Published on *UCSF Institutional Review Board* (http://irb.ucsf.edu)

Consent Form Guidelines and Suggested Wording

General Guidelines

Ensure your consent document follows these general guidelines:

Use the IRB consent form templates

There are several consent form templates [1] customized for different types of research and subject groups. Find the template/s that most closely fit your research and use them as a guide for formatting, organization of sections and standard statements.

Write at an eighth-grade reading level and use lay language vs. medical terminology

Write the consent document at the most likely level of understanding of the subject population?in general, an eighth-grade reading level. Use everyday vocabulary and simple sentence structure throughout.

Replace or define scientific or technical terms in lay language. For example, use "blood draw" instead of "venipuncture." See the **NCCN Informed Consent Language Database** [2] for standardized lay language descriptions of risks and events in clinical research.

The initial written description of the study should be simple and straightforward, so that subjects will have an easily understood consent form to take home. You can always verbally describe the study in more detail or using more scientific language during the consent conversation (if appropriate).

Avoid legalistic language

Avoid legal-sounding language, such as "You hereby agree," "You certify that," "You, the undersigned, do acknowledge that," or ?You understand that.?

Use the correct forms for parental permission and child assent

In research with children, considerations regarding consent ? both process and documentation ? become more complex than with adult subjects. See IRB guidance on Children and Minors in Research [3] for information about the documentation needed for consenting children and parents, and use the Sample Consent and Assent Forms [1] for examples of how to write age-appropriate forms.

Give each consent a unique name in iRIS

When uploading consent forms in iRIS, give each consent document a unique name so the IRB can easily identify the forms (e.g. Control Group Consent, Parental Consent, Optional Specimen Collection Consent, Information Sheet, etc.).

Include version dates and numbers in iRIS

iRIS also requires that each consent document have a version date and version number. Please note that everytime you modify [4] the consent document, iRIS will automatically update the version number. For example, if you add a revision to version 1.0, iRIS will then create version 1.1. We strongly suggest that you also update the version date when you modify the consent document. If you wish, you can include an internal version number or date in the footer. However, remember to update the date or number each time you revise the document.

Leave 1.25" upper margin for an approval stamp and number each page

Approved consent forms will be stamped in iRIS, and study subjects should sign the stamped version. The approval stamp appears in the upper right-hand corner of each page, so do not include any information in this section of the header. In addition, the upper margin should be at least 1.25" to leave room for the stamp.

After the consent form expires or is superseded, iRIS will automatically void the consent document. If you need a copy for your records, please print out the consent form before it is voided.

Number the pages of every consent document, preferably in a format like "1 of 2," "2 of 2," in the footer of the document.

Section-by-Section Guidance and Suggested Wording

Start with the appropriate IRB consent form template [1] and follow these guidelines when tailoring each section of the form:

Main heading

Include the reference to UCSF and the information that a research project is being discussed in the consent form heading, e.g.:

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

If the study will be conducted at a site such as SFGH or another hospital or clinic, also include the name of this institution.

Study title

You must include the ***study title*** in the first part of the form. If the official title is technical and difficult to understand, a simplified non-technical title should be used in addition to the official title.

If a study has more than one consent form, ***label each form*** or title them appropriately, and use the same references within the IRB Application to avoid confusion.

Introductory paragraphs

This section presents the introduction to the study, indicating who is conducting the research, why the individual has been asked to be in the study and that participation in research is voluntary.

Identify all **principal investigators** by first and last names, titles, and departments.

Explain the **voluntary nature of participation.**

Simply state the **reason a person has been asked to participate** (e.g., "Because you have tried to quit smoking in the past but have not been successful," "Because you are undergoing surgery and will be given a general anesthetic," "Because you are a healthy person"). Do not discuss detailed inclusion/exclusion criteria here, as they are the responsibility of the investigator, not the subject.

Use the phrase **"asked to take part in the study,?** rather than "chosen" or "invited to be in the study.?

Why is this research study being done? (Purpose and Background)

Discuss the **aim** of the study and give a *brief* summary of the **background or reason for the project.**

Name the *study sponsor(s)*. The IRB requires that all consent forms disclose which agencies or institutions (e.g., National Institutes of Health, Department of Defense, state agencies), cooperative groups (CALGB, COG, ACTG), foundations or industry sponsors are funding the research or providing study drugs or equipment for the study.

If the study is not being funded by an external agency, then identify the internal funding source, (e.g. Department funds, personal funds). This information should be included either in the **Purpose and Background** section, or in a section headed with the question **Who pays for this study?**

Disclose any **financial or proprietary interests of the investigator(s).** This disclosure can be in general terms. See Conflicts of Interest (COI) in Research [5] page for more information.

Identify any ***investigational drug(s) or device(s)*** that will be used in the study. Use the drug or device name consistently throughout the consent form.

Refer to the drug or device as **"investigational" or "experimental"** rather than "new," since "new" can connote that something is automatically better.

How many people will take part in this study?

State the **total subject accrual goal**. If it is a *multi-site study*, the **# of subjects from UCSF** can be noted as well. Where appropriate, a short description about cohorts may be given.

What will happen if I take part in this research study? (Procedures)

Clearly state **what will happen** to the individual as a result of taking part in the study, **how this differs from standard treatment** (if applicable), and what will happen if the individual chooses **not to participate.**

List each procedure in the order in which it will occur, and discuss it in a separate point. If screening procedures are involved, list them first and identify them as tests that will determine eligibility to continue in the study.

Randomization is considered a research maneuver, and thus should be described as a study procedure. Define terms the first time they are mentioned ? e.g., ?randomized? as ?assigned by chance,? ?placebo? as ?inactive substance? ? or use a lay term used (e.g., "group" rather than "arm").

Also describe in lay language the probability of assignment to each treatment or condition (e.g., ?You have a 50/50 chance of being assigned to either group?).

Note the **amount of time for each procedure** and **number of times** each procedure will be done.

State the **location(s)** where the procedures will be done.

Specify the **amounts of blood or tissue** to be taken for study purposes should be specified using **teaspoons or ounces** vs. metric terms.

If you are **reviewing subjects' medical records review,** list this as a procedure.

?Standard? medical procedures included in the study: The consent form must make clear whether such procedures are being done for clinical reasons or for study purposes (including whether the procedures are being done *more often* because of the study).

The following guides should be used to determine the extent to which standard procedures and their associated risks need to be described in consent forms:

A. If the standard procedure is not explicitly required by the study protocol, the consent form need **not** describe that procedure or its risks.

B. If the standard procedure is a *main focus of the study* (e.g., one or more arms of a randomized study is standard), the consent form must include a full description of the procedure and its risks.

C. If the standard procedure *is explicitly required by the study protocol*, the consent form must include a description of the procedure and its risks. In the case of C, the form may include *abbreviated* descriptions of the procedure and its risks *if the procedure itself is not being investigated* and:

1. The study population is experienced with the standard procedure; or
2. The study population would undergo the standard procedure regardless of study participation.

Study chart or plan (optional): You may choose to add a simplified calendar or schema (study plan) to the narrative explanation of procedures (see the Biomedical and Cancer consent form template [6]).

How long will I be in this study?

Specify the **duration of the study** and the **total amount of time required** for participation in the study should be specified.

Can I stop being in the study?

Explain that the subject can **stop participation at any time**. Clearly explain if there are issues around safely terminating the study treatment or procedures.

What side effects or risks can I expect from being in the study? (Risks and/or Discomforts)

Include the **risks and/or possible side effects** or discomforts of all study procedures and/or treatments. Include a brief general statement followed by a listing of all risks arranged and described according to their **severity** and the **likelihood** of their occurrence. See see the Biomedical and Cancer consent form template [6] for details.

Also explain the **consequences of these risks** in lay terms, where needed. For example, "lower white blood cell counts" could be explained as follows: "The treatment may weaken your immune system so that you might get more frequent colds or more serious infections."

If appropriate, specify what **precautions** will be taken to avoid certain side effects or outcomes from occurring, and what will be done should they occur.

The IRB has developed **standard wording for risks** that may be required in this section. Unless there is substantive reason to use different wording, these statements should be used verbatim where appropriate. See see the Biomedical and Cancer consent form template [6] for the exact current wording of these risks:

- Radiation risks
- CT scan risks
- MRI risks
- Reproductive risks
- Unknown risks
- Blood draw risks -- Additional note: If more than one unit of blood is to be drawn within an 8-week period, a medically appropriate precaution concerning subsequent blood donation is required.

Are there benefits to taking part in the study? (Benefits)

Describe any **potential direct benefits to the subject first, then potential general benefits** (e.g., to the group of patients to which the individual belongs, to medical knowledge, etc.). Descriptions of possible direct benefits may add the phrase, "...but this cannot be guaranteed."

If there is **no direct benefit** to the subject anticipated from the study, state this at the beginning of the section.

Do not include payment as a benefit. Benefits such as medical or societal benefits are considered separate from payment for participation in a study; thus, discussion of payment or reimbursement is included in its own separate section.

What other choices do I have if I do not take part in this study? (Alternatives)

When appropriate, outline what **options are available to an individual who does not take part in the study** (e.g., treatment without being in a research study, participating in another study or getting no treatment).

It is not sufficient to say that a patient will receive ?standard care??if there are **specific alternatives**, you must describe them.

Will my medical information be kept private? (Confidentiality)

One risk of participating in any research is a loss of privacy. There is no legal privilege between investigator and subject as there is between physician and patient or counselor and client. Thus, **do not give or imply a guarantee of ?complete? or "strictest? confidentiality.**

Explain how the researchers will **protect confidentiality** (e.g., coding of records, limiting access to the study records, not using any individual identifiers in publications or reports resulting from the study).

Indicate what **regulatory or other agencies might have access to the research records** (e.g., the FDA, sponsoring company, IRB).

Possible discovery of illegal activities: Because research records do not enjoy the same legal privilege as medical records, subjects are placed at risk when they are asked about possible illegal drug use or other illegal activities.

For such cases, you may wish to obtain a Certificate of Confidentiality From NIH [7], which can help protect identifiable research information from forced disclosure. Certificates can be given regardless of whether or not the research is federally funded.

Whether or not a Certificate is obtained, **warn prospective subjects as follows:**

> Participation in research may cause a loss of privacy. In this study, you will be asked about drug use and other possibly illegal activities. The researchers will keep information about you as confidential as possible, but complete confidentiality cannot be guaranteed. On rare occasions, research records have been subpoenaed by a court.

If you obtain a Certificate of Confidentiality, discuss it at the end of this section using the standard Certificate consent form wording [7].

Confidentiality statement for studies conducted at a UCSF Clinical Research Services site or SF Veterans Administration Medical Center: At certain sites, including CRS sites and the SFVAMC, every research participant is required to have a medical record. Use a confidentiality statement such as the following (adapted as appropriate):

> Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. A UCSF medical record will be created because of your participation in this study. Your consent form and some of your research test results will be included in this record. Therefore, your other UCSF doctors may become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.

Will any research-related procedures be billed to me? (Costs/Financial Considerations - Note: Section heading change November 2017)

For any human research study that includes the use of ANY clinical procedures (including the administration of drugs, devices, and/or tests), the UCSF IRB requires investigators to include one of the following two standard statements:

For studies in which the sponsor pays ALL costs:

> No. The sponsor has agreed to pay for all procedures associated with this research study; you or your insurer will not be billed.

> [*Study team can only add the following statement, if applicable:* ?The sponsor will provide ?drug x and administration of drug x? at no cost to you.?]

For studies where subjects may be responsible for SOME costs:

Two types of procedures will be done during this study. Some are part of your standard medical care and others are only for research. You or your insurer will be billed for the standard medical care. You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all standard medical care costs if you are receiving medical services out of network. Any procedures done only for research will not be charged to you or your insurer.

[*Study team can only add the following statement, if applicable:* ?The sponsor will provide ?drug x and administration of drug x? at no cost to you.?]

For studies that do not involve ANY clinical procedures, include a simple statement that there will not be any costs, such as:

No. There will be no costs charged to you.

Will I be paid for taking part in this study? (Payment/Reimbursement)

If there will be no payment for study participation, explain that subjects will not be paid. See the Research Subject Payments [8] page for more information on payment guidelines.

Refer to money that subjects receive in return for study participation as "**payment**." You can use the term ?reimbursement? if participants are paid for specific costs they incur. Do not use the term "compensation."

Avoid connotations of undue influence to participate or that the subject is being employed by the investigator. Rather, the sense should be that subjects will be paid for their time and the inconvenience of being a research subject.

List the **total amount** that the subject will be paid for study participation, **plus any information on pro-ration of payment** if a person does not complete the study or **bonus payment** at the end of the study. Subjects should not be required to complete the entire study in order to be paid. Any bonuses for study completion should be modest.

Describe the **method of payment** (e.g., cash, check, gift card).

Explain **when subjects will be paid** [8] (e.g. immediately or in 6-8 weeks). If appropriate, include a payment schedule.

For payment by check [8], specify that subjects need to provide their home address and social security number to receive payment.

If subjects are paid more than $600 [8] total in a calendar year for participation in research studies, UCSF will report this income to the IRS. Subjects will need to provide their home addresses and social security number for reporting purposes.

Sample Consent Form Wording by Payment Method

No Payment: You will not be paid for taking part in this study.

Payment by Check: If you complete the entire study, you will be paid $120 -- $25 for each clinic visit and a $20 bonus for finishing the study. If you withdraw from the study early, you will receive $25 for each visit you complete. You will be paid by check, and you should receive the check four to six weeks after your last visit. You must give the researchers your address and Social Security number so the check can be processed.

Payment by Debit Card: In return for your time, effort and travel expenses, you will be paid up to $45 for taking part in this study. We will give you a prepaid debit card worth $15 after each study visit. We will give you separate instructions on how to use the debit card.

Payment by Debit Card (over $600/year): In return for your time, effort and travel expenses, you will be paid up to $650. We will give you a prepaid debit card worth $50 after each study visit. We will give you separate instructions on how to use the debit card.

UCSF must notify the Internal Revenue Service (IRS) when it pays a subject $600 or more in a year, so your payment will be reported to the IRS. You must give the researchers your address and Social Security number for IRS reporting purposes.

Payment by Cash: You will be paid $10 in cash for participating in the focus group. You will be paid immediately after the focus group ends.

What happens if I am injured because I took part in this study? (Treatment and Compensation for Injury)

The University of California and UCSF have developed a simple standard statement regarding treatment and compensation for injury. **See the Treatment and Compensation for Injury Statement [9] page** for the complete UC policy and the exact required wording of this statement.

If sponsors ask that the wording of this statement be altered, please refer them to the Treatment and Compensation for Injury Statement [9] page. Very few changes to the statement are allowed, and these requests will delay study approval.

Note: The SFVAMC requires slightly different wording. [9]

What are my rights if I take part in this study?

This section **emphasizes the individual?s freedom to choose** to participate or not participate in the study, and to do so without penalty. It promises to inform the subject of any new information or changes in the study that may affect his/her health or willingness to continue in the study.

Who can answer my questions about the study? (Questions)

Questions for the study team: Provide contact information to the participant in case of questions, concerns or complaints about the study. Include the PI's name and phone number ?even if he/she is a faculty advisor only ? as subjects may wish to contact the individual who is supervising the project. Additional names and phone numbers of study staff may also be included.

Questions for the IRB and other resources: Give the phone number for the IRB office in a separate paragraph. Also include a brief explanation about the role of the IRB, which specifically states that the IRB is independent of the research team and available for questions regarding the rights and welfare of research participants.

You can also list contact info for any additional informational sources related to the study (e.g., local patient representatives or individuals at other study sites as appropriate).

ClinicalTrials.gov registration: The FDA issued a final rule [10] requiring that consent forms for applicable drug and device clinical trials include a specific statement that clinical trial data will be entered into ClinicalTrials.gov [11]. See the see the Biomedical and Cancer consent form template [6] for the required language.

The mandatory language only needs to be entered if the study meets the FDA?s definition of a *clinical trial*. The language must appear verbtaim in consent forms for all clinical trials **approved on or after March 7, 2012.**

The HUB has additional information about clinical trial registration and the FDA definition. [12]

Consent

Receipt of consent form copy and Experimental Subject's Bill of Rights: This section should state that the subject has been given (not just "offered") a copy of the consent form.

If it is a biomedical study, a copy of the Experimental Subject's Bill of Rights [13] also should be given. Attach a copy of the current UCSF version of the Bill of Rights to the consent form.

Re-state that participation in research is **voluntary** and that subjects can **decline to participate or withdraw** from the study at any time without penalty or loss of benefits to which prospective subjects are otherwise entitled.

Do not use wording such as "I have read this form and understand it? or ?based on this understanding, I hereby agree to participate," since providing consent does not guarantee an individual's comprehension, legally or otherwise.

Rather, simply state that **if the subject wishes to participate in the study, he/she should sign the consent form**; the signature will indicate agreement to participate.

Signature Section

Subject Signature: Unless the IRB approves a waiver of signed consent (i.e., use of an Information sheet rather than a consent form), include lines for the subject's signature and the date of signature. The subject should date the form personally.

Signature of Person Obtaining Consent: So that subjects have a record of who explained the study to them, include lines for the signature of the specific individual obtaining consent and the date of signature.

Witness Signature: Only include a witness signature line if you may consent non-English speaking subjects using the short form consent method [14] AND this request has been approved in the IRB Application. This signature line should read, "Witness ? Only required if the participant is a non-English speaker." The witness can be the interpreter or another person (other than the person obtaining consent) who witnesses the involvement of an interpreter.

Third Party Signature: If the study involves subjects who cannot give consent for themselves (e.g., individuals with cognitive impairments [15], individuals requiring surrogate consent [16] or children [3]), a separate, appropriately worded and labeled signature section for the parent(s) or legally authorized representative may be required for the consent form.

See the Biomedical and Cancer consent form template [6] for examples of these types of signature sections.

Page last updated:
Jan 8, 2018

Source URL: http://irb.ucsf.edu/consent-form-guidelines-and-suggested-wording

Links
[1] http://irb.ucsf.edu/consent-and-assent-form-templates
[2] http://www.nccn.org/icl/default.aspx
[3] http://irb.ucsf.edu/children-and-minors-research

[4] http://irb.ucsf.edu/modification
[5] http://irb.ucsf.edu/conflicts-of-interest-research
[6] http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/biomedical-cancer-consent.doc
[7] http://irb.ucsf.edu/certificate-confidentiality-nih
[8] http://irb.ucsf.edu/research-subject-payments
[9] http://irb.ucsf.edu/treatment-and-compensation-injury
[10] http://edocket.access.gpo.gov/2011/2010-33193.htm
[11] http://clinicaltrials.gov/
[12] http://hub.ucsf.edu/clinicaltrialsgov
[13] http://irb.ucsf.edu/experimental-subjects-bill-rights
[14] http://irb.ucsf.edu/consenting-non-english-speakers
[15] http://irb.ucsf.edu/enrolling-individuals-cognitive-impairments-and-assessing-decisional-capacity
[16] http://irb.ucsf.edu/surrogate-consent