## The Short Form Consent Process—REVISED

The Short Form consent process should be used for the **occasional and unexpected** enrollment of non-English speaking subjects.

The IRB will use its best judgment to ensure the protection of human research subjects when considering whether the use of the short form method for non-English speaking subjects is appropriate based on the researcher’s justification and the specifics of the research.

For example, given the patient census of UCI Medical Center the short form method should not be used for Spanish speaking subjects. Should a clinical researcher believe that enrollment of Spanish speaking subjects is not expected based on the disease or condition being studied and/or the anticipated study enrollment, study specific justification must be provided in Appendix Q.

Also the short form method should not be used for Phase 1 clinical trials, clinical research that targets vulnerable subject populations such as children and pregnant women, and for ‘true’ placebo-controlled studies.

When the short form method is approved by the IRB, the investigator is required to provide the subject the short form consent translated into the subject’s language. In addition, the English version of the IRB-approved consent form must be orally interpreted by a qualified interpreter. Further, once the subject has consented and eligibility is confirmed, the English version of the IRB-approved consent form must be translated into the subject’s language by a professional or certified translator and provided to the subject within one month from the subject’s initial consent.

**What is a professional translator?**

A professional translator is an individual who is fluent in the language specified. Fluency in another language means being able to comprehend, speak, read, and write in that language at the level of an educated native speaker. This includes the ability to speak, read, and write in that language using medical or other technical terminology.

**What is a certified translator?**

When a translation is certified, both it and the original are accompanied by a signed statement from the translator attesting to the completeness and accuracy of the translation. This is then notarized by a notary public. Due to the costs related to a certified translation, researchers should plan for these costs as part of their study budget.

For more information about the short form process visit the HRP page: ‘Informed Consent Process.’

For access to translated short forms (along with other translated forms) visit the HRP page: ‘Application and Forms’ and look under the subheading of ‘IRB Forms Foreign Language Translations.’
Congratulations! Your new study has been approved by the IRB! If your study involves a prospective informed consent process, are you prepared to obtain the subjects’ consent?

This article describes some key considerations to incorporate as part of your consent process.


Remember that both written consent and verbal consent for participation in research must involve an informed consent process. Informed consent involves an education and information exchange that takes place between the researcher and the potential subject. This process is ongoing. The responsibility of ensuring that a potential subject understands the research and the risks and benefits involved in the research falls upon the Investigator and not upon the potential subject.

Unless a waiver of signed consent has been granted by the IRB, once an individual has had all his/her questions answered and has agreed to participate in the study, the subject must sign and date the UCI IRB-approved consent form; next the Investigator who answered the questions and obtained the subject’s consent must sign and date the consent form.

Is a Witness Needed? A witness to the consent process is required when:

- Consent is obtained from the subject via the Short Form process, as approved by the IRB.
- The subject has decision-making capacity, but cannot read, write, talk or is blind.
- The subject’s guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
- The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive research procedures).
- The witness must be impartial (i.e. not a member of the subject’s family, not a member of the study team).

Is HIPAA Research Authorization Required? If the IRB requires HIPAA Research Authorization this form must also be signed and dated. HIPAA Research Authorization requirements are listed on the IRB approval letter. The form should also be available for download from the Doc Depot.

Does the Subject Need a Copy of the Consent? The subject should always receive a copy of the consent form and a copy of the HIPAA Research Authorization form to use as continual reference for items such as scheduling of procedures and for emergency contact information.

**What is ClinicalTrials.gov?:** ClinicalTrials.gov is a publicly available registry and results database of federally and privately supported clinical trials conducted in the United States and around the world. ClinicalTrials.gov captures significant summary protocol information before and during the trial as well as summary results and adverse event information of a completed trial.

**The purpose of ClinicalTrials.gov is to disclose to the public key information about clinical trials that are currently available or that have been conducted.**

**Do I Need to Register My Clinical Trial?:** Yes, if your research meets the definition of clinical trial and you meet the requirements of the responsible person for registering the trial.

**What Is the Definition of a Clinical Trial for Registration Purposes?:** If your study meets any one of these definitions, the trial must be registered.

1. **The Food and Drug Administration (FDA) requires registration for “applicable clinical trials” defined as follows:** For any trials of drugs and biologics: controlled clinical investigations, other than Phase I investigations, of a product subject to FDA regulation. For trials of biomedical devices: controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-market surveillance.

2. **International Committee of Medical Journal Editors defines a clinical trial as** any research study that prospectively assigns human subjects or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

3. **The National Institute of Health defines a clinical trial as** a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).

**Who is Responsible for Registering the Trial?** By law, the “responsible party” must register a clinical trial. The responsible party is:

- For industry-authored clinical trials, the industry sponsor is responsible.
- For cooperative group trials, the cooperative group is usually responsible.
- For UCI investigator-authored clinical trials, where the investigator initiates and conducts the trial, the investigator is responsible.
- To ensure that extramurally-authored and funded trials are properly registered, check whether the trial is listed in ClinicalTrials.gov, or contact the study sponsor for clarification.
- Also see NIH’s definition of a responsible party and a clinical trial @ [http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf](http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf).

**When should a investigator register a trial?** UCI recommends registering a trial before any subjects are enrolled to satisfy both the ICMJE requirements and the law (Section 801 of the Food and Drug Administration (FDA) Amendments Act).

**What are the Steps for Registering?** Clinical trials are registered at ClinicalTrials.gov via a web-based data entry system called the Protocol Registration System (PRS). UCI School of Medicine Research Support Services (SOMRSS) serves as a PRS Administrator. Visit the HRP page, ‘ClinicalTrials.gov Registry’ for contact information for SOMRSS and for the step-by-step registration details.
The first thing you should do when you receive IRB approval is download the UCI IRB Approval Letter, Protocol Narrative, Consent Form or Study Information Sheet, Recruitment Material and Data Abstraction Sheet (and anything else approved by the IRB) from the Document Depot.

Keep a copy of each IRB-approved document for your research records.

Also keep a copy of any applications that are formally submitted to the IRB (preferably signed versions), including the signed copy of the IRB Application, which includes affirmation of the Investigator’s Assurance Statement.

Remember, the Document Depot only maintains the LATEST versions of your IRB-approved documents. Once a modification request or continuing application is approved, the previously approved documents are removed from the Document Depot.

Regarding record retention, the official retention period begins upon submission of a closing report to the IRB or study expiration. IRB records should be maintained a minimum of 3 years.

For more information on record-keeping and specific record retention requirements (it can vary based on the research) visit the HRP page on record keeping.