Policy for Obtaining Informed Consent of Potential Patients for Therapeutic and Non-Therapeutic Oncology Clinical Trials

Purpose

This policy defines research personnel who may obtain consent (Key Personnel) and describes the steps required by the Key Personnel of a therapeutic and non-therapeutic clinical trial for obtaining informed consent from the study participant who is potentially eligible to participate in a clinical trial at the Helen Diller Family Comprehensive Cancer Center (HDFCCC). This policy applies to both therapeutic and non-therapeutic trials, regardless of the type of sponsor.

Background

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

The informed consent form (ICF) is one part of the larger process of informed consent that occurs between the potential study participant and Key Personnel on the research team. The written contents in the ICF are governed by Federal Regulations, and by institutional policy and guidance. The ICF and any required revisions to the original must be approved by the UCSF Institutional Review Board (IRB) as the IRB of record. The approved versions serve as a reference for monitoring and auditing the conduct of informed consent throughout the life of the study.

An ICF must be signed by the study participant and the Key Personnel before any study specific procedures can be conducted.

References

45 CFR 46.116
21 CFR 50
UCSF HRPP website: http://irb.ucsf.edu

Definition of Key Personnel

Key Personnel are defined as the Principal Investigator, the Co-Investigator, or a Sub-Investigator (i.e., MD or NP) employed by the research program that are listed as “Key Personnel” in the UCSF IRB protocol application and 2) on the protocol specific Delegation of Responsibility form (Attachment 1) with the role of obtaining consent. For therapeutic trials in the HDFCCC, the Clinical Research Coordinator (CRC) and the Registered Nurse (RN) are not considered Key Personnel for obtaining consent, including re-consent.
Non-therapeutic, minimal risk trials (including germ-line tissue banking trials) involve the collection of blood and urine specimens or archival tissue from a previously obtained biopsy or from tissue collected at Standard of Care (SOC) biopsies. The CRC or RN requesting approval for consenting privileges for these non-therapeutic minimal risk trials would need to submit a request for approval to the Research Personnel Manager, Manager of the DSMC, and Regulatory Affairs Unit Manager with the protocol and ICF for the clinical trial in question. The request for approval should be sent to the Regulatory Affairs Unit Manager, Research Personnel Manager, and the Manager of the DSMC, and should include the following: protocol study number; UCSF IRB approved consent form; and the protocol. Once approval is granted, the CRC or RN would then be trained by the PI, co-PI, PPM, Lead CRC or the Education and Training Coordinator (ETC) on the following items: 8 basic elements of informed consent, ICF documentation requirements, HIPAA and Bill of Rights documents, short form consenting process, consenting responsibilities of Investigators for therapeutic trials, and the consenting responsibilities of CRCs for non-therapeutic trials. This training would be documented on the UCSF Non-Therapeutic CRC Consent Training Completion and Certification Statement document (see attachment 4). Additionally, the trained CRCs will be listed as KSP (Key Study Personnel) as a Sub-Investigator and their responsibilities for consenting will be outlined in section 3.1 of the UCSF IRB Application.

Procedures

1) Responsibilities of the Principal Investigator, the Co-Investigator, or a Sub-Investigator listed as Key Personnel.

   a) Patient Selection:
      • Determines that a study participant may be a candidate for a specific clinical trial.

   b) Document the Verbal Consent Process:
      • Discusses with the study participant/parent 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, and expected outcomes of this study, alternatives to participation, potential costs of research participation to the participant, and the right to refuse to participate.
      • Documents the consent process in the study participant’s study chart in the format recommended in Attachment 2 of this policy.

   c) Sign the California Experimental Bill of Rights, HIPAA Authorization, and the Informed Consent Form (ICF):
      • Contacts the CRC to obtain the California Experimental Bill of Rights document, the HIPAA Authorization document, and the most recent UCSF IRB-approved ICF. The Principal Investigator, the Co-Investigator, or a Sub-Investigator will ensure that the study participant/parent reviews and signs the California Experimental Bill of Rights document prior to review of the HIPAA Authorization form and ICF. Next, the Investigator will ensure that the study participant/parent reviews and signs the HIPAA Authorization form. The Investigator will then review the ICF item by item with the prospective study participant/parent. The study participant/parent will then sign the ICF after acknowledging that the trial and trial procedures have been presented in a manner that he/she understands and acknowledges their wish to participate during their
subsequent new study participant or follow-up appointment at the UCSF Helen Diller Family Comprehensive Cancer Center (HDFCCC) clinic, or if applicable, if they are hospitalized or are at a UCSF affiliate. The Investigator will document this consent process clearly in the study participant’s study chart. If the study participant/parent requires more time to review the ICF, the study participant/parent may further review the consent form at home. However, if the study participant/parent cannot travel back to the clinic to sign this consent prior to starting screening procedures due to extenuating circumstances or if the investigator finds it unnecessary for the study participant to have to return in-person to clinic, then the study participant/parent may sign the consent over the phone during a phone conversation with the investigator after all questions have been answered by the investigator. The study team should follow the process below (Telephone Consenting) for obtaining a signed copy of all documents.

- Telephone Consenting for therapeutic and non-therapeutic trials: The study team may send an electronic version of the clinical trial ICF, HIPAA (Health Insurance Portability and Accountability Act) Authorization form and the California Experimental Bill of Rights form to prospective study participants/parents for their review. Once the Investigator reviews the California Bill of Rights, HIPAA, and consent documents item by item with the prospective study participant/parent, and the study participant/parent acknowledges that all questions have been answered, then the consenting personnel will instruct the patient to sign each document. All elements of consent will be reviewed over the phone and documented by the investigator. In general, it is not required for these prospective study participants/parents to travel to the clinic prior to consenting for these trials. After consent is obtained with an Investigator, the study participant/parent will then fax, mail or send a scanned pdf of this consent, Bill of Rights and HIPAA to the study team. The consent must be signed prior to performing any screening procedures by both the study participant/parent and the Investigator who had obtained consent for the study. The Investigator will document the consents clearly in APeX/study chart. The study participant/parent will then mail or bring this signed original consent documents with them to the clinic at their next scheduled visit. Should the study participant/parent forget to mail or bring in their original copies, then the study participant/parent must be re-consented during their clinic visit.

Consenting Requirements:
- The California Experimental Bill of Rights document must be signed first by the study participant/parent prior to signing the HIPAA and ICF documents. When the study participant/parent acknowledges that the trial and trial procedures have been presented in a manner that he/she understands and acknowledges they wish to participate, the study participant/parent will sign the consent and the PI, Co-Investigator, or Sub-Investigator signs the ICF as “person obtaining consent”.
- The Investigator will document in the study participant’s study chart the discussion and signing of this ICF.
- Follows the UCSF IRB’s Guidance in Attachment 3 of this policy for non-English Speaking patients.

- Additional HIPAA Guidance:
  The study participant/parent must personally sign and date the HIPAA form.
- The study participant/parent must initial all relevant options in Section C. If the study participant/parent does not consent to any of the options in Section C, the CRC should
d) Re-consent when there is a modification to the ICF is approved by UCSF IRB:

- The PI, Co-Investigator, or Sub-Investigator will receive the UCSF IRB approved one page summary of changes document from the Clinical Research Coordinator while waiting for the updated ICF to be approved by the UCSF IRB. As per the UCSF Policy of Newly Identified Risks for Research Participants, the verbal notification of each study participant/parent by the PI must be performed as per policy. Hence, for newly identified risks that are high as per the PI, the study participant/parent must be notified within 10 business days if the PI determines the risk/benefit ratio of the study is changed or the risk is significant or immediate. For newly identified risks that are deemed intermediate by the PI, the study participants/parents must be notified within 30 business days if the PI determines that the risk does not meet the definition of high risk, however, the new risk may impact the study participant's/parent's decision to continue to participate in the study. Finally, for newly identified risks that are considered low risk by the PI, the study participants/parents will be notified within 60 business days if the PI determines that the risk does not meet the definition of a high risk and the risk will only have a minor impact on the study participant's/parent's decision to participate in the study.

- The Investigator will review the summary of changes document with the study participant/parent.

- When the study participant/parent understands the changes and acknowledges they wish to continue participating in the study, the study participant/parent and the PI, Co-Investigator, or Sub-Investigator signs the summary of changes document.

- The clinician documents in the study participant's study chart the discussion of changes and the signing of this summary of changes document.

- If the study participant is in the follow-up portion of the trial and is unable to come to the clinic to sign the consent, then the study participant/parent may be consented on the phone during a phone conversation with the investigator, with the Investigator documenting the consenting process in the patient's study chart. The participant/parent will then mail the signed consent to the study team as per the telephone consenting process in section 1C of this policy.

- The study participant/parent must sign the revised ICF once it has been approved by the UCSF IRB; however, the study participant/parent is not required to sign the HIPAA and UCSF Experimental Subject's Bill of Rights document for the re-consent process.

- For re-consenting non-English speaking patients, the same UCSF IRB Guidance in Attachment 3 of this policy would be followed, namely the Investigator, with assistance from the translator, would consent the study participant/parent with the revised English version of this ICF and the Investigator and translator would then sign the revised English version of the ICF. The translator and the study participant/parent would sign the translated UCSF Experimental Subject's Bill of Rights document. However, the study participant/parent would not be required to re-sign the translated HIPAA document.

e) Additional guidance for consenting:

- Re-consenting study participants/parents on "renewed" ICFs that are updated from the annual Continuing Renewal process where only the UCSF IRB stamp has been updated will not be required.

- Additionally, reconsenting will not be required for minor changes to the ICFs that do not involve patient safety (i.e., pagination corrections, grammatical errors, etc.).
University of California, San Francisco  
Helen Diller Family Comprehensive Cancer Center  
Policy and Procedure

2) Responsibilities of the Clinical Research Coordinator:

a) When contacted by the PI, Co-Investigator, or Sub-Investigator:
- Provides a copy of the most current UCSF IRB-approved version of the ICF, UCSF Experimental Subject’s Bill of Rights and HIPAA authorization for this study to them.
- Describes the visit schedule to the study participant/parent.
- Reviews with the study participant/parent their understanding of what they will do while on study and refer any questions or concerns about the science and conduct of the study back to the investigator before proceeding.
- Schedules a return appointment for the study participant/parent, if the study participant/parent is taking the consent home to read and share with significant others.
- If the study participant/parents do not speak English and no ICF is available in the study participant/parent’s native language, the CRC will:
  - arrange for a UCSF Interpreter to be present at the meeting, and at subsequent meetings regarding study participation.
  - provide the Investigator with a UCSF Experimental Subject’s Bill of Rights in the study participant/parent’s native language
  - provide the translated HIPAA authorization, if a copy is available in the study participant/parent native language.
  - ensure UCSF IRB policy on correct signing of the consent for non-English speaking patients is followed. (Attachment 3)

b) Distribute copies of the ICF after the consent has been signed:
- Makes 3 copies of the signed ICF, signed UCSF Experimental Subject’s Bill of Rights and signed HIPAA authorization;
- or 4 copies if the study participant will be treated in the infusion center or CCRC/PCRC.
- Gives the study participant/parent a copy of the signed ICF, signed UCSF Experimental Subject’s Bill of Rights, and signed HIPAA authorization to take home.
- Records the study participant’s UCSF medical record number on the copies of the signed ICF, signed UCSF Experimental Subject’s Bill of Rights, and signed HIPAA authorization.
- Files the original signed ICF, signed UCSF Experimental Subject’s Bill of Rights, and signed HIPAA authorization in the study participant’s study chart as determined by the unit.
  - Files one copy of each document in the study participant’s study chart and uploads into APeX.
  - Takes a signed copy to the Infusion Center or CCRC/PCRC at the time of the first infusion. (when applicable)
- Registers study participant into OnCore® CTMS, along with ICF signing date and version date of ICF.
- Tracks re-consent of study participants for the Principal Investigator.

Alternate Procedures

There are no alternate procedures to the HDFCCC policy of Key Personnel who can obtain consent.
Policy Approval

Guidance Document Approval

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

Kate Shumate
Director, Scientific Programs Administration
Helen Diller Family Comprehensive Cancer Center
Investigational Trials Resource

Thierry Jahan, MD
Professor of Medicine
Chair, Data and Safety Monitoring Committee
UCSF, Helen Diller Family Comprehensive Cancer Center

Eric Small, MD
Director, ITR
Helen Diller Family Comprehensive Cancer Center
Chief, Division of Hematology/Medical Oncology
Delegation of Responsibility & Staff Signature Log

<table>
<thead>
<tr>
<th>Protocol Title:</th>
<th>UCSF IRB Approval #:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol Number:</td>
<td>Sponsor:</td>
</tr>
<tr>
<td>Facility:</td>
<td>Investigator:</td>
</tr>
</tbody>
</table>

Use One Vertical Column for Each Designee

<table>
<thead>
<tr>
<th>Designee (full name)</th>
<th>Title &amp; Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delegated Activity (see codes)</td>
<td></td>
</tr>
<tr>
<td>Designee Signature &amp; Dates</td>
<td></td>
</tr>
<tr>
<td>Designee Initials (signed)</td>
<td></td>
</tr>
</tbody>
</table>

Activity Codes:
- 01: Informed Consent
- 02: Perform Physical Exam
- 03: Subject Interviews
- 04: CRF Entries
- 05: Drug Dispensing
- 06: Drug Administration
- 07: Drug Reconciliation
- 08: Adverse Event Assessment
- 09: Adverse Event Documentation/Reporting

Investigator’s Authorization: I hereby delegate the above significant research-related duties to the following persons and understand that the overall responsibility for conduct of the research remains with me.

1Investigator’s Signature:
Date:
1Investigator must re-sign this log with any change in key research personnel

Source: [http://www.research.ucsf.edu/chr/Qip/hsppQipTools.asp](http://www.research.ucsf.edu/chr/Qip/hsppQipTools.asp)
Attachment 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).

The following points were discussed and must be yes:

☐ Yes ☐ No The California Experimental Subject’s Bill of Rights and HIPAA documents have been reviewed with the study participant/parent prior to signing the consent form. Note: 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 Authorization form and the ICF.
☐ Yes ☐ No Alternative treatment to the study participant’s disease in lieu of clinical trial participation, has been discussed with the study participant/parent.
☐ Yes ☐ No Possible risks and possible side effects of participation in this clinical trial have been discussed.
☐ Yes ☐ No The study participant/parent has been given the opportunity to ask questions.
☐ Yes ☐ No The study participant/parent 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 ☐ No The study participant/parent has been given a copy of signed consent form, signed Bill of Rights, and signed HIPAA Authorization form.
☐ Yes ☐ N/A A copy of the prohibited medication list has been provided to the study participant/parent. This list has been reviewed with the study participant/parent. The study participant/parent has been instructed to provide this list to any health care providers that may prescribe medication for the study participant outside of this clinical trial.

Comments:

PRINT THE NAME OF PERSON OBTAINING CONSENT: 

__________________________________________

KSP (MD/NP) Date signed

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Attachment 3  Obtaining and Documenting Informed Consent for Non-English Speaking Patients:

UCSF IRB policy listed below for reference; please check their website in the event you have a subject in this category. Source: http://research.ucsf.edu/chr/Guide/chrG_SpSpeakWrite.asp#4http://irb.ucsf.edu

Background

The San Francisco Bay Area is a diverse region, and you likely will encounter eligible subjects with limited English proficiency when recruiting locally. The governing principles of human subject research require that investigators a) not exclude subjects based solely on their inability to read, speak or understand English and b) find a way to communicate with subjects to ensure that consent is voluntary and informed.

Federal regulations from OHRP and FDA state that informed consent “shall be in language understandable to the subject or the representative” and describe how consent is to be documented. California state law also requires the Experimental Subject's Bill of Rights be provided “in a language in which the subject is fluent” to individuals participating in a biomedical study.

Two Methods of Consent: Preferred and Short Form

If you anticipate that your study may enroll non-English speaking subjects, explain in the IRB Application which method(s) of consent you will utilize.

Preferred Method: The preferred method is to provide consent forms written in the subject’s language. The researcher obtains and submits written translations of the IRB-approved consent form(s) after the study is approved.

Short Form Method: This method only should be used for the occasional and unexpected enrollment of a non-English-speaking subject in a study for which there is no translated consent form in the subject’s language. Instead of signing the English-language consent form (which the subject does not understand), the subject signs a "short form consent" — the Experimental Subject’s Bill of Rights in his/her language. Routine use of this method is strongly discouraged by the University and federal regulators.

Reminders for Both Methods

The IRB must approve the enrollment of non-English speakers in your study.

Describe the consent process for non-English-speaking subjects in the IRB Application.

Use a qualified interpreter (not a family member) to facilitate the consent discussion.
Explain how you will continue to communicate with non-English speakers throughout the study.

It is the investigator’s responsibility to judge the subject’s comprehension of the consent info.

Contact the IRB if the Experimental Subject’s Bill of Rights is not available in the subject’s language.

Preferred Method

The IRB strongly encourages you to use the preferred method and provide subjects with a written consent document in language they can understand. In particular, use the preferred method if you anticipate a substantial portion of eligible subjects will be non-English-speakers.

A qualified interpreter should facilitate the consent process. If you are conducting a biomedical study, provide the subject with a copy of the Experimental Subject’s Bill of Rights in a language in which the subject is fluent. If HIPAA applies to your study, review information on obtaining HIPAA authorization.

IRB Review Process for Translated Consent Materials (Preferred Method)

Step 1. PI requests approval to enroll non-English speakers and submits English-language consent and other study documents

Step 2. The IRB reviews and approves this request

Step 3. PI obtains translations and submits them as an administrative modification

Preferred Method Documentation

<table>
<thead>
<tr>
<th>Translated Informed Consent</th>
<th>Experimental Subject’s Bill of Rights</th>
<th>HIPAA Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>(IRB Approved)</td>
<td>(Download in the subject's language – contact the IRB for add'l translations)</td>
<td></td>
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</tbody>
</table>

Signatures required:

1. Subject
2. Person obtaining consent

Document in the research file that an interpreter was used.

Signatures required: None

Give a copy to the subject.

Only required for biomedical studies when using the preferred method.

If you need to obtain HIPAA authorization from the subject, follow the instructions below.
Give a signed copy to the subject.

Short Form Method

The “short form” method for obtaining informed consent should only be used for the occasional and unexpected enrollment of a non-English-speaking subject in a study for which there is no translated consent form in the subject’s language. The University and federal regulators strongly discourage routine use of the short form method.

Short Form Consent Method Steps:

Step 1. PI requests IRB approval to enroll non-English speakers using the short form consent method

Step 2. A qualified interpreter helps present the consent info and facilitates the consent discussion

Step 3. The subject signs the short form consent doc, the Bill of Rights in the subject's language

Short Form Method Documentation

<table>
<thead>
<tr>
<th>English-Language Informed Consent (IRB Approved)</th>
<th>Experimental Subject’s Bill of Rights</th>
<th>HIPAA Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signatures required:</td>
<td>Download in the subject's language - contact the IRB for add’l translations</td>
<td></td>
</tr>
<tr>
<td>1. Person obtaining consent</td>
<td>The Bill of Rights written in a language in which the subject is fluent serves as the “short form.”</td>
<td></td>
</tr>
<tr>
<td>2. Witness</td>
<td>Signatures required:</td>
<td>If you need to obtain HIPAA authorization from the subject, follow the instructions below.</td>
</tr>
<tr>
<td>Document in the research file that an interpreter was used.</td>
<td>1. Subject</td>
<td></td>
</tr>
<tr>
<td>Give a signed copy to the subject.</td>
<td>2. Witness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Write a statement on the Bill of Rights that the elements of consent were presented orally.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Give a signed copy to the subject.</td>
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</tbody>
</table>
Hint: The subject and person obtaining consent sign the document that they each understand – that is, the subject signs the Bill of Rights in his/her native language and the person obtaining consent signs the English consent form.

Short Form Method FAQs

Who can sign as a witness using the short form method?

The witness is signing to document that an oral presentation in a language the subject can understand took place. The witness can be the interpreter or another person (other than the person obtaining consent) who witnessed the involvement of an interpreter.

How do I add the short form signature lines to the Experimental Subject’s Bill of Rights?

If necessary, add the required signature and date lines by hand to the form. Each signature line should have its own date. In addition, write or type a statement on the Bill of Rights that the elements of consent from the consent form were presented orally.

Does the interpreter need to translate the consent form verbatim?

The interpreter does not need to “read” an entire consent document to the potential subject. As in a normal consent process, the person obtaining consent should ask the interpreter to provide the subject with key information about the study (e.g. the elements of informed consent described on the Bill of Rights).

Obtaining HIPAA Authorization

If you need to obtain HIPAA authorization from a non-English-speaking subject, follow the instructions based on whether a translated UCSF HIPAA Authorization form is available in the subject’s language.

A translated UCSF HIPAA Authorization form is available in the subject’s language.

A translated UCSF HIPAA Authorization form is NOT available in the subject’s language.

The subject is being enrolled at the SF VAMC

Providing a Qualified Medical Interpreter

The medical and technical information discussed during the initial consent discussion and throughout the study can be very complex. It should be communicated to non-English speaking subjects through an interpreter with training and understanding in medical terminology, as well as a professional commitment to maintain strict confidentiality.
Although it may be necessary in some rare cases to have a bilingual family member or staff person serve as a medical interpreter, keep in mind the following issues.

- The routine use of ad hoc interpreters should be avoided.
- Children should not be asked to serve as an interpreter.
- Complex ideas and treatment regimens may demand that a trained professional be employed.
- Issues of privacy must be considered if family members are asked to translate.

**Contacting In-Hospital Medical Interpreter Services**

UCSF Medical Center

San Francisco General Hospital

**Working Effectively with Medical Interpreters**

Topics to discuss with interpreters

Professional organizations

**Translating Study Documents**

After the IRB reviews and approves the consent documents and other study materials (such as advertisements or questionnaires), the investigator is responsible for having these documents translated.

The investigator is responsible for the cost of translating study materials. These costs may be quite high. Include the costs of written translations, as well as medical interpreter services, on grants and contracts. Industry sponsors often are willing to pay these costs.

Translation companies (Note: The IRB does not endorse any translation service.)

Validating translations

Page last updated: Mar 21, 2016
Attachment 4: CRC/RN Consent Training Completion and Certification Documentation
For Non-Therapeutic Trials

All non-therapeutic clinical trials must be reviewed and approved by the Regulatory Affairs Unit
Manager, Research Personnel Manager, and Data and Safety Monitoring Committee Manager, in
conjunction with training and guidance from the Education and Training Coordinator, before the
Research Coordinator/ RN is granted consenting privileges.

The following Informed Consent topics were covered:

- 8 basic elements of Informed Consent
- Additional elements
- Informed Consent Form documentation requirements
- HIPAA and Bill of Rights
- Short Form consenting process
- Consenting responsibilities of Investigators for therapeutic trials
- Consenting responsibilities of CRCs/RNs for non-therapeutic trials

Completion Date: ____________________________

After completing the above trainings, scan and send a copy of this completed form as a PDF to the ITR
Education and Training Coordinator.

Certification Statement: I hereby certify that I have completed the HIPAA training modules
above, and agree to adhere to the HIPAA patient privacy and security regulations, as well as
related UCSF policies and procedures.

Employee's Name: ____________________________

Employee's Signature and Date: ____________________________

Principal Investigator's Name: ____________________________

Principal Investigator's Signature and Date: ____________________________

Lead CRC, or Education and Training
Coordinator
Name: ____________________________

Title: ____________________________

Signature and Date: ____________________________