Human Research Protection Program Training

Preparing Consent Documents and the Consent Process
Goals

• What’s the purpose of consent forms and when they are needed?
• Writing techniques for clarity and readability
• Unique consenting issues for vulnerable populations and special situations
• Consenting process
• Resources available to help write consent forms
Why Consent?
Why Consent?

• Ethics:
  – Belmont Report: “subjects … be given the opportunity to choose what shall or shall not happen to them.”
  – Voluntary consent for research participation
  – To be voluntary, consent must be informed

• Federal Regulations:
  – Require signed consent from participants (some exceptions)
  – Consent process
When Is Written Consent NOT Required?

**Exception #1**

- **Waiver of signed consent (verbal consent and/or information sheet)**
  - Allowed in minimal risk research in which:
    - confidentiality is main risk or
    - signed consent is not usually required
When Is Written Consent NOT Required?

Exception #2

• Waiver of all consent – the CHR can waive consent if:
  - The research is minimal risk,
  - The waiver will not adversely affect subjects,
  - It’s impracticable to obtain consent, and
  - Provide subjects with additional pertinent information after participation (when applicable).
Top CHR Consent Form Issues

- **#1** Required elements of consent are missing
- **#2** Too technical
- **#3** Consent form is not consistent with other study documents
- **#4** Required UCSF template language is not used
- **#5** Formatting Issues
- **#6** Special populations or situations are not considered
#1 Elements of Consent Are Missing

- There are 8 Required Elements of Consent (45 CFR 46) (21 CFR 50):
  - Statement that the study involves research
  - Purpose, procedures and experimental aspects
  - Time commitment
  - Reasonably foreseeable risks and benefits
  - Alternatives and confidentiality of records
  - Compensation for participation
  - Whom to contact for questions and what to do in case of injury
  - Voluntary participation

**TIP:** In general, also include this info in an info sheet or verbal script.
#1 Elements of Consent Are Missing

- Additional Elements of Consent – add when applicable
  - Approx. # of subjects
  - Unforeseeable risks, e.g., if subject becomes pregnant
  - Participation may be terminated without the subject’s consent
  - Additional costs to subjects
  - What happens if the subject withdraws
  - Significant new findings will be provided
  - *Clinical Trials Only*: A statement that the study will be listed on ClinicalTrials.gov (FDA requirement)
#1 Elements of Consent Are Missing

- **To ensure that you include all necessary elements of consent …**
  - Use the CHR consent form template that best fits your study
  - Look at the sections and make a list of the information you need for each section
    - Review the “Section-by-Section Discussion” website guidance and Consent Form Requirements handout if you’re not sure what info to include.
  - Insert relevant info and remove *italicized instructions*.
#2 Consent Language is Too Technical

- **How can you simplify consent forms?**
  - Use everyday vocab – 8th-grade level is ideal
  - Remove unnecessary “doctor-speak”
  - Short sentences/paragraphs
  - Focus on what’s most important and avoid repetition
  - Use acronyms sparingly
  - Be consistent with terminology
  - Include pictures/graphs/charts
  - Use active verbs
Everyday Vocabulary

• **Complex**: The purpose of this study is to determine the nature and characteristics of immune cells and tumor cells in patients treated with concomitant cisplatin-based chemotherapy regimens and high-dose radiotherapy.

• **Simple**: We want to study people who will get both chemotherapy and radiation. We want to see what the treatment does to their tumors and their immune systems.
What Are Some Alternate Everyday Terms?

- Baseline visit
- Efficacious
- Chronic
- Adverse event
- Feasible
Remove Unnecessary “Doctor Speak”

- Subjects may not be able to comprehend (or care about) technical background.

- **Technical:** The study drug belongs to a class of drugs called opioid receptor antagonists, which help patients overcome urges to abuse alcohol by blocking alcohol’s euphoric effects.

- **Simplified:** The study drug helps reduce your craving for alcohol.
  - Remember: You can always give more background info during the consent discussion.
Short Sentences – Short Paragraphs

Complex: We are asking you to participate in this study, which is evaluating pregnant women’s attitudes about birth control by asking them to complete a 1-hour interview during which they will be asked about their attitudes toward different birth control methods, as well as their past contraceptive choices.

Simple: We are studying pregnant women’s attitudes about birth control.

If you participate in this research study, we will interview you for about 1 hour. We will ask how you feel about different types of birth control. We also will ask what kind of birth control you used in the past.
Focus on What’s Most Important

• During the focus groups, you will be asked to share information about your diet, weight, smoking history, drinking habits, exercise routine, family history, blood pressure levels, and sodium intake.

• What is a more focused revision of the sentence above?
Avoid Unnecessary Repetition

• In the discussion of procedures, avoid unnecessary repetition.

• In the discussion of risks, avoid unnecessary repetition.

• In the discussion of benefits, avoid unnecessary repetition.

• In the discussion of confidentiality, avoid unnecessary repetition.
Use Acronyms Sparingly

- Ideally only use acronyms that study participants commonly use/understand.
- Spell out/explain acronyms before using them.
- Consider the audience
- Avoid too many acronyms in one consent:

Participants with PTSD (Posttraumatic Stress Disorder) who enroll in this study will receive a cognitive-behavioral therapy (CBT) known as Stress-Inoculation Training (SIT) or an SSRI (selective serotonin reuptake inhibitor) drug. This study is being done because doctors want to know whether SIT CBT or an FDA-approved SSRI is more effective in treating PTSD.
Avoid Exculpatory Language

• **Definition:** Language where the participants waive or appear to waive their rights, or release or appear to release the PI, sponsor, institution, or its agents from liability for negligence.

• **Example:** I understand that UCSF or the sponsor is not liable for any injuries I sustain during exercise testing.

• **Remember:** The consent form is **not** a contract.
Use Consistent Terminology

- **Drug/Device Names** – e.g. use either the generic or commercial name throughout
- **Procedures or Tests**
- **Locations or Room Names**
Include Pictures/Graphs/Charts

<table>
<thead>
<tr>
<th></th>
<th>Week 1</th>
<th>Week 4</th>
<th>Week 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interview and Questionnaires</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Blood Draw</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Physical Exam</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Hints for Simplifying Consent Language

- If there is a sponsor’s template, read it and highlight terms or sentences that are confusing.
- Ask someone outside your field to read the consent form.
- Modify your approved consent form if subjects find certain sections confusing.
- Proofread!
Practice Sentence 1

• You understand that by choosing to enroll in this study, you will be not be excluded from taking other prescribed or over-the-counter treatments for your condition, except for other non-steroidal anti-inflammatories (NSAIDs).
Practice Sentence 2

- During this study, we will collect qualitative data through semi-structured interviews that will help us investigate the medical and social consequences of amphetamine use in youth ages 13-18.
#3 Consistency With Other Study Docs

- Compare the schedule of events, confidentiality info, benefits, risks, etc. with the CHR application, sponsor’s protocol, advertisements, etc.

- Explain experimental vs. standard of care.

- Be very careful if you are reusing an old consent form!
#4 Required UCSF Wording is Missing

- **Treatment and Compensation for Injury**
  - Must be used verbatim – sponsors can add 1-2 sentences, but can only say what they will cover.

- **“Consent” section**
  - Experimental Subject’s Bill of Rights -- “You have been given. …”
  - HIPAA -- “You will be asked to sign a separate form authorizing …”
  - “Participation in research is voluntary. …”
  - Person obtaining consent
  - Dated signature lines
#5 Technical Requirements

- Leave **1.25” top margin** to accommodate approval stamp in iRIS.

- Upload **Word documents**

- When revising, revise existing documents instead of adding them as new

- Use a **readable font size** (12 point)
#6 Considering Special Situations or Populations

- **Children** – assent and parental permission
- **Non-English Speaking Subjects**
- **Surrogate Consent**
- **VAMC Patients**

**NOTE:** You must obtain approval to include these groups before they can be enrolled.
Children: Assent and Parental Permission

- **Parental permission** = Parents/guardians give legal permission by signing the consent form
- **Assent** = Permission from children to participate

### Table of CHR Consent Guidelines for Children by Age Group

<table>
<thead>
<tr>
<th>Age of Minor</th>
<th>Assent Form Recommended</th>
<th>Separate Parental Permission Form Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infant – Age 6</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Ages 7-12</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Ages 13-17 (Option A)</td>
<td>Yes</td>
<td>No [add line to adolescent assent form for parent(s) to sign]</td>
</tr>
<tr>
<td>Ages 13-17 (Option B)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Note: Option B is for a very complex protocol and/or involving adolescent subjects whose medical condition demands a simpler form than the adult’s form.
Assent and Parental Permission

• If a study involves subjects ages 1-25, how many assent and consent forms would be required?
Assent

• If child does not assent, should not be enrolled in the study.

• CHR may waive assent if …
  – Children lack cognitive ability to assent; or
  – The research holds out a prospect of direct benefit that is important to the child’s health and is available only in the context of the research.
Parental Permission

• How many parents must sign the consent form?
  
  – 1 parent if research is …
    • Minimal Risk or More Than Minimal Risk with Prospect of Direct Benefit (Categories 404 or 405)

  – 2 parents if the research is …
    • Greater than Minimal Risk with No Direct Benefit to Subject (Category 406 or 407)
      – Unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child.
Waiving Parental Permission

- Parental permission can be waived if the minors are …
  - Emancipated or self-sufficient minors
  - Seeking care for certain services, such as the prevention or treatment of pregnancy
  - See HRPP website or call for details.
    - May depend on local laws.
Consenting Non-English Speaking Subjects

#1 Preferred Method – Use this method if many potential subjects are non-English speakers.

– Obtain written translations of the consent form(s) *after the study is approved* and submit to CHR for approval.

– Qualified interpreter facilitates the consent discussion.
### Preferred Method Documentation

<table>
<thead>
<tr>
<th>Translated Informed Consent</th>
<th>Experimental Subject’s Bill of Rights</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHR Approved</td>
<td>Download in the subject's language</td>
</tr>
</tbody>
</table>

**Signatures required:**

1. Subject
2. Person obtaining consent

Document in the research file that an interpreter was used.

Give a signed copy to the subject.

**Signatures required:**

None

Give a copy to the subject.
Consenting Non-English Speaking Subjects

#2 Short-form Method – Only use for the occasional and unexpected enrollment of a non-English-speaking subject.

– A qualified interpreter verbally presents the consent form info to the subject and facilitates the consent discussion in the subject’s language.

– Experimental Subject’s Bill of Rights serves as the “short form.”
## Short Form Method Documentation

<table>
<thead>
<tr>
<th><strong>English-Language Consent</strong></th>
<th><strong>Experimental Subject’s Bill of Rights</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>CHR Approved</td>
<td>Download in the subject's language</td>
</tr>
<tr>
<td><strong>Signatures required:</strong></td>
<td><strong>Signatures required:</strong></td>
</tr>
<tr>
<td>1. Person obtaining consent</td>
<td>1. Subject</td>
</tr>
<tr>
<td>2. Witness</td>
<td>2. Witness</td>
</tr>
</tbody>
</table>

Document in the research file that an interpreter was used.

Give a signed copy to the subject.

Write a statement on the Bill of Rights that the elements of consent were presented orally.

Give a signed copy to the subject.
Who Can Sign as a Witness?

- Witnesses that an oral presentation in the subject’s language took place.
- Interpreter or another person who witnesses the involvement of an interpreter.
  - Does not need to speak the subject’s native language.
  - Not the person obtaining consent or other study staff.
Using Interpreters

• Who is a qualified interpreter?
  - Medical interpreters
  OR
  - Fluent investigators or knowledgeable Key Personnel
  - *Strongly discourage* using bilingual family members as medical interpreters.

• Interpreting via phone is OK
Surrogate Consent

- Used to enroll subjects who are unconscious or lack adequate decision-making capacity.

- PI submits a plan to CHR about how the study team will assess the decision-making capacity of subjects.
Surrogate Consent (con’t)

Steps to follow:

• Study team identifies the highest level surrogate using the Surrogate Priority Tree in UCOP guidance.
  – Emergency research: Priority does not matter.

• The surrogate completes and signs the “Self-Certification of Surrogate Decision Makers for Participation in Research” form as an attachment to the informed consent document. (Can be faxed.)

• If subject expresses resistance or dissent, do not enroll.

• If subject regains capacity, consent the subject at that time to continue study and or/use data
VAMC Consent Documents

- **VA-specific documents/language:**
  - VA 10-1086 template
  - VA HIPAA Authorization form
  - Treatment and Compensation for Injury statement

- Follow other guidelines here: www.research.ucsf.edu/chr/VA/chrVA.asp

**Reminder:** The VA Research & Development Committee must approve your study before you can begin at the VA.
The Consent Discussion

What are the components of consent?

- **Decision-making capacity**
  - Are subjects able to understand nature and consequences of decision?

- **Voluntary choice**
  - Free from coercion and undue influence

- **Information disclosure**
  - Risks, benefits, burdens, alternatives, etc.

Verbal explanation and dialogue with the subject is important!
The Consent Discussion

• Who should conduct the discussion?
  – “Qualified” investigators or Key Study Personnel
    • May depend on study and complexity
    • Identify individuals on the CHR Application
    • Must take human subjects training through CITI

  – Investigator should be available to answer questions, when needed
The Consent Discussion

- Do **not** read the consent form verbatim.
- Most critical info to include in the discussion:
  - **Purpose** – Why are we doing this study? Why are you being asked to participate?
  - **Procedure** – What, when, where, and how?
  - **Alternatives** – What other options are available?
  - **Risks** – What are commonly reported risks? Any serious or unknown risks? How will risks be minimized?
  - **Benefits** – Benefits to subjects and society? Be objective.
  - **Questions** – Who to contact for more information or if injured?

- For details, see Consent Process Quick Guide
The Consent Discussion

• Other Topics to Cover:
  – Confidentiality – How will you keep the subject’s private info secure? Will it be shared outside UCSF?
  – Financial Issues – What costs will the subject/insurance need to cover? When/how will subjects receive payments?
  – Discontinue – What should the subject do to withdraw from the study?

• Therapeutic Misconception: If treatment study, distinguish goals of research vs. goals of regular medical care.
The Consent Discussion

• How can you ensure understanding?
  – Make a list of important info from consent form to help guide your discussion.
    • Or use a consent checklist (see handout).
  – Ask subject to repeat his/her understanding of your words.
  – Ask questions throughout the process.
    • Just so we’re on the same page, can you tell me what this research is about?
    • Why did you decide to volunteer for this study?
    • Can you explain to me what you’ll be asked to do during the study?
    • What questions do you have?
Consent Documentation

- Consent *before* subjects undergo any screening procedures
- Sign the currently approved consent form!
  - Download the stamped copy from iRIS.
  - Subjects should sign and date the consent form themselves.
Consent Documentation

• **Give a copy, keep a copy:** Keep the original in your research files.

• **Research file:** Document when the consent discussion took place and any issues
  – Include consent checklist, if used.

• **Medical record:** Include a copy when …
  – Study may affect the subject’s health/treatment, and
  – It would be helpful to share this info with care providers who may not know that the subject is/was on study.
Add’l Forms: HIPAA Authorization

- **Consent form** = agreement to participate in the study
- **HIPAA Authorization** = allows researchers/UCSF to access, use, create, or disclose the individual's protected health information (PHI) for research purposes
  - Examples: Obtain HIPAA authorization if …
    - You add research results to the subject’s medical record.
    - You abstract data (e.g. medical history, clinical test results, etc.) from the subject’s health record for research purposes.
HIPAA Authorization (con’t)

• If HIPAA applies to your study …
  – Subjects must sign a research HIPAA authorization.
  – Do not need to submit to the CHR.
  – Keep a copy of the signed authorization.
  – Put a copy in the medical record, if applicable.
  – Include HIPAA-specific language in the “Consent” section of the consent form.

Check your approval letter if you’re not sure if HIPAA applies!
HIPAA and Non-English Speakers

- UCSF HIPAA Authorization form is now available in 20 languages

- If a translated form is available:
  - Subject signs the translated version.
  - An interpreter should be available to speak with the subject, but does not need to sign the form.
  - Document that an interpreter was available in research file.

- If a translated form is not available:
  - An interpreter verbally presents the English form.
  - The subject, interpreter, and a separate witness sign the form.
Add’l Forms: Experimental Subject’s Bill of Rights

• Give a copy to subjects in biomedical studies.
• Does not need to be signed.
• Document that you gave the Bill of Rights (BoR) to each individual subject:
  – Keep a copy of the BoR in the subject’s study file with the consent and HIPAA forms;
  – Write a note that the subject received the BoR on the consent form (study file copy); or
  – Write a note in the subject’s research record.
Summary

• **Use HRPP Resources**
  – Start with the HRPP guidance, samples and templates

• **Keep it simple**
  – Everyday vocabulary
  – Short sentences and paragraphs
  – Use HRPP recommended wording, especially if sponsor’s or group’s wording is twice as long and twice as legalistic

• **Make sure to document consent appropriately and obtain all necessary signatures**
Questions?

• Contact the CHR Office and ask the Analyst of the Day
  • Phone: 415-476-1814
  • E-mail: chr@ucsf.edu

• Check our website for more consent guidance and templates:
  www.research.ucsf.edu/CHR