Salisbury University
Institutional Review Board (IRB)
Guidance on IRB Protocol Assessment

The following is a list of topics that are important for an IRB reviewer to assess when evaluating the human subject protections in a protocol submitted for review. This list is not meant to be exhaustive, but is provided as guidance for reviewers. All protocols are unique, and as such a form will not cover every possible issue that could be present in a protocol.

1. Purpose and objectives
    a. Have the Purpose and Objectives been sufficiently explained?
        i. Is it clear why the research is important/legitimate/appropriate?
        ii. Has the researcher described what they intend to do with the results of the research?
2. Sample selection and participant recruitment
    a. Has the selection of potential participants been sufficiently explained? This section should include details as to why participants are selected as well as which participants will be excluded.
    b. Has all of the information related to the plan for recruitment of subjects (e.g., fliers, webpage text, etc.) been provided? The PI should include the actual text for all advertisements and announcements.
    c. Has the PI identified an estimate on required sample size?
    d. Has the PI provided information on the subject pool? Are the subjects a protected population (e.g., minors, pregnant women, prisoners, mentally ill, etc.).
3. Procedures
    a. Is there sufficient description of the intervention(s) proposed or methods utilized (e.g., interview, recording, or video taping, etc.)? How are the participants involved? Are the participants rights and welfare protected?
        i. Researcher should include scripts detailing how procedures will be described to participants if this information is not specified in writing to the participants.
        ii. Researchers should include all interview/survey instruments (e.g., self-report measures) to allow review of the questions being asked (i.e., review for subject sensitivities).
        iii. Researchers should include a clear description of pedagogical methods of research being conducted in an educational setting. This is true even if the research design uses common educational practices.
        iv. The sequence of the research procedures should be explained thoroughly.
4. Risks and protections
    a. Have the possible risks and protection of the participants been explained thoroughly?
        i. Researcher should explain how risks and benefits will be communicated to participants.
            1. There is no such thing as “no risk” in research. Utilization of participant’s time is an often overlooked risk. Another common risk is loss of anonymity (identification of the participant). For sensitive topics, researchers should include a list of resources for the participant to utilize after completion of the research (Life Crisis Center, etc. – see #10)

ii. Researcher should explain what steps are taken to assure confidentiality and/or anonymity, or explain why confidentiality/anonymity is not required or impossible to assure.

5. Benefits
    a. Have the potential benefits to participation in the research been explained thoroughly?
        i. Will a participant benefit (materially or intellectually) from participation? Keep in mind, a participant may benefit by learning more about a topic. When participants are students enrolled in the investigator's class, a potential benefit may be the awarding of extra credit. If this is the case, the investigator needs to explain how students choosing not to participate in the study can also earn extra credit. There should always be a benefit.
6. Location and collaboration
    a. Where will research be conducted?
    b. Does the research require collaboration with another entity? Have letters of permission/collaboration been included?
        i. Researchers must include letters of collaboration from all involved parties. While not limited to collaborations with schools and medical facilities/records, these are two common examples of collaboration.
7. Timeframe
    a. Has the time frame of the study been provided (e.g., beginning and ending)?
8. Informed consent
    a. Has the informed consent form been developed and provided with the proposal?
        i. Researcher should explain if participants are able to participate in the treatment even if they do not consent for their data to be used.
        ii. Informed consent should include the contact information for the Office of Graduate Studies and Research as well as the researcher's own contact information.
        iii. Informed consent should ask for participant's age if there is a chance that minors (participants under the age of 18) may be in included in the sample. Participants under 18 years of age require additional protections.
        iv. For studies involving minors, assent is necessary. Written assent is required for children 8 – 17 years of age, and verbal assent is required from participants approximately 5 – 7 years of age. The wording of the assent and consent forms should be appropriate for the age and background of the intended participant. For studies involving minors, written informed consent of parents or legal guardians is required.
9. Data storage

a. Has the location and manner of data storage and security been explained sufficiently? (e.g., a single computer or laptop; across multiple computers; or computing devices, access to staff or students).
    i. Researchers should describe a "chain of custody" for the data. Data should generally be stored on a password protected computer or in a locked filing cabinet.
    ii. Researchers should provide evidence that online data collection mechanisms that involve 3rd party data management enterprises (e.g., Qualvu®) are secure and do not utilize or store data beyond the conclusion of the study.
b. Who will have access to data?
    i. Are they all qualified to access data? If student research assistants are involved, have researchers provided any evidence showing that they are qualified? (e.g., CITI certificates)
c. If others will have access to data, how will data be securely shared?
d. How long will the data be kept and what it the plan for destroying the data?

10. Additional features
    a. Is there a plan to provide feedback to the participants?
    b. Should the researcher provide information to populations who may need additional resources after taking the survey (e.g., mental health resources)?
    c. Has the research collected all necessary signatures on the submission forms?
        i. This includes the PI, faculty mentors, program directors, etc. The protocol will not be reviewed until all required signatures have been obtained.