Checklist for Submitting an Application to Conduct Research with Human Participants

Check ✓ that you have included the following before submitting your research ethics application.

Be sure to review the online guide to completing the Form 101. This guide will aid you in preparing your application.

**Purpose**
- Objectives of the study are clearly described
- Rationale for the study is clearly outlined

**Methodology/Procedures**
- Description of the procedures is complete
- Procedures per session are clearly described in multiple session studies
- Study design is clearly described
- Eligibility criteria (screening, inclusion, exclusion) are clearly defined
- Methods/procedures are appropriate to achieve the intended results

**Participants**
- Description of study participants is complete
- Selection of participants is appropriate for this study
- The source and number of participants are clearly stated

**Recruitment Procedures**
- Description of recruitment procedures is complete
- Recruitment materials are included
- Methods of recruitment is appropriate
- Recruitment procedures are not coercive

**Remuneration**
- Relative to commitment and effort, level of remuneration is appropriate
- Amount or type of remuneration is not coercive

**Feedback to Participants**
- Feedback included is adequate

**Description of Benefits**
- Benefits if any to participants are clearly described
- Absence of benefits to participants is indicated
- Benefits to society are clearly described

**Description of Risks to Participants**
- Description of risks to participants is complete
- All potential risks for participants have been identified
  - economic
  - emotional
  - financial
  - physiological
  - psychological
  - social
- Description of how these risks will be mitigated or addressed is complete
Informed Consent Process
- Information in the letter and consent form corresponds one-to-one with study protocol
- Letter meets all elements in the Checklist for Information Letter and Consent Form

Confidentiality and Security of Data
- Plan to ensure confidentiality of data is adequate
- Plan to ensure security of data is adequate

Anonymity
- Description of how participants’ identity will be protected is adequate
- Potential does not exist to identify participants through the information gathered

Partial Disclosure and Deception
- Is the justification provided acceptable? Yes □ No □
- Is there provision for written and verbal debriefing? Yes □ No □
  - If yes, is it acceptable? Yes □ No □
- If deception, is a post-debriefing consent form included? Yes □ No □
  - If yes, is it acceptable Yes □ No □

Other Considerations
- Confirmation of support from cooperating agencies/institutions
- Potential for conflict of interest disclosed
- Confirmation of ethics clearance from collaborating institutions’ REB
- The following are additional requirements that must be outlined if personal health information is being collected or as secondary data analysis (PHIPA):
  - A description of the research proposed to be conducted and the duration of the research.
  - A description of the personal health information required and the potential sources.
  - A description of how the personal health information will be used in the research, and if it will be linked to other information, a description of the other information as well as how the linkage will be done.
  - An explanation as to why the research cannot reasonably be accomplished without the personal health information and, if it is to be linked to other information, an explanation as to why this linkage is required.
  - An explanation as to why consent to the disclosure of the personal health information is not being sought from the individuals to whom the information relates.
  - A description of the reasonably foreseeable harms and benefits that may arise from the use of the personal health information and how the researchers intend to address those harms.
  - A description of all persons who will have access to the information, why their access is necessary, their roles in relation to the research, and their related qualifications.
  - The safeguards that the researcher will impose to protect the confidentiality and security of the personal health information, including an estimate of how long information will be retained in an identifiable form and why.
  - Information as to how and when the personal health information will be disposed of or returned to the health information custodian.
  - The funding source of the research.
  - Whether the researcher has applied for the approval of another research ethics board and, if so the response to or status of the application.
  - Whether the researcher’s interest in the disclosure of the personal health information or the performance of the research would likely result in an actual or perceived conflict of interest with other duties of the researcher.

Guidelines to review that may aid in preparing your 101 application.