Written Procedures for IRBs: What Does the New Final Guidance from FDA and OHRP Mean to You?

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In May 2018 the U.S. Food and Drug Administration (FDA) and the U.S. Office for Human Research Protections (OHRP) issued final guidance titled Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs. The 21st Century Cures Act requires the Secretary of the Department of Health and Human Services (HHS) to harmonize differences between the HHS human subject regulations and FDA's human subject regulations. This guidance, which was issued in draft form in August 2016, marks another step towards the more complete harmonization of the OHRP and FDA regulations.

What is the guidance?

With four pages of guidance and a nine-page checklist, the goal of the document is to assist staff at institutions and IRBs who are responsible for preparing and maintaining written procedures including standard operating procedures (SOPs) and policies. The guidance notes that "OHRP and FDA believe that when institutions and IRBs develop and follow clear written procedures, there is an increased likelihood that the rights and welfare of human subjects will be protected." People are often surprised to learn that the regulations governing IRBs require only seven specific written procedures. Both the HHS regulations at 45 CFR 46.103(b)(4) and (5) and the FDA regulations at 21 CFR 56.108(a) and (b) state that IRBs must follow written procedures for the following functions and operations:

1. conducting initial and continuing review of research and for reporting IRB findings and actions to the investigator and the institution;
2. determining which projects require review more often than annually and determining which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review;
3. ensuring prompt reporting to the IRB of proposed changes in a research activity;
4. ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review

and approval except where necessary to eliminate apparent immediate hazards to the human subjects ensuring prompt reporting to the IRB, appropriate institutional officials, and, as applicable, any department or agency head, OHRP, and/or FDA of any unanticipated problems involving risks to human subjects or others;

5. ensuring prompt reporting to the IRB, appropriate institutional officials, and, as applicable, any department or agency head, OHRP, and/or FDA of any unanticipated problems involving risks to subjects or others;

6. ensuring prompt reporting to the IRB, appropriate institutional officials, and, as applicable, any department or agency head, OHRP, and/or FDA of any instance of serious or continuing noncompliance with the applicable HHS and/or FDA regulations, or the requirements or determinations of the IRB, and any suspension or termination of IRB approval; and

7. ensuring prompt reporting to the IRB, appropriate institutional officials, and, as applicable, any department or agency head, OHRP, and/or FDA of any suspension or termination of IRB approval.

While these are the only specifically-required written procedures, there are other IRB activities that require findings and determinations for which the underlying regulations do not explicitly require the IRB to follow a written procedure, such as the requirement that IRBs determine that proposed research meets the criteria for a waiver of documentation of informed consent. Many IRBs have additional procedures for these processes as well. Finally, the Association for the Accreditation of Human Research Protection Programs (AAHRPP) will also have additional procedures that are required in order for IRBs to achieve and maintain AAHRPP accreditation.

What does this mean?

There are several ways in which the new guidance is helpful to IRBs.

- The guidance is clear regarding what items are required by the regulations versus recommended by FDA/OHRP. In response to the 2016 draft version of the guidance, the HHS Secretary's Advisory Committee on Human Research Protections (SACHRP) recommended that final guidance be clear on this point.
- FDA/OHRP also clarify that the regulations provide a great deal of flexibility in how IRBs choose to format their written procedures and how much detail to include. With this in mind, an IRB can define their written procedures to include traditional documents such as policies and SOPs, but can also include other types of controlled documents including work instructions, checklists, and other tools that guide IRB members and staff in fulfilling regulatory expectations.

With these clarifications in the guidance, the written procedures checklist that forms the bulk of the guidance is a helpful tool that IRBs can use to evaluate their written procedures. The checklist provides extensive recommendations regarding what information could be considered for inclusion within the required seven written procedures. It also goes beyond the required procedures to include recommendations for written procedures in additional areas of relevance to the IRB. Section V of the checklist, Additional Topics the Institution/IRB May Consider provides suggestions for what might be included in written procedures in numerous areas including IRB membership and IRB records.

The checklist should serve as a useful tool for IRBs and institutions that want to ensure that they have covered not only the minimal regulatory requirements, but that are interested in creating and maintaining a comprehensive set of written procedures that reflect best practices for IRBs.

About the Author

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References

[1] U.S. Department of Health and Human Services and the Office for Human Research Protections (OHRP). Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs. https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM512761.pdf. Accessed June 20, 2018.

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