

Date:

CPHS#: **OPHS WORKSHEET – 45 CFR 46.116(a) & (b) and 21 CFR 50.25**
INFORMED CONSENT CHECKLIST

Except as described in IC 702 – Waivers of Informed Consent, no investigator may involve a human being as a subject in research unless s/he has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. The information presented in the consent document must be in language likely to be understood by the subject population. Informed consent documents may not contain any exculpatory language through which the subject is made to waive or appear to waive legal rights, or release or appear to release the Investigator, the Sponsor, or UC Berkeley from liability for negligence.

Note: Elements of informed consent under 45 CFR 46.116(a), 46.116(b), and 21 CFR 50.25 of the federal regulations are indicated with an asterisk (*). The other elements are CPHS/OPHS recommendations/preferences, unless otherwise noted.

BASIC ELEMENTS OF INFORMED CONSENT <i>Unless a waiver is approved by CPHS, the following information must be included.</i>	YES	NO	N/A	WAIVED
1. Letterhead: Is the consent form presented on letterhead?				
2. Heading & Title: Does the consent form include a heading (e.g. "Consent Form for Controls") and the title of the study?				
3. Key Information: * Are all five key elements presented at the beginning of the consent form and organized in a way that facilitates comprehension? ¹ (Consent forms that are two pages or less need not contain a separate key information section as they already meet the requirements for being clear, concise, and containing key information in an appropriate format.)				
4. Introduction & Identification of Researchers: Are the researchers and departmental affiliation identified? (Student researcher should include Faculty Advisor)				
5. Invitation & Purpose: Is there an explanation of why the individual is being asked to take part in the study, using language that avoids connotations of requirement or demand?				
*Is the purpose of the research clearly explained, including the fact that the study involves "research"?				
6. Procedures: *Is there a full and clear description of study procedures using non-technical language? (If appropriate, screening procedures should be included.)				
*Are the duration of each procedure and total expected time of the subject's participation stated?				
*Are procedures or elements of the procedure that are experimental clearly identified as such?				
7. Risks/Discomforts: *Is there a clear description of any reasonably foreseeable risks or discomforts?				
Is there a description of measures that will be taken to minimize these risks or discomforts?				

<p>8. Benefits:</p> <p>*Is there a description of benefits to the subjects, to others, and/or to scientific knowledge that may reasonably be expected from the research?</p>				
<p>9. Alternatives:</p> <p>*Does the form disclose appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject?</p>				
<p>10. Confidentiality:</p> <p>*Is there a statement describing the extent to which confidentiality of records identifying the subjects will be maintained? (If applicable, the possibility that the FDA and/or other agencies or individuals may inspect the records should be noted.)</p> <p>*For NIH-funded studies, is there a statement describing the additional privacy protections (and limitations) afforded by a Certificate of Confidentiality?</p>				
<p>11. Collection of private information or identifiable biospecimens for future research:</p> <p>*One of two statements must be included:</p> <ul style="list-style-type: none"> • <i>Identifiers might be removed and the de-identified information or biospecimens used for future research without additional informed consent from the subject; or</i> • <i>The subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed.</i> 				
<p>12. General Data Protection Regulation (GDPR):</p> <p>If collecting identifiable data from subjects located in the European Economic Area (EEA), has GDPR language been included (as required by EU law)?</p>				
<p>13. Discontinuing Study Participation:</p> <p>*Does the consent form state clearly that participation in the research is voluntary?</p>				
<p>*Does the consent form state that 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?</p>				
<p>14. Treatment and Compensation for Injury:</p> <p>* If the study involves more than minimal risk, does the consent form include an explanation as to whether any compensation and/or any medical treatments are available if injury occurs, and if so, what they consist of or where further information may be obtained? (See Informed Consent Guidelines.)</p>				
<p>15. Contact information: (Local contacts should be provided for research abroad.)</p> <p>*Is contact information provided for questions regarding the research?</p>				
<p>*Is contact information provided for questions about participants' rights or treatment as research subjects?</p>				
<p>16. Consent/Signature Section:</p> <p>*Will written consent be obtained? (The consent form should indicate that if the individual has considered the pertinent information presented and wishes to participate, s/he should indicate agreement by signing the form. Signature line and date should be provided.)</p>				
<p style="text-align: center;">ADDITIONAL ELEMENTS OF INFORMED CONSENT</p> <p><i>When appropriate, one or more of the following elements should also be included.</i></p>	YES	NO	N/A	WAIVED
<p>*Is there a statement that the particular treatment or procedure may involve risks to the subject (or to an embryo or fetus) which are currently unforeseeable?</p>				

*Have anticipated circumstances under which participation may be ended or terminated by the researcher without regard to the subject's consent been included?				
*Is there a description of any additional costs to the subject that may result from taking part in the research?				
*Is there a description of any consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject?				
*Is there a statement indicating 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?				
*Has an approximate number of subjects involved in the study been provided?				
*Is there a statement indicating that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and explaining whether or not the subject will share in this commercial profit?				
*Is there a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions?				
*For research involving biospecimens, is there a statement indicating 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)?				
*When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), the following statement shall be provided to each clinical trial subject in informed consent documents and processes. This will notify the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act. The statement is: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov , as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."				

Note:

- These informed consent requirements are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.
- No required elements of informed consent as described in 21 CFR 50.25 are intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local law.

ⁱ 46.116(a)(5) Key Information should include:

1. The fact that consent is being sought for research and that participation is voluntary.
2. Purpose(s) of the research, expected duration of the prospective subjects' participation, and procedures to be followed in the research,
3. Reasonably foreseeable risks or discomforts to the prospective subject.
4. Benefits to the prospective subject or others that may reasonably be expected from the research.
5. Appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the prospective subject.