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IRB Questions

September 18, 2021

1. Briefly describe the history of development of the Institutional Research Board. What do you now understand about the need for such protection for human subject's research?

Before 1906, there were no documented regulations on using human subjects in scientific research. There were many instances where researchers used human subjects, and they were never asked to be part of the research or were not told of the risks. At different times in history, regulations were created, like the Nuremberg Code in 1948 and the Declaration of Helsinki in 1964. However, these were on an international level.

The Institutional Research Board was created as a review and approval system for all research with human subjects. In 1974, the United States government made a National Commission for the Protection of Human Subjects to study what system was needed to govern research with human subjects. They presented their findings in the Belmont Report in 1979. The government created the Office for Human Research Protections (OHRP) to oversee the federal regulations and requirements for human testing. OHRP would work through Institutional Research Boards, built at the Institutional level, as a way to make sure research with human subjects was being done ethically and lawfully.

Before reading *The Immortal Life of Henrietta Lacks,* I had no accurate understanding of what was needed for working with human subjects. I am appalled that it took so long for rules and regulations to be created. There must be a process for researchers and scientists to go through before working with human subjects. Without rules and regulations, working with

human subjects would depend on the individual ethics of the researcher or scientist. Dr. Chester Southam, a doctor who gave patients cancer cells without their consent, believed he was doing what was best for science. He didn't tell patients the cells were cancerous because he didn't want to cause unnecessary fear (Skloot, 2011). I had no idea what an IRB was before this class. I am happy that they exist.

2. What is the role and purpose of an IRB? What is the required make-up of the committee?

The Institutional Review Board (IRB) is a committee that reviews research studies to make sure that the researchers follow ethical standards and regulations for research with people. The committee checks that participants' privacy and confidentiality will be protected and that they will have the necessary information to make a sound decision to be in the research study. The IRB makes sure that the research is not unnecessarily risky to the participant and that the participant understands the risks involved with the research study. They also make sure that the participants are free to choose whether or not to participate.

It is required that the committee be made up of five or more people with various backgrounds, who must be free and independent from other interests. One person cannot be connected to the institution affiliated with the research, and one cannot be a scientist. The members must review specific types of research it oversees and know the community where the research takes place.

3. Describe Informed Consent. What kinds of protections does it provide for participants? Why is this an important requirement of human subject's research?

Informed Consent is the patient's right to receive information and ask questions about possible research, study, or medical treatment that could happen to them and make an informed decision to participate or not. The information that needs to be given to the participant is the purpose of the study, expected duration, a description of procedures, identifying anything that might be experimental, and if there are any alternative procedures or courses of treatment. The participant must be told of the risks, possible harm, and possible benefits of the study/research/treatment. The participant must also be told how their information will remain private and confidential, and they can stop participating at any time. Participants must be informed if they will be compensated or what will happen if there is an injury. Doctors, researchers, and scientists must get informed consent from their participants before any work is done.

Informed Consent protects the patient because no work or study can be done without compliance from the participant. It also outlines specific information a participant must know before participating in the study/research/medical treatment. The doctor/researcher/scientist must speak to the participant with words that they would understand, and participants cannot be coerced or pressured into signing informed consent.

Informed Consent is an important requirement of human subject's research because it makes sure that all parties involved are educated on the specifics of what is going to happen or could happen. It gives the participant all of the power to say yes, no, or drop out later.

4. Review the IRB Approval and Proposal From CHECKLIST on the MBU IRB site.

   Where do you think the following study would fit among the three choices of study

requirements described on the checklist (full review, expedited review, or exempt review) for IRB, and explain why you think it would fit into that category.

> *A teacher plans to survey students at a racially diverse upper elementary school (grades 3-5) to find out what kinds of activities they find the most interesting. In particular, she would like to find out if or what differences exist based on gender and ethnicity of the children and if there are certain activities the school could use to better engage minority boys. She develops a short and anonymous survey that students would be asked to complete during homeroom. The only qualifying questions on the survey are about race and gender- grade levels are not requested because that might make it too easy to identify specific students. All other questions are related to possible activities the school could do that might be engaging for the children. To implement the project, homeroom teachers will be asked to collect consent forms (from parents) to collect all completed surveys and drop them into a private collection box so that the researcher is not able to match surveys to homerooms.*

I think the above study would use the Expedited Review Form for the IRB proposal. The study will be a survey that will be given to students in grades third through fifth. The surveys would be given in homeroom by their teacher, and the only qualifying questions would be about race and gender. The teacher would then turn in the informed consent and survey to a private collection box, so the researcher does not know from which classroom they came. I believe this falls under Step two, number nine: Research that will include minors (under 18 years of age) as

participants and is employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies, and the investigators will be recording the information in such a manner that the subjects cannot be identified, either directly or through identifiers link to the subject.

5. Compare the three Review Forms on the MBU IRB site: Full Review, Expedited Review, and Exempted Review Form. Briefly explain how they are similar and how they are different from each other.

All three forms, Full Review, Expedited Review, and Exempted Review, all start out asking the same questions: project title, name of investigators, contact information, advisor contact information, other non-MBU investigator's contact information, and current funding sources. All three also ask if the study will involve vulnerable populations (such as prisoners, pregnant women, minors, mentally disabled persons, and economically or educationally disadvantaged persons). All forms ask questions about the methods of research, how participants will be recruited, data collected and stored, privacy maintained, and possible risks. Each form asks if there will be a collection of voice, video, digital, or image recordings, how informed consent will be obtained if non-public locations are necessary, and if the study requires not personally owned equipment. Lastly, with all three review forms, the person submitting the form must attend a CITI human subjects training and attach the certificate for participating.

The Expedited and Exemption Form are identical on the MBU website. The Full Review Form is different from the other two and has more detailed questions about the potential for participants to feel pain or be put through purposely stressful situations. It also asks if there are

any procedures that are not anonymous and may be considered an invasion of privacy, responses would place participants at risk of criminal or civil liability or damaging to them in some way. Lastly, it asks if there would be more than minimal risk for the subject.

References

Skloot, R. (2011). *The Immortal Life of Henrietta Lacks*. Crown.