E&R

Ethical and Practical Concerns about IRB Restrictions on the Use of Research Data

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Table 1.
IRB Policies on Data Use

Institution	*Authority to restrict data use*	*Relevant policy language**
Johns Hopkins Medicine (JHM)	The institutional review board (IRB) and institutional officials (IOs) will determine the actions required and consider a range of options, but data restriction is not listed specifically.	The IRB will determine the actions required and will take into consideration the nature, severity, and frequency of the noncompliance and the risk that noncompliance poses to human subjects. The JHM IRBs and [i]nstitutional officials may consider a range of options to address documented cases of noncompliance.[1]
University of California, San Francisco	Policies list possible IRB actions, including referral to appropriate IOs, but do not list data restriction.	Report event to OHRP [Office for Human Research Protections], appropriate university officials and study sponsors, and FDA [U.S. Food and Drug Administration] (for studies under FDA regulatory oversight) if a full IRB panel review determines that the event report is [a] UP [unanticipated problem] or (after investigation) determines an instance of serious or continuing noncompliance.[2]
University of Michigan	IO may restrict data use.	Each IRB, as well as the IO and other institutional authorities, has the authority at any time to suspend or terminate approval of human subjects research that is not being conducted in accordance with applicable laws and regulations, institutional policy, or an IRB's requirements . . . . The IO may institute any or all of the following additional sanctions: • embargo or destruction of research data . . . .[3]*

University of Pennsylvania	Policies list possible IRB actions, including referral to other organizational entities, but do not list data restriction.	The IRB may take the following actions in response to a determination of serious or continuing noncompliance: . . . • referral to other organizational entities (e.g., legal counsel, risk management, institutional official).[4]
University of Pittsburgh	The IRB may take whatever actions deemed necessary to address the UP/noncompliance including notification to other organizational entities, but data restriction is not listed specifically.	The reviewing Committee takes whatever actions are deemed necessary to address the unanticipated problem(s). Examples of actions that might be taken include, but are not limited to . . . • notifying other organizational entities (e.g., legal counsel, institutional risk management, the Authorized Institutional Official, the Research Integrity Officer, the UPMC [University of Pittsburgh Medical Center] Clinical Trials Office, UPMC Privacy Officer) as warranted; . . . • requiring other action as determined to be appropriate by the University IRB committee.[5]
Stanford University	Policies list possible IRB actions, including referral to other organizational entities, but do not list data restriction.	The IRB will consider: • suspension or termination of the protocol pursuant to Chapter 9.4 [and] • notification of current participants (required when such information may relate to participants' willingness to continue to take part in the research).* Other possible IRB actions include but are not limited to the following . . . • referral to other organizational entities (e.g., legal counsel, risk management, institutional official, School Dean, Department Chair).[6]
University of Washington	The IRB may request that an IO restrict data use.	Actions the IRB can take: Require the HSD [Human Subjects Division] Director to forward to the appropriate institutional office a request to consider one of the actions listed below (for which the IRB itself does *not* have authority). The HSD Director determines which institutional office [is] the most appropriate office to which the request should be directed[:] (a) requiring that data not be published or presented; (b) requiring that data not be used for a thesis or dissertation; (c) requiring that data be destroyed; and/or (d) any other actions for which the institutional office has authority.[7]

Duke University	The IRB will specify any required corrective actions, including referral to other organizational entities and the IO, but data restriction is not listed specifically.	The IRB will specify any required corrective actions which may include . . . • referral to other organizational entities such as legal counsel, risk management, human resources, the privacy office, or the IO; • providing additional recommendations to the IO; • other actions appropriate for the local context.[8]*
Washington University	Organization officials may restrict data use.	PARC [Washington University Protocol Adherence Review Committee] determines whether or not an event constitutes serious or continuing noncompliance, and may require corrective actions as noted (but not limited to) below: . . . • referral to the organizational official (Vice Chancellor for Research) and Dean, if applicable, for determining and imposing additional sanctions such as formal reprimands or limitations on research activity or publications.[9]
Yale University	The IRB may take any action it deems necessary, including referral to other organizational entities, but data restriction is not listed specifically.	If the IRB determines that the incident constitutes serious and/or continuing noncompliance, it may take any action it deems necessary to protect the rights and/or welfare of the research participants involved, including, but not limited to . . . • referral to other University authorities or committees for possible further review and resolution by those bodies including possible disciplinary action up to and including termination in accordance with the appropriate disciplinary procedures for faculty, staff, and students.[10]
University of California, San Diego	The IRB may restrict data use.	Sanctions that may be imposed by the IRB include, but are not limited to . . . • embargo or retraction of publications . . . [11]
University of North Carolina at Chapel Hill	Vice chancellor may restrict data use.	Recommend that the Vice Chancellor for Research: • limit use of research data (e.g., prohibition on use of data collected as part of protocol noncompliance), • require that the investigator submit a correction to publication, • require that the investigator request a retraction of the publication, • require that the investigator disclose to publisher/others that the data were collected unethically/outside protocol, • require that the investigator discard the data.[12]

Columbia University Health Sciences	The IRB may restrict any study it determines to warrant such action, but data restriction is not listed specifically.	The Boards have the responsibility and the authority to. . . • suspend or terminate approval of any study that has an unanticipated problem involving risks to human subjects or others, serious or continuing noncompliance with any federal regulation, or serious or continuing noncompliance with the requirements or determinations of the IRB [and] . . . • restrict any study it determines to warrant such action, including situations in which one aspect of a study fails to comply with federal regulations or Board requirements or determinations . . .[13]
University of California, Los Angeles	The IRB may impose sanctions or refer to other organizational entities, but data restriction is not listed specifically.	The IRB will consider which of the following actions is required. This consideration may include but is not limited to the following: . . . • impose sanctions to achieve compliance or prevent recurrence of noncompliance [and] • refer the Principal Investigator or all of the researchers to another University entity (i.e., Institutional Official, Campus Counsel, Risk Management) . . .[14]
Massachusetts General Hospital	The IRB may take any action it deems appropriate to the noncompliance, but data restriction is not listed specifically.	By majority vote of a quorum of the membership present at the convened meeting, the PHRC [Partners Human Research Committees] will make a determination as to the noncompliance and take one or more of the following actions with respect to the research: . . . • any other action the PHRC deems appropriate to the noncompliance.[15]
Brigham and Women's Hospital	The IRB may take any action it deems appropriate to the noncompliance, but data restriction is not listed specifically.	By majority vote of a quorum of the membership present at the convened meeting, the PHRC will make a determination as to the noncompliance and take one or more of the following actions with respect to the research: . . . [a]ny other action the PHRC deems appropriate to the noncompliance.[16]
Emory University	The IRB may restrict data use.	The full IRB Committee shall then vote on whether to accept the report and recommendations, or alternative steps that should be taken. These actions may include one or more of the following actions, as well as any other action recommended by the IRB Committee: . . . • other actions as appropriate, including, but not limited to . . . restricting use of the research data for publication . . .[17]

Icahn School of Medicine at Mt. Sinai	The IRB may take corrective actions as needed, but data restriction is not listed specifically.	The IRB is responsible to investigate allegations and findings of noncompliance and take corrective actions as needed. The Organizational Official is responsible to investigate all other reports and take corrective actions as needed.[18]
University of Wisconsin at Madison	The IRB may take corrective actions as needed, but data restriction is not listed specifically.	The convened IRB will review reports of noncompliance referred to it by the IRB staff or IRB chair to determine whether the report constitutes serious or continuing noncompliance and any appropriate remediation measures, such as changes to the protocol, suspension, termination, reporting to federal agencies and department heads, and other corrective actions as appropriate.[19]
Fred Hutchinson Cancer Center	The IRB may restrict data use.	If the IRB determines that the noncompliance is serious or continuing, then the IRB will consider at a minimum the following actions to remedy the noncompliance and protect research participants and others: . . . • prohibiting use of the data collected for publication . . . [20]

This list should not be interpreted as a ranking of institutions by the National Institutes of Health (NIH) but is compiled from a list of NIH awards to institutions during the fiscal year of 2018 using https://report.nih.gov/, last accessed February 18, 2019.

*To improve readability of the quoted language, some letters have been changed from uppercase to lowercase, and some punctuation at the end of bullet points has been added or changed (from periods to commas, for instance).

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2. "Protocol Violation or Incident," University of California, San Francisco, Institutional Review Board, 2018, last updated June 1, 2020, https://irb.ucsf.edu/protocol-violation-or-incident.

3. "Quality Assurance and Research Compliance," part 12 in *Operations Manual: University of Michigan Human Research Protection Program*, University of Michigan, July 2020, https://research-compliance.umich.edu/operations-manual-quality-assurance-and-research-compliance#determinations.

4. "Standard Operating Procedures," RR 408, section 3.5, version 11.1, *Institutional Review Board Standard Operating Policies*, University of Pennsylvania Institutional Review Board, June 2019, https://irb.upenn.edu/mission-institutional-review-board-irb/irb-policies.

5. "Responsibilities of the IRB: Possible IRB Committee Actions," University of Pittsburgh Human Research Protection Office, 2019, at https://www.irb.pitt.edu/content/responsibilities-irb.

6. Stanford University, *Human Research Protection Manual*, chapter 3.9, March 29, 2020, https://researchcompliance.stanford.edu/panels/hs.

7. "Worksheet: Options for IRB Actions," in "Forms and Templates," UW Research, University of Washington, 2015, https://www.washington.edu/research/forms-and-templates/worksheet-options-for-irb-actions/.

8. "Non-compliance with the Requirements of the Human Research Protection Program," Duke University Health System Human Research Protection Program, June 23, 2020, https://irb.duhs.duke.edu/sites/irb.duhs.duke.edu/files/Non-Compliance%206-23-2020FINAL.pdf.

9. "Washington University Institutional Review Board Policies and Procedures," section X(F)(8), Washington University in St. Louis Human Research Protection Office, May 15, 2020, https://hrpo.wustl.edu/research-toolkit/policies/.

10. Yale University Human Research Protection Program, "700 PR.3 IRB Review and Investigation of Reports of Noncompliance," It's Your Yale, October 23, 2012, at https://your.yale.edu/policies-procedures/procedures/700-pr-3-700-pr3-irb-review-and-investigation-reports-noncompliance.

11. University of California, San Diego, "Communications, Sanctions, Appeals, and Disciplinary Actions," section 5.2 in "Standard Operating Policies and Procedures," University of California, San Diego, Human Research Protection Program, May 16, 2017, https://irb.ucsd.edu/5.2.pdf.

12. "Safety Committee Review Worksheet," supplement 1, "IRB Reviewer Checklists," University of North Carolina at Chapel Hill, last accessed

February 2019, via http://irbmember.web.unc.edu/what-you-will-find-here/member-orientation/review-materials/.

13. Columbia University in the City of New York, "Institutional Review Board Standard Operating Procedures," section II.A.3, February 12, 2019, https://research.columbia.edu/sites/default/files/content/HRPO/IRB_SOP_v5.2_2.12.19_TOC_CUIMC.176a.9.12.19.pdf.

14. UCLA Office of the Human Research Protection Program, "Policy: Noncompliance and Allegations of Noncompliance Regarding the Conduct of Human Subjects Research," June 17, 2011, http://ora.research.ucla.edu/OHRPP/Documents/Policy/11/Noncompliance.pdf.

15. Partners Healthcare, "Noncompliance in Human Subjects Research," August 16, 2015, https://www.massgeneralbrigham.org/sites/default/files/2020-06/Noncompliance-in-Human-Subjects-Research.pdf.

16. Ibid.

17. Emory University, "Institutional Review Board Policies and Procedures," section 62, September 18, 2020, http://www.irb.emory.edu/documents/PoliciesandProcedures.pdf.

18. "Mount Sinai Human Research Protection Program Plan," Icahn School of Medicine at Mount Sinai, June 11, 2018, https://icahn.mssm.edu/research/pphs.

19. "Research Knowledge Base Noncompliance," University of Wisconsin-Madison, 2019, https://research.wisc.edu/kb-article/?id=29507.

20. Fred Hutch Institutional Review Board, "Policies and Procedures: Noncompliance (Policy 1.9)," February 24, 2020, https://extranet.fredhutch.org/en/u/irb/policies-and-procedures/_jcr_content/leftParsys/download_25/file.res/Noncompliance.pdf.