



## Institutional Review Board (IRB) Approval

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### Frequently Asked Questions

#### **What is an IRB?**

An Institutional Review Board (IRB) is established as a safeguard to promote ethical and responsible treatment of human subjects/participants in research. The purpose of the IRB is to assure, both in advance and by periodic review, that appropriate steps are taken to consider:

1. The rights and welfare of subjects involved,
2. The appropriateness of methods used to secure informed consent, and
3. The balance of risks and potential benefits of the investigation.

#### **Who are the members of an IRB?**

IRB regulations require that the IRB have a diverse membership. The IRB should consist of both individuals from the sponsoring institution and individuals unaffiliated with the sponsoring institution. IRB members should represent a diversity of disciplines and backgrounds, “including consideration of race, gender, cultural backgrounds and sensitivity to such issues as community attitudes...” (FDA regulations [21CFR 56.107(a)]) Additional requirements include that at least one member of the IRB have primary concerns in the scientific area and at least one have primary concerns in the non-scientific area (e.g. lawyers, clergy or ethicists).

#### **How do I find an IRB to review my project?**

Most universities and institutions that sponsor medical education programs have an IRB that will be able to review and approve projects. Faculty advisors or the family medicine department chair will be able to advise you on identification of an appropriate IRB in your community.

#### **What information will the IRB require?**

The IRB will need to see a complete description of your project, including the title, purpose, and duration of the project. You will need to provide information on how you will recruit and select your subjects and where the study will take place. Clearly describe the scientific research design and what procedures will be used (e.g., interviews, questionnaires, laboratory testing). It will be very important to include background on the potential risks and benefits of your study to participants and what follow-up you will occur with the subjects.

#### **How long does it take to get IRB approval?**

Approval may take anywhere from a few weeks to a couple of months. It is best to communicate with the IRB staff when you are beginning your research to identify key timelines.

#### **Where can I find more information about IRBs?**

[www.fda.gov/oc/ohrt/irbs/faqs.html](http://www.fda.gov/oc/ohrt/irbs/faqs.html)