Human Subjects Privacy and Confidentiality Protection

HRPP Operations Manual Section Part 3, III, C, 6, g

“Privacy” refers to the willingness of research participants to allow access to themselves and their information. “Confidentiality” refers to the agreement between the researcher and participants on how the participants’ identifiable private information will be managed and used. SOPs must provide for all of the following:

1. As part of the IRB’s duty to protect the rights and welfare of study participants, the IRB must ensure that the research plan contains adequate provisions to protect the privacy of participants and maintain the confidentiality of their identifiable data for the duration of the study and, in the case of the confidentiality of the research data, after the study is finished;

2. That the researcher must include a plan to protect participants' privacy and confidentiality in the eResearch application, protocol or other documents submitted to the IRB;

3. A description of the types of privacy and confidentiality information that the researcher must include in its plan;

4. That the IRB reviews the researcher's plan to protect participants' privacy and confidentiality to assess the adequacy of the protection;

5. A description of the issues and points of interest that will be used to evaluate the protocol appropriately and adequately protects privacy and confidentiality;

6. A description of the regulatory, institutional, and IRB policies, procedures, and guidance that will be used to confirm that the protocol appropriately and adequately protects privacy, including, but not limited to, the following:

   - Code of Federal Regulations/Protection of Human Subjects (45 CFR 46)(link is external)
   - Food and Drug Administration (FDA)/Protection of Human Subjects (21 CFR 56)(link is external)
   - Health Insurance Portability and Accountability Act (45 CFR Parts 160 and 164)(link is external)
   - University of Michigan Website Guidance for Sensitive Human Subjects Data

Issues and points of interest considered when reviewing privacy protections include all of the following:

1. The research setting, participant population, manner in which participants will be approached and enrolled, and inclusion of any un-consented individuals about whom the primary participants will provide information.
2. Whether the protocol proposes an invasion of privacy through observation or intrusion into situations where participants would otherwise have a reasonable expectation of privacy.

3. Where there is a risk that privacy will be compromised, the IRB will evaluate:

- Whether reasonable people might be offended by the invasion of privacy;
- Whether the research can be redesigned to avoid the possible invasion of privacy;
- Whether the importance of the research objective justifies the invasion of privacy;
- Whether the participant will be informed of the invasion of privacy, its implications, and available privacy protections; and
- Whether documentation of consent should be waived in order to protect participant privacy.

Issues and points of interest considered when reviewing confidentiality protections include all of the following:

1. The research setting, participant population, the manner in which participants will be approached and enrolled, where private information will be collected, the nature of information, who will collect, receive and use the information and inclusion of any un-consented individuals about whom the primary participants will provide information or for whom the researchers will obtain information through record review or chart abstraction;

2. Whether appropriate permission is sought for access to records when reviewing existing records for participant selection or to abstract data;

3. Whether the protocol proposes the collection of sensitive individual information;

4. Where the research includes the collection of sensitive individual information the IRB will evaluate:

   - Whether adequate provisions have been identified to protect the confidentiality of the data through coding, destruction of identifying information, limiting access to the data, and any other methods that may be appropriate, given the context of the study;

   - Whether the disclosure of the data might place the participant at legal, social, reputational, employability, or insurability risk;

5. Where compelled disclosure of the data might place participants at risk, whether a Certificate of Confidentiality should be sought to protect the researcher from disclosure of the data under subpoena or other legal process;
6. Where accidental disclosure of the data might place participants at risk, whether data management procedures ascribe to institutional policies and IRB guidance for appropriate and required data security measures;
7. Whether disclosures to participants about confidentiality risks and protections are adequate; and
8. Whether documentation of consent should be waived in order to protect confidentiality.

For more on privacy and confidentiality, see the OHRP IRB Guidebook (link is external) – Chapter III (D), from which the above list of considerations was obtained.