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Human Research Protection Office new member training: guidance for the non-scientist IRB member

Human Research Protection Office, Washington University School of Medicine in St. Louis

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Washington University in St. Louis

Human Research Protection Office



New Member Training

Guidance for the Non-
Scientist IRB Member





Welcome!

Thank you for joining the Washington University in St. Louis Institutional Review Board (IRB). We greatly appreciate your contribution and hope to make your experience engaging and rewarding. In general, IRB members volunteer their time and expertise because of their interest in the kinds of research conducted at WU and their concern for the rights, safety, and welfare of volunteers and/or patients who participate in research. In becoming a member of the WU IRB, you contribute in a very real way to both the progress of new scientific knowledge, the well-being of research participants, and the vitality of the St. Louis community.

[What Does an IRB Do?]

Medical research on human subjects has long been practiced by doctors and researchers, however, this research has not always been conducted in an ethical manner. IRBs are mandated by the federal government to protect the rights and welfare of research participants at a given institution, and are founded on the three principles of ethical research established in the Belmont Report (1979): *justice*, *beneficence*, and *respect for persons*.

[Mission Statement]

As a member of the Washington University in St. Louis IRB, your mandate is to participate in the review of research to ensure that approved protocols meet ethical, regulatory, and institutional requirements, and to protect the rights and welfare of human research participants in “human research” as defined in 45 CFR 46.102(d) and (f) and “clinical investigations” as defined in 21 CFR 50.3(c).

[IRB Membership]

- **Chair**

The Committee Chair guides discussion, voting, and regulatory decision-making.

- **Scientist**

Members whose **primary concerns are in scientific areas** provide the expertise necessary to evaluate specific types of research. These IRB members are able to contribute things like risks and benefit evaluation, assessments of participant vulnerabilities, and confirmation of consent form accuracy. (The WU IRB distinguishes between “Physician Scientists” and “Other Scientists.”)

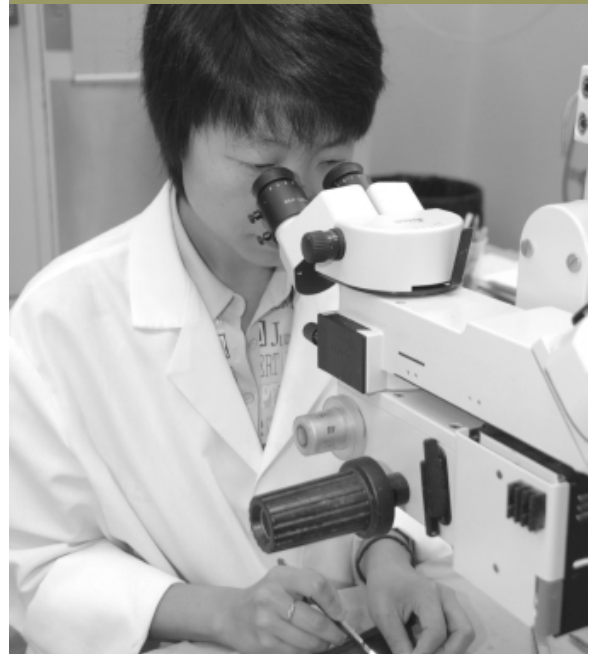
- **Non-Scientist**

Members whose **primary concerns are in non-scientific areas** are able to provide perspectives on proposed research not offered by scientific review alone. These IRB members contribute things like comments on consent readability, perspective on consent and recruitment processes, and evaluations of risks related to the research that stem from issues like privacy, confidentiality, social stigma, etc...

- **Unaffiliated**

Members who are **unaffiliated with the institution** are the voice of the community. They are also able to comment on proposed research without the pressure of institutional concerns.

The regulations (45 CFR 46.107/21 CFR 56.107) describe specific membership requirements for a duly constituted IRB. There are three types of members required to reach quorum, and while all IRB members are able to comment on all aspects of proposed research – each type of member does bring a specific perspective to the review process.



The Non-Scientist Reviewer

Bringing Your Perspective to the IRB

Collaboration is the key to a successful review board. Each committee member is a valued part of the group and as such we hope you will establish and maintain a relationship of functional trust with all members. All members regardless of job title, level of educational preparation, or any other differences are essential to the review process.

As a nonscientist, your role is primarily that of an advocate for the research participants; you serve as the voice of the subject, particularly regarding issues related to informed consent, participant vulnerabilities, and risks or benefits posed by the research. Consent is based on what a reasonable person would want to be told; you are able to speak from this point of view as the informed outsider, bridging the information gap between researchers and subjects. Essentially, during the review process you are able to present concerns in a different way than scientists, helping to ensure that participants are adequately protected.

The Institutional Review Board reviews **several types of applications**. Non-scientist members are typically assigned to review New and Continuing Review applications:

- **New Protocols:** New studies are assigned to two full board members for review and presentation.
- **Continuing Reviews:** Required annual reports of approved research are assigned to two full board members for review and presentation.
- **Modifications:** Most changes to approved research requires review and approval by the IRB. These are typically assigned to one full board member.
- **Reportable Events:** Problems often arise during research that require review by the IRB. These are assigned to a review with expertise in the field of research.
- **Expedited and Exempt Protocols:** Are assigned to HRPO staff reviewers (who may refer items to the full board for review).

[Vulnerable Populations]

The regulations (45 CFR 46 Subpart B, C, D) provide specific guidance for research participants that are considered vulnerable. While the three described here are mentioned specifically in the regulations, cognitively impaired, economically disadvantaged, educationally disadvantaged, student, transnational participants are examples of other populations considered vulnerable in the context of research. The Non-Scientist member plays a role in identifying these participants.



- **Pregnant Women, Human Fetuses and Neonates**

Research involving pregnant women and fetuses may only be approvable if it meets a lengthy list of conditions described in the regulations. For research that holds out the prospect of direct benefit solely to the fetus, the consent of the pregnant woman and the father is required. For research that holds out the prospect of direct benefit to the pregnant woman, both to the woman and the fetus, or when a minimal risks study offers no benefit to the woman and fetus and the proposed research is the only way to collect important biomedical knowledge – the consent of the pregnant woman is necessary.

- **Prisoners**

Prisoners are considered vulnerable due to being in an environment that can inhibit free choice. Research involving prisoners may only be allowed in four categories described in the regulations. An IRB prisoner representative is required for the review of these studies.

- **Children (Minors)**

The regulations define children as participants that have not reached the legal age to consent to treatments or procedures involved in the research. There are four categories of research for children, generally distinguished by the risks and benefits of proposed research. Each category has specific assent and consent requirements that need to be discussed during the IRB meeting. An appropriate consent and assent process should be described in the IRB application. When evaluating the assent process for a study that involves children, the age, physical condition, psychological state, and maturity of the proposed study population should also be considered.

Three Types of IRB Review

Nuts and Bolts of Reviewing Studies

New Protocols:

Review the myIRB application and all material for approval (located in myIRB under “attachments”):

- Study Protocol.
- Grant Application (if applicable).
- Investigational Brochure (if applicable).
- Informed Consent Document.
- Recruitment Materials.
- Data Collection instruments.
- Answer the question: *Does the protocol, as presented, meet all the criteria for approval?*

Continuing Reviews:

Begin with the assumption that the previous review was adequate/appropriate. The focus here should be on the ongoing progress of the study:

- Have there been any changes or new information which affects the approvability of the study? If so, should changes be made to the consent form or study documents?
- Is there anything which might alter the willingness of subjects to continue/enroll?
- Are recruitment goals being met?
- Answer the question: *Given the progress/events that have occurred since the last review, does the study still meet all the criteria for approval?*

Modifications :

Review the proposed changes to previously approved research in the myIRB application, which:

- May involve significant change in aims or study design.
- May have the potential to adversely affect the previous risk/benefit analysis.
- May require revisions to the Informed Consent document and/or the reconsent of participants.
- Answer the question: *Given the proposed changes, does the study still meet all the criteria for approval?*



Before The Meeting

Here are some things to keep in mind when sharing your review with the IRB during a meeting.

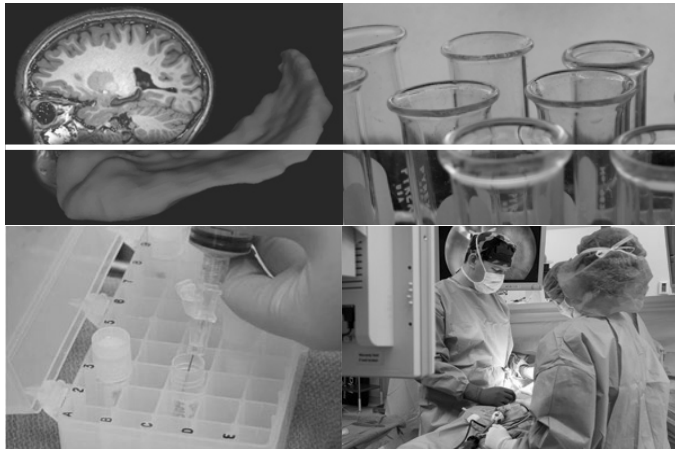
- Review the myIRB application, study documents, and Informed Consent documents.
- If you have questions, look for answers **before** the meeting by:
 - ⇒ *Contact the PI directly*
 - ⇒ *Contact HRPO staff/analysts and they can route your question to the PI*
 - ⇒ *Contact your meeting chair or the other IRB member assigned to review the study*
- If you have recommended revisions to the consent form that involve the addition of specific language, note your proposed additions for HRPO staff/analysts.
- When you come to the meeting, you should be prepared to recommend the study for approval or provide specific contingencies to approval.
- Be sure to fill out the reviewer sheet in myIRB and include any comments you wish to address in the spaces provided.



During The Meeting

Here are some things to keep in mind when sharing your review with the IRB during a meeting.

- Limit the initial summary of the purpose and procedures of the study (“what will happen to participants”) to a few minutes. Provide a succinct, simple statement of the proposed research with enough background to justify the performance of the research. Defer to other reviewers if you would prefer.
- Provide any additional information that the entire committee needs to supplement the limited materials they were provided for initial review.
- If you have revisions to the Informed Consent document, the comments or proposed revisions should be provided. Do not engage in “wordsmithing.” Proposed changes should be meaningful and defined by the criteria for approvability.
- The concerns in your critique should be framed around the criteria for approval. For example, if you have a concern about the participant recruitment, state “I have a concern with regard to equitable subject selection,” and then state your concern.
- Address any relevant regulatory issues related to pregnant women and fetuses, children, prisoners, or other vulnerable participants.
- End presentation with a motion and vote, indicating risk level and length of approval:
 - ⇒ *Approve as is*
 - ⇒ *Approve with contingencies - the study is only approvable if the following changes are made...*
 - ⇒ *Tabled - there is insufficient information to evaluate the approvability of the study, or the study is not approvable without significant revisions.*
 - ⇒ *Disapprove - the study is not approvable.*



On Being an IRB Member

The Challenge

As previously stated, it is imperative to include both scientist and nonscientist voices on protocol reviews. However, some new members have expressed feelings of intimidation when starting out as a reviewer, being on a committee with researchers or doctors who may have a better understanding of the scientific terms and milieu. Self confidence is essential to being a successful reviewer: please realize how important your viewpoint is and feel free to express concerns during a meeting. Many members claim it takes up to 12 meetings (one year) to become truly comfortable in their role as a reviewer.

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"Primary benefits include an opportunity to give back to the St Louis area communities which have provided many blessings to me these past 19 years as well as the opportunity to learn from fellow members and staff."

Bruce Lane, J.D.

The Reward

Attending meetings and reviewing protocols can be an excellent source of self education; you will become familiar with terms, processes, and ongoing medical protocols, all the while building relationships with other IRB members. Finally, by volunteering as an IRB member, you are serving your community and contributing to ground-breaking medical research, which can be used worldwide to address health concerns.

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"Non-scientific community members are equally qualified (and sometimes more qualified) to determine whether the risks are reasonable in relation to the benefits and whether the consent form is complete and understandable. Maybe we find it easier to put ourselves in the position of the patient or the parent of the pediatric patient. It's a valuable perspective to bring to the table and makes you feel like you are making a small but real contribution to these important activities."

Karen Davis, J.D.

Resources:

Human Research Protection Office (HRPO) Staff and Website

314-633-7400 or <http://hrpohome.wustl.edu/>

- SWAT! and On Call staff
- myIRB online system
- Scheduling issues
- Protocol review questions

Linda Van Zandt, New Member Liaison

314-633-7452 or zandtl@wusm.wustl.edu

- Assists in orientation
- Available for myIRB training
- Accessible during first review process

Nikki Koehnemann, Administrative Coordinator/Assistant to Dr. Green

314-633-7478 or koehnnemann@wusm.wustl.edu

- General membership
- Buddy system
- Any other questions
- New Member Training questions

Additional Reading:

Allen Hornblum. Acres of Skin: Human Experiments at Holmesburg Prison. (New York: Routledge, 1999)

James H. Jones. Bad Blood: The Tuskegee Syphilis Experiment. (New York: The Free Press, 1992)

Jordan Goodman and Anthony McElligo , eds. Useful Bodies: Humans in the Service of Medical Science in the Twentieth Century. (Baltimore: The Johns Hopkins University Press, 2008)

Rebecca Skloot. The Immortal Life of Henrietta Lacks. (New York: Broadway, 2011)

Laura Stark. Behind Closed Doors. (Chicago: University of Chicago Press, 2012)

