Information to include with a new proposal

Please provide the requested information in a WORD file**.** **Name the file** with the last name of the primary investigator, like this: *Smith NEW proposal details.*

Number the items of information as we have numbered them here. Please minimize the use of technical jargon; the IRB members may not be specialists in your academic discipline.

1. **Provide an overview of the project**, including:
    a. goals
    b. design
    c. hypotheses and/or research questions
    d. location
    e. procedures / how data will be obtained

2. **Describe your participant population(s), including:**
    a. age, sex, and approximate number of participants
    b. inclusion/exclusion criteria, if any
    c. method of selection/recruiting; if random, describe the method of randomization (e.g., every other name, every other street, random-digit dialing)
    d. inducement to participate.

3. **Describe how data will be analyzed and disseminated.**

4. **Describe security procedures.** Explicitly state whether and how your procedures guarantee your participants anonymity or confidentially (Note: a guarantee of anonymity is extremely rare in human subjects research and can only be included if the identity of research participants is not known to the researcher. In most cases the proposal will commit to confidentiality and explain steps taken to protect the identity of the individual subject). Explicitly state the locations where completed questionnaires and entered data will be stored (e.g., in a locked file cabinet in the office of the primary investigator OR on a password protected laptop).

    Please note that surveys involving 30 or more members of the Calvin Community (students, staff, faculty and alumni) **may also need to be approved** by the Calvin University Survey Control Team (SCT), after being approved by the IRB. (For questions about the SCT, please contact the Dean of Research.)

    The SCT's policy for storage of *non-deidentified* data is as follows:

    Survey administrators must agree to adhere to federal, local, and institutional policies for handling data. Data containing participant names, identifying information, e-mail addresses, or other confidential information must be saved in a secure format, and normally such data ***should reside only on computers or drives that belong to the college*** *(data transfers to other media should follow institutional policies). All of these data should be disposed of when the project's IRB approval expires.*

5. **Identify risks to participants**
    a. Describe any foreseeable risks (physical, emotional and social) to the participants. Include any methods or devices that will be used to limit participant risk. Describe any distress that might be caused by the research. If distress is a possible outcome, describe the planned procedures for debriefing the participants after the research is conducted.

    b. If you believe your research qualifies for a waiver of written informed consent, explain how the use of written consent would impede the research or needlessly jeopardize the participants' confidentiality. Explain how you will guarantee that oral consent has been secured. *Researchers proposing to use oral consent must provide a copy of the consent document that will be read to participants. The consent document should include the statement that completion of the research exercise will confirm the participants' consent to participate.*

    c. Describe the consent process by explaining when and how the participants' consent will be obtained. Describe additional steps that will be taken to ensure the participants' right to withdraw without penalty at any time and to guarantee their privacy and ensure confidentiality. If participants include minors or other populations who may not be able to give consent for themselves, describe how parents/guardians will be informed of the study and give their consent. If the research is part of an in-school or institutional study, state explicitly what teachers, officials, or administration will be told about the study, and how will their permission be obtained.

        Per CITI guidelines, consent forms should be written at an 8th grade level and include all of the elements listed in the *Informed Consent Checklist* (link on the IRB website).

    d. If you will be using a third party software system (e.g., Qualtrics, NVivo, Quickbase, Survey Monkey), please include the following statement (or similar) in your consent form. This will save you and the IRB a lot of trouble later if you have technical problems accessing your data.

    Data will be stored in password-protected files that are accessible only to the researchers. In the unlikely event that the researchers encounter a technical problem with the files, the researchers may give software technical support staff temporary access to the files. In such cases, the technical support staff will access the files for the express purpose of resolving issues. Once the issues are resolved, the researchers will revoke the technical support staff's access to the files.

6. **Identify benefits to participants or others**. (If no direct benefits to participants, you can refer back to 1a.)

7. **Attach complete copies of all:**
    a. solicitations / promotional materials
    b. consent forms
    c. interview or questionnaire instruments