

Policy Number: 29

Title: Informed Consent Process and Documentation

Date of Last Revision: February 11, 2008

I. Introduction

The IRB requires investigators to obtain the legally effective informed consent of each subject or their legally authorized representative. Informed consent is an on-going process between the subject and investigator which starts with the initial presentation of a research activity to a prospective subject (including advertising), includes obtaining documented informed consent, and continues through the research activity until the subject ends his/her participation or the study closes. The IRB will evaluate the information to be provided to potential subjects in the informed consent documents in light of the risks and benefits of the proposed research procedures.

The consent form gives potential research subjects sufficient written information to decide whether to participate in a research study. Legally effective informed consent requires that potential human subjects be given a full and fair explanation of the proposed research in order to understand the nature of their participation. The consent form documents and protects all parties: the subject, the investigator, and the institution. Therefore, it is important that consent forms present information in an organized and easily understood format.

II. Informed Consent Document

A. **Required Elements:** In accordance with the federal regulations at 45 CFR 46.116 and 21 CFR 50.25, except as provided elsewhere in the federal regulations, the informed consent document must include the following required elements of 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 which 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 which 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, and that notes the possibility (for FDA-regulated research) that the FDA may inspect the records;
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; and
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.

B. Additional Elements: The following additional elements of informed consent are required when they are appropriate to the research being conducted:

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) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject'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 which 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; and
1. When HIV testing is conducted as part of research procedures, individuals whose test results are associated with personal identifiers must be informed that they will be provided with their test results and provided with the opportunity to receive appropriate counseling.¹

C. Second Person: The language of the consent documents should be written in the second person (i.e., "You have been invited to participate..."; "Your participation in the research is voluntary"), as though the study was being explained to the subject, which may help convey the message that the subject is choosing to participate. The first person should be used only for the section of the consent form that designates the subject's statement of willingness to participate.

¹ U.S. Public Health Service (PHS) Policy requires that individuals whose HIV test results are associated with personal identifiers must be informed of their own test results and provided with the opportunity to receive appropriate counseling, and provides guidance for health care personnel with respect to notification of sex and needle-sharing partners of HIV-infected persons. <http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc88jun.htm>

- D. **Lay Language:** The information provided in the informed consent documents must be written in lay language. All medical and scientific concepts and terminology should be defined and explain in ordinary language (for example, the amount of blood to be drawn should be described in terms of teaspoons or tablespoons). Technical jargon should be avoided. Whenever possible, the language should be written at a sixth grade level or lower.
- E. **Exculpatory language:** The informed consent documents may not involve the use of exculpatory language through which the subject or legal representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, sponsor, institution, or agents from liability for negligence.

III. California Experimental Subject's Bill of Rights

- A. The California Health & Safety Code, Section 24172, describes a bill of rights that must be provided to all subjects of a medical experiment. This list of rights must be written in a language in which the subject is fluent.
- B. The bill of rights document does not need to be part of the informed consent form, nor does the document need to be signed.² However, the document must be provided to subjects as part of the informed consent process. The fact that the document is provided should be noted in study records.
- C. A standardized version of this document is available from the OPRS website (<http://www.oprs.ucla.edu/human/forms/biomedical-informed-consent>) in several languages. OPRS provides a copy of this document with all informed consent documents that are stamped as IRB-approved.

IV. Informed Consent Process

Informed consent is obtained from the subject and/or his or her legally authorized representative prior to initiating all research activities, including screening procedures. Informed consent is an educational process that takes place between the investigator and the prospective subject. Informed consent is an on-going process that starts with the initial presentation of a research activity to a prospective subject (including advertising), includes obtaining documented informed consent and continues through the research activity until the subject ends his/her participation or the study closes. The IRB may consider whether subjects participating in longitudinal studies should be re-consented on an annual basis.

² UCLA investigators are not required to have subjects sign the bill of rights because of the exemption granted in Section 24178 of the California Health & Safety Code to institutions operating under a Federalwide Assurance (as UCLA does) and obtaining informed consent in the method and manner required by federal regulations.

The following should be considered when evaluating the efficacy of the informed consent process:

1. The subject and/or his or her legally authorized representative should have an opportunity to discuss with the investigator the risks, benefits and all appropriate alternatives to participation in the study and to have all of his or her questions answered.
2. The subject and/or his or her legally authorized representative must be given adequate time to review the informed consent documents and consider the risks and/or benefits of participating in the research prior to obtaining their signature.
3. The consent process must be conducted in a manner and location that will ensure that the subject's participation is voluntary.

The informed consent form should be signed and dated by the subject and, when required by the IRB, signed and dated by an investigator (or an IRB-approved designee) named on the consent form. The subject will be given a copy of the signed consent form.

The idea of informed consent as a process requires that subjects be provided with any new information that arises (such as modifications to the research plan, the results of related research, etc.). This allows subjects to decide whether or not to continue participation in light of the new information.

So that subjects do not have to review and sign a complete revised consent form, subjects may be presented with an addendum to the consent form that describes what has changed since they last provided consent. Templates are available on the OPRS website (see the Attachments section at the end of this policy).

V. Stamped Copies of Consent Documents

Informed consent documents that have been approved by the IRB will be stamped with the official IRB approval stamp that includes the approval date. The IRB number and expiration date will also be included in the footer of each page of the document. The copy of the informed consent form signed by the subject should include the official IRB approval stamp. Translated versions of the consent form will include the IRB number and expiration date only, unless the IRB has received documentation that the form has been translated by a certified translator.

VI. Waiver or Alteration of Informed Consent

In accordance with the federal regulations at 45 CFR 46.116(d), the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or may waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The waiver described above does not apply to FDA-regulated research. See [OPRS/IRB Policy 3: Human Subjects Research Determinations](#) for details about whether research is FDA-regulated.

VII. Waiver of Documentation of Informed Consent

In accordance with the federal regulations at 45 CFR 46.117(c), the IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality; or
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

For FDA-regulated research, 21 CFR 56.109(c)(1) allows the IRB to waive documentation of informed consent in the second scenario above. FDA regulations do not include a waiver corresponding the first scenario above.

For projects in which the IRB waives the requirements for documentation of informed consent in the first scenario above, federal regulations require that each subject be asked whether he or she wants documentation linking the subject with the research and the subjects wishes shall govern.

For projects in which the IRB waives the requirement for documentation of informed consent, the IRB will determine whether to require that subjects be provided with a written statement regarding the research. The IRB must review any such written statements prior to dissemination to subjects.

For projects of minimal risk involving the use of questionnaires, the required elements of informed consent may be included in an introductory letter attached to the instrument, which includes a statement that completion and return of the questionnaire will constitute consent to participate in the project.

VIII. Waiver of Documentation of Informed Consent to Conduct Screening Procedures

The collection of data from or about a person during screening constitutes a research interaction or intervention and is subject to informed consent requirements. Although screening activities do not necessarily result in data that are used to evaluate study outcomes, such procedures must

be reviewed by the IRB during consideration of the protocol in order to ensure appropriate informed consent is obtained, when required, and so that all potential risks to subjects may be evaluated.

If such screening will occur prior to obtaining informed consent for participation in the study, the IRB may determine that a waiver of documentation of informed consent is applicable for the purposes of minimal risk screening activities only (according to the criteria in Section VII above). If screening will only occur after obtaining informed consent for participation, then such a waiver is unnecessary.

For more information regarding screening activities, see [OPRS/IRB Policy 30: Recruitment Methods & Tools](#).

IX. Child Assent and Parent/Legal Guardian Consent Process

Investigators should refer to [OPRS/IRB Policy 21: Special Subject Populations- Children](#) and [OPRS/IRB Policy 50: Special State Laws: Minor Subjects](#) for detailed requirements for obtaining the consent or permission of parents and the assent of children, as well as details about when individuals are categorized as “children” under federal regulations for the protection of human research subjects.

X. Guidelines and Procedures for Proxy/Surrogate Informed Consent

California Health & Safety Code 24178 authorizes specific individuals to give surrogate or proxy informed consent for the enrollment of subjects in limited circumstances. The law distinguishes between emergency room and non-emergency room research and describes specific surrogate trees or surrogate options for each type of research. Individuals authorized under state law are considered to meet the DHHS and FDA definitions of “legally authorized representatives.” Please see both the OPRS [Guidelines and Procedures for Proxy/Surrogate Informed Consent](#) as well as [OPRS/IRB Policy 24: Special Subject Populations- Cognitively Impaired](#) for additional details.

XI. Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable

Under FDA regulations for clinical investigations of devices, an individual becomes a research subject when his or her specimens are used. FDA regulations for the protection of human subjects do not allow IRBs to approve research involving human specimens unless the requirement for informed consent has been met (except in limited circumstances related to emergency research or military research). However, informed consent may be difficult, if not impossible, to obtain for use of specimens that are left over from clinical care or other research.

The FDA has issued guidance to address this situation.³ The FDA will use its enforcement discretion so that informed consent requirements do not apply to *in vitro* diagnostic device studies meeting the criteria outlined in Section 4 of the guidance.

Investigators wishing to conduct a study according to this FDA guidance should submit an application for IRB review. In addition to the information required by the application, the investigator should also provide information or assurances that address the criteria in Section 4 of the FDA guidance. If the IRB determines that the research meets the criteria in Section 4 of the FDA guidance, the investigator will not be required to obtain informed consent.

XII. Exception From Informed Consent Requirement for Emergency Use of Test Article

For an emergency use of a test article, a physician is required to obtain informed consent of the patient or a legally authorized representative unless the criteria in 21 CFR 50.23(a) are met. Because there is no equivalent provision in DHHS regulations, this exception may only be used for the emergency use of a test article for purposes of patient care, which is not “research”. For more information, see [OPRS/IRB Policy 36: Emergency Use of a Test Article](#).

XIII. Exception from Informed Consent for Planned Emergency Research

The conduct of planned research in life-threatening emergent situations may involve exception from informed consent requirements as provided for in 21 CFR 50.24 (and in a corresponding waiver from the Secretary of HHS for research not regulated by the FDA). See [OPRS/IRB Policy 35: IRB Approved Research in an Emergency Setting](#) for more information.

XIV. Non-English Speaking Subjects

The federal regulations require the translation of consent documents into the language which is most easily understood by research subjects. A potential subject’s inability to read or to read English is not an appropriate basis for exclusion from most research. The IRB approved informed consent documents should be available in English and other languages as appropriate to the subject population(s). See [OPRS/IRB Policy 26: Special Subject Populations- Non-English Speaking Subjects](#) for additional information.

XV. Individuals Qualified to obtain Informed Consent

The IRB will assess whether individuals identified in the application as eligible to obtain subjects’ informed consent have sufficient training and qualifications to obtain subjects’ informed consent. If a study involves procedures that are not within the scope of practice of non-physician investigators, the IRB will require that only those physician investigators who are continuously involved in the research and are qualified to answer any questions regarding the

³ <http://www.fda.gov/cdrh/oivd/guidance/1588.pdf>

nature of a subject's participation and explain the alternatives to participation can obtain subjects' informed consent.

XVI. Research Conducted Outside California

When planning to conduct research outside of California, investigators are responsible for awareness of any additional informed consent requirements of other states or other nations. This is especially important for research involving "children" or "legally authorized representatives" where the definitions in DHHS and FDA regulations rely on local laws.

Regulations:

21 CFR 50.20
21 CFR 50.23
21 CFR 50.24
45 CFR 46.116
45 CFR 46.117
45 CFR 46.408-409
45 CFR 46 Subpart D
California Health & Safety Code 24178

References:

HHS Office for Protection from Research Risks (OPRR, now OHRP), Tips on Informed Consent, Revised March 16, 1993. <http://www.hhs.gov/ohrp/humansubjects/guidance/ictips.htm>

Memorandum from Assistant Secretary for Health, "Policy on Informing Those Tested About HIV Serostatus", May 9, 1988. <http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc88jun.htm>

OPRR, Cooperative Oncology Group Chairpersons Meeting, November 15, 1996; "Exculpatory Language" in Informed Consent. <http://www.hhs.gov/ohrp/humansubjects/guidance/exculp.htm>

OPRR Reports: Informed Consent--Legally Effective and Prospectively Obtained, August 12, 1993. <http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc93-03.htm>

FDA, *IRB Information Sheets: A Guide to Informed Consent*, September 1998. <http://www.fda.gov/oc/ohrt/irbs/informedconsent.html>

FDA, *Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable*, April 25, 2006. <http://www.fda.gov/cdrh/oivd/guidance/1588.pdf>

Attachments (all available from <http://www.oprs.ucla.edu/human/forms/>):

- OPRS-40 UCLA IRB/OPRS Informed Consent Checklist
- OPRS-54 UCLA IRB/OPRS Form HS-2, Consent to Participate in Medical Research
- OPRS-55 UCLA IRB/OPRS Form HS-2(a), Consent Form for Research That Includes Identified Tissue or Genetic Material
- OPRS-56 UCLA IRB/OPRS Form HS-2(b), Consent Form for Research That Includes Anonymous or Anonymized Tissue or Genetic Material
- OPRS-57 UCLA IRB/OPRS Form HS-3(a), Assent Form (Aged 7-12 Years) For Research (Medical)
- OPRS-58 UCLA IRB/OPRS Addendum to the Consent Form for Continuing Research Subjects (Medical)
- OPRS-59 UCLA IRB/OPRS General Consent Form
- OPRS-60 UCLA IRB/OPRS General Research Information Sheet
- OPRS-61 UCLA IRB/OPRS General Child Assent to Participate in Research
- OPRS-62 UCLA IRB/OPRS General Addendum to the Consent Form for Continuing Research Subjects
- OPRS-63 UCLA IRB/OPRS General Youth (Ages 13-17) Assent to Participate in Research
- OPRS-64 UCLA IRB/OPRS General Consent to Participate in Research Screening
- OPRS-65 UCLA IRB/OPRS General Parent Permission for Minor to Participate in Research
- OPRS-66 UCLA IRB/OPRS General Parent Consent to Participate in Research
- OPRS-67 UCLA IRB/OPRS Tips and Suggestions for Consent and Assent Forms
- OPRS-68 UCLA IRB/OPRS Guidance: Withholding Information and/or Deceiving Subjects
- OPRS-69 UCLA IRB/OPRS Oral Consent Script