Northeastern University
Human Research

Guidance: Helpful tips when submitting a human research protocol application

Overview

Submitting to the IRB, for a first timer or seasoned investigator, can be confusing and at times overwhelming. Below are some helpful tips and considerations when submitting a human research protocol application.

Tips & Considerations

1. Use the most current version of the submission forms found on our website.
2. Make sure everyone listed on the research team has completed the required human subject training.
3. Make sure the principal investigator has read the protocol and signed PI Assurance form.
4. Provide all research material including, but not limited to: protocol application form, consent forms and scripts, data collection instruments, recruitment material, etc.
5. Ensure information is consistent across all research material. For example, the study duration in protocol is different from the consent form.
6. Use lay language and explain discipline specific terms and concepts.
7. Use pictures in your application documents, if possible. For example, a table if there are multiple data collection points; a visual if a device is being used, etc.
8. Use a track changes features when responding to IRB stipulations or when modifying an approved protocol.
9. Update version dates when any study document is revised.
10. Plan ahead if you intend to conduct research internationally. Additional considerations and at times additional oversight from non-U.S. ethics committees may be required.
11. Report if anything unanticipated happens.
12. Be mindful of typos.
13. And remember… do not begin any research until you are in receipt of an IRB approval letter or exempt determination.