Policy for Obtaining Informed Consent of Potential Participants for Oncology Research

Process and workflows for obtaining and documenting informed consent

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Purpose

This policy defines research personnel who may obtain consent [i.e., Key Study Personnel (KSP)] and describes the steps required by the KSP for obtaining informed consent from potential study participants in a clinical research study at the Helen Diller Family Comprehensive Cancer Center (HDFCCC).

Scope

This policy applies to all clinical research studies, including Investigator-Initiated, Industry-Sponsored, and Cooperative Group trials.
Definitions

- **Certified Bilingual/Multilingual Clinicians and Staff**: UCSF faculty or staff who are certified by the Interpreting and Translation Services Department to discuss medical or clinical information directly with participants and their family/guardians without the assistance of a Professional Medical Interpreter and: a) are proficient in speaking and understanding both spoken English and at least one other spoken or signed language, including any necessary specialized vocabulary, terminology and phraseology, and b) are able to effectively, accurately, and impartially communicate directly with Individuals in their preferred languages. Certified Bilingual/Multilingual Clinicians and Staff are not permitted to act in the capacity of an interpreter for third parties, only to conduct their normal job duties in their certified language(s).

- **Informed Consent Form (ICF)**: a document outlining possible study procedures, risks, benefits and alternatives, along with the participant’s rights. The ICF serves as a way of documenting the participant’s understanding and is only part of the informed consent process.

- **Key Study Personnel (KSP)**: KSP for therapeutic trials are defined as the Principal Investigator, the Co-Investigator, or Sub-Investigators (i.e., MD or NP only) employed by the research program that are listed as “Key Personnel” in 1) the UCSF IRB protocol application and 2) on the protocol-specific Delegation of Authority (DOA) log or its equivalent with the role of obtaining consent.
  - Fellows: Refer to HDFCCC Policy for Fellows Obtaining Informed Consent for Potential Patient for Therapeutic Oncology Clinical trials
  - For therapeutic trials in the HDFCCC, the Clinical Research Coordinator (CRC), Registered Nurse (RN), and other study staff are not considered Key Study Personnel for obtaining consent and re-consent.
  - CRCs, RNs and other study staff may be listed as KSP and obtain informed consent for non-therapeutic minimal risk trials (including collection of blood and urine samples, germ-line tissue banking trials, imaging studies without an investigational product, etc.).
    - The Clinical Research Manager (CRM) submits a request for CRCs/RNs/other study staff to have consenting privileges for the non-therapeutic minimal risk trial to the Associate Director of Clinical Research Programs and the DSMC Director. This request includes the protocol and ICF for the non-therapeutic trial. After this one-time approval is granted for the trial, any CRC, RN, or other study staff who needs consenting privileges would be trained by the DSMC Education and Training Manager (ETM) or approved trainer on the consent process. Additionally, the trained CRCs, RNs, or other study staff will be listed as Research Support Staff and their responsibilities for consenting will be outlined in the UCSF IRB Application.

- **Participant**: Persons enrolled in clinical research. Studies may enroll people with a specific disorder or people without health problems to provide baseline information on overall health. The term “participant” covers all people enrolled in studies regardless of their health status. For the purpose of this policy, participant may also refer to the guardian of a minor child. Quick reference guides for consenting pediatric participants can be found in Appendix 1.
Background

Informed consent is a term for the communication process used by a clinical investigator to facilitate an individual’s educated choice about beginning or continuing participation in a clinical research study. Informed consent is an ongoing exchange of information between the study participant and the research team before the start of eligibility screening and throughout the duration of the clinical trial. As part of the informed consent process, a discussion of the study’s procedures, interventions, time investment, risks, benefits, purpose, costs, other treatment options, and the voluntary nature of participation must occur with the participant and, if required, a legally authorized representative.

The written contents of the informed consent form (ICF) are governed by Federal Regulations, and by institutional policies and guidance. The ICF and any required revisions to the original consent must be approved by the UCSF IRB or the IRB of record. The approved versions serve as a reference for monitoring and auditing the conduct of participant informed consent throughout the clinical trial.

An ICF must be signed by the participant, the person obtaining informed consent, and witness (if applicable) BEFORE any study specific procedures can be conducted in the clinical trial.

Procedures

1.0 Responsibilities of the Key Study Personnel:

1.1 Participant Selection: Determine that a participant may be a candidate for a specific clinical research study.

1.2 Review and have the participant sign the California Experimental Subject’s Bill of Rights document.

1.3 Review the ICF and conduct the informed consent discussion:

1.3.1 Discuss with the study participant the prospect of clinical trial participation, including: the purpose of the clinical trial, a general description of the study (including information about the investigational product), risks, possible benefits, expected outcomes of this study, alternatives to participation and the right to refuse to participate.

1.3.2 Answer all questions to the participant’s satisfaction. Arrange for a follow-up discussion if unanswered questions remain.

1.4 Sign the HIPAA Authorization Form:

1.4.1 After the ICF discussion, the investigator will ensure that the participant reviews and signs the HIPAA Authorization Form.

1.4.2 The participant must personally sign and date the HIPAA Authorization Form.

1.4.3 The participant must initial all relevant options in section C and G of this document. If the participant does not consent to any of the options in section C and G, then the CRC should write a note at the top of the form indicating that all options were reviewed, and the participant decided to
1.5 Sign the Informed Consent Form (ICF):
   1.5.1 The participant will sign the consent to acknowledge that the study and its procedures have been presented in a manner they understand and that they wish to participate in the clinical research study.
   1.5.2 Then, the Investigator will sign as the person obtaining consent.
   1.5.3 If the participant cannot travel back to the clinic to sign the consent prior to starting screening procedures, then the participant may sign the consent while on the phone with the Investigator, after the Investigator has answered any questions. The study team should follow the process below (remote consenting) to obtain a signed copy of all documents.

1.6 Document the Verbal Consent Process: Document the consent process in the study participant’s medical chart in the format recommended in Appendix 2 of this policy.

1.7 Distribute copies of the signed California Experimental Subject’s Bill of Rights, HIPAA Authorization Form and ICF.
   1.7.1 Make one copy of all signed consent documents.
   1.7.2 Give the participant a signed copy of all consent documents to take home.
   1.7.3 Record the study participant’s UCSF medical record number on the copies of the signed ICF, signed California Experimental Subject’s Bill of Rights, and signed HIPAA authorization.
   1.7.4 File the original signed ICF, signed California Experimental Subject’s Bill of Rights, and signed HIPAA authorization in the participant’s research source document binder as determined by the unit.
   1.7.5 Upload a copy of the consent documents into APeX.
   1.7.6 Register participant into OnCore CTMS, along with ICF signing date and version date of ICF (and language, if applicable).

2.0 Remote Consent

In situations where the person obtaining informed consent and the study participant are unable to connect in person prior to any study procedures (including screening for eligibility), remote consent may be an option. The consent discussion should be conducted via secure UCSF Zoom video visit so that the identity of the potential participant can be confirmed (see details below). UCSF Zoom is HIPAA compliant.

2.1 The person obtaining consent should remind the potential participant that the informed consent discussion should occur in a private location to help ensure privacy and confidentiality. The study team should also advise participants against the use of public computers when signing the ICF, California Experimental Subject’s Bill of Rights, and HIPAA forms electronically.
2.2 The person conducting the consent process should confirm the identity of the participant through government issued ID where possible (e.g., ask the potential study participant to hold up their ID up to screen to verify their identity). The person conducting the consent process should document how the potential participants identify was verified in their consent documentation (Appendix 2). Use of study personnel generated security questions can also be considered. Note: Minimal risk studies do not need to have identify verified prior to obtaining informed consent.

2.2.1 If UCSF Zoom video visit details and copy of the consent form were shared via MyChart, it is not necessary to require government issued ID to verify identity. Anyone with MyChart access has had their identity confirmed when MyChart access was provided. Use of MyChart to confirm identity should be documented in the consent note (Appendix 2).

2.3 The consent process should follow the same process as described in Section 1.0.

2.4 At the end of the conversation, the person obtaining consent should confirm the best way to send digital copy of all documents for signature:

2.4.1 FDA regulated studies: when using electronic signatures, the participant, the person conducting the consent process and the witness (where applicable) should sign all documents using a 21 CFR Part 11 compliant system (note: an FDA compliant version of DocuSign was made available to UCSF Investigators as of April 14, 2021). Alternatively, the participant can print all documents and follow the process for a wet-ink signature as described in Section 1.0. Instructions for using the FDA compliant version of DocuSign are available on the UCSF Information Technologies website: https://it.ucsf.edu/how-to/signing-21-cfr-part-11-compliant-document-docusign

2.4.2 For all other studies, the best practice is to send the link to sign the documents using MyChart since MyChart requires the user to use a secure username and password to access the system. If MyChart is not available, the participant should confirm the correct email address to use. If email is used, the ICF should be sent to the participant using secure email.

2.5 If the participant does not sign during a meeting with the investigator, once the participant signs all documents, best practice is for the person conducting the consent process should arrange for another video visit or telephone call to confirm that 1) the participant did in fact sign using their e-signature and 2) that the participant had no further questions. Once the follow-up discussion has occurred, the person conducting the consent discussion may sign the ICF.

2.6 Copies should be provided to the participant and filed in the research chart and medical record as detailed above. If a 21 CFR Part 11 compliant system is used for signature, copies of the signature certification should be downloaded and stored with the ICF.
2.7 If the consent discussion occurred in person, but the participant is unable to return to the clinic to wet-ink sign the documents prior to the start of the study, Sections 2.4-2.6 may be followed above.

3.0 Re-consent for risk and ICF modifications

3.1 High Risk Adverse Events: For participant notification of new high-risk adverse events, the study team should follow the process as outlined in the HDFCCC Policy for Verbal Notification of High-Risk Adverse Events.

3.2 ICF Modifications: If the ICF has been significantly modified and requires reconsent per the IRB, participants must be re-consented at the study participant’s next scheduled visit. It is a reportable violation to the IRB for study participants to not be consented by their next visit for the trial. The procedures outlined in Section 1.0 should be followed for any re-consent discussions. Participants are not required to re-sign the HIPAA authorization and the Experimental Subject’s Bill of Rights Document for the re-consent process.

3.3 For study participants in the survival follow-up phase of the trial, re-consent is not necessary unless mandated by the sponsor (for delayed risks) or the IRB.

3.4 Re-consenting participants on “renewed” ICFs that are updated from the annual Continuing Renewal process where only the IRB stamp has been updated is not required.

3.5 Reconsenting will not be required for minor changes to the ICFs that do not involve participant safety (i.e., pagination corrections, grammatical errors, etc.). Changes that do not affect study participants would not require re-consent (i.e., a study participant may have completed the part of the trial with the specific changes or was not enrolled in the arm of this trial that included these changes).

4.0 Consenting Non-English Speaking Participants

Certified bilingual staff and clinicians can consent participants, but they cannot interpret for another clinician or staff member who does not speak the participant’s language and is consenting the participant. The UCSF IRB has published guidelines for consenting non-English speaking participants. Appendix 3 summarizes the process to follow and the signatures to obtain.

USCF faculty or staff may act as translators for the consent discussions if they are certified by the UCSF Interpreting and Translation Services. Further details on how faculty or staff can be certified by UCSF Interpreting and Translation Services can be found in Appendix 4.
Policy Exemptions

None

References

45 CFR 46
21 CFR 50
Federal HIPAA Privacy Rule (45 CFR 164)
UCSF HRPP website: irb.ucsf.edu


Appendices

Appendix 1 – Pediatric Consenting Requirements
Appendix 2 - Document consent process in clinic chart
Appendix 3 - UCSF IRB Informed Consent for Non-English Speaking Participants
Appendix 4 – Process for Requesting Bilingual/Multilingual Certification
Policy Approval

This policy document was approved by the following personnel on the following dates:

Kate Shumate  
Chief of Staff  
Helen Diller Family Comprehensive Cancer Center  
Date: 6/7/2022

Charalambos Andreadis  
Clinical Research Support Office Medical Director  
Helen Diller Family Comprehensive Cancer Center  
Date: 6/6/2022

Eric Small, MD  
Deputy Director, HDFCCC  
Helen Diller Family Comprehensive Cancer Center  
Date: 6/8/2022

Policy contact:  
Andrea Skafel, Clinical Research Support Office Director  
andrea.skafel@ucsf.edu; +1 415 502 5805
Appendix 1 – Pediatric Consenting Requirements

REQUIRED DOCUMENTS

- California’s Experimental Subject Bill of Rights
- HIPAA Form
- Informed Consent Form (additional Assent or Youth Information Sheet, which depends on the IRB and child’s age)

For pediatric participants ages 17 years or younger, the Experimental Subject Bill of Rights (BOR) and HIPAA form will be signed by the participant’s parent or legal guardian. Pediatric participants ages 18 and older will sign their own BOR and HIPAA forms.

CENTRAL IRB (CIRB)

For studies under the CIRB, there is an ICF and starting, September 2019, an additional Youth Information Sheet (YIS) or an assent form.
- For newer studies, CIRB provides Youth Information Sheets for ages 7-12 and 13-17.
- For older studies, the HDFCCC Central Regulatory Team will create an assent for ages 7-12. Participants ages 13-17 will sign the participant line on the ICF to document assent.

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<th>7-12 years old</th>
<th>13-17 years old</th>
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- Person Obtaining Consent | - Parent (also initials*)  
- Person Obtaining Consent | - Participant (if there is no YIS)  
- Parent (also initials*)  
- Person Obtaining Consent | - Participant (also initials*)  
- Person Obtaining Consent |
| Youth Information Sheet (newer studies) | - Person Obtaining Consent | - Person Obtaining Consent | - Person Obtaining Consent | - Person Obtaining Consent |
| Assent (older studies) | - Person Obtaining Consent (if there is no YIS) | - Person Obtaining Consent | - Person Obtaining Consent | - Person Obtaining Consent |

*Initials are for the optional procedure sections on the ICF

UCSF IRB

For studies under the UCSF IRB, there are three types of consent forms available. The type of consent form or combination of consent forms that you will use is dependent on the participant’s age. Please utilize the correct document and obtain the necessary signature(s) for each document.

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- Person Obtaining Consent | - Parent (also initials*)  
- Person Obtaining Consent | - Parent (also initials*)  
- Person Obtaining Consent | - Parent (also initials*)  
- Person Obtaining Consent |
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<th>- Person Obtaining Consent</th>
<th>- Person Obtaining Consent</th>
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<td>Adult/Adolescent ICF</td>
<td>- Participant - Parent (also initials*) - Person Obtaining Consent</td>
<td>- Participant (also initials*) - Person Obtaining Consent</td>
</tr>
</tbody>
</table>

*initials are for the optional procedure sections on the ICF
Appendix 2 - Document consent process in clinic chart

Suggested standardized consent process documentation which can be printed on UCSF clinic progress note.

**CLINICAL TRIAL NUMBER:** (insert number)

Informed consent was discussed for participation in the above referenced study with (insert study participant’s name) who has voluntarily agreed to participate by signing the consent form document on (insert date, mm/dd/yyyy). <<If remote consent was used>> Identification was confirmed by (insert method to confirm identification).

The following points were discussed and must be yes:

- **□ Yes □ No** The UCSF Experimental Subjects Bill of Rights and HIPAA documents have been reviewed with the study participant/parent prior to signing the consent form. The California Experimental Subject’s Bill of Rights document MUST be presented first and signed by the study participant/parent prior to signing the HIPAA document and the ICF.

- **□ Yes □ No** A signed copy of the ICF, HIPAA, and Bill of Rights documents have been given to the participant/guardian.

- **□ Yes □ No** Alternative treatment to the participant’s disease in lieu of clinical trial participation has been discussed.

- **□ Yes □ No** Possible risks and possible side effects of participation in this clinical trial have been discussed.

- **□ Yes □ No** The participant/guardian has been given the opportunity to ask questions.

- **□ Yes □ No** The participant/guardian has acknowledged that his/her questions were satisfactorily answered.

- **□ Yes □ No □ N/A** The requirement for the use of birth control while participating in this clinical trial was discussed.

- **□ Yes □ N/A** A copy of the prohibited medication list has been provided to the participant/guardian. This list has been reviewed with the participant. The participant has been instructed to provide this list to any health care providers that may prescribe medication for the participant outside of this clinical trial.

Comments:

PRINT THE NAME OF PERSON OBTAINING CONSENT: _____________________

PI/Sub-Investigator’s signature    Date signed
Appendix 3 - UCSF IRB Informed Consent for Non-English Speaking Participants

Background: Non-English speaking participants are not allowed to sign the English version of the Experimental Subject’s BOR, HIPAA and ICF. The person obtaining consent must use a translated BOR and HIPAA when consenting non-English speaking participants.

As per the UCSF IRB, if consenting:

- More than two non-English speaking participants who are fluent in the same language, it is required for investigators to consent using the preferred method. Therefore, a translated ICF must be made available.
- Only 1-2 non-English speaking participants who are fluent in the same language, then investigators may consent using the short form method.

Please always obtain and document the interpreter’s full name and license number each time a consenting/re-consenting process takes place.

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<td>English ICF</td>
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</tr>
<tr>
<td>Optional procedure initials</td>
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</table>

*The witness is signing to document that an oral presentation in a language the participant can understand took place. For the BOR and the ICF, the witness can be the interpreter or another adult (other than the person obtaining consent/family member) who witnesses the involvement of an interpreter. The witness may be the CRC or other study staff member.
Appendix 4 – Process for Requesting Bilingual/Multilingual Certification

1. Email Bilingual@ucsf.edu to request certification and indicate if you are a clinician (MD, NP, PA, Pharm D) or staff (all others from RN – Social Work, etc.).
2. UCSF Interpreting and Translation Services will send the appropriate Qualtrics Survey link via email.
3. Once the survey is complete, information is entered into the database for candidates who qualify for certification.
4. If available for the candidate’s language(s), telephone language assessments are assigned.
5. The candidate receives an email from ALTA Language Services with instructions and an access code for the appropriate language assessment.
6. Upon completion of the language assessment, results are reported out to the candidate.
7. RETESTS are only allowed under the following circumstances:
   a. Technical difficulty lead to an incomplete exam that cannot be scored (credit issued to UCSF).
   b. An emergency interruption lead to an incomplete exam – PLEASE NOTIFY BILINGUAL@UCSF.EDU IMMEDIATELY SO A CREDIT CAN BE REQUESTED BEFORE THE EXAM IS SCORED.
   c. A marginal passing score is obtained on the clinician exam (75%-79%).
   d. The candidate failed the test and has proof of 6-12 months of enhanced language learning or coursework.

Note: UCSF Interpreting and Translation Services will accept the ALTA test from another institution. If a UCSF faculty or staff were certified at one of the UCSF sister “Health” organizations (UCD, UCLA, UCI, UCSD), UCSF Interpreting and Translation Services would look at those on a case-by-case basis and confer with the manager of Interpreting Services at that institution to determine which test was used. If you have one of these certifications, provide the details in the initial request.
### Clinical Research Policy Revision
#### Summary of Changes

**Policy Title:** Policy for Obtaining Informed Consent of Potential Participants for Oncology Research  
**Version Date:** 06/06/2022  
**Version Number:** Revision 9 (replaces version 8 dated July 8, 2016)

<table>
<thead>
<tr>
<th>Section(s)</th>
<th>Summary of Change</th>
<th>Rationale</th>
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<tr>
<td>Title</td>
<td>Change title of policy. Previous policy title “Policy for Obtaining Informed Consent of Potential Patients for Therapeutic and Non-Therapeutic Oncology Clinical Trials”</td>
<td>Simplified title to encompass all oncology research</td>
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<td>All</td>
<td>Restructured and reordered policy to match new format as defined in the Policy for Clinical Research Policies</td>
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<tr>
<td>Section 2</td>
<td>Added detailed instructions for obtaining remote consent</td>
<td>21CFRpart 11 compliant version of DocuSign was made available April 2021. Due to the COVID-19 pandemic, many visits and consent discussions are now occurring remotely.</td>
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<td>Section 4</td>
<td>Updated process for consenting non-English speaking participants</td>
<td>Matches the IRB process for consenting non-English speaking participants</td>
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<td>Removed Attachment 1 – Delegation of Responsibility and Staff Signature log</td>
<td>Delegation of Authority log incorporated into separate policy (“Delegation of Authority Log Completion Policy”)</td>
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<td>Appendix 3</td>
<td>Replaced Attachment 3 with Appendix 3</td>
<td>Updated instructions to match IRB process</td>
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<td>Removed Attachment 4 – CRC/RN Consent Training Completion and Certification Documentation for Non-Therapeutic Trials</td>
<td>Training documentation maintained by the DSMC Education and Training Manager.</td>
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<td>Added Appendix 1 – Pediatric Consenting Requirements</td>
<td>Detailed process for consenting pediatric patients</td>
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<td>Appendix 4</td>
<td>Added Appendix 4 – Process for Requesting Bilingual/Multilingual Certification</td>
<td>Detailed process for staff and faculty to obtain bilingual certification</td>
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| Eric Small  
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Professor  
University of California, San Francisco  
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| Katherine Shumate  
kate.shumate@ucsf.edu  
Chief of Staff, Director of Administration  
University of California, San Francisco  
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<td>Security Checked</td>
<td>6/7/2022 10:22:36 AM</td>
</tr>
<tr>
<td>Completed</td>
<td>Security Checked</td>
<td>6/8/2022 8:40:12 AM</td>
</tr>
<tr>
<td>Payment Events</td>
<td></td>
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</tr>
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