"Theirs was not to make reply, Theirs was not to reason why."[1]

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Background: In 1974, the United States passed the Research Act, which required creating and implementing guidelines for conducting research on humans and animals. In 1978, universities and hospitals created Institutional Review Boards for reviewing and approving research protocols in the United States.

Objectives: This article will define and explain the components of a research protocol, research team member roles and responsibilities, pre-protocol submission training requirements, and provide suggestions for improving how researchers obtain research approval.

Lessons learned: The author failed to provide all the required information before collecting Informed Consent to prospective participants for four different study protocols.

Conclusions: Obtaining research approval is necessary for most study designs. It is a complex and frequently tedious process, but obtaining approval gives research studies greater credibility.

Background

In 1964, the World Medical Association met in Helsinki, Finland, and published the first guidelines for conducting research.[2-3] In 1974, the United States passed the Research Act, which mandated forming a National Committee. Between 1974 and 1978, the National Committee published ten documents, which included the requirements for membership and rules for running an Institutional Review Board. Those documents became known as the Code of Federal Regulations (Federal Regulations).[4]

The purpose of the Institutional Review Board (IRB) is to ensure humane and ethical treatment of study participants. The Office of Human Research Protection Program Personnel (HRPP personnel) handles the pre-screening of research protocols to ensure basic requirements (e.g., completion of Citi Training,[5] Conflict of Interest statements, inclusion of required documentation, etc.) are met before passing the protocol on for review by the IRB. The HRPP personnel wrote the Belmont Report[6] to assist researchers in understanding and submitting compliant research protocols. In 2018, the Federal Regulations Common Rule changed the definitions of and documentation requirements for Exempt and Not Human Subjects research.[7] Citi Training mentions these changes but provides no guidance or additional information on what a researcher

should include in an IRB protocol.

Objectives

Requirements around training, documentation, and processes for IRB submissions vary by location. By reviewing and defining each of these topics, researchers will have a better idea of how to write protocols and obtain IRB approval.

Pre-Protocol Training Requirements

Many IRBs require researchers to complete Biomedical or Social, Behavioral, and Educational Researchers Citi Training before submitting protocols. The training explains why IRBs came into existence and how to conduct humane and ethical research. The Belmont Report, specifically, discusses the rights of participants, procedures for recruiting participants, and the importance of protecting the privacy and confidentiality of participants, when publishing or presenting study results.[8] Finally, the training briefly explains the different types of research protocols.

Roles and Requirements of the IRB Research Protocol Members The Principal Investigator (PI) serves as the point person for the IRB or the Research Ethics Committee (REC).[9] The PI is responsible for reviewing and revising protocols, reporting any protocol deviations (e.g., changes to the study procedure, engagement in research without approval, etc.) or violations (e.g., improper collection of Informed Consent, etc.), writing and submitting reports by the requested deadlines, and closing the protocol upon completion of the study.[10-11] Some IRBs require a PI to have faculty status. In this case, for individuals who do not have faculty status or simply want to get research experience, consider including them as Non-Research Personnel on IRB protocols. See **Appendix A** to learn more about the training requirements and responsibilities of non-PI or Co-PI research team members.

Types of IRBs

Most colleges, universities, and hospitals in the United States have one IRB, which reviews both biomedical and social, behavioral, and education protocols. Research-focused institutions or institutions looking to improve their research output frequently have two IRBs. The frequency of IRB meetings, the average protocol approval time, IRB submission systems, and research experience and training of HRPP personnel varies by location.

Components of an IRB protocol typically include background, objectives or purpose of the study, recruitment of study participants, informed consent (e.g., privacy, confidentiality, risks, benefits), data collection instruments, and data storage and availability. To better understand each section of an IRB protocol, please see **Table 1**.

Table 1. Definitions and descriptions of information required by most IRBs.

Background or introduction	Explain why you decided to do the study.
Study objectives or purpose	Briefly explain what you hope to learn from this research project.
Recruitment information	These are flyer(s), social media post(s), email(s), etc. the study will use to recruit prospective participants. **Note**: Provide an email from list administrator granting permission if distributing study recruitment information via a group email.
Consent information	1) Study purpose and objectives. 2) Outline the roles, responsibilities, and time commitment of study participants. 3) Risks and Benefits of participating in the research study. 4) Protecting Privacy and Confidentiality of a Study Participant by: a) assigning participant numbers, keeping the office door closed, etc. b) storing collected and de-identified data in a password protected location available only to members of the study team.
Data collection instrument	Provide copies of your survey, interview, focus group, clinical trial protocol, etc.
Data storage and retention plan	This varies by location, but it is usually 3-5 years.

Different types of IRB protocols, which are defined in **Appendix B**, require different amounts of information. PIs must submit annual and final reports for Expedited and Convened Protocols. Depending on the study design, additional reporting might be required.

IRB Systems and Conducting Research

In Fall 2019, the author's institution implemented IRB Manager for submitting and revising research protocols.[12] While this was a vast improvement over the previous IRB system, the author uses a Microsoft Word template for writing the protocol and then copies and pastes information into IRB Manager. Additionally, the author saves the protocol at the completion of each page. Pre-submission, the author saves a copy of the entire protocol.

Steps for Minimizing Approval Process Delays

Step 1: *Write the protocol in plain text language – specifically aim for a sixth-grade reading level.*Pretend as if the IRB or HRPP personnel have no previous knowledge of your field and define everything. It is prudent to avoid using field or specialty (e.g., medical, library) specific language.

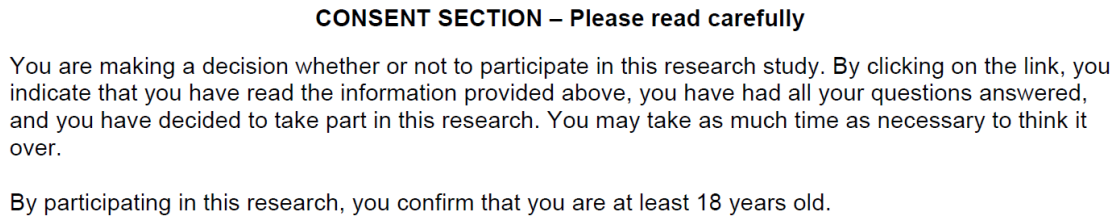
Step 2: *Respond politely and respectfully to IRB comments.* Unless the suggestion(s) by the IRB drastically alter the purpose of the research project, the author recommends making the IRB-requested updates, acknowledging the updates and comments throughout the protocol, saving a copy of the updated protocol, and submitting the revised protocol. Step 3: *Get approval for multi-institutional research projects.* It is worth investigating and perhaps having team members chat with IRB about the proposed project. Then – identify the IRB with the longest approval time and get approval from that location first. While waiting for approval, check if other IRBs have a system in place for approving participation in a study as a Co-PI or Researcher. If they do, use this system, because this approval process takes less time. If no such system exists, consider listing team members as Non-Research Personnel, which limits them to working with only de-identified data. The most time-consuming approach is to submit and to obtain separate IRB approval from each institution or hospital.[13]

Step 4: *Review previously approved protocols with similar study designs.* This gives researchers an idea of how much information to provide and what required language to include in protocols. It could also provide an approximate idea of the submission-to-approval time. If this is not feasible for a researcher's current location, even reviewing approved protocols from other locations can be useful.

These are four examples of preventable delays. Depending on the IRB or REC, however, delays could be caused due to turnover in HRPP staff, changing submission systems, or even completion of new training requirements by novice or experienced IRB or REC members.

Lessons Learned

During a conversation with HRPP personnel on July 7, 2022, the author reported providing prospective study participants with a paragraph as seen in **Image 1**



CONSENT SECTION – Please read carefully

You are making a decision whether or not to participate in this research study. By clicking on the link, you indicate that you have read the information provided above, you have had all your questions answered, and you have decided to take part in this research. You may take as much time as necessary to think it over.

By participating in this research, you confirm that you are at least 18 years old.

instead of the complete IRB approved consent, which is available in **Appendix C**. On July 11, 2022, the author completed four deviation reports as requested by the HRPP personnel. Upon reviewing the materials, the HRPP office requested that the author complete violation reports, because in each of the protocols the participant did not have the opportunity to read all the study participants' risks, benefits, study procedures, confidentiality, etc. before consenting to participate in the study.[11] After a two-month delay, the IRB required the author to complete remedial training from the Public Responsibility in Medicine and Research (PRIMR)[6] organization and contact any journal which included publications with data collected on participants who had not received the full informed consent[14]. On November 23, 2022, the IRB informed the author that the collected data could not be used for research purposes but must be securely stored per the institution's research data retention guidelines.

Conclusions

By sharing this information and these experiences, the author hopes that others will have a better understanding of and appreciation for the complexities involved with getting approval to do research. Even when it takes longer than anticipated, the author continues to advocate for obtaining IRB approval. In the future, the author plans to determine whether the approval process barrier influences chosen study designs and to improve her understanding of how the research approval process works in other countries.

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