Informed Consent Form – Which Template Should I Use?

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Background:

Over the years, the IRB has developed different consent form template to target certain types of protocols, and to limit the content when appropriate.

Q: What is contained in a consent form?

An informed consent provides a description of a proposed research project, which explains what will happen, and what the risks and benefits might be; all written at a reading level that a potential study subject can understand. Beginning in 2003 with the enforcement of the Privacy Law (HIPAA), most IRBs, including those at UF, added “HIPAA Authorization” language to the end of the informed consent. This language is meant to provide the potential study subject information on who can use their protected health information (PHI) and how it will be kept secure. If you are doing research at the VA Medical Center, see VA question below.

In both cases, the informed consent and the attached HIPAA authorization contains language required by the federal and state governments, as well as language from the UF\Shands Privacy Offices and from Shands Legal and the UF General Counsel’s Office.

Many of the UF IRB consent form templates come with and without HIPAA language. If you are collecting PHI as part of your research, you should always use the consent form with HIPAA.

Q: Which informed consent template should I use?

A brief description of each informed consent template follows. Again, if you are collecting PHI as part of your research, you should always use the consent form with HIPAA:

1. Full Consent – this is the traditional consent form used for all “Greater-than-minimal risk” studies. It is also used for minimal risk studies that do not fit the criteria for the Short Form consent.
2. Brief Consent – this is used for certain “No greater than minimal risk” studies only. Examples are studies that involve only surveys, minor tissue collection (eg. blood, saliva), educational testing, where the intervention and involvement of the study subject is minimal, and easy to explain.
3. Tissue\Data Bank Consent – this is used only when all that is being done, is to collect tissue and\or data for use in future studies only.
4. Multi-Center Studies Consent Form – If you are involved in a multi-center study, where UF is serving as the reviewing IRB (aka: sIRB, single IRB, central IRB), the follow informed consent templates are used:
   a. Core Consent - To be used as the main consent, the consent includes HIPAA language. Each site uses this Core Consent, this consent is un-editable by the participating site(s) and references the local addendum.
b. Local Addendum – each site, including UF, also uses this Local Addendum, in which all local context information is located. The UF IRB will approve both the Core Consent and each local addendum.

Q – What about the signature sections?

There are several options for the signature section depending on if children are involved or not, if more than one parent has to sign, etc. If you are not sure about assent and children, please refer to the Investigator Guideline on Assent in Children.

Q – What if my research is at the VA Medical Center?

The IRB-01 website has the VA Medical Center informed consent template, which must be used for any subject consented at the VA. Also, the VA requires that a physically separate HIPAA Authorization be provided to the potential subject for a separate signature. The VA Privacy Officer provides the HIPAA Authorization Agreements.