

# Institutional Review Board (IRB) Tip Sheet

## Tip 1. IRB purpose

IRBs are committees consisting of five or more members. This committee oversees research involving human subjects in an institution. The purpose of the IRB is to protect the rights and welfare of people who participate in research studies and to balance potential risks to participants with potential benefits for society. Such peer-review processes protect the integrity of the scientific work and the overall safety of participants.

## Tip 2. Before you begin

Navigating the IRB process can be daunting to anyone, especially the New Practitioner. Begin by searching the IRB website at your institution for any advice offered directly by your IRB offices. Oftentimes, specific websites contain “how to” guides and instruction. Further, many IRB offices employ contact persons that are willing to assist you through the process.

## Tip 3. IRB decisions

When an investigator submits a proposal for IRB consideration, usually one or two members of the IRB will review the documentation and make a recommendation to the board. Possible decisions are: approval, approval pending revisions, denial, and revise and re-submit. Investigators must receive IRB approval status before beginning any chart review, data collection, or patient contact.

## Tip 4. IRB exemption

The term “exempt” means the research will be reviewed for approval by the IRB chair or designee and will not be subject to continuing review under federal regulations. Although a research project may qualify for IRB exemption, this designation can only be granted by the IRB. In general, the following research may qualify for exemption status:

- Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior
- Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens if these sources are publicly available or if the information is recorded in such a manner that the subjects cannot be identified either directly or through identifiers linked to the subjects
- Taste and food quality evaluation and consumer acceptance studies

## Tip 5. IRB timeline

The IRB usually convenes several times per month, yet due to the number of applications received and amount of time invested in each application, it may take several weeks for an investigator to receive a final decision. Practitioners performing research on a strict timeline should submit new research to the IRB office as soon as possible. There may be no activity on a project until it has been approved or considered exempt by the IRB.

## Tip 6. Expedited review

Research that presents no more than minimal risk to participants and does not involve vulnerable populations (children, prisoners, mentally disabled, etc.) may qualify for expedited review. Protocols submitted for expedited review are reviewed as they are submitted; however, the overall review process is not guaranteed to be “quicker” than a full review.

### **Tip 7. Research protocol**

A well-developed, well-written protocol will likely make completing the IRB documentation easier. IRB boards must include a non-scientific member and a member not employed by your institution, so remember to explain your research in terms that will be easily understood by someone without an extensive scientific background and unfamiliar to your institution.

### **Tip 8. Informed consent**

Informed consent is a process that involves a comprehensive discussion between the investigator and subject to ensure the subject's understanding of a proposed research study. This process is documented and reinforced by a written consent form. Informed consent is not valid unless the subject or the subject's legally authorized representative comprehends the information in the consent document; therefore, consent forms should be written in simple language that is understandable to a layperson. Contact the IRB offices at your institution to clarify what items are required on the informed consent form.

### **Tip 9. IRB application**

Completing IRB documentation erroneously or omitting sections will likely cause your IRB application to be delayed or denied. Before you initiate an IRB application, you may find it useful to review copies of IRB documentation (application, informed consent form) that were previously approved by your IRB office. Senior researchers at your institution may be willing to share examples.

### **Tip 10. Dealing with time constraints**

Stay in contact with your IRB office. Oftentimes, new practitioners (those in residencies or fellowships) must follow a strict timeline to complete a research project. Requesting an update on your application status is not unreasonable.

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