



*Accelerating research towards a
cure for multiple sclerosis*

Protecting Your Rights in Clinical Research

By Hollie Schmidt

Our last newsletter included an article describing clinical research – the study of health and illness in people. A key goal of clinical research is to see whether the benefits of a treatment outweigh its risks for the people taking it. Benefits and risks are also factors to consider when it comes to research itself. Nobody should be asked to participate in a study where the risks they could face are high and the possible benefits are low.

The job of making sure that the benefits and risks of research studies are in balance falls to special groups called Institutional Review Boards (IRBs). IRBs are responsible for reviewing and overseeing clinical research, and protecting the rights and well-being of research participants. IRBs were established in response to abusive, unethical studies conducted in the past. These notorious studies put their participants at risk of undue harm, often without their full knowledge and agreement.

I've been a member of an IRB for several years and greatly appreciate the important role they play in research. I wanted to share what IRBs do and how they will look out for you if and when you choose to participate in a research study.

Most IRBs are based in major hospitals and other institutions that engage in human research. There are also “independent” IRBs that can review studies when the researcher doesn’t have a local IRB. At ACP, we don’t have our own IRB, so we use an independent IRB to review our proposed research studies.

Researchers who want to conduct research with human participants will provide their IRB with a packet of material describing their study. When evaluating a research study, IRBs pay very close attention to the possible risks a participant might be exposed to. These might include:

- Side effects caused by a drug used in the study
- Personal information being released to someone who shouldn’t have it
- Worsening of an existing disease through taking an ineffective drug or placebo

IRBs also look at the benefits of study participation, such as:

- Improvement in a disease through receiving a helpful treatment
- Free medical care
- Important knowledge gained about a disease or treatment

Some benefits are experienced by individual participants (e.g., free medical care) and some apply to the wider community (e.g., important knowledge about a new treatment). An IRB will seek to make sure that the risks of a study are as low as possible, and are reasonable when compared with the expected benefits.

The process of inviting people to join a study also comes under IRB review. For example, everyone invited to join a study should receive the information they need to make a fully informed decision. The IRB reviews the consent form that describes the study, recruitment ads, and other information given to prospective participants, to make sure everything is accurate and complete.



To be successful, research studies must recruit enough participants to meet their needs. IRBs ensure that the methods used to find participants enable them to make a free and informed choice. Here are a couple of situations that would trigger a concern for an IRB:

- The head of a lab plans to ask his/her employees to participate in the study; it would be hard for them to say no because they are being asked by their boss.
- A researcher offers an overly generous payment for participating in a study; this might influence some people to join the study without carefully considering the risks involved.

IRBs also make sure that research being done with vulnerable groups such as prisoners or children does not take advantage of them. Special guidelines are followed when reviewing studies involving these groups. For example, in research studies involving children, the IRB would make sure the parents and guardians are appropriately included in discussions and decisions about participation.

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Group discussions are usually richer when the people involved have a diversity of experience. Likewise, IRBs benefit from having people with different backgrounds and expertise, such as doctors, nurses, and scientists working in different fields; pharmacists; data specialists; lawyers; social workers; clergy members; and so on. IRBs are required to have at least one member who isn't affiliated with the IRB's institution.

There also needs to be at least one non-scientist.

At each meeting the IRB members discuss the different proposed studies that are on the agenda. Often one or more people in charge of the study are present to summarize the study and answer questions. Then the IRB members discuss the merits and risks of the study. They also discuss the information proposed to be used in the study, such as the consent form or recruitment ads.

The IRB can take different types of actions following its review. Sometimes an IRB votes to defer a study because the members don't have all the information they need. The researcher is then asked to add the missing information and come back to a future meeting. Sometimes they reject the study because there are fundamental problems with it. They can approve the study outright, or approve it upon certain conditions being met. These conditions might include, for example, editing the consent form to be more complete or more readable.

Once a study is approved, the IRB stays involved by periodically checking on the study's progress to make sure it's being conducted correctly. The IRB also needs to approve any changes the researcher wants to make to the study while it's in progress, such as increasing the number of participants. Sometimes unforeseen problems arise during a study that increase the risks for participants. For instance, a medical device may develop new safety problems midway through a study. Enrollment may need to be halted and existing participants may need to be notified. In these cases, the IRB will be alerted and involved in the follow-up.

Not all human studies need to be reviewed by an IRB. For example, an anonymous survey on a non-sensitive topic might not need IRB review. The same is true for a study analyzing samples that have already been collected and can't be linked with the donors' identities. Studies using samples from the ACP Repository often fall into this category. Low-risk studies can sometimes undergo expedited review. These studies still need to be evaluated, but this can be done by the IRB chair or one or more IRB members, not the full committee.

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Although the laws and regulations that govern IRB activities are constantly changing, as long as scientists are conducting research with living people, there will be a need for careful review to make sure this research is ethical.

Participating on an IRB as a volunteer member is very satisfying. It feels good to help to protect the rights of people who are being asked to join research studies. It's also very interesting to learn about the new drugs, devices, and approaches that are being developed to treat the range of human diseases and injuries.

If you ever get the opportunity to join an IRB, or to sit in on a meeting, consider taking it. And the next time you're invited to join a research study, remember that a group of diverse, committed people have taken a close look at it to make sure your rights and well-being are protected.