Module 2: Research Protocol

After completing this module, you should be able to list the elements of a social and behavioral research IRB protocol; explain the importance of standard operating procedures (SOPs); explain and evaluate treatment and lastly, recognize protocol deviations and understand the importance of documentation.

Elements of a Protocol

A thorough, well written protocol can prevent issues down the road and serve as a roadmap to success.

The content of a protocol may vary from institution to institution. Each IRB may have their own required elements/sections and/or format. What elements are required at your institution? List them below. If you're not sure, visit your IRB's website or contact the IRB office to obtain a list of required protocol elements.

What strategies can you use to ensure that you are submitting a strong IRB protocol? Consider whether or not the document is complete and easy to read. Does it correspond with all your consent and other supporting documents? Is the document named using a version control system?

Supporting Documents

Remember to note where you can find your study SOPs and who is responsible for writing and updating them.

SOPs are meaningless if no one can access them or if they aren't followed. Where are your study SOPs located? Are they easy to access and use? What kinds of things will help you regularly use your SOPs?

One great way to confirm whether or not your SOP is detailed enough is to run through a mock practice of the study. What other ways can you think of to ensure your SOP is detailed, yet easy to follow?

Treatment Fidelity

Treatment fidelity is a process that ensures every team member is delivering an intervention in the way the protocol specifies, and that treatment is being correctly received by participants.

What strategies will help you and your team optimize treatment fidelity? What resources are available to help you monitor and enforce fidelity?

Protocol Deviations

Deviations from a protocol occur when methods are not followed or when events do not go as planned.

Who on your study team is responsible for recording protocol deviations? Who is responsible for reporting protocol deviations?

What is your IRB's process for reporting a protocol deviation?

Other Notes

Resources

Assessing intervention fidelity in a multi-level, multi-component, multi-site program: the Children's Healthy Living (CHL) program
http://www.ncbi.nlm.nih.gov/pubmed/26622918

Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium
http://www.ncbi.nlm.nih.gov/pubmed/15367063

NIH Clinical Research Study Investigator's Toolbox
https://www.nia.nih.gov/research/dgcg/clinical-research-study-investigators-toolbox/startup