OFFICE OF THE ATTORNEY GENERAL
STATE OF ILLINOIS

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Via electronic mail
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Via electronic mail
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RE: FOIA Request for Review – 2018 PAC 53007, 53008 and 53009

Dear Ms. Cohen and Mr. Hardy:

This determination is issued pursuant to section 9.5(f) of the Freedom of Information Act (FOIA) (5 ILCS 140/9.5(f) (West 2016)). For the reasons stated below, the Public Access Bureau concludes that the University of Illinois (University) improperly denied portions of records responsive to three FOIA requests submitted by Ms. Jodi Cohen.

On February 21, 2018, Ms. Cohen submitted a FOIA request to the University seeking seven records or categories of records referenced in a November 28, 2017, letter related to an investigation into Professor Mani Pavuluri's research. On March 7, 2018, the University provided certain records but redacted or withheld portions pursuant to sections 7(1)(a), 7(1)(b), 7(1)(c), 7(1)(f), 7(1)(j)(ii), 7(1)(j)(iv), and 7(1)(n) of FOIA (5 ILCS 140/7(1)(a), (1)(b), (1)(c), (1)(f), (1)(j)(ii), (1)(j)(iv), (1)(n) (West 2017 Supp.)). In connection with section 7(1)(a), the University asserted that section 8-2101 of the Code of Civil Procedure (Medical Studies Act) (735 ILCS 5/8-2101 (West 2016)) and Federal regulations (42 C.F.R. § 93.108(a), (c) (2018)) prohibited disclosure of letters dated March 22, 2013, and April 8, 2013. On May 3, 2018, Ms.

Cohen submitted a Request for Review (2018 PAC 53007) contesting the redaction or withholding of letters dated March 22, 2013, and April 8, 2013.

On March 9, 2018, Ms. Cohen submitted another FOIA request to the University seeking eight letters or reports with specific dates concerning the investigation into Professor Pavuluri's research. On March 23, 2018, the University provided responsive records but redacted portions of a May 22, 2013, letter pursuant to section 7(1)(f) of FOIA (5 ILCS 140/7(1)(f) (West 2017 Supp.)). On May 3, 2018, Ms. Cohen submitted a Request for Review (2018 PAC 53009) disputing those redactions.

On March 28, 2018, Ms. Cohen submitted a third FOIA request to the University seeking five records or categories of records related to Professor Pavuluri's research grants. On April 11, 2018, the University responded that it did not possess any records responsive to the fifth part of the request and denied the other four parts pursuant to sections 7(1)(a) and 7(1)(j)(ii) of FOIA (5 ILCS 140/7(1)(a), (1)(j)(ii) (West 2017 Supp.)). In connection with section 7(1)(a), the University again asserted that section 8-2101 of the Medical Studies Act and section 93.108 of title 42 of the Code of Federal Regulations prohibited disclosure of the records. On May 3, 2018, Ms. Cohen submitted a Request for Review (2018 PAC 53008) contesting the redaction or withholding of letters dated September 23, 2015, and October 26, 2015, and documents attached to September 28, 2015, and November 6, 2015, e-mails from Dr. Teresa D. Johnston to "IRPT (HHS/OASH)."[1]

On May 11, 2018, the Public Access Bureau sent each Request for Review to the University and asked it to provide copies of the records at issue together with a detailed explanation of the factual and legal bases for the applicability of the exemptions under which those records were denied. On June 8, 2018, the University furnished copies of the records and a consolidated response letter clarifying that it redacted or denied the records in these matters pursuant to sections 7(1)(a), based on section 8-2101 of the Medical Studies Act, and 7(1)(f) of FOIA. In connection with 2018 PAC 53008, the University also clarified that the documents attached to the September 28, 2015, and November 6, 2015, e-mails are the same September 23, 2015, and October 26, 2015, letters that were denied in response to the underlying request.

DETERMINATION

"All records in the custody or possession of a public body are presumed to be open to inspection or copying." 5 ILCS 140/1.2 (West 2016); *see also Southern Illinoisan v. Illinois Department of Public Health*, 218 Ill. 2d 390, 415 (2006). A public body "has the burden

[1]Letter from Jodi S. Cohen, ProPublica Illinois, to Sarah Pratt, Public Access Counselor, Office of the Attorney General, Public Access Bureau (May 3, 2018), at 4.

of proving by clear and convincing evidence" that a record is exempt from disclosure. 5 ILCS 140/1.2 (West 2016).

Sections 7(1)(a) and 7(1)(f) of FOIA

Section 7(1)(a) of FOIA exempts from inspection and copying "[i]nformation *specifically prohibited* from disclosure by federal or State law or rules and regulations implementing federal or State law." (Emphasis added.) "[A]n exemption restricting the expansive nature of the FOIA's disclosure provisions must be explicitly stated-that is, such a proposed disclosure must be *specifically* prohibited." (Emphasis in original.) *Better Gov't Ass'n v. Blagojevich*, 386 Ill. App. 3d 808, 816 (4th Dist. 2008).

The records denied in their entireties pursuant to section 7(1)(a) consist of four letters concerning research misconduct from a University Institutional Review Board (IRB) to the United States Department of Health and Human Services. The United States Food and Drug Administration requires IRBs to review and monitor biochemical research "to protect the rights and welfare of humans participating as subjects in the research. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research."[2] The University's response to this office asserts that disclosure of the IRB letters is specifically prohibited by section 8-2101 of the Medical Studies Act.

Section 7(1)(f) exempts from inspection and copying "[p]reliminary drafts, notes, recommendations, memoranda and other records in which opinions are expressed, or policies or actions are formulated, except that a specific record or relevant portion of a record shall not be exempt when the record is publicly cited and identified by the head of the public body." The section 7(1)(f) exemption applies to "inter- and intra-agency predecisional and deliberative material." *Harwood v. McDonough*, 344 Ill. App. 3d 242, 247 (1st Dist. 2003). In construing the deliberative process exemption in Federal FOIA,[3] the United States Supreme Court held that communications with third parties that have independent interests and that stand to obtain a government benefit from the public body's final decision cannot be characterized as intra-agency communications. *Department of Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 14-15, 121 S. Ct. 1060 1069 (2001).

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[2]U.S. Food & Drug Administration, Institutional Review Board Frequently Asked Questions – Information Sheet, https://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm (last visited November 26, 2018).

[3]5 U.S.C. § 552(b)(5) (2000).

Pursuant to section 7(1)(f), the University redacted the substantive portions of a fifth letter that responded to issues about Professor Pavuluri's research raised by the National Institute of Mental Health, which is part of the United States Department of Health and Human Services. Although the University's response to this office acknowledged that the University and federal agencies have independent interests in this matter, it cited *Klamath*[4] in support of its assertion that the letter is exempt from disclosure under section 7(1)(f) as an inter-agency communication that is privileged under the MSA.

Section 8-2101 of the MSA provides:

> Information obtained. All information, interviews, reports, statements, memoranda, recommendations, letters of reference or other third party confidential assessments of a health care practitioner's professional competence, or other data of the Illinois Department of Public Health, local health departments, the Department of Human Services (as successor to the Department of Mental Health and Developmental Disabilities), the Mental Health and Developmental Disabilities Medical Review Board, Illinois State Medical Society, allied medical societies, health maintenance organizations, medical organizations under contract with health maintenance organizations or with insurance or other health care delivery entities or facilities, tissue banks, organ procurement agencies, physician-owned insurance companies and their agents, committees of ambulatory surgical treatment centers or post-surgical recovery centers or their medical staffs, or **committees of licensed or accredited hospitals or their medical staffs,** including Patient Care Audit Committees, Medical Care Evaluation Committees, Utilization Review Committees, Credential Committees and Executive Committees, or their designees (but not the medical records pertaining to the patient), used **in the course of internal quality control or of medical study for the purpose of reducing morbidity or mortality, or for improving patient care or increasing organ and tissue donation, shall be privileged, strictly confidential and shall be used only for medical research, increasing organ and tissue donation, the evaluation and improvement of quality care, or granting, limiting or revoking staff privileges or agreements**

[4]"To qualify, a document must * * * satisfy two conditions: its source must be a Government agency, and it must fall within the ambit of a privilege against discovery under judicial standards that would govern litigation against the agency that holds it." *Klamath*, 532 U.S. at 8, 121 S. Ct. at 1065.

> **for services**, except that in any health maintenance organization proceeding to decide upon a physician's services or any hospital or ambulatory surgical treatment center proceeding to decide upon a physician's staff privileges, or in any judicial review of either, the claim of confidentiality shall not be invoked to deny such physician access to or use of data upon which such a decision was based. (Emphasis added.)

"The purpose of the Medical Studies Act is to encourage candid and voluntary studies and programs used to improve hospital conditions and patient care or to reduce the rates of death and disease." *Grosshuesch v. Edward Hospital*, 2017 IL App (2d) 160972, ¶15, 83 N.E.3d 1185, 1189 (2017). Section 8-2101 of the Act "protects against disclosure of the mechanisms of the peer-review process, including information gathering and deliberation leading to the ultimate decision rendered by a hospital peer-review committee." *Chicago Trust Co., v. Cook County Hospital*, 298 Ill. App. 3d 396, 402 (1st Dist. 2003). It does not, however, "apply to the restrictions that may be imposed as a result of that process." *Richter v. Diamond*, 108 Ill. 2d 265, 269 (1985); *Nielson v. SwedishAmerican Hospital*, 2017 IL App (2d) 160743, ¶38, 80 N.E.3d 706, 715 (2017) ("Results of the peer-review process *are not* privileged and are discoverable."). (Emphasis in original.)).

Results "take the form of ultimate decisions made or actions taken by that committee, or the hospital, and include the revocation, modification or restriction of privileges, letters of resignation or withdrawal, and the revision of rules, regulations, policies and procedures for medical staff." *Ardisana v. Northwest Community Hospital, Inc.*, 342 Ill. App. 3d 741, 747 (1st Dist. 2003); *see also Anderson v. Rush-Copley Medical Center, Inc.*, 385 Ill. App. 3d 167, 181 (2nd Dist. 2008) ("actual changes, such as modifications to hospital policy or procedure, that were adopted [by the hospital] as a direct result of the recommendations and internal conclusions in the Action Plan must be disclosed, as they constitute the 'ultimate decisions made or actions taken' as a result of the peer-review process."); *Green v. Lake Forest Hospital*, 355 Ill. App. 3d 134, 138 (2d Dist. 2002) ("findings of a peer-review committee are not privileged under the Act.").

The letters denied in their entireties pursuant to section 7(1)(a) on the basis of the MSA detail an IRB's findings and corrective actions concerning research misconduct. The letter redacted pursuant to section 7(1)(f) on the basis that it is an inter-agency communication privileged under the MSA was sent to the National Institute of Mental Health by the University's director of the Office for the Protection of Research Subjects and the vice chancellor for research. The brief, unredacted portion states: "Thank you for providing the University of Illinois at Chicago (UIC) the opportunity to respond to the issue NIHM raises regarding Dr. Pavuluri's research. It is hoped that the Agency will find the actions taken to date to be

satisfactory and reflective of our Institution's commitment regarding the protection of human subjects participating in research at UIC."[5]

The University's response to this office stated that the confidentiality provisions of the MSA apply to the University because it is an allied medical society and a medical organization under contract with health maintenance organizations or with insurance or other health care delivery entities or facilities. Although Ms. Cohen does not dispute the applicability of the MSA to the University's peer review process, she asserts that the MSA's confidentiality provisions do not apply to information originating from IRB files. According to Ms. Cohen, section 8-2101 of the MSA does not prohibit disclosure of the letters because they "were created for purposes of meeting the University's obligation to report certain events to [the United States Department of Health and Human Services],[6] they were not created and used exclusively for the purposes of peer review or quality improvement, and, consequently, do *not* fall within the protections of the MSA."[7] (Emphasis in original.).

We disagree. In *Doe v. Illinois Masonic Medical Center*, 297 Ill. App. 3d 240, 244 (1st Dist. 1998), the Illinois Appellate Court ruled that a hospital's IRB was "a 'committee of the hospital'" within the scope of section 8-2101 of the MSA. The court rejected the assertion that the confidentiality provisions of the MSA are only applicable to peer review committees and that IRBs are excluded from the MSA because they are creatures of Federal law: "The IRB here qualifies as the type of committee covered by the Act. Although we believe that peer review functions are probably an inherent and inextricable part of the IRB's review process, promoting peer review is not the *only* purpose of the Act." (Emphasis in original.) *Doe*, 297 Ill. App. 3d at 243-44. The court went on to conclude that section 8-2101 of the MSA prohibited disclosure of records related to a genetic testing procedure which were submitted to a hospital's IRB. *Doe*,

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[5]Letter from James H. Fischer, PharmD, Director, Office for the Protection of Research Subjects, Human Protections Administrator, and Mitra Dutta, PhD, Vice Chancellor for Research, UIC Distinguished Professor, Department of Electrical and Computer Engineering, to Rebecca Claycamp, M.S., CRA, Chief Grants Management Officer, National Institute of Mental Health (May 22, 2013), at 1.

[6]Section 46.103(b)(5) of title 45 of the Code of Federal Regulations (45 C.F.R. § 46.103(b)(5) (2018)) provides: "Written procedures for ensuring prompt reporting to the IRB appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and (ii) any suspension or termination of IRB approval."

[7]Letter from Jodi S. Cohen, ProPublica Illinois, to Sarah Pratt, Public Access Counselor, Office of the Attorney General, Public Access Bureau (May 3, 2018), at 7.

297 Ill. App. 3d at 245-46.[8] Further, it is irrelevant for purposes of section 8-2101 of the MSA that an external source prompted the creation of records that clearly concern internal quality control. *See Anderson*, 385 Ill. App. 3d at 182 (characterizing as a "red herring" the fact that an action plan created by a hospital's peer review committee may have been mandated by the Joint Commission on Accreditation of Healthcare Organizations).

The letters at issue pertain to allegations of research misconduct in connection with a medical study. Based on this office's confidential review, the IRB and medical staff who reviewed those allegations were concerned about internal quality control for purposes that included improving patient care. Portions of the letters describing fact gathering and other aspects of this internal quality control process fall squarely within the scope of section 8-2101 of the MSA. Therefore, the University did not improperly withhold those portions of the letters pursuant to section 7(1)(a) of FOIA.

The letters, however, largely consist of the IRB's findings and corrective actions that resulted from the IRB review process. Such results are not confidential under the Act. *Ardisana* 342 Ill. App. 3d at 747. Because section 8-2101 of the MSA does not prohibit disclosure of these results, this office concludes that the University has not sustained its burden of demonstrating that the letters are exempt from disclosure in their entireties pursuant to section 7(1)(a) of FOIA. That finding compels the conclusion that portions of the letter to the National Institute of Mental Health detailing the corrective actions taken to protect human research subjects are not exempt from disclosure pursuant to section 7(1)(f) because they do not constitute inter-agency communications that are privileged under the MSA.[9]

Sections 7(1)(j)(ii) and 7(1)(j)(iv)

The University response to the request in 2018 PAC 53008 also cited section 7(1)(j)(ii), which exempts from disclosure "information received by a primary or secondary school, college, or university under its procedures for the evaluation of faculty members by their academic peers." The University's response to this office stated: "deliberations, opinions and recommendations regarding the peer evaluations or that the University had received during the

[8]In her reply to this office, Ms. Cohen cited three court decisions that concluded medical studies overseen by IRBs are not encompassed by peer review statutes in other states. *P.J. ex. rel. Jensen v. Utah*, 247 F.R.D. 664 (D. Utah 2007); *Esdale v. American Community Mutual Insurance Co.*, 1995 WL 263479 (N.D. Ill., 1995); *Konardy v. Osterling*, 149 F.R.D. 592 (D. Minn. 1992). Those decisions did not analyze section 8-2101 of the MSA and therefore have no relevance to this matter in light of the *Doe* court's decision that the Act covers IRBs.

[9]Because that determination is dispositive, this office declines to address whether the independent interests of the University and the Department excluded the letter from the scope of section 7(1)(f).

course of the peer review process were withheld or redacted from the responsive records."[10] In addition, the University's response to this office cited section 7(1)(j)(iv) of FOIA, stating that "[i]nformation contained in both the letters and the research protocols contains information that the University generated during the peer review and research process."[11] The section 7(1)(j)(iv) exemption applies to "course materials or research materials used by faculty members."

The University has not demonstrated that sections 7(1)(j)(ii) and 7(1)(j)(iv) apply to the findings and corrective actions resulting from the IRB review process. As discussed above, the IRB review process monitors research to protect the rights and welfare of research subjects; there is no indication that it is among the University's procedures for evaluating faculty members even though monitoring the research may include the conduct of researchers. Further, because the results of the IRB review process were not generated by research or used to conduct research, they do not constitute "research materials used by faculty members." Accordingly, this office concludes that the results of the IRB review process are not exempt from disclosure pursuant to section 7(1)(j)(ii) or 7(1)(j)(iv) of FOIA.

In accordance with the conclusions expressed above, this office requests that the University disclose to Ms. Cohen portions of the letters reflecting the findings and corrective actions resulting from the IRB review process. The Public Access Counselor has determined that resolution of this matter does not require the issuance of a binding opinion. If you have any questions, please contact me at (312) 814-6756. This file is closed.

Very truly yours,

STEVE SILVERMAN
Bureau Chief
Public Access Bureau

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[10]Letter from Thomas P. Hardy, Executive Director and Chief Records Officer, University of Illinois System, to Joshua Jones, Deputy Public Access Bureau Chief, Office of the Public Access Bureau, Office of the Illinois Attorney General (June 8, 2018), at 12.

[11]Letter from Thomas P. Hardy, Executive Director and Chief Records Officer, University of Illinois System, to Joshua Jones, Deputy Public Access Bureau Chief, Office of the Public Access Bureau, Office of the Illinois Attorney General (June 8, 2018), at 12.