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Human Research Protection Program Training

Preparing Consent Documents and the Consent Process

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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

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Why Consent?

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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

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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

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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).

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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

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#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

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#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)

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#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.*

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#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

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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.

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What Are Some Alternate Everyday Terms?

- Baseline visit
- Efficacious
- Chronic
- Adverse event
- Feasible

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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.

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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.

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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?**

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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.

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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.

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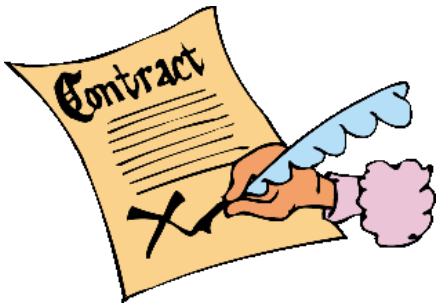
Avoid Exculpatory Language

- **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 <u>not</u> a contract.**



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Use Consistent Terminology

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

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Include Pictures/Graphs/Charts

	Week 1	Week 4	Week 8
Interview and Questionnaires	X	X	X
Blood Draw	X		X
Physical Exam	X		

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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!

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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).

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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.

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#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!**

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#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

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#5 Technical Requirements

- Leave **1.25" top margin** to accommodate approval stamp in iRIS.
- Upload **Word documents**
- When revising, revise existing documents instead off adding them as new
- Use a **readable font** size (12 point)

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#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.

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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

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

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.

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Assent and Parental Permission

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

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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.

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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.

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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.

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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.

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Preferred Method Documentation

Translated Informed Consent CHR Approved	**Experimental Subject's Bill of Rights** Download in the subject's language
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. 

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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."

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Short Form Method Documentation

English-Language Consent CHR Approved	**Experimental Subject's Bill of Rights** Download in the subject's language
Signatures required: 1. Person obtaining consent 2. Witness Document in the research file that an interpreter was used. Give a signed copy to the subject.	**Signatures required:** 1. Subject 2. Witness Write a statement on the Bill of Rights that the elements of consent were presented orally. Give a signed copy to the subject.

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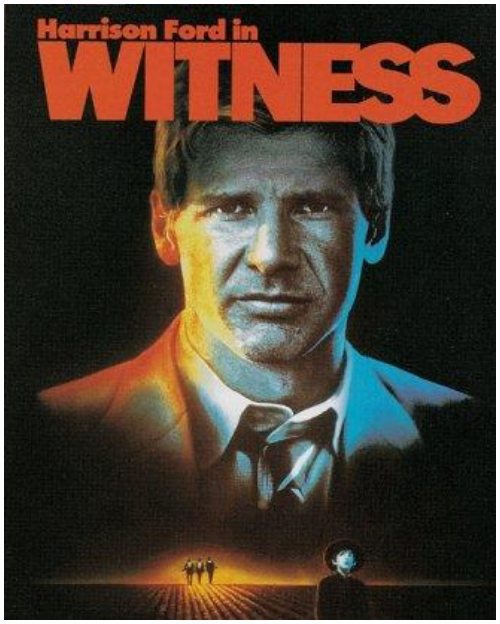
Who Can Sign as a Witness?

- 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.



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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**

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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.

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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

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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.

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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!

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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

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The Consent Discussion

- **Do <u>not</u> 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**

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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.

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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?*

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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.

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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.

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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.

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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!

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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.
  - A 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.

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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.

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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**

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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

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