**Informed Consent Form (ICF) Guidance**

Investigators are required to obtain informed consent as a legal and ethical obligation as outlined in the HHS regulations 45 CFR part 46, FDA regulations 21 CFR 50, and the Belmont Report principle of respect for persons. An informed consent form is required unless the research is exempt, or the IRB finds and documents that informed consent can be waived. For more information on [Informed Consent Requirements](https://hrpp.usc.edu/policies/informed-consent-requirements/), please refer to Chapter 9 of our policies.

The below checklist is to help investigators and study teams remain compliant with requirements. The IRB provides informed consent form templates on the [Forms and Templates](https://hrpp.usc.edu/irb/forms-and-templates/) page.

[If you would like to watch a video on the informed consent form guidance please click here.](https://www.youtube.com/watch?v=692DMJGJ-nc&t=8s)

Please remember: **Careful Documentation is required. Proper storage of this private information is paramount.**

1. Use the IRB approved [stamped] ICF. To ensure that you are using the IRB approved ICF, log in to your study in iStar and click [view] next to “Approved Documents.”
2. Obtain consent prior to starting any research procedures.
3. If applicable to the study, include the CA Experimental Subject’s Bill of Rights. It must be presented and signed prior to the ICF and is signed and dated by the participants. If the participants have a legally authorized representative, their signature and date must be included.
4. Ensure the ICF includes the signature of the participant or, if applicable, the participant’s legally authorized representative.
5. Ensure the ICF includes the signature of the person obtaining consent. All study personnel that are responsible for obtaining consent **must** be listed in iStar, section 2.1.

1. Provide a full copy of the signed, stamped informed consent to the participant.
2. Keep the full original consent form that was approved by the IRB with the participant’s original signature. If applicable maintain a copy of the informed consent form in the participant’s research chart, medical record, or equivalent file in medical research studies.
3. Keep a log/binder of all participants that have been consented.
4. Properly store consent.