IRB Protocol Submission Checklist – Steps to Follow

Review the Cabrini IRB website for information on application procedure and review process:
https://www.cabrini.edu/about/departments/academic-affairs/institutional-review-board

Complete IRB human subject ethics training course and include a copy in your protocol file::
http://tcps2core.ca/welcome

Items Required for IRB Project Submission:

- **Protocol Review Request Form**
  - Determine if requesting "Exempt" or "Expedited" or "Full" review (the IRB website describes each type pf review in detail). Exempt research occurs when there is no identifying data; expedited is the most common. Full review will occur if your participants are in a protected class (e.g., minors, incarcerated individuals) or your research is a sensitive topic or involves potential trauma.
  - Explain how you are recruiting your participants.
  - Determine how you will protect your research participants through *confidentiality* and *anonymity*.
    - An activity is *confidential* if participants provide personal identifying information but the connection between participant and results is not shared.
    - In an *anonymous* activity, the individual's responses or results cannot be linked to their identity in any way.
  - Confirm dates for beginning and ending data collection. Provide ample time for data collection. Include date when research data will be destroyed.
- **Description of research including purpose and methodology.**
  - Purpose of research:
    - Clearly explain reasoning for your topic and methodologic choices.
  - Describe the study in detail:
    - Accurate details of procedures and data collection methods
      - Indicate observational study or experiment.
        - If experiment, detail the intervention.
      - Use of participant deception
    - Participant recruitment: Who will you recruit? How will you recruit?
      - Note vulnerable participants and how they will be protected.
      - Ensure compensation and/or incentives are not coercive.
    - Data collection and analysis plan must protect participants from unintended risk to confidentiality and/or anonymity.
      - Consult *Data Management and Security Questionnaire*
    - How will data be used? (Poster presentation, publication, dissertation, etc.)
    - When will data be destroyed?
  - Risk of harm assessment and risk management/mitigation plan:
    - Identify worst-case psychological, physical, social, economic, privacy or other risks to participants and identify resources in the event of negative outcome and how adverse event data will be collected.
  - Benefits: Participants usually will not directly benefit from the research study.
  - Privacy, confidentiality, anonymity and data management strategies:
    - What identifying information will be collected, and how will it be protected?
      - Data storage security measures and who has access
      - Audio/video recordings

- Informed consent:
  - Review guidelines for consent process. Who will be collecting consent and how? Do not assume the IRB understands what you meant. You must explicitly explain your consent procedures, especially for children and vulnerable participants.
  - Indicate possible coercion or undue influence to participants.

- **Research instruments**
  - Attach copies of ALL instruments used as part of the research project, including questionnaires, surveys, tests, and interview questions.
  - If using established instrument, provide permission to use, adapt or amend.
  - These must be readable copies. Web links to research instruments are not acceptable.
- **Consent and/or assent forms for participants.**
  - Consent forms must be completed by all adult participants over age 18. For participants under the age of 18, a parental consent form and age-appropriate child assent form are required.
  - Select the appropriate Consent Forms from the templates provided on the Cabrini IRB website. Read the templates. If the information doesn't apply, you must delete it.
  - Address all aspects of the consent/assent as outlined in the template.
  - Use clear language that is age appropriate and avoids jargon.
  - Be sure to briefly describe what the participants will have to do in the study.
  - Explain the risks, even if minimal, to participants AND researcher. Provide protections for all risks. Include phone numbers and websites for participants to contact in the event that intervention is required due to physical or psychological harm.
  - Specifically, address privacy including *anonymity* and *confidentiality*.
  - Describe potential direct benefits, if any. If you are not providing a direct benefit to participants, you can state that *the research will not directly benefit participants.*
  - State that participants may refuse to participate in the study, or may withdraw from the study at any time, without penalty. Also, indicate that participants may refuse to answer any research questions or participate in any research-related activities that makes them uncomfortable, without penalty.
  - Disclose your role and any connection you may have to the location or to the participants. Implement protections to eliminate or mitigate coercion or bias.
  - Indicate how the research data will be used (publication, presentation, audio/video interview, etc.), and provide a date when the research data will be destroyed.

- **Gatekeeper letters** if collecting data outside of Cabrini University.
  - Include documentation supporting data collection from the site where data will be collected if a site will be used other than Cabrini University.
  - The document should include the full name and title of the individual with authority to grant approval and should clearly state that the site supports the particular study by the primary investigator. This is best on letterhead with signature.

- **Faculty Supervision:** Ensure that the professor who is your faculty sponsor/adviser has fully reviewed your protocol and has approved your document before you submit it to the IRB submission portal.

- If other institutions with their own IRB processes are involved, approval letters from the IRB at the partnering institutions that have reviewed the project will be required.

- Please provide a single Word document with all the required components. Submit your protocol by enrolling in the Institutional Review Board option on the Cabrini Portal (log-in required).: **https://learn.cabrini.edu/webapps/blackboard/content/listContentEditable.jsp?content_id=_764333_1&course_id=_22841_1**