Informed Consent in

Human Subjects Research

Office for the Protection of Research Subjects (OPRS)

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INTRODUCTION

Voluntary informed consent is a prerequisite for a subject's participation in research. This booklet provides an overview of informed consent: its importance, required elements of consent, the consenting process, and documenting consent. Above all, informed consent and the consenting process is about the protection and respect for research subjects. USC's resources for informed consent include: forms, templates, iStar (IRB e-application system) guidance, and contact information, which can all be found in this booklet for reference.

I. WHAT IS INFORMED CONSENT?

Informed Consent is a voluntary agreement to participate in research. It is not merely a form that is signed but is a process, in which the subject has an understanding of the research and its risks. Informed consent is essential before enrolling a participant and ongoing once enrolled. Informed Consent must be obtained for all types of human subjects research including; diagnostic, therapeutic, interventional, social and behavioral studies, and for research conducted domestically or abroad. Obtaining consent involves informing the subject about his or her rights, the purpose of the study, the procedures to be undergone, and the potential risks and benefits of participation. Subjects in the study must participate willingly. Vulnerable populations (i.e. prisoners, children, pregnant women, etc.) must receive extra protections. The legal rights of subjects may not be waived and subjects may not be asked to release or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The Informed Consent is described in ethical codes and regulations for human subjects research. The goal of the **informed consent process** is to provide sufficient information so that a participant can make an informed decision about whether or not to enroll in a study or to continue participation. The **informed consent document** must be written in language

easily understood by the participant, it must minimize the possibility of coercion or undue influence, and the subject must be given sufficient time to consider participation.

A. Why is Informed Consent required?

The Belmont Report (http://ohsr.od.nih.gov/guidelines/belmont.html) and the Nuremberg Code (http://www.cirp.org/library/ethics/nuremberg/) both address voluntary informed consent as a requirement for the ethical conduct of human subjects research. Informed Consent is the process through which researchers respect individual **autonomy**, the fundamental ethical principle. An autonomous individual is one who is capable of deliberation and personal choice. The principle of autonomy implies that responsibility must be given to the individual to make the decision to participate. *Informed Consent* means that subjects are well informed about the study, the potential risks and benefits of their participation and that it is research, not therapy, in which they will participate.

The Nuremberg Code states that the voluntary consent of the human subject is absolutely essential not only to the safety, protection, and respect of the subject, insofar the integrity of the research itself.

B. The Informed Consent Process

Informed consent is more than a form, it is also a process. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. Informed consent process must be a dialogue of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits. The process of consenting is ongoing and must be made clear to the subject that it is his or her right to "withdraw" or "opt-out" of the study or procedure at any time, not just at the initial signing of paperwork. The location where the consent is being discussed, the subject's physical, emotional and psychological capability must be taken into consideration when consenting a human subject.

The informed consent process should ultimately assure that the subject understands and really "gets" what they are signing up for.

C. What elements should be included in an informed consent?

The regulations for the protection of human subjects 45 CFR 46 (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html) require whenever human subjects participate in a research study, they need to be given enough information to provide a truly voluntary and informed consent. Subjects must be provided the following information:

- *Purpose* of the research
- *Procedures* involved in the research
- *Alternatives* to participation
- All *foreseeable risks and discomforts* to the subject. *Note: that these include not only physical injury but also possible psychological, social, or economic harm, discomfort, or inconvenience.*
- *Benefits* of the research to society and possibly to the individual human subject
- *Length of time* the subject is expected to participate
- *Person to contact* for answers to questions or in the event of a research-related injury or emergency
- Statement indicating that *participation is voluntary* and that refusal to participate will not result in any consequences or any loss of benefits that the subject is otherwise entitled to receive
- Statement regarding the subjects' *right to confidentiality and right to withdraw* from the study at any time without any consequences

Waiver of one or more elements of informed consent may be obtained from the IRB for some research projects that could not practically be done without an alteration to the required elements or for studies where required elements are not applicable.

D. What additional informed consent elements might be needed for certain projects?

Depending on the project and the subject population, the Informed Consent must also contain information on:

- Certificate of Confidentiality (if any)/limitations of certification protection
- *Payment* for participation (if applicable)
- *Risks* to vulnerable subjects, e.g., embryo, fetus, pregnancy
- *Circumstances* for investigator "withdrawing" the subject
- *Additional* costs from participation
- Early *withdrawal consequences*
- *Statement regarding how* significant new findings will be communicated
- *Number* of subjects participating
- *Probability* of random assignment or placebo placement
- Additional information required by the IRB

E. Health Insurance Portability and Accountability Act (HIPAA):

The Health Insurance Portability and Accountability Act (HIPAA), also called the Privacy Rule, is a federal law that prohibits health care providers (i.e. physicians, hospitals, and clinics) from using or disclosing "Protected Health Information" (PHI) without written consent from the patients.

Protected Health Information (PHI) is health information transmitted or maintained in any form or medium that includes ALL of the following three parts:

- identifies or could be used to identify an individual; and
- is created or received by a healthcare provider, health plan, or healthcare clearinghouse; and
- relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual.

An investigator must inform the IRB if they intend to use or release identifiable health information in the course of their research.

The full text of the Privacy Rule can be found at the HIPAA website: http://www.hhs.gov/ocr/hipaa

F. California Experimental Research Subject' s Bill of Rights:

California law, Health & Safety Code Section 24172, requires that any person asked to take part as a subject in research involving *a medical experiment*,* or any person asked to consent to such participation on behalf of another, shall receive the California Experimental Research Subject's Bill or Rights (see www.*ag.ca.gov/research/pdfs/bill_of_rights.pdf* for full text) in the subject's language. Subjects must be informed of the following:

- the nature and purpose of the experiment.
- an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
- a description of any attendant discomforts and risks reasonably to be expected from the experiment.
- an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
- a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
- information regarding medical treatment, if any, available to the subject after the experiment if complications should arise.
- an opportunity to ask any questions concerning the experiment or the procedures involved.
- that consent to participate in the medical experiment may be terminated at any time and the subject may discontinue participation in the medical experiment without prejudice.
- a copy of the signed and dated informed consent form.
- opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

Medical Experiment* - (a) the severance or penetration or damaging of tissues of a human subject or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice of research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject

G. Use language that subjects understand / Non-Technical Language

Consent documents must be clearly written and understandable to subjects. The language must be non-technical (comparable to the language in a newspaper or general circulation magazine). Scientific, technical, and medical terms must be defined or explained in lay terms. It is often recommended that the informed consent be written at the eighth grade reading level. When enrolling minors in a study, related recruitment materials must reflect the reading level of minors.

Informed consent may not include exculpatory language, that is, language that appears to waive subjects' legal rights or appears to release the investigator or anyone else involved in the study from liability for negligence.

Furthermore, consent must be provided in the language of the subject or alternatively a translator and the "short-form" can be used. The "short form" is a type of informed consent used when there is a language barrier and an English IRB-approved consent form is orally translated in the subject's native language. The short form contains basic and additional elements of a consent that must be explained to the subject. No informed consent, whether oral or written, may include exculpatory language.

II. THE ROLE OF THE MENTOR / FACULTY ADVISOR IN THE INFORMED CONSENT PROCESS

USC Faculty Advisors (FAs) of students conducting research projects play an important role in human subjects protections. Faculty Advisors bear the ultimate responsibility for their students and the ethical conduct of research. Faculty Advisor support can significantly influence data quality and IRB approval time.

As with other aspects of the mentor-student relationship, the informed consent process benefits from a collaborative effort. The mentor should guide the trainee/student in the informed consent process so that it is well understood and implemented correctly. Ultimately, the mentor is responsible for ensuring that students are using appropriate IRB-approved informed consent documents and correctly obtaining subject consent. Therefore, the mentor should discuss the informed consent, both document and process, or waiver, if applicable, while providing adequate supervision and by reviewing the work of the trainee/student to ensure accuracy. On the other hand, it is expected by the mentor that students follow ethical research practices when conducting research, follow the mentor's guidance and comply with institutional standards and ethical principles.

To Ensure Successful Student Projects—Faculty Advisors Must:

1. Take an active role in mentoring
2. Remain involved in students' research through all phases of the study
3. Check on the student's use of IRB approved consent and recruitment documents
4. Evaluate and approve study design and methodology
5. Allocate adequate time for student/student projects
6. Assure scientific merit in student projects

7. Discuss informed consent or waiver applicability with students
8. Understand the levels of IRB review and attendant study requirements: Exempt, Expedited, Full Board, or "NHSR"
9. Help students determine the level of risk. *Is the project less than or greater than minimal risk?*
10. Complete mandatory CITI training

III. TYPES OF INFORMED CONSENT

Consent – An adult subject, capable of giving permission to participate in a research study, can provide consent. The subject must be 18 years of age and competent to make the decision to participate.

Parental Permission – When children/minors are included in research, the parent/guardian must sign a parental permission consent document. Some situations require permission from at least one parent, while other situations require permission from both parents. In some cases, it may be necessary to waive the requirement to obtain parental permission. Refer to 45CFR46* subpart D for more information.

Assent – Assent is a child's affirmative agreement to participate in research. If the subject is 7-17 years of age, assent must be obtained. The assent form must be written at the appropriate reading level of the youngest subject in the age range and use simple terminology.

Verbal – Verbal consent still contains all elements of written consent, however, the participant is verbally read the elements and verbally agrees to participate.

Short Form – A "short form" is generally used when there is a language barrier and an English IRB-approved consent is orally translated in the subject's native language.

Information/Fact Sheet – An information sheet many be used as a form of consent in certain circumstances where a signature could compromise the participant or in studies where signed consent is not required by regulations (research procedures involving minimal/ no risk).

Waiver of Documentation of Informed Consent – A waiver of documentation of informed consent can be obtained when the written consent is the only link to the study and record of subjects name could compromise the participant. In this case a verbal or information sheet can be used, or the consent may be read to the subject.

Waiver of Elements of Informed Consent – A waiver of elements of informed consent may be obtained from the IRB for some research projects that could not practically be done without an alteration to the required elements.

IV. INFORMED CONSENT RELATED LINKS

Informed consent templates are available on the OPRS/IRB website (http://oprs.usc.edu/review/forms/). These templates provide the necessary elements and language for informed consent needs. Each allows researchers to fill in blank areas to reflect the study specifics.

Independent Translation Services for Informed Consent Forms

The University Park IRB (UPIRB) does not offer translation services for informed consent documents. However, provided below is a list of independent, fee based translation services that investigators can utilize. Investigators must bear all cost associated with the service.

- The Language Bank
- Transperfect
- Accredited Language Services (ALS)

Additional Human Subjects Research Information and Guidelines

Additional information and guidelines are available to assist investigators in preparing their IRB applications and in conducting research with human subjects. Please refer to the following information:

- Significant New Findings Policy
- Policy Concerning Human Subjects Research at the Dana & David Dornsife Imaging Center

- Criteria for Advertisements
- The Research Advisory Panel of California (California requires proposed research projects involving certain opioid, stimulant, and hallucinogenic drugs classified as Schedule I and Schedule II controlled substances to be pre-reviewed and authorized by the Research Advisory Panel of California in the Attorney General's Office.)

Guidelines for the Use of a Short Form

If there is occasional need to enroll subjects who are not fluent in English or Spanish, a written short form informed consent must be used to obtain consent in conjunction with the written IRB-approved English version of the Informed Consent Form. The IRB provides short form consent templates (which include basic and additional elements of disclosure) including the Experimental Subject's Bill of Rights in English and twelve different languages. (Click on http://oprs.usc.edu/hsirb/hsirb-forms/ to access short forms in Amharic, Armenian, Cambodian, Chinese, English, Farsi, French, Hebrew, Hindi, Japanese, Korean, Romanian, Russian, Spanish, Tagalog, Thai and Vietnamese)

The process for enrolling subjects with the short form is outlined below. All of the following requirements must be completed:

- A translator must orally translate the entire IRB-approved English version of the consent form to the subject in a language understandable to him/her, and the subject must be given a copy of the written translation of the "short form" consent document to read;
- The entire consent process must be witnessed by an individual who is fluent in both English and the language understandable to the subject. The translator may serve as the witness;
- The IRB-approved English version of the consent form must be signed by the investigator (or study staff member) authorized by the IRB to obtain consent, and signed by the witness to the consent process. The short form must be signed by the subject and the witness to the consent process; AND
- The subject must be given copies of both the IRB-approved English version of the consent form and the translated version of the "short form" consent document. The original signed English version with the original signed short form attached should be placed in the subject's research record and a copy of both placed in his/her medical record, if appropriate.

FDA regulations at 21 CFR 50.27 and 45 CFR 46.117 provide the following requirements for the use of the short form (adapted to California state law):

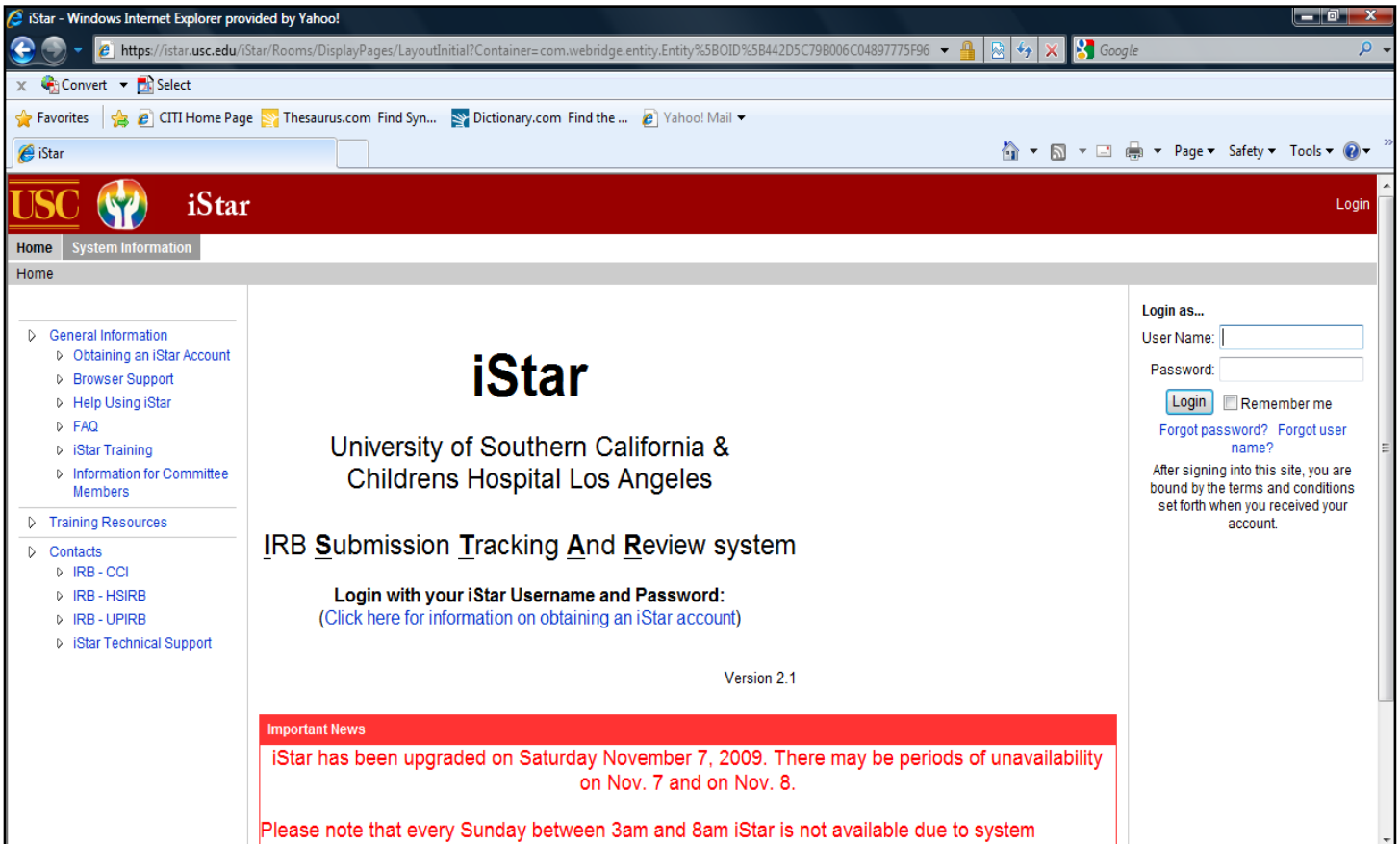
Only the short form is to be signed and dated by the subject or the subject's legally authorized representative. The witness (at USC, the oral translator) shall sign the short form and the summary (English version of the IRB-approved Informed Consent Form). The investigator or study staff member authorized by the IRB to obtain consent shall sign a copy of the summary. A copy of the short form, summary (English version of the IRB-approved Informed Consent), and the Experimental Subject's Bill of Rights shall be given to the subject or the subject's legally authorized representative in the language he or she understands.

For more information on who signs the consent and/or short form, click here: http://oprs.usc.edu/files/2013/01/Consent_and_Short_Forms_Final.pdf.

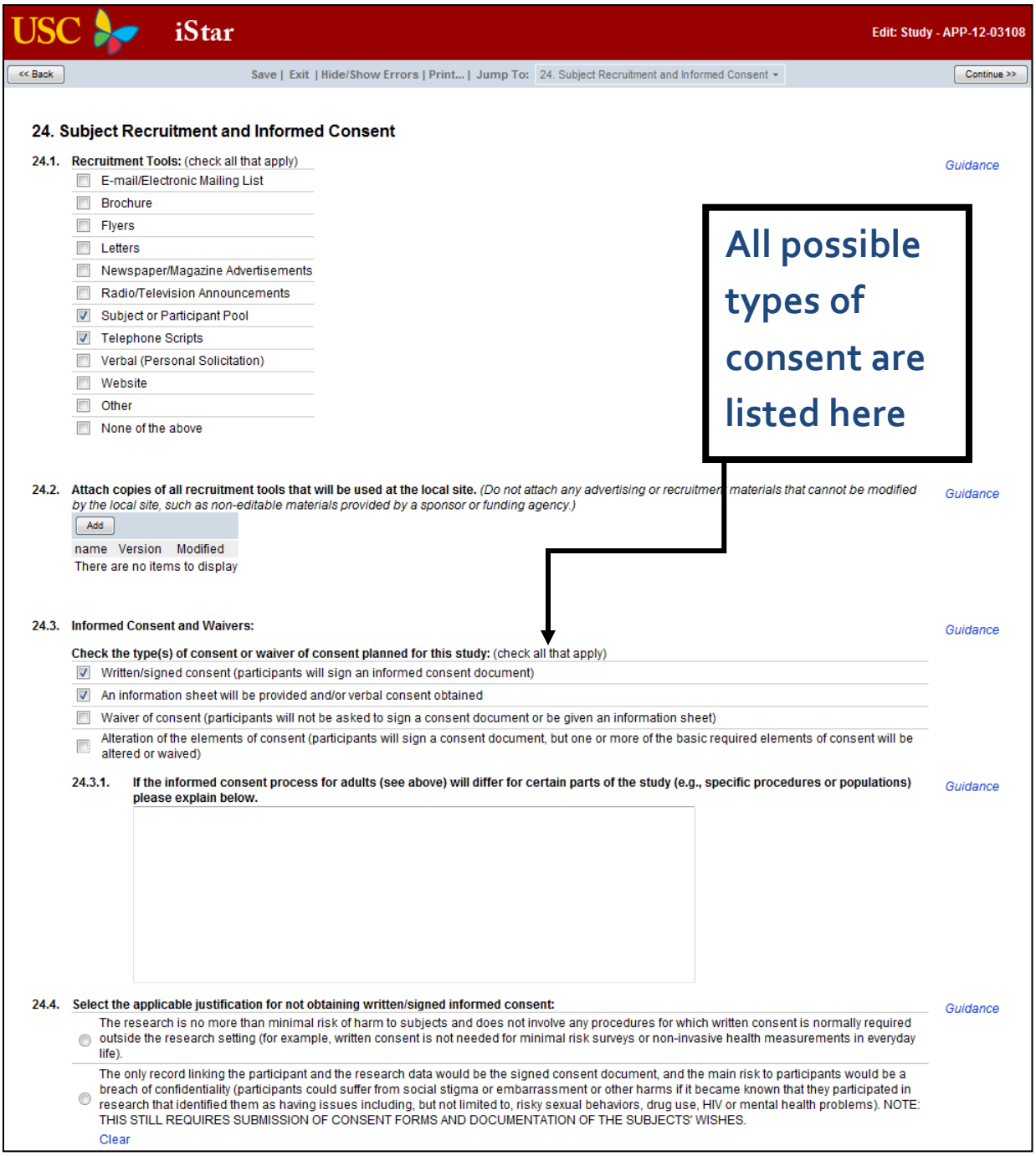
V. INFORMED CONSENT AND ISTAR

iStar (IRB Submission Tracking And Review System) is the online IRB submission application used at USC. Consent documents are submitted to IRBs through iStar. The approved consent document will be stamped by IRB and available at iStar.

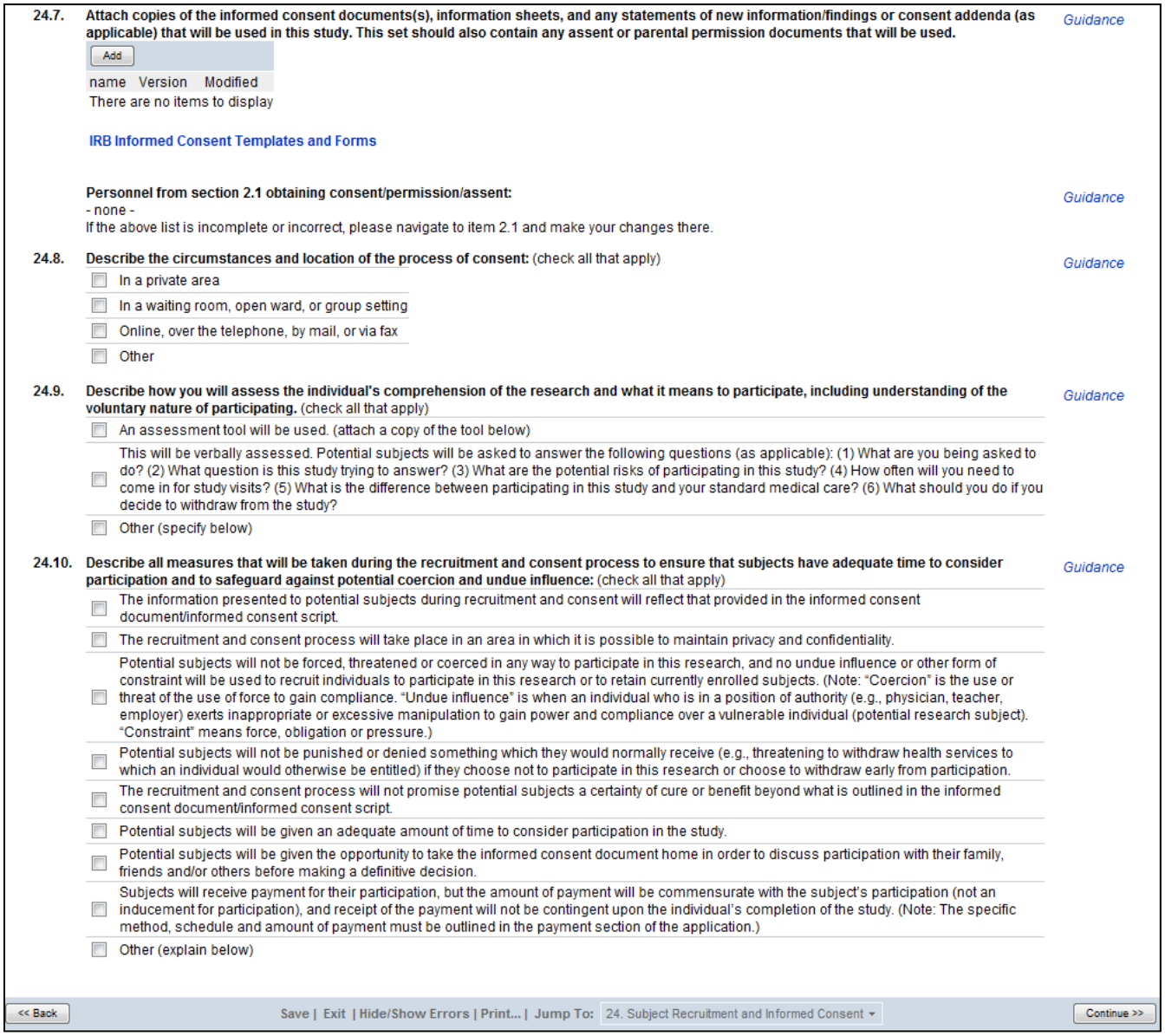
A. How Do I Access iStar?



B. Where is Subject Recruitment and Informed Consent Information entered in iStar?



Requests for waiver of consent will generate additional questions



24.7. **Attach copies of the informed consent documents(s), information sheets, and any statements of new information/findings or consent addenda (as applicable) that will be used in this study. This set should also contain any assent or parental permission documents that will be used.** *Guidance*

Add

name Version Modified

There are no items to display

IRB Informed Consent Templates and Forms

Personnel from section 2.1 obtaining consent/permission/assent: *Guidance*

- none -

If the above list is incomplete or incorrect, please navigate to item 2.1 and make your changes there.

24.8. **Describe the circumstances and location of the process of consent:** (check all that apply) *Guidance*

- ☐ In a private area
- ☐ In a waiting room, open ward, or group setting
- ☐ Online, over the telephone, by mail, or via fax
- ☐ Other

24.9. **Describe how you will assess the individual's comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.** (check all that apply) *Guidance*

- ☐ An assessment tool will be used. (attach a copy of the tool below)
- ☐ This will be verbally assessed. Potential subjects will be asked to answer the following questions (as applicable): (1) What are you being asked to do? (2) What question is this study trying to answer? (3) What are the potential risks of participating in this study? (4) How often will you need to come in for study visits? (5) What is the difference between participating in this study and your standard medical care? (6) What should you do if you decide to withdraw from the study?
- ☐ Other (specify below)

24.10. **Describe all measures that will be taken during the recruitment and consent process to ensure that subjects have adequate time to consider participation and to safeguard against potential coercion and undue influence:** (check all that apply) *Guidance*

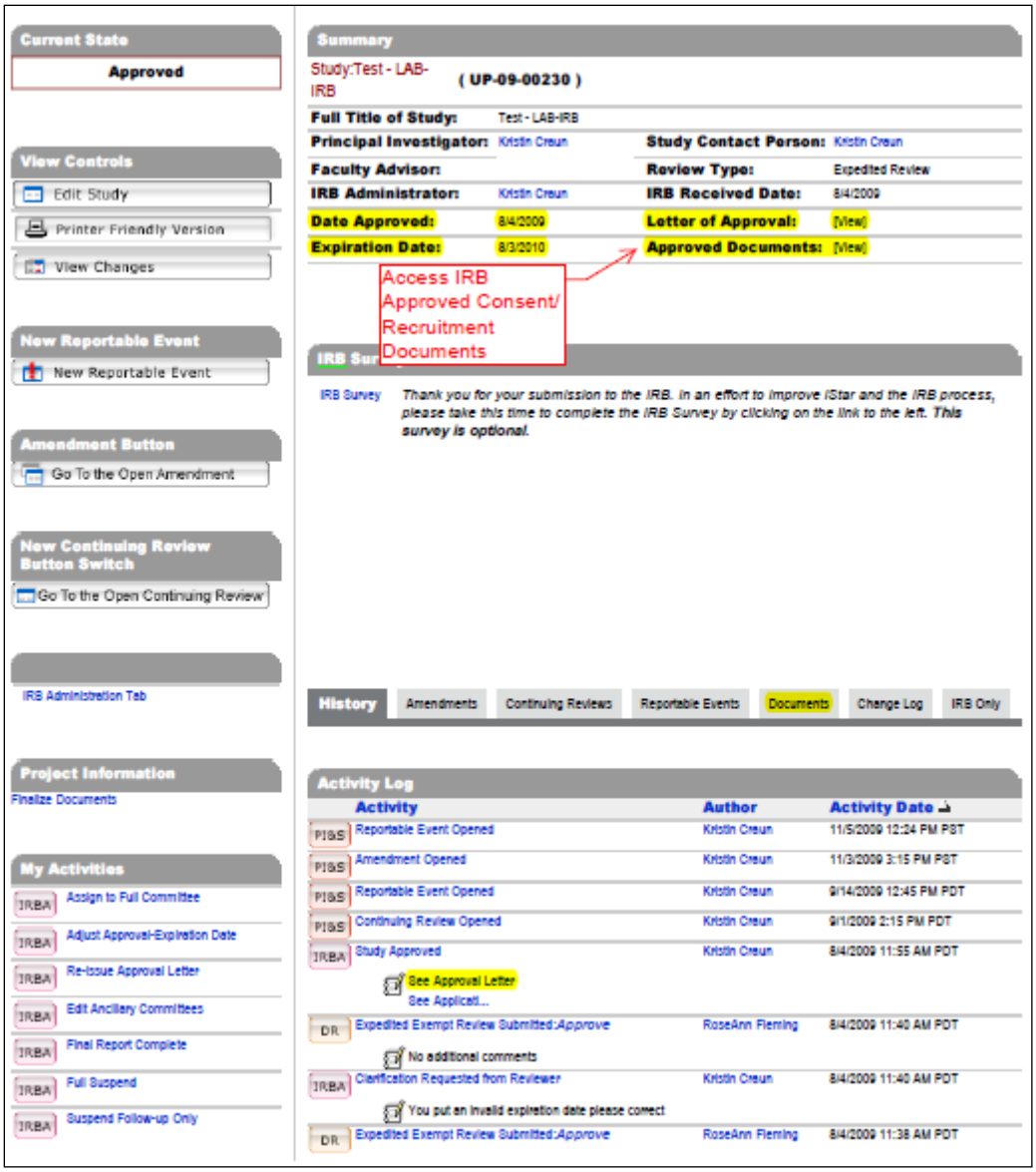
- ☐ The information presented to potential subjects during recruitment and consent will reflect that provided in the informed consent document/informed consent script.
- ☐ The recruitment and consent process will take place in an area in which it is possible to maintain privacy and confidentiality.
- ☐ Potential subjects will not be forced, threatened or coerced in any way to participate in this research, and no undue influence or other form of constraint will be used to recruit individuals to participate in this research or to retain currently enrolled subjects. (Note: "Coercion" is the use or threat of the use of force to gain compliance. "Undue influence" is when an individual who is in a position of authority (e.g., physician, teacher, employer) exerts inappropriate or excessive manipulation to gain power and compliance over a vulnerable individual (potential research subject). "Constraint" means force, obligation or pressure.)
- ☐ Potential subjects will not be punished or denied something which they would normally receive (e.g., threatening to withdraw health services to which an individual would otherwise be entitled) if they choose not to participate in this research or choose to withdraw early from participation.
- ☐ The recruitment and consent process will not promise potential subjects a certainty of cure or benefit beyond what is outlined in the informed consent document/informed consent script.
- ☐ Potential subjects will be given an adequate amount of time to consider participation in the study.
- ☐ Potential subjects will be given the opportunity to take the informed consent document home in order to discuss participation with their family, friends and/or others before making a definitive decision.
- ☐ Subjects will receive payment for their participation, but the amount of payment will be commensurate with the subject's participation (not an inducement for participation), and receipt of the payment will not be contingent upon the individual's completion of the study. (Note: The specific method, schedule and amount of payment must be outlined in the payment section of the application.)
- ☐ Other (explain below)

<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: 24. Subject Recruitment and Informed Consent | Continue >>

All consent forms (i.e., consent, assent, information sheet, verbal script) to be used in the study are uploaded in Section 24.7

The informed consent process is of particular interest to the IRB. Answers to Section 24 help IRB staff understand how investigators will ensure participants are properly informed before deciding to participate in a study.

C. Where are my Approved Consent forms in iStar?



Approved Consent forms are found in the Documents tab in the main menu page

VI. INFORMED CONSENT / INFORMATION SHEET SAMPLES

A. Where do I find Templates for Consent Documents?

https://oprs.usc.edu/review/forms/

B. Sample of an IRB-approved Consent Document

University of Southern California*The Department of Politics and International Relations*
INFORMATION SHEET FOR NON-MEDICAL RESEARCH

Political Activism among Women in Turkey between 1990 and 2009

*All approved documents will have this stamp

You are invited to participate in a research study conducted by Ph.D. Candidate, from the University of Southern California. You must be 18 years or older to participate in the study. Your participation is voluntary. Please take as much time as you need to read the information sheet. You may also decide to discuss it with your family or friends. You will be given a copy of this form.

PURPOSE OF THE STUDY
We are asking you to take part in a research study because we are trying to learn more about women`s political experiences in Turkey as well as patterns of women`s participation into electoral politics.

Completion and return of the questionnaire or response to the interview questions will constitute consent to participate in this research project.

PROCEDURES
You will be asked to be interviewed as one of the male politicians in Turkey. The interview will take approximately one hour and the location will be determined according to your preference. It may be conducted in your office, nearby coffee shop, or other locations you prefer. You will be asked some questions regarding how you perceive women`s political participation in electoral politics.

POTENTIAL RISKS AND DISCOMFORTS
There are no anticipated risks to your participation. When you feel some discomfort at responding some questions, please feel free to ask to skip the question.

POTENTIAL BENEFITS TO SUBJECTS AND/OR TO SOCIETY
You will not directly benefit from your participation in this research study.

This research will not provide a benefit to you. The overall goal is to reveal the experiences of female politicians. The findings may provide better understanding of "being a woman and being politician in the Turkish context". Thus, it may give an outlook to young women who aim to be involved in Turkish politics.

PAYMENT/COMPENSATION FOR PARTICIPATION
You will not receive any payment for your participation in this research study.

POTENTIAL CONFLICTS OF INTEREST
The investigators of this research do not have any financial interest in the sponsor or in the product being studied.

CONFIDENTIALITY
Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. The information collected about you will be coded using a fake name (pseudonym) or initials and numbers, for example abc-123, etc. The information which has your identifiable information will be kept separately from the rest of your data.

The data will be stored in the investigator's office in a locked file cabinet/password protected computer

The data will be stored for approximately seven years after the study has been completed and then destroyed. Your consent will be asked for audio recording. You may decline to be taped.
The Principal Investigator will transcript the tapes and may provide you with a copy of the transcripts upon request. You have right to review and edit the tapes. Sentences that you ask investigator to leave out will not be used and they will be erased from all relevant documents.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audio-tape recordings of you will be used for educational purposes, your identity will be protected or disguised.

PARTICIPATION AND WITHDRAWAL
You can choose whether to be part of this study or not. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. You may also refuse to answer any questions you are reluctant to answer and still remain in the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so.

ALTERNATIVES TO PARTICIPATION
Your alternative to participation is not to participate.

RIGHTS OF RESEARCH SUBJECTS
You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have any questions about your rights as a study subject or you would like to speak with someone independent of the research team to obtain answers to questions about the research, or in the event the research staff can not be reached, please contact the University Park IRB, Office of the Vice Provost for Research Advancement, Credit Union Building, Room 301, Los Angeles, CA 90089 213) 821-5272 or upirb@usc.edu

IDENTIFICATION OF INVESTIGATORS
If you have any questions or concerns about the research, please feel free to contact the Principal Investigator, Ph.D. Candidate or Faculty Advisor, Dr. Advisor:

Ph.D Candidate
University of Southern California
Politics and International Relations
3518 Trousdale Parkway
Los Angeles, CA 90089-0043
+90-419-+789+7(Turkey)
001-123-252-8766 (U.S.)

Prof. Advisor
University of Southern California
School of International Relations
3518 Trousdale Parkway
Los Angeles, CA 90089-0043

C. Information Sheet Template and Sample for Exempt Research

An information sheet may be used as a form of consent in exempt studies for which signed consent is not required by regulations and also in certain circumstances when a signature could compromise the participant. Below is a template for an information sheet and a sample information sheet from a summer trainee project.

INFORMATION SHEET TEMPLATE

Study Title: Generic Title

PI: Tommy Trojan

Date: 1/23/08

You are invited to participate in a research study conducted by _(Who)_____ from the University of Southern California.

We are asking you to take part in this study because__(Purpose/brief description of study) _.

Your participation is voluntary and would consist of __(Provide procedures & length of time it will take)_.

There are no anticipated risks to your participation and there are no direct benefits to you for taking part in this study (Or explain possible risks/benefits if applicable).

You will receive __(provide description of payment-if applicable)_ for your participation. You will be given a copy of this form.

If you have any questions about this research study, please contact: _(Provide contact information)_.

SAMPLE INFORMATION SHEET

Study Title: Health Survey in Brillo Nuevo, Peru

PI: Tommy Trojan

Date: 1/23/08

We invite you to participate in a research study conducted by John Doe from the University of Southern California.

We are asking you to take part in this study because we are trying to learn more about the health practices in your community.

You were selected as a possible participant because you are a resident of Brillo Nuevo. We will ask you about 40 questions related to your family's health, such as common illnesses and how you care for them. It will take about 20 minutes of your time.

Your participation is voluntary. There are no anticipated risks or benefits to your participation. You may decide to discuss your participation with your family or friends. You will be given a copy of this form.

VII. ADDITIONAL RESOURCES FOR HUMAN SUBJECTS RESEARCHERS

A. Booklets

USC HSR booklets are available to guide investigators, students, participants, and others through the human subjects research process. Contact the IRB or the OPRS to obtain these brochures or visit the OPRS website to view or print them online at: https://oprs.usc.edu/education/booklets/

Titles include:

Are You the Holder of an IND or IDE?

Describes the responsibilities of IND/IDE holders. A reference for investigators holding an IND or IDE and/or IRB staff who will be reviewing IND/IDE studies.

Guide to Human Subjects Research For USC Medical Students

Guidance for medical students who conduct biomedical, social and behavioral research or otherwise participate in research activities at the Keck School of Medicine (KSOM).

Student Handbook: Making Sense of Human Subjects Research

This comprehensive manual aids student with the IRB process. Provides information about the intricacies of human subjects research.

Mentoring USC Student Researchers

The mentor has the potential to draw the best from the student by acting as an adviser, teacher, role model, motivational friend and supportive advocate. This booklet is a guide and overview of that process.

You Want to be an IRB Community Member…Now What?

Guides IRB community members through the human subjects research process and helps them transition into a valuable members of the IRB committee. It can also serve as a great introduction for anybody new to human subjects research and the IRB.

Should I Participate in Research?

Aimed at assisting potential research participants in their decision to participate in research.

Also available en Español: **¿Debería participar en una investigación?**

Are You Conducting Research Using Human Subjects? A Guide for Investigators

Designed to guide Principal Investigators through the IRB process. Includes information on defining human subjects, the levels of IRB review, and informed consent requirements.

Is Your Project Human Subjects Research? A Guide for Investigators

A guide to help investigators determine if their project is human subjects research. Offers definitions and examples of human subjects research.

Are You a Faculty Advisor? The ABCs of Human Subjects Responsibilities

For Faculty Advisors (FA) serving on student IRB projects. Provides a brief overview of the FA role and tips for navigating the IRB process from the FA perspective.

B. Contact Information

Office for the Protection of Research Subjects (OPRS)
3720 South Flower Street, Third Floor Los Angeles, CA 90089-0706
Tel: (213) 821.1154 Fax: (213) 740.9299 E-mail: oprs@usc.edu
Web: http://oprs.usc.edu/

Health Sciences Institutional Review Board
General Hospital, Suite 4700 1200 North State Street Los Angeles, CA 90033
Tel: (323) 223.2340 Fax: (323) 224.8389 E-mail: irb@usc.edu
Web: http://oprs.usc.edu/hsirb/

University Park Institutional Review Board
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