

## PROPOSAL FORMAT FOR RESEARCH USING: HUMAN SUBJECTS

Put your name and the title of your proposal at the top of the first page and follow the format below in preparing any proposal (exempt, limited, expedited, or full review). The proposal narrative, recruitment materials, surveys and instruments should be submitted in one document, single-spaced, and with page numbers. Proposals may be returned to the PI if these instructions are not followed.

### **I. Rationale:**

Describe the problem, the state of present knowledge relevant to the problem, and the aims of the proposed study. This section should clearly state the potential benefits of the work to the subjects involved and/or the importance of the knowledge to be obtained. The greater the potential risk, the more detail is needed to justify the proposal.

### **II. Subjects:**

Describe:

(a) the specific population of human subjects involved (e.g., patients referred by local cardiologists, students participating in collegiate organizations, volunteers from First Baptist Church, etc.), including the number of subjects and salient characteristics such as age range, gender, etc.

(b) inclusion/exclusion criteria, and

(c) how subjects will be recruited (e.g., by letter, oral presentation, advertising). Submit as appendices the following when relevant: scripts for person-to-person solicitation, and/or copies of newspaper ads, fliers, notices, etc.

### **III. Procedures:**

(a) Describe step-by-step procedures involving all subjects. In the narrative, describe what the subjects do or what is done to them, the number of observations that will be made, and how confidentiality will be maintained.

(b) Identify and assess all potential risks (physical, psychological, privacy, social, etc.), if any, with an estimate of their frequency, severity, and reversibility. Include only risks of more than negligible probability and/or severity including possible delayed effects. Finally, include

any precautions that will be taken to avoid such risks (including breaches of confidentiality), and actions to be taken if these risks materialize.

(c) Describe any inducement or compensation for subject participation.

#### **IV. Adverse Events and Liability:**

If the proposed research increases risks for subjects more than minimally beyond the ordinary risks of daily life, indicate:

(a) steps to be taken to deal with unexpected adverse events (trained personnel standing by; referral for psychological services, etc.) and

(b) arrangements for handling liability for unexpected injuries. If no specific liability plan is offered, state that in this section.

#### **V. Informed Consent:**

Describe the informed consent process including verbal interactions, written correspondence, etc. Explain how you will insure that subjects understand the purpose of the study, their involvement in the study, that their participation is voluntary, and that they may withdraw at any time without penalty. Provide a method for subjects to demonstrate their understanding of the extent to which their identifiable private information or identifiable biospecimens will be held in confidence. Lastly, explain how you will ascertain that the subjects understand what they are agreeing to do. For more information regarding informed consent, please refer to the Informed Consent Instructions at the end of this document.

**Note:** Exempted research typically does not require consent; however, some exempted research may require consent in the form of either informed consent or broad consent. Please, be certain to include consent documentation in those cases. For all other proposals (limited, expedited, or full board review), attach consent documentation covering all the relevant elements of informed consent or broad consent.

**Attachments:** Attach recruiting materials, questionnaires, interview schedules, etc., requests for waivers of consent, requests for alterations of consent, a copy of the related grant proposal (if any), and other relevant information. If a cooperating institution (school, hospital, prison, etc.) is involved, written permission **MUST** be obtained and included in the proposal. If a reliance agreement is being sought, please provide institutional contacts for each institution participating in the research.

## INFORMED CONSENT INSTRUCTIONS:

*Informed consent is a process, not just a form!*

The purpose of consent is to help the investigator protect *subjects* by *informing research subjects* about the research and their rights as human subjects. Thus, it takes two components in achieving this goal: the consent process and the consent documentation (form).

A written consent must contain all the required information as codified in 45 CFR 46 and it must be capable of being fully understood by the individuals expected to read it. All the relevant information should be included. It is not sufficient to say, “Dr. Mendez has explained” such things as the procedure or risks and discomforts. You should put these explanations in the written consent form or use a short form consent that requires a script of the accompanying oral presentation about the procedure, risks, etc. The IRB must know *what* the subjects will be informed of, and how they will be informed of it—not merely that they *will* be informed. Technical material and the purpose of the study must be explained in lay terms. Procedures should be explained from the point of view of what will happen to the subject in the course of the study. The Office for Human Research Protections (OHRP) provides detailed information about informed consent. The WTAMU IRB urges all human subjects’ researchers to explore this information prior to developing an informed consent process and documentation.

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html>

A general rule of thumb used by federal regulators is that consent forms aimed at the general public should be written at a 7th grade reading level. Adjustments up or down from that standard can be made depending on the target population of subjects. Short sentences and the use of smaller words help to achieve lower reading levels. Guidance for selection of language to use on consent forms for the general public is located at <http://www.plainlanguage.gov/>

The informed consent document is not intended to be a legal document that somehow protects the *researcher*. In fact, courts have ruled that a signed consent form which is too difficult for the subject to understand neither constitutes consent nor protects the investigator or the institution from liability. Therefore, pseudo-legal language such as “hereby”, “aforementioned”, etc. should be avoided on the grounds that it detracts from communication.

Federal regulators also suggest that, in order to facilitate communication, consent forms need to be written in the second person and avoid phrases such as “I understand that...” because they add nothing meaningful beyond the subject’s signature.

West Texas A&M University does not have a “model” consent form per se, but does have sample consent forms located on the IRB Forms and Instructions web page. The IRB believes that subjects’ rights will be better protected if investigators think through the best way to inform subjects rather than simply filling out a university-generated generic form.

Any format is acceptable as long as it serves its intended purpose and includes the elements of consent. Investigators should craft consent forms that clearly include the elements of consent and are specific to their own research program and to particular projects.

The consent process is a critical component in achieving understanding of the research and the participant’s involvement throughout the study. There are different methods of conducting the consent process and the researcher can determine the best method based upon the project’s procedures. The end result of the consent process should also be two-fold: (1) the participant’s understanding of his/her involvement in the research project and (2) the researcher’s assurance that the participant has been properly informed and comprehended the research requirements involved.

One copy of the consent form must be given to the subject and one copy must be retained by the investigator. The investigator must keep consent forms for a period of three years after the termination of the IRB approval. Expiration dates on consent forms change when annual reviews are conducted and approved. Investigators should be cognizant of consent form expiration dates.

[Note: Informed consent requirements may be different based upon funding agency guidelines or directives. If consent requirements are other than those codified in 45 CFR 46, please ensure to annotate that in the application package and ensure the appropriate consent documents are included.](#)

#### **45 CFR 46 Informed Consent General Requirements**

1. Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subjects legally authorized representative.

2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion and undue influence.
3. The information that is given to the subject or legally authorized representative shall be in language understandable to the subject or legally authorized representative.
4. The prospective subject or legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
5. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

#### **45 CFR 46 Informed Consent Requirements**

1. **Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.**
  - a. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
2. **Basic elements of informed consent.** In seeking informed consent the following information shall be provided to each subject or the legally authorized representative:
  - a. 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, and identification of any procedures that are experimental;
  - b. A description of any reasonably foreseeable risks or discomforts to the subject;
  - c. A description of any benefits to the subject or to others that may reasonably be expected from the research;
  - d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
  - e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
  - f. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are

available if injury occurs and, if so, what they consist of, or where further information may be obtained;

- g. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
- h. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
- i. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
  - i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
  - ii. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

3. *Additional elements of informed consent.* Use when appropriate.

- a. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
- b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
- c. Any additional costs to the subject that may result from participation in the research;
- d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- e. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
- f. The approximate number of subjects involved in the study;
- g. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- h. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

- i. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.*, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

#### **45 CFR 46 Broad Consent General Requirements**

1. Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subjects legally authorized representative.
2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion and undue influence.
3. The information that is given to the subject or legally authorized representative shall be in language understandable to the subject or legally authorized representative.
4. The prospective subject or legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
5. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

#### **45 CFR 46 Broad Consent Requirements**

Broad consent may be obtained as an alternative to traditional informed consent for non-exempt storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes). Additionally, broad consent may be required for certain exemption categories (7 and 8). If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

1. *Basic elements of broad consent.*
  - a. A description of any reasonably foreseeable risks or discomforts to the subject;
  - b. a description of any benefits to the subject or to others that may reasonably be expected from the research;
  - c. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
  - d. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

2. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;
3. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
4. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);
5. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
6. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and
7. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.
8. Additional elements of broad consent. Use when appropriate.
  - a. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
  - b. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.*, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

#### **45 CFR 46 Waiver of Consent**

In research involving public benefit and service programs conducted by or subject to the approval of state or local officials, an IRB may waive the requirement to obtain informed consent under the following conditions. The waiver is for all elements of informed consent (general requirements, basic elements, and additional elements).



1. In order for an IRB to waive consent the IRB must find and document that:
  - a. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
    - i. Public benefit or service programs;
    - ii. Procedures for obtaining benefits or services under those programs;
    - iii. Possible changes in methods or levels of payment for benefits or services under those programs; and
    - iv. The research could not practicably be carried out without the waiver.

General Waiver – for research not described above

1. In order to waive consent the IRB must find and document that:
  - a. The research involves no more than minimal risk to the subjects;
  - b. The research could not practicably be carried out without the requested waiver;
  - c. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
  - d. The waiver will not adversely affect the rights and welfare of the subjects; and
  - e. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Note Regarding Waivers: If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements for broad consent as outlined in this document, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

#### **45 CFR 46 Alteration of Consent**

An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent provided the IRB finds and documents the following:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
  - i. Public benefit or service programs;
  - ii. Procedures for obtaining benefits or services under those programs;
  - iii. Possible changes in methods or levels of payment for benefits or services under those programs; and
  - iv. The research could not practicably be carried out without the waiver.

General Alteration – for research not described above

1. In order to alter consent, the IRB must find and document that:

- a. The research involves no more than minimal risk to the subjects;
- b. The research could not practicably be carried out without the requested waiver;
- c. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- d. The waiver will not adversely affect the rights and welfare of the subjects; and
- e. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Note: An IRB **may not** omit or alter any of the informed consent general requirements and the altered consent must still provide a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. An IRB **may not** alter or waive the requirements for broad consent.

#### ASSENT INSTRUCTIONS – FOR MINORS

The purpose of consent documentation for minors, called assent, is to help the investigator protect *subjects* by *informing* them about the research and their rights as human subjects, even as a minor. There are several components in achieving this goal when research involves minors: 1) the assent process and documentation for the minor; and 2) the consent process and documentation for parents (parental permission). A minor in the State of Texas is an individual under the age of 18.

Follow the same guidelines described in this document regarding consent.