



IRB Frequently Asked Questions

Question: What is the charge or purpose of an IRB?

Answer: An IRB is charged with reviewing proposed human subject research with the goal of protecting the rights and welfare of subjects. In doing so, it considers the implications of both ethical and regulatory issues.

Subject welfare relates not just to subjects' physical condition, but also to their psychological and social state. Research that can do harm to a subject's body must be carefully designed and monitored, but so must research that subjects participants to emotional distress and physical discomfort that likely will not result in long-term damage. Studies must also be designed to protect subjects' social standing, educational and employment prospects, and financial health. Opportunity costs must be taken into account: even if the subject loses nothing tangible from participating in research, that subject at least loses the opportunity to do something else with his time and thus gain some other good. These examples are not collectively exhaustive of the types of harm to a subject's welfare.

Often an IRB will conceive of its charge as focusing on *risks* and *harms*. The idea here is that not only must harm to the subject be avoided or at least minimized, but so must the risk of harm, even if no harm ends up resulting from the study. In cases where some harm or risk of harm is unavoidable, this must be balanced against the benefits (both to the individual subject and to society more broadly) expected of the study. Such balancing can be hard to do, but sometimes is necessary since no study is completely free of risk.

Question: From an IRB perspective, what constitutes *research*?

Answer: *Research* involves (1) systematic investigation and (2) its design or purpose is to produce generalizable knowledge. Any investigation that does not meet these twin criteria does not fall under the purview of the IRB, even if it involves issues that an IRB might consider in another context, such as privacy concerns or the safety of interventions on human subjects.

Question: So what specifically is *human subject* research?

Answer: According to the Department of Health and Human Services, a *human subject* is "a living individual about whom an investigator (whether professional or student) conducting

research obtains (1) data through intervention or interaction with the individual, or (2) identifiable personal information.” *Intervention or interaction* includes both physical procedures on the person or manipulation of the subject’s environment, and communication or interpersonal interaction.

Question: Who has to submit formal applications to York’s IRB?

Answer: Anyone at York College, whether they be faculty, student, or staff, who wishes to engage in human subject research should submit an application to the IRB before commencing the data-collection stage. (Investigators not affiliated with the College must also submit to the our IRB process if they are collecting human subject data at the College or from a College population.)

When in doubt, an investigator may contact the Chair of the IRB for guidance on whether a formal application is in order.

One category of IRB review is known as “exempt”, but since “exempt” in this sense is a technical term with a specific (though somewhat complex) definition in federal law, it should be left to the IRB to determine whether a project meets these standards. To facilitate our review, we do ask whether you believe your study should be reviewed according to exempt guidelines. But be aware that the terminology can be misleading: exempt research is **NOT** exempt from all IRB review.

Question: What is the difference between exempt, expedited, and full review?

Answer: Only research that falls into very specific categories can be deemed exempt or expedited by an IRB; further details of these criteria can be found elsewhere on this site. Briefly, however, exempt research encompasses six categories in which there is minimal risk to subjects. Expedited review encompasses nine categories in which subjects will be exposed to no more than minimal risk, or for minor modifications to previously approved research. In most cases, investigators at York can ignore the distinction between these three categories of review, trusting that the IRB will apply the proper standards in any given case.

It is important to keep in mind that **not all** research that entails minimal risk counts as exempt. Research on vulnerable populations (e.g., minors, prisoners, the mentally disabled, the homeless) **never** counts as exempt. Furthermore, FDA regulations do not recognize an exempt category, so research on drugs, biologics, and medical devices is never exempt. Categories often found in the College that do count as exempt are studies done in the normal course of normal education practice; the anonymous use of educational tests, surveys, or observational data; and the collection or study of existing data. Even in these cases, however, care must be exercised, for example because it can be difficult to anonymize observational data and because it is easy to improperly apply the existing data exemption.

The practical difference between these categories is that when research is deemed exempt, it is not subject to further review beyond initial IRB approval. Full review has to be approved by the entire IRB, which can require significantly longer approval times at York since we rarely get applications that require full review. Most of the applications we receive require expedited review.

Question: Can I publish the results of research that has not been IRB approved?

Answer: In certain circumstances, yes. The safest course of action, if you plan on engaging in studies involving human subjects, is to either apply through normal IRB channels or at least consult with the Chair of the IRB. Journals may ask whether a study has been approved by an IRB, so approval may be useful even if strictly not required by federal rules or institutional policy. That said, *intent* is one key component of the IRB notion of research: when one collects information, the purpose of collection can be crucial in determining whether one is engaging in research or some other activity such as quality improvement or normal educational practice. If one thinks one might publish the results of analysis of data being collected, one is likely doing research. An exception would be a medical case study, which is not meant to lead to generalizable knowledge; but even studies on a single individual may be research if one expects to be able to generalize from the results, so simple rules-of-thumb can be risky to follow.

Question: Where can I go to learn more about IRBs and the rules governing them?

Answer: Federal oversight of human subject research is in the hands of two departments within the Department of Health and Human Services (DHHS): the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA). Any research involving a drug, a biologic, or a medical device is subject to FDA regulation, whereas the OHRP is only concerned with research that is funded or otherwise supported by the DHHS. Relevant federal regulations may be found at 45 CFR 46 (OHRP), and at 21 CFR 50 and 56 (FDA). CFR is the Code of Federal Regulations. In addition, the ethics codes of professional bodies such as the American Psychological Association are generally viewed as authoritative sources of rules and guidance in human subject research. While OHRP and FDA rules are only statutorily binding in certain cases, the regulations of these bodies, particularly the former, determine much of commonly established practice for institutional review more broadly.

The unofficial literature on the roles and functions of IRBs is extensive. A good place to start is Bankert and Amdur's *Institutional Research Board: Management and Function*, currently in its second edition (2006). A copy of this book is on permanent reserve in York's Schmidt Library. There are also a number of journals in the field, such as *IRB: A Review of Human Subjects Research* and the *Hastings Center Report*.

Question: Is the charge of IRBs limited to following federal regulations?

Answer: No. IRBs have obligations to the subjects of human research; and in addition to the rules imposed by federal regulations, IRBs may feel obliged to impose further rules based on ethical standards such as fairness or justice, or based on common practice.

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