## Preparation and Submission Process (Procedures)

Steps – and Resources: The Canvas materials lead student and faculty researchers through the following steps, linked to the relevant resources associated with each step.

- To determine whether the proposal needs to undergo full IRB review, expedited IRB review, or exempt IRB Review, please consult the two documents: "IRB Reviews: Exempt, Expedited, and Full Reviews", and the "Is My Project Research?" flowchart. After reviewing the flowchart, and the information available on the Canvas IRB course for researchers, if you are still unsure as to how to proceed, please contact the Chair of the IRB Committee to ask for clarification.
- 2. Fill out, print, and sign the appropriate forms based on your proposal's classification, and attach them to the front of your proposal.
- 3. Include the following elements in your proposal (examples are included). The studies should be described in sufficient detail that IRB members should fully understand the research design and proposed procedures. The goal is to have such clarity in your description that another researcher could replicate the proposed study without consulting you:
  - Statement of the research question
  - Description of the research methods
  - Description of the research setting and duration of the study
  - Description of sampling procedures and demographics of the participants
  - Description of plans to maintain participants' confidentiality and anonymity. Explanation of how you will keep your data under lock and key for a period of three years
  - Description of any potential risks to participants
  - Description of plans to ensure informed consent, including plans to communicate with participants whose first language is not English
  - Letters of informed consent to participants, guardians (if applicable), and agency or site administrator(s). Letters to non-English speakers must be translated into the appropriate language. Letters to children must be in age-appropriate language.

- Data collection instruments must be accompanied by permission to use any copyrighted materials or documentation that the instruments are available for public use.
- Bibliography of secondary sources consulted in the development of the proposal
- De-briefing statement or description of plans to share the results of the research with participants and agency or site administrator(s)

Note: Examples of each of these required elements are available on Canvas.

- 4. Submit an electronic copy of the completed proposal and attached forms to the IRB Chair, via the Canvas portal before or on the submission due date (see IRB Dates).
- 5. IRB member comments will be noted on your IRB Canvas submission. You will be alerted when these are published for your review.
- 6. If your proposal is approved, the IRB chair will notify you and provide a link to the signed approval page. You may then begin your research.
- 7. If your proposal is **not approved**, you will receive notification through Canvas outlining the changes you need to make in the proposal in order for it to be approved. The notification will identify specific changes or additions that are required. Changes should be made and the proposal submitted within 1 week if possible.
- 8. In cases of full or expedited IRB proposals, IRB approval will remain in force for no more than 12 months after the date of review. If you require additional time to complete the study, submit a Study Renewal/Continuation Form.
- 9. If there are any unanticipated adverse effects as a result of your research, stop the project immediately and inform the IRB through Canvas. Submit a Report of Unanticipated Problem or Serious Adverse Event form to the IRB through Canvas and await the IRB's decision before resuming any research activity.
- 10. When the research is complete, submit a Research Completion Form to the IRB through Canvas.