#9

Human Subject Protection
And
IRB Resources
When conducting research, investigators and (supervisors of research) have a responsibility to perform a **systematic review** of our research plans (proposals) to determine the extent to which our human subjects (also known as participants) may be at **risk** as a result of our research processes.
Are you including Human Subjects in your research?

No, if you are …
Exploring or preparing *something* without the involvement of others in testing or otherwise experiencing your work
*Theoretical paper
*Physical model or structure
*Patent (without human testing)
*Etc.

Yes, if you are…
Exploring *something* utilizing the involvement of people in any way
*Research Question
*Proposition
*Hypothesis
*Idea
*Concept
*Model
*Product
*etc.
Yes, I’m utilizing human subjects, but I’m not a medical researcher. My research is pretty safe, it can’t hurt anyone. I’m only going to ask a few questions.
There is *always* a potential for risk to humans participating in research as subjects.
The exploration of something* with human subjects prompts an experience for the participant and/or those who have access to the data and have influence with or over the participant.
• We often do not anticipate the experience of the participant or subject
• We often do not control the (inner) experience of the participant or subject
• We often do not offer assistance, or even know when assistance is needed, when a participant or subject has an unwanted or negative experience.
Research:

• Provokes an experience

  +

• Researchers cannot control the participant’s experience of participation in the research

Therefore, there is risk to the participant when a human subject participates in research.
What tool do we use in research that provokes an experience?

Interviews and Surveys!
Risk

Risk can be low, high or anywhere in between.
Examples of experiences triggered in participants...

- Various behaviors
- Embarrassment
- Stress
- Loss of face
- Emotions both positive and negative
- Exposure
- Pain
- Agony

Low

High
Examples of what the experience may result in for the participant:

- Loss of life
- Loss of health (mental/physical)
- Loss of livelihood
- Loss of privacy
- Loss of important relationship
- Loss of positive regard from important other
- Loss of status
- Lowering of self esteem
- Unexpected shift in beliefs, values, ways of thinking or knowing
- Unwanted Repercussions
Examples of what can be triggered in influential others who have access to the data – and inadequate protection for the subjects.

- Lower regard for participant
- Action(s) taken for or against a participant
- Re-examining relationship with participant (for better or worse)
- Emotions both positive and negative
- Questioning the participant’s knowledge, commitment, etc.
What can we do to Continuously Improve our approach to Human Subject Protection via IRB applications

Know how our human subjects experience risks, and “get” why this process is so important.

• Investigator, read the entire application before completing it.
• Complete the application, inserting supporting information where designated. (Do not add appendices, or change the order of the items.)
• Investigator, send the application to your mentor for review.
• Mentors, read the complete application and provide feedback.
• When the application has been revised, mentors review again then submit to the IRB.
• Expect a quick turn around (1-3 days). However, administration reserves the right to take up to 15 business days (especially for a non-exempt application).
• When the application is approved, the mentor will be notified, and the mentor will inform the investigator
• The approved application will be filed on the SharePoint IRB site.
The following resources should be in the Instructor’s File of this course:

- IRB Application
- IRB review for research without human subjects
- SharePoint uploading instructions
- Blank Informed Consent Form

Questions about the IRB applications and processes should be directed to Dr. Mike Alexander (malexander@coloradotech.edu)
Discussion