Human Subjects Research – The Ethics of Tackling

Dr. Ahmed Jones, a sports and exercise researcher, is seeking to evaluate a revolutionary new material for football helmets. Once the material is inserted into the helmet, it is designed to lessen the impact of football tackles. Dr. Jones intends to ask football players at his university to participate in his research. This would involve lightly tackling a participant who is wearing a football helmet fitted with the new material and comparing the impact intensity to participants that are tackled while wearing the standard football helmet. In a frenzy to be the first to publish research on this new material, Dr. Jones is insistent that IRB approval isn't needed. **Roles** • Principal Investigator (Dr. Jones) • PhD Student (Yao Fan) **Scenarios** • Scenario One: A graduate student in Dr. Jones' lab has some serious doubts about pushing forward with a study involving human subjects without first obtaining IRB approval. • Scenario Two: Yao Fan fails to convince her PI that IRB approval is required in studies involving human subjects, Yao Fan decides to consult a former professor. • Alternative Scenario: A graduate student is excited to begin recruiting participants for a new study. So much so that she suggests recruiting participants from an intellectual disability center that she works for.	**Role Play Tips** • Detailed role descriptions and prompts are provided to guide the role play. This is not a strict script. Encourage role players to familiarize themselves with their characters and get creative! • Encourage role players to use their actual names in place of character names. • Experiment with changing the prompts to inject some variability in role play dynamics (e.g., have a character offer a conciliatory opening line or a belligerent opening line to see how that changes the course of the role play). • Run a role play more than once, changing role players.

Role Play: PhD Student

Character Description: Yao Fan, PhD Student

You are a graduate student working with Dr. Jones on developing a new structural material for football helmets. Based on prior experiments, you are confident that the new material will reduce football related head injuries by a large margin. You and Dr. Jones agree that the next step is to test the new material on human subjects, looking for differences in impact intensity between the standard football

helmets and football helmets fitted with the new structural material. For this reason, you begin to draft the IRB application for this study.

Role Play: Dr. Jones, Principal Investigator

Character Description: Principal Investigator

You are working with a graduate student, Yao Fan, to develop a revolutionary new material for football helmets to reduce the impact from tackles. The material is cutting-edge in the realm of sports and exercise and you are confident that it will revolutionize the design of football helmets. Unfortunately, you have heard that other research teams are working on developing a material with similar properties. For this reason, you are extremely eager to begin trials with human subjects right away in order to beat the other research teams to the punch.

Role Play Dr. Krishna, Trusted Confidant

Character Description: Trusted Confidant

A former student of yours contacts you out of the blue to discuss a private matter which concerns her academic and professional success.

Scenario One

Yao Fan sits down with Dr. Jones to discuss how the project and the IRB application is coming along.

Prompt

Dr. Jones: "How are we today?"

Yao Fan: "Fine thanks. I'm almost done drafting the IRB application for the study on the new material."

Dr. Jones: "Well, since the primary aim of the research is to assess the new material, the project is privately funded, and the tests will be conducted using a low tackle intensity, it is not the type of research that requires IRB approval."

Yao Fan: How do you respond?

Questions to Consider

1. Is the research described in this scenario considered human subjects research?
2. What are the consequences if Yao Fan decides not to stand her ground regarding obtaining IRB approval for this study?

Scenario Two

After failing to convince Dr. Jones that IRB approval is absolutely necessary prior to implementing the study protocol which includes human subjects, Yao Fan decides to meet with her former professor, Dr. Krishna, to receive advice on how to navigate her way through this ethical quagmire.

Prompt

Yao Fan: "Thank you for meeting with me, Dr. Krishna. It's a private matter and I was unsure who to go to. The principal investigator that I work for is absolutely insisting on forgoing the IRB submission process on a high-stakes research study that we are in the process of designing. He's made it clear that if we don't begin the study immediately another research team is likely to publish similar findings before us. I understand where he is coming from but the study includes human subjects so we absolutely have to obtain IRB approval before proceeding. I'm really not sure how to handle this situation."

Dr. Krishna: How do you respond?

Questions to Consider

1. Do you think there is still a chance of persuading your PI to see reason?
2. If so, when you speak to the PI what do you plan to propose?
3. What are the pros and cons of going to an authority figure regarding this?

Alternative Scenario

Yao Fan persuades Dr. Jones to submit the study protocol to their IRB before moving forward with the study. Yao Fan completes the IRB application and compiles the necessary materials which includes a detailed and thorough informed consent form. Yao Fan submits the application with corresponding materials to her IRB. Yao Fan checks the status of the IRB submission and discovers that the study protocol has been approved. Yao Fan hurries over to Dr. Jones' office to share the good news with him.

Prompt

Yao Fan: "This just in: we have officially received IRB approval to begin the study!"

Dr. Jones: "Wonderful! We can begin right away."

Yao Fan: "Yes, I actually have several friends from the Intellectual Disability Center that I volunteer at who are interested in participating."

Dr. Jones: "Do these individuals have mental disabilities?"

Yao Fan: "Well yes but I've known them for some time now. I'm confident that they have the mental capacity to participate."

Dr. Jones: How do you respond?

Questions to Consider

1. Should individuals with cognitive impairment be included in research studies? Why or why not?
2. If an individual with cognitive impairment fails to understand the informed consent form, should they still be allowed to participate? Why or why not?
3. Might there be an issue of conflict of interest in this case? If so please explain.

Take Away Points

- Research projects involving human subjects MUST be reviewed by an IRB. This is federally mandated.

References

Shahnazarian, D., Rose, S., Hagemann, J., & Aburto, M. (n.d.). University of Southern California. Retrieved October 28, 2019, from https://oprs.usc.edu/training/rcr/.