University of La Verne Institutional Review Board Policy and Procedure on Informed Consent, Broad Consent
Approved November 10, 2017

Informed consent must obtained for all participants in human subjects research, pursuant to 45 CFR 46.116. This means that all expedited and standard review level research must have an informed consent attached to the application that will undergo a strict review to ensure compliance with the federal regulations. The informed consent process must also be detailed and documented to verify federal compliance. The La Verne IRB requires the use of the La Verne IRB approved informed consents available on their website: https://sites.laverne.edu/institutional-review-board/irb-forms-and-examples/informed-consent-forms-templates/

General Information and Procedures for Gathering Informed Consent

1. Informed consent must be obtained from human subjects or their legally authorized representative prior to involvement in the research.
2. Informed consent will be obtained, "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 or undue influence" (45 CFR 46.116 (a)(2)).
3. The information will be provided in a language understandable to the human subject or legally authorized representative.
4. "The prospective subject or the 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" (45 CFR 46.116 (a)(4)).
5. Informed consent must begin with an executive summary of the project that is 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" (45 CFR 46.116 (a)(5)(i)). This does not apply to broad consents.
6. "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" (45 CFR 46.116 (a)(5)(ii)). This **does not** apply to broad consents.
7. "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 46.116 (a)(6)).

Required Elements of the Informed Consent (45 CFR 46.116 (b) is reproduced below). These requirements do not pertain to broad consent.

1. 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;

2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others that may reasonably be expected from the research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. 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;

7. 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;

8. 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

9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens (e.g., tissue, blood, urine, hair, and saliva samples, pathological specimens, DNA (all types), etc., specific to your study):

    i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens (e.g., tissue, blood, urine, hair, and saliva samples, pathological specimens, DNA (all types), etc., specific to your study) 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 (e.g., tissue, blood, urine, hair, and saliva samples, pathological specimens, DNA (all types), etc., specific to your study) collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional Elements of an Informed Consent to be Added when Applicable (45 CFR 46.116 (c) is reproduced below)
These requirements do not pertain to broad consent.

1. 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;

2. 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;

3. Any additional costs to the subject that may result from participation in the research;

4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

5. 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;

6. The approximate number of subjects involved in the study;

7. A statement that the subject's biospecimens (e.g., tissue, blood, urine, hair, and saliva samples, pathological specimens, DNA (all types), etc., specific to your study) even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

9. For research involving biospecimens (e.g., tissue, blood, urine, hair, and saliva samples, pathological specimens, DNA (all types), etc., specific to your study), 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).

Waivers and Alterations of Informed Consent

Applicants can apply for waivers and alterations of informed consents provided certain conditions are met (45 CFR 46.116 (e) and 45 CFR 46.116 (f)). Alterations will be considered that omit or alter some of the required elements of an informed consent, but the provisions under **General Information and Procedures for Gathering Informed Consent** cannot be altered or waived. Waivers and alterations can be considered under the following two conditions if all of the criteria are satisfied for the particular condition:

1. Public benefit and service programs conducted by or subject to the approval of state or local officials:

    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 or alternatives to those programs or procedures; or
        iv. Possible changes in methods or levels of payment for benefits or services under those programs; and
    b. The research could not practicably be carried out without the waiver or alteration.
2. Other research:
    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 or alteration;
    c. If the research involves using identifiable private information or identifiable biospecimens (e.g., tissue, blood, urine, hair, and saliva samples, pathological specimens, DNA (all types), etc., specific to your study), the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
    d. The waiver or alteration 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.

Exceptions to Obtaining Informed Consent

The La Verne IRB may approve proposals without informed consent when, "an investigator will obtain information or biospecimens (e.g., tissue, blood, urine, hair, and saliva samples, pathological specimens, DNA (all types), etc., specific to your study) for the purpose of screening, recruiting, or determining the eligibility of prospective subjects" (45 CFR 46.116 (g)). In order for this to be considered one of the following two conditions must be met:

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
2. The investigator will obtain identifiable private information or identifiable biospecimens (e.g., tissue, blood, urine, hair, and saliva samples, pathological specimens, DNA (all

types), etc., specific to your study) by accessing records or stored identifiable biospecimens.

Documentation of Informed Consent

Informed consent must be documented by obtaining a signed written consent (which may be satisfied with an electronic signature) by the subject or their legally authorized representative and a copy of the informed consent must be given to the person signing the document. There are two forms an informed consent can take (pursuant to 45 CFR 46.117 (b), reproduced below):

1. A written informed consent form that meets the requirements of § .116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.
2. A short form written informed consent form stating that the elements of informed consent required by § .116 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by § .116(a)(5)(i) was presented first to the subject, before other information, if any, was provided.
    a. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

Assent and Parental Permission

Pursuant to Subpart D, child's assent and parental permission are typically required for studies involving children. The assents must be written at a level the child understands.