University of Texas Southwestern (UTSW)
sIRB Consent Form Guidance

Description

Informed consent must be appropriately documented in accordance with, and to the extent required by 45 CFR 46.117 and/or 21 CFR 50 [Subpart B]. The IRB is responsible for the review and approval of the informed consent process and form submitted by the investigator. The wording on the informed consent form must contain all required elements and must meet all other requirements as described within the HRPP Policy 3.1 Informed Consent Requirements. Additional informed consent policies are available in UTSW HRPP Policies and Procedures section 3. Informed Consent. This guidance includes the specific requirements needed for the UTSW IRB to approve single IRB (sIRB) submissions requiring informed consent and/or HIPAA Authorization.

Written documentation of consent

A master template consent form [sIRB Consent Part 1 *or* sIRB Repository Consent Part 1] and site-specific consent form(s) [sIRB Consent Part 2 *or* sIRB Repository Consent Part 2] should be created for all engaged enrolling sites when written documentation of consent is required. **The standard University of Texas Southwestern consent form template should not be utilized**. We have provided templates that include the required consent elements to build your master and site-specific consent form(s). Study teams must present both documents to the subjects during the consenting process for the consent to be considered valid.

The master consent form [Part 1] provides overall information about the study, as it pertains to all participating sites. It covers the primary components of the study [procedures, risks, benefits, study purposes, etc.] There are no site or investigator names and no site-specific text included in this document. The Part 1 master consent is approved by the UTSW IRB at the study-wide level at the time of initial review, study-wide amendment, and continuing review. **This master template consent form cannot be edited by relying sites.** Concerns about Part 1 master consent documents that conflicts with regulations may be brought to the sIRB Program Manager for review.

The Part 2 consent contains site-specific information. The UTSW IRB expects this template to be used by all enrolling sites, local and relying. In most cases, the Part 2 template language (text in black) should not be changed. Local sites, including UTSW affiliates, are expected to retain the UTSW site-specific language related to cost, injury, and compensation in the Part 2 document. For all non-local sites, site-specific information should be inserted where applicable. UTSW will ensure that any institutional policy and local or state law is provided for review in the Institutional Profile completed for each site.

Note: If a project transitions from a single-site study to a multi-site, sIRB study, UTSW HRPP requires that the currently approved consent form be transitioned to the master [Part 1] and site-specific [Part 2] consent form model.

Waiver of Documentation of Consent [Information Sheet, Oral Consent]

An sIRB Information Sheet should be created for all enrolling sites when a waiver of documentation of consent is granted by the IRB to use an oral script. There will be not be a site-specific consent. Submit a master version of these documents for each enrolling site. The sIRB Information Sheet template allows site customization by highlighting sections where site-specific information [e.g., site name, site PI contact information] may be inserted.

HIPAA Authorization Language

The language required under the HIPAA Privacy Rule to obtain authorization for the use and/or disclosure of PHI will be incorporated into the site-specific consent form [Part 2] unless the relying institution indicates that it requires the use of separate HIPAA Authorization form(s). In this case, the Relying institution would be responsible for providing any site-specific determinations and ensuring the separate form complies with applicable requirements in the HIPAA Privacy Rule. The UTSW IRB (Privacy Board) will not review or accept stand-alone Authorizations.