

Top Ten Tips to Avoid Delayed HRPP/IRB Protocol Review

1. Incomplete CITI training

All research personnel must complete CITI training (Social and Behavioral Research), and **current** CITI certificates must be uploaded to the Attachments tab.

2. Incomplete, unclear descriptions

Ensure the protocol application and supporting document(s) (recruitment, consent, instruments, etc.) are written in plain English (e.g., no scientific jargon, no citations, no academic language pasted from a grant application). The application should be written so that non-scientists and researchers from other disciplines can easily understand the study aims, goals, and plans. Include research questions or a hypothesis to clearly define a project as research. Consent document(s) should be written to ensure they are appropriate for the proposed consent procedures and targeted subject population.

3. Missing study team members

All personnel engaged in any research activities (including recruitment, consenting, data collection, data analysis, etc.) must be listed in the IRB Manager application. These include CUNY-affiliated personnel and personnel from engaged collaborating entities.

4. No risks

Nearly all the research submitted to the IRB has at least the risk of a breach of confidentiality. Other common risks include: discomfort with sensitive questions; revealing personal, sensitive, or identifiable information in response to open-ended questions; embarrassment. Be sure to clearly identify risks associated with participation in the study, outline the steps to mitigate any identified risks, and include this information in the application and consent document(s).

5. Missing documents

All documents to be used during the study, such as recruitment materials, interview scripts/questions, survey tools, consent & assent documents, data use agreements and other contracts, IRB approval or site permission from collaborating sites, etc., must be finalized and included.

6. Inconsistencies

Ensure all information throughout the protocol and supporting documents include consistent information (e.g., ensure number of subjects, age of subjects, compensation, etc., as well as risks and benefits are consistent across all sections of the application and consent documents).

7. Consent missing required elements

SPH researchers should use the template consent documents provided by [CUNY Central HRPP](#) when developing their materials. These documents should be carefully reviewed for edits and applicability to the study and proposed consent process.

8. Confidential, not anonymous

Much of the research reviewed by the SPH HRPP maintains the confidentiality of participants, but very few studies have truly anonymous participants. If any identifiers are collected at any point in the study, if participants will be face-to-face with study team members, or if any information is collected/tracked for recruitment or compensation, the participants are not considered anonymous. Even seemingly benign pieces of demographic information can easily identify an individual. Please ensure the protocol

application and consent documents address the confidentiality of participants, as opposed to identifying participants as anonymous.

9. No direct benefits

In minimal risk research, there is very rarely any direct benefit to participants that can be proven or guaranteed. Ensure the protocol application and consent documents clearly indicate "There are no direct benefits to participants in this study."

Please note that compensation (monetary, course credit, etc.) is NOT considered a benefit of research.

10. Delays from the study team

The HRPP/IRB review process requires actions from the HRPP Office, IRB members, and the study team. The most significant delays in the review and approval process stem from the study team not responding to issues in a timely manner or the Principal Investigator not (re)submitting their application. Pay close attention to IRB Manager email notifications, as they are designed to communicate the current status of the protocol application to the study team and clearly document completed activities.