Does Your Survey Require an IRB Approval or Waiver?

An Institutional Review Board or IRB is a group that has been formally designated by the FDA to review and monitor biomedical research involving human subjects. An IRB has the authority to approve, require modifications to, or disapprove a research plan. IRBs serve an important role in protecting the rights and welfare of those people who participate in research projects that involve human subjects.[1]

Most academic institutions and larger hospitals have their own IRBs that will review your research plan if/when you intend to conduct research under their purview. There are also central IRBs run by third parties that can review research that is conducted across institutions. Both types of IRBs have well-defined requirements for the submission of research requests and meet frequently to review and make decisions.

When conducting surveys, there are certain cases where an IRB (or IRB waiver – see below) may be necessary. If your research plan meets any of the requirements below, you should have your survey reviewed by an IRB.

- Your survey is part of a "clinical investigation" that is governed (or will ultimately be governed) by the FDA or other regulatory body.
- You hope to contribute the results of your survey research to generalizable knowledge and dissemination of the results is intended to inform the field of study.
- The results are intended to be replicated in other settings.
- Your survey relates to a specific, regulated human intervention.
- Your survey collects data from the individuals that includes private, identifiable information and you plan to publish it.

Note that IRB-governed research requires informed consent of individuals participating in the research.

IRB waivers allow you to conduct research that you can use for publication without formal IRB approval. The following are conditions under which you likely would only need an IRB waiver:

- The research involves no more than minimal risk to human subjects;
- The research could not be carried out practicably without the waiver or alteration;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects; and,
- Where appropriate, the subjects will be provided with additional information about their participation.

If your survey meets any of the requirements for IRB review, don't try to determine on your own if your survey requires IRB approval. Submit your research plan to an IRB and they will make that determination for you.

There are a few circumstances where you can be sure that neither an IRB approval or an IRB waiver is needed:

- Your survey is merely for internal research purposes and will be kept within your team/classroom.
- The initial purpose of your survey is not to develop or contribute to generalizable knowledge, and the project is not classified as research at the outset. Later, if someone decides to use identifiable private information from that project with the aim of developing or contributing to generalizable knowledge, that analysis may need IRB review.

When in doubt ask you instructors for guidance and/or reach out to the relevant IRB.

Notes

[1] "Institutional Review Boards: Frequently Asked Questions," US Food and Drug Administration, January 1998, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-boards-frequently-asked-questions (January 15, 2021).