



Office of Human Research Ethics Training Tips

15 Questions for an IRB to Ask About Privacy, March 2017

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“Happy Trials to You”

15 Questions for an IRB to Ask About Privacy

By Dennis J. Mazur and Norman M. Goldfarb

Clinical researchers have ethical and legal obligations to protect the privacy of study participants by maintaining the confidentiality of their identifiable personal information. From a legal perspective, these obligations most commonly arise under the HHS Common Rule at 45 C.F.R. 46.111(a)(7) and FDA IRB regulations at 21 C.F.R. 56.111(a)(7).

Also, if the clinical researcher is an employee of a “covered entity” under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, the clinical researcher likely has additional obligations to protect the “protected health information” (PHI) of study participants, including data that identifies or could be used to identify the study participants and discern their associated health information. FDA 21 CFR Part 11 also lays out requirements for securing study data, including the personal information of study participants, but without an emphasis on privacy.

While IRBs generally do not have oversight responsibility for HIPAA, HITECH or 21 CFR Part 11 compliance, they are responsible for protecting the welfare of study participants. This responsibility includes ensuring there are adequate measures in place to protect the privacy of study participants and to maintain the confidentiality of their data. Many IRBs also serve as the HIPAA privacy board for their institutions and, as such, have direct obligations under HIPAA.

The following 15 questions can assist IRBs in determining whether the privacy of study participants will be adequately protected:

1. What private information (including biosamples) will be collected?
2. Who will have access to this information?
3. What measures will be taken to protect the privacy of this information?
4. What measures will be taken to ensure that personnel with access to private information understand their responsibilities to protect it?
5. What legal or contractual obligations does the study sponsor (and CRO) have to protect private information?
6. What information, if any, will be shared outside the study, and with whom will this information be shared?
7. What measures (e.g., de-identification or anonymization) will be taken to protect the privacy of the shared information?
8. Will any of the information be especially sensitive and require extra protective care?
9. What additional measures, if any, will be taken to protect the privacy of this information?
10. Will study participants be adequately informed (what, when, how and by whom?) about the nature of their private information, how it will be protected, and their rights — and limits thereto — to authorize any disclosures?
11. When and how will study participants authorize any disclosures of their private information?
12. What rights and mechanisms will study participants have to grant or withdraw their authorization(s) during and after the study?
13. Will private information be obtained — directly or indirectly — about family members or blood relatives?
14. If so, will the permission to collect such information be obtained from such people, and how will the privacy of this information be protected?
15. What measures will be taken to ensure the above protections will be applied correctly?

Authors

Dennis J. Mazur, MD, PhD, is the author of *Evaluating the Science and Ethics of Research on Humans: A Guide for IRB Members*, published by the Johns Hopkins University Press, Baltimore, Maryland, 2007. Contact him at mzrdj11@gmail.com.

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.