Angelina College

Institutional Review Board

College Analytics and Reporting

IRB Guidelines for Informed Consent

The following pages contain guidelines to help you write an informed consent form. You may use it as a template, or use it as a guide. If you prefer to create your own format, be sure that it includes all of the same information that is on the template, so that research participants are given all the information they need to make an informed decision as to whether or not to participate in the project.

As you create your form, ask yourself:

- Is the consent form written in simple language that is free of jargon and acronyms?
- Is the consent form free of language that requires the subjects to waive their legal rights, including any release of the investigator, sponsor or college or its agents from liability for negligence?
- If minors are included in the study, have provisions been made to obtain parental consent?
    - NOTE: There are other participants besides minors whose ability to consent is limited and/or who may face the possibility of coerced or perceived coerced consent. In the federal regulations, fetuses, prisoners, and minors are listed specifically because of their inherent inability to consent either for legal or practical reasons. Though not listed in the federal regulations specifically, there are other groups that can be considered “vulnerable populations” such as individuals who are cognitively impaired. Special issues of consent may exist with these populations, and the IRB will notify you if this is the case with your study.
- Does the consent form include each of the following basic elements of informed consent?
    - A statement that the study involves research, an explanation of the purposes of the research, and the expected duration of the subject’s participation.
    - A description of the procedures to be followed.
    - A description of any benefits to the subject or others.
    - A description of any reasonably foreseeable risks or discomforts.
    - A statement describing the extent to which confidentiality of records identifying the participant will be maintained.
    - Information regarding whom to contact for answers to questions about the research study and the research subject’s rights.
    - A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits, and that the participant may discontinue participation at any time, without penalty or loss of benefits.

Depending on the focus of your study, there may be limits to the confidentiality you can offer. This is rare, but if there are any limits to confidentiality, state them very clearly. These include breaking confidentiality if a participant informs you that they are planning to commit self-harm or harm someone else, or if they inform you about a case of child abuse or neglect. State that you will have to break confidentiality and exactly what will happen in these circumstances.

Informed Consent Form Template

Protocol Title:

Please read this consent document carefully before you decide to participate in this study.

Purpose of the research study: Briefly describe using simple, straightforward language.

Who is conducting and funding the study: Name the study director(s), and if external funding has been obtained, state who is funding the study.

What you will be asked to do in the study: Describe what you are asking the participant to do. This includes how you will collect data (e.g., interview, focus group, self-administered questionnaire), what topics will be included in the data collection, when and where data will be collected.

Time required: Specify the approximate amount of time required for participation and any information about scheduling, if relevant.

Access to Existing Records: State whether you are requesting access to any other information (e.g., education or medical records).

Longitudinal Study: If you are conducting a longitudinal study, you must inform the participant about all planned data collection. You must state that participating in the baseline data collection does not obligate the participant to participate in any of the subsequent data collection. State that they can decide at that time whether or not they want to participate in the next wave of data collection.

Risks and Benefits: Briefly explain possible risks and benefits to the subject, and/or to the field of study in general.

Compensation: If any compensation will be offered to participants, state exactly what they will receive and when, and how it will be delivered to them.

Confidentiality or Anonymity:

- Confidentiality: Explain how confidentiality will be assured and maintained. State where the data will be stored and who will have access to the data. State who will be able to see the list linking names and study ID numbers. You may want to say something like:

  > *Your identity will be kept confidential to the extent provided by law. Your information will be assigned a code number that is unique to this study. The list connecting your name to this number will be kept in a locked file and only the Study Director and other researchers involved in the study will be able to see the list or the interview you participated in. No one else will be able to see your interview or even know whether you participated in this study. When the study is completed and the data have been analyzed, the list will be destroyed. Study findings will be presented only in summary form and your name will not be used in any report.*

- Anonymity: If you are offering anonymity, you should omit the section on confidentiality, and instead state:

  > *Your identity in this study will be anonymous. It will not be possible to know who chose to participate in this study and who did not. It will also not be possible to know who completed which questionnaire.*

Voluntary participation: State that participation is voluntary and that there is no penalty for not participating. Describe the lack of penalty in terms that are relevant to your study. You may want to say something like:

> Your participation in this study is completely voluntary. If you choose not to participate in this study, this will have no effect on the services or benefits you are currently receiving. You may refuse to answer any of the questions we ask you and you may stop or end the interview at any time.

Right to withdraw from the study: State that the participant may withdraw from the study at any time without consequences. You may want to say something like:

- *You may choose to stop participating in the study at any time. This will have no effect on the services you receive from* name of agency. . .(or your grade, etc)
- For online surveys, state that they can choose to stop completing the survey and not submit the part they already completed.

Recording: If you will be audio- or video-recording the interview or focus group you must state this. Also state whether agreeing to be recorded is required for study participation, or whether the participant can choose not to be recorded. Also state that the participant can request that the recording be stopped at any time during the interview or focus group, either permanently or temporarily, as appropriate to your study. State who will have access to the recordings, where they will be stored, and when they will be destroyed. State that they will not be used for any purpose other than the research study. If you will be transcribing the recording, state that a typewritten version will be created. State that no names or other information that could be used to identify the participant will be included in the typewritten version. State that anything that could possibly indicate the identity of the participant will not be included in the typewritten version or will be disguised.

Who to contact if you have questions about the study: Put your contact information here.

Who to contact about your rights as a research participant in the study: Dr. Cynthia Casparis, Vice President of Academic Affairs, Phone: 936-639-1601 E-mail: car@angelina.edu

If you agree to participate in this study please sign below. Thank you.

Agreement:

I have read the procedure described above. I voluntarily agree to participate in the procedure and I have received a copy of this description.

If recording is used and required for participation, add:

> *I understand that this (interview/focus group) will be (audio-/video-)recorded).*

Name (Printed) _____

Signature: _____ Date: _____

Principal Investigator: _____ Date: _____

If recording is used but is optional, add: *I agree to allow this interview to be (audio-/video-) recorded. I understand that I can request that the recording be stopped at any time.*
Signature: _____

If this study will be anonymous, do not include the signature lines. Instead, state:

> *Your completion and return of the questionnaire indicates your consent to participate in this study.*