Institutional review board and consent requirements for research conducted in a clinical practice setting

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Federal (Department of Health and Human Services) regulations requiring institutional review board (IRB) review of research are very specific about the issue of what research activities they cover. They cover research that is funded by the federal government.

Here are details:

From: **OS OPHS OHRP (HHS/OPHS)** <OHRP@hhs.gov>
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Subject: RE: do I need IRB?

In general, IRB review and approval would be required under the following scenarios:

- Non-exempt human subject research that is conducted or supported by a federal entity that has adopted the Common Rule.

- Research conducted under the auspices of an institution that has elected to apply its Federalwide Assurance (FWA) to all research, regardless of the source of support.

- Research that falls under the jurisdiction of other federal entities, e.g., the Food and Drug Administration, research conducted in Public Schools may be subject to certain DEd, requirements, among others.

- Research conducted within a jurisdiction that requires human research protections for all research conducted within its jurisdiction; e.g., some States have applicable regulations or require the application of federal regulations. OHRP does not interpret or track State requirements.

If none of the above apply, IRB review and approval would not generally be required, unless the entity conducting the research elects to do. I hope this is helpful. Freda

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Thus, there are no general legally required standards for the review of research that is not funded by the federal government. In that case, some sort of IRB review and consent process are recommended, but not required. These are recommended so the researcher can feel confident s/he is following ethical procedures, and to provide some protection for the researcher in the event that an adverse event occurs or a research participant or someone else becomes distressed about the research.

The clinician's review process and the consent mechanism need not be as cumbersome as the Department of Health and Human Services (DHHS) requires. A guiding principle is: The level of review and consent ought to be commensurate with the level of risk of the research.

The type of review process that the clinician might use ranges from a formal IRB that meets DHHS standards to an informal consultation from a colleague. The consent process ranges from a formal consent document that meets DHHS standards to a paragraph in the clinician's Treatment Agreement.

Data that are collected for clinical or training purposes, and that the researcher prospectively or retrospectlvely elects to use for research purposes (research = contributing to generalizable knowledge), where the database does not include patient or trainee identifiers, likely meets exempt criteria in the DHHS standards, and if it is reviewed by an IRB, could be reviewed by the chair alone, not the full IRB.

If the database does include some way of linking the data to the patient or trainee ID, then these data would likely meet DHHS criterion 5 for an expedited review (research based on data collected for non-research purposes), assuming that risk is minimal, including risk of a breach of confidentiality.

It is a good idea for a clinician or clinical operation that is conducting research to establish the following:

1. A basic organizational policy about research.

2. Standard operating procedures for review of the research.

3. Forms to support the review process.

4. Training for those involved in conducting and reviewing the research.

Data repository

In a clinical setting, the clinician doesn't always know in advance when the data are valuable for research. The clinician can ask the patient's permission in the initial treatment agreement for permission to save the data for research, making sure that there is an option that allows the patient to opt out of permitting the use of his/her data for research purposes. If the patient agrees to the use of data for research purposes, the data are saved in the data repository. The organization's policy might typically state that no formal review process is needed to put data in the repository, but that an IRB review or some other review is needed to pull data out of the repository. Someone in the organization should oversee the data repository, especially the process of pulling data out of the repository, and the organization's policy should specify who that person is and how that person is selected.

State law

Although there are no federal requirements for IRB review of research that is not federally-funded, some states have laws or regulations about this.

Professional association ethics codes

Ethics codes of professional associations provide guidelines for research, confidentiality, dual relationships, and other relevant issues.

Malpractice insurance provider

The clinician who is conducting research will want to inform his/her malpractice insurance carrier that s/he is doing this, and verify that the insurance carrier will cover that activity.

Journals

Sometimes journals or professional organizations require an IRB review even if the federal regulations do not require it.