested by OBA after review of this report depending on the nature of the incident.**

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NIH OBA Incident Reporting Template

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http://oba.od.nih.gov/oba/rac/Adverse_Event_Template.pdf

Does this incident involve research subject to the <i>NIH Guidelines</i> ?	YES If no, this incident does not have to be reported to OBA
Institution name:	The University of Iowa
Date of report:	February 17, 2014
Reporter name and position:	Louis V. Kirchhoff, MD, MPH; IBC Chair
Reporter telephone:	319-356-7227
Reporter email:	louis-kirchhoff@uiowa.edu
Reporter mailing address:	Dept of Internal Medicine UIHC – SW54 GH Iowa City, IA 52242
Date of incident:	Unapproved rDNA experiments began September 17, 2013 and were halted on February 3, 2014
Name of principal investigator:	Stanley Perlman, MD, PhD
Is this an NIH funded project?	YES
If yes, please provide:	NIH grant or contract number: A1060699.06A1
	NIH funding institute or center: NIH NIAID
	NIH program officer contact information (name, email etc): Erik Stemmy Email: erik.stemmy@nih.gov
What was the nature of incident?	Receiving recombinant MERS-CoV DNA from an outside institution and performing experiments with rMERS-CoV without obtaining prior approval from the IBC. Failure to register a laboratory worker with the IBC prior to his performing rDNA experiments and the failure of that worker to complete the University's rDNA course required for persons working with rDNA.

Did the Institutional Biosafety Committee (IBC) approve this research	NO If yes, on what date?
If yes, please provide:	Approval date:
	Approved biosafety level(s) for the research:
	Additional approval requirements:
What section(s) of the <i>NIH Guidelines</i> is the research subject to?	Section III-D-1
Has a report of this incident been made to other federal or local agencies? If so please indicate by checking the appropriate box.	NO
Description of recombinant or synthetic agent or material involved (please indicate strain, attenuation etc. as relevant.)	<p>The construction of rMERS-CoV viral clones expressing GFP and RFP has been completed, and <i>in vitro</i> experiments demonstrating the expression of GFP and RFP by the rMERS-CoV clones have been performed. The propagation of these clones for subsequent experiments has not been performed.</p> <p>The construction of a rMERS-CoV viral clone having a point mutation in the ADRP (adenosine diphosphate ribose-1"-monophosphatase) region of the NSP3 (non-structural protein 3) coding sequence has been completed, but no propagation of that clone has been performed.</p>

DESCRIPTION OF INCIDENT: (use additional space as necessary)

Introduction:

On February 3, 2014, the University of Iowa's Biosafety Officer (BSO) became aware that experiments involving rMERS-CoV that had not been reviewed and approved by the IBC were being performed in the laboratory of Dr. Stanley Perlman, a principal investigator (PI) in the Departments of Microbiology and Pediatrics. The BSO contacted the PI, who confirmed that such unapproved work was in fact being performed in his laboratory. The BSO then ordered the PI to immediately halt all experiments involving rMERS-CoV and the PI indicated that he would do so. This incident constitutes a violation of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (Appendix G-II-B-2-k) and therefore must be reported to the Office of Biotechnology Activities at the National Institutes of Health (NIH/OBA). This report, which follows our initial notification of NIH/OBA on February 3, 2014, provides a description of the investigation of this incident, an analysis of the factors underlying the incident, and the University's planned remedial measures intended to prevent the recurrence of incidents of this type.

Description of incident:

September 14, 2013 The PI received a BAC clone carrying a full-length MERS-CoV cDNA from a collaborator in Spain.

September 17, 2013 Two post-doctoral researchers in the PI's laboratory transformed bacterial cells with the MERS-CoV BAC clone with the goal of making back-up stocks for freezing.

October 22, 2013 The post-doctoral researchers initiated cloning experiments in which genes encoding GFP and RFP were inserted individually into the BAC clone, replacing open reading frames (ORFs) 3 or 5.

November 8, 2013 Construction of rMERS-CoV BAC clones into which GFP or RFP had been inserted and the making of back-up stocks was completed. Up to this point all the work with rMERS-CoV had been done in the PI's laboratory at BSL2 containment and when interviewed in early February by Environmental Health & Safety (EHS) staff the two researchers stated that they had used standard PPE for this work, which included laboratory coats and gloves. In mid-November the work with MERS-CoV BAC GFP and RFP clones was moved to the Carver College of Medicine's BSL3 facility. Some time prior to moving the work with these clones to the BSL3 facility the Oversight Committee for the latter had approved a standard operating procedure (SOP) submitted by the PI entitled "Host-virus interactions in human SARS-CoV extension to MERS-CoV," but this SOP only covers experiments involving non-recombinant MERS-CoV.

December 5, 2013 Construction of a MERS-CoV BAC clone having a point mutation in the ADRP (adenosine diphosphate ribose-1"-monophosphatase) region of the NSP3 (non-structural protein 3) coding sequence was initiated in the PI's laboratory at BSL2 containment. This construct was completed two weeks later.

December 6, 2013 In the BSL3 facility the post-doctoral researchers initiated transfections with the rMERS-CoV BAC clones to produce viral clones carrying the GFP and RFP coding sequences. This work was carried forward to the point at which resulting stocks of the rMERS-CoV viral

clones were titered and expression of the markers was demonstrated.

January 10, 2014 In the BSL3 facility the post-doctoral researchers initiated transfections with the rMERS-CoV BAC clone containing the point mutation in the NSP3 coding sequence. Collections of supernatants from the transfected cells have been collected, but no further experiments have been done with this material.

When interviewed in early February the post-doctoral researchers stated that they had used all standard PPE for such work in the BL3 facility, which includes scrubs, wrap-around gowns, PAPR, double pair of gloves with initial pair taped to cuff of gown, dedicated shoes, socks and shoe covers..

As of the time of the incident, the PI and one of the post-doctoral researchers had completed the required course "rDNA Research-*NIH Guidelines*". The other post-doctoral researcher had not completed this course. Moreover, he had not been listed on any of the PI's approved rDNA Registration Documents as a staff member working with rDNA. All other training required by the University for biological research as well as additional training for BSL3 work, which include Basic Biological Safety; Lab Chemical Safety; PPE Awareness for Labs; and BSL3 Orientation/Refresher training had been completed by the post-doctoral researchers. The latter individuals also had completed the occupational health requirements mandated for all persons working in the BSL3 facility, which include archiving an initial blood sample, respirator evaluation, and an annual clinic visit.

Has the IBC reviewed this incident?	YES If yes, please provide a copy the minutes of the IBC meeting in which the incident was reviewed.
Has a root cause for this incident been identified?	YES This incident was the result of negligence on the part of the PI. He did not obtain IBC approval for the experiments involving the rMERS-CoV performed by the two post-doctoral researchers in his laboratory and in the BSL3 facility. In addition, the PI did not effectively communicate to his post-doctoral researchers the importance of obtaining prior approval from the IBC for experiments involving rDNA and the importance of reviewing relevant SOPs prior to initiation of any experiments in the BSL3 facility. The importance of completing all training requirements prior to the initiation of experimental work also was not effectively communicated. The PI has a long history of obtaining IBC approval for work with rDNA.
Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation: (use additional space as necessary)	
To ensure compliance of the PI with the <i>NIH Guidelines</i> , we propose setting up an administrative structure under which the PI's rDNA research will be monitored closely during a substantial probationary period. Under this structure, the PI and his subordinate staff members who work with	

rDNA will meet on a monthly basis with the BSO, one other EHS staff member involved in the regulation of rDNA work, and one of the virologist members of the IBC. At these meetings the PI and his staff will be asked to present in detail their planned and current rDNA work. The information provided will then be discussed in the light of the PI's approved and pending rDNA Registration Documents (rDNARDs) to ensure appropriate registration of rDNA work. The effectiveness of this monitoring program will be assessed by EHS staff after the initial probationary period and the findings will be presented to the IBC. The members of the latter will then decide to end the monitoring or continue it for an additional probationary period. I welcome your thoughts and suggestions on the structure and duration of this approach for ensuring the PI's compliance with the *NIH Guidelines*.

In addition to the above, the following actions have been taken. On February 10, 2014, the BSO met with the PI and reviewed all his approved rDNARDs. The PI's electronic portal to the latter documents was also reviewed and he was instructed on how to designate laboratory staff as "viewers" so that they can access them.

Following the meeting with the PI, the BSO met with the laboratory staff members assigned to the MERS-CoV and SARS-CoV projects and demonstrated how to access and review the rDNARDs.

Established BSL3 procedures require that all approved BSL3 SOPs must be accessible to persons inside the BSL3 facility. The BSO requested that a binder containing the PI's SOPs be assembled and placed in a common room inside the BSL3 facility. A staff member in the PI's laboratory has been instructed to contact the BSO when copies of all the PI's SOPs have been placed in the binder. All BSL3 users are aware that any experiment carried out in the BSL3 facility must be in an approved SOP, and the PI's staff members have been reminded of the requirement for their review of SOPs prior to initiating new experiments.

- **Please provide copies of any documents referenced in this report. Copies of minutes for the IBC meetings held on February 13 and February 17, 2014, are attached.**
- **Additional information may be requested by OBA after review of this report depending on the nature of the incident.**