

Introduction

Consent to participate in a research study should be understood as a process rather than an event. The primary focus of ethical concern should always be on the quality of the consent process. As part of the informed consent process, the consent document 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.

Documentation of the consent process is required unless specifically waived by the Institutional Review Board (IRB). One of the most common reasons for delay in IRB approval is incomplete, inaccurate, or unclear consent documents.

This guide is to assist you in creating a comprehensive consent document. However, UCR informed consent templates can be found under the IRB/UCR templates on our resources page:

<https://research.ucr.edu/ori/resources>.

Format and Style of Informed Consent Documents

- The IRB requires that the consent and assent documents be written in the 2nd person, i.e., "you" rather than "I." Preferred language would be "The researchers are inviting you to be a part of a study..." Do not start sentences with "You understand..."
- Consent forms should be written in lay language, at a level understandable to the participants in the study. Researchers may use flowcharts and tables to enhance reading comprehension. Also, try to avoid medical/scientific/technical language or include simple explanations for such terms if they must be used. You can access the Flesch-Kincaid for assistance with readability levels.
- The use of a 12-point font is recommended. A larger type size may be appropriate for some populations, such as children, the elderly, or the visually impaired.
- Depending on the type of research and the methods of the study, differing terminology may be used to refer to those that are in the study: "subject," "participant," or even "student".
- The purpose of the research should be consistent with what was described in the IRB application. If the study is funded by a US federal entity, it should be consistent with the funded grant.
- Consent document or script should have version dates to ensure that only the most recent and approved ones are being used.
- Researchers should stay away from using language that seems to indicate that the IRB has endorsed the research study (e.g. "This study has been reviewed and approved the IRB").
- If applicable, a place for the subject to sign and date must appear on the consent document. Additional signature lines may be required if obtaining surrogate consent.
- The consent form should identify any external sponsor or funding agency, as well as the student's and faculty supervisor's affiliation.
- The informed consent, whether oral or written, may not include any language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, including release of the researcher, the sponsor, the university or its agents from liability for negligence.
- A summary of research results, and a mechanism to provide the summary, may be offered to participants.

* For the purposes of this guideline, the terms 'subject' and 'participant' are used interchangeably

GENERAL REQUIREMENTS FOR INFORMED CONSENT [45 CFR §46.116]

Key Information Section

Provide a concise and focused presentation of the key information that is most likely to assist a prospective participant 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. Key details may include purpose, risks, benefits, compensation, alternatives and the voluntary participation statement. These details are explained in greater detail, if necessary, later in the consent form.

For studies that typically utilize shorter consent forms, the details in the Key Information section may not necessarily have to be further elaborated or repeated later in the consent form if all the information is presented in the initial section.

Purpose of the Study

Include a statement in the consent form that informs participants they are participating in a research study conducted by UCR researchers. Describe the purpose(s) of the research study in lay terms. Include a statement that indicates why this is considered a research study. Provide definitions for specific research design features (e.g., randomization, longitudinal, causation). When appropriate, include the approximate number of subjects in the study.

Procedures

Provide a thorough description of the specific procedures involved in the study including which procedures are considered experimental and why. Include inclusion/exclusion criteria and length of involvement. Please note that if participants are required to speak English and/or be at least 18 years of age, this would be considered an age and language criteria. If the subject will be interviewed or asked to complete a questionnaire, describe the types of questions that he/she will be asked to answer.

Additional Requirements to Procedural Information involving Biospecimens

When applicable for research involving biospecimens, include details informing participants whether the research will (if known) or might include whole genome sequencing (WGS). WGS is the sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.

Compensation and Reimbursement

If participants will be compensated for their participation or reimbursed for costs, describe in detail the type of payment, amount, and terms including circumstances where partial or pro-rated compensation would be provided. Specify any additional costs to the subject that may result from participation in this study that will not be reimbursed. Note: Reimbursement is money given to research participants that reflects out-of-pocket expenses associated with research participation (e.g., childcare, transportation, parking, etc.); Compensation is money or items given to research participants that acknowledges the time and effort they have provided in participating in the research.

Risks

Include information on any reasonably foreseeable risks or discomforts to the participants (physical, psychological/emotional, social, or legal). If applicable, include a statement that the treatment or procedure may involve risks, which are currently unforeseeable, to the subject (or to the embryo or fetus, if the subject is or may become pregnant). Most studies that collect identifiable information will have a potential risk of breach of confidentiality.

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Benefits

Describe all expected benefits and who will benefit from participation in the research. In some instances, it is acceptable to say that there are no direct benefits to participants. Please note that compensation or provisions of free study drugs or procedures is not a direct benefit of participation in research.

Withdrawal or Termination from Study

When applicable, participants should be informed of circumstances under which their participation may be terminated by the investigator without the participant's consent. Participants should also be informed of procedures for safe and orderly termination should they themselves decide to withdraw from the study before it is completed. Any conditions on withdrawal of data if participant chooses to withdraw from the study should be clarified (e.g., focus group discussions). If appropriate, describe possible consequences of participants' decision to withdraw from the research (i.e., will data be retained or destroyed, will there be implications if a participant withdraws at a certain date, etc.).

Confidentiality

Include information about the protection of participants' privacy, method of protecting research data, and who may have access to study records. If relevant, different degrees of confidentiality should be described. Information regarding the use of photos, audio and video recordings should be broken out as a separate option, to which participants can consent or not. Researchers should notify their participants that in some instances, a representative of Office of Research Integrity may review research-related records for quality assurance in order to ensure that relevant laws and guidelines are followed. All information accessed by ORI will be held to the same level of confidentiality that has been stated by the research team. UCR requires encryption for sensitive data in research. (NB: Confidentiality refers to the methods used by researchers to ensure that information obtained by them about their participants is properly protected. Privacy refers to how much control a person has over the circumstances of sharing oneself with others.)

Additional Requirements to Confidentiality if Using Identifiable Private Information or Identifiable Biospecimens

For studies involving collection of identifiable private information or identifiable biospecimens, one of the following statements must be in the informed consent:

- A statement that the identifiers might be removed from the information, and after such removal, the information could be used for future research studies or distributed to another investigator for future research without additional informed consent; OR
- A statement that the subject's information or specimens, even if identifiers are removed, will not be used or distributed for future research

Alternatives to Participation

Include applicable information on alternative procedures or courses of treatment that may be advantageous to the potential participant if he/she refuses to participate or withdraws from the study. Class-specific credit - if compensation for participation in the research is extra credit for a specific class, explain that the instructor is to provide a reasonable alternative way to earn extra credit. Psychology Department Subject Pool – if compensation for participation in the research is research credit, explain that an alternative to earning research credit is to complete the alternative assignment assigned by the department.

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Compensation for Injury

If applicable, standard non-alterable text describes the provision for participant injury incurred as a result of this study:

Social-Behavioral Research

If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor [sponsor name], depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may contact the UCR Office of Research Integrity via telephone at 951-827-4802 or via email irb@ucr.edu.

Biomedical-Clinical Research

If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor [sponsor name], depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may contact the UCR Office of Research Integrity via telephone at 951-827-4802 or via email irb@ucr.edu.

Research Results

If applicable, include a statement regarding whether clinically relevant research results, including individual results, will be disclosed to the subject and under what conditions.

Other Considerations

If biospecimens are collected as part of the study, the following statement should be included:

- Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

If a research team member has a disclosable financial interest in the outcome of this particular study or research program, a statement to that effect should be inserted into the application and the researcher will be contacted by the UCR [PRO](#) committee for additional information. If the study involves collection of specimens, the appropriate standard language should be included. Some studies could generate findings that may affect participant's willingness to participate. Such findings should be disclosed to potential participants and this should be indicated in the consent form.

Contact Information

Include researchers' contact information to answer study-related questions. Also, participants should be instructed to contact the UCR IRB if they have any concerns or questions regarding the study and/or their rights as research participants: "If you have questions about your rights or complaints as a research subject, please contact the IRB Chairperson at (951) 827 - 4802 during business hours, or to contact them by email at irb@ucr.edu."

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Voluntary Participation

Include a statement that emphasizes that the decision to participate, or not participate, is solely up to the participant. Participants should be informed they may decline or discontinue participation at any time without penalty or loss of benefits to which they are entitled to or already have.

Signature Lines

Print, signature and date line(s) should be included for the participant. A “Legally-Authorized Representative” signature line should be included if you will obtain surrogate consent or are developing a parental permission form for enrollment of a minor. Also, you may need to obtain the assent for some minors in addition to parent’s consent.

Waiver of Written (Signed) Informed Consent [45 CFR §46.117(c)]

The IRB may waive the requirement to obtain a signed informed consent document in three situations:

- The only record linking the participant and the research would be the consent document;
- The principal risk would be potential harm resulting from a breach of confidentiality;
- Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; AND
- The research is not a clinical investigation subject to FDA regulations

OR

- The research presents no more than minimal risk of harm to participants, AND
- The research involves no procedures for which written consent is normally required outside of the research context

OR

- The participants or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm;
- The research presents no more than minimal risk of harm to participants; AND
- There is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases where the documentation requirement for informed consent is waived, the IRB often requires the researchers to provide participants with a written statement regarding the research. This written statement requires IRB approval.

Researchers interested in obtaining a waiver of written (signed) informed consent should make sure that their research qualifies for one of the above options, and should address how the research qualifies for each of the option's requirements in their human participants research application.

Waiver or Alteration of Informed Consent [45 CFR §46.116(f)]

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the researcher documents

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in their human subjects research application and the IRB finds that:

- The research involves no more than minimal risk to the participants;
- The waiver or alteration will not adversely affect the rights and welfare of the participants;
- The research could not practicably be carried out without the waiver or alteration;
- 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;
- Whenever appropriate, the participants will be provided with additional pertinent information after participation;
- The research is not a clinical investigation subject to Food and Drug Administration regulations

When an IRB waives the requirement to obtain informed consent, it waives the entire requirement for informed consent process. However, when the IRB grants an alteration of some or all of the elements of the informed consent (e.g., removes a required element of consent from the document), the process of obtaining informed consent is still required. Researchers interested in obtaining a waiver or an alteration of the consent process should select this as a procedure in their human participants research application and address how the research qualifies for each of the above-listed requirements.

Obtaining Consent for Non-English Speaking Participants [45 CFR §46.116 & §47.117]

Department of Health and Human Services regulations for the protection of human participants require that informed consent information be presented "in language understandable to the subject" and, in most situations, that informed consent be documented in writing. The consent document must be written in a language understandable to the subject.

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