

IRB Website <http://rgp.ufl.edu/irb>

# IRB InvestiGATOR

University of Florida Institutional Review Boards

Volume 4, No. 8

August 2001

## Simplify Informed Consent Forms

Informed consent is one of the most important aspects of conducting human subjects research. Federal regulations control the process of fully informing prospective study participants. The sample Informed Consent Form at the IRB website conforms to the regulations by incorporating into the Informed Consent Form (ICF) all of the elements of informed consent. Also built into the sample ICF are standardized text suggestions that should be included in the ICF for certain situations.

The straightforward language of the standardized ICF text is recommended because it is easily understood by most people with at least an 8<sup>th</sup> grade education, another Federal requirement. While some of the suggested language may apply, most of the ICF will be written by PIs. They must write their own descriptions of the study purpose in a way that will be meaningful to potential subjects. Also, PIs must write a detailed account of what the study participant can expect to do or undergo during the study. A well-written ICF that is accurate, concise, simplified, and includes the required elements of informed consent will gain swift IRB approval.

Tips for Writing the ICF. The IRB glossary can assist PIs in breaking down technical terms, procedures, and treatment regimens into 8<sup>th</sup> grade language. Be accurate in your descriptions. Use shorter sentences and fewer words with fewer syllables. Think of ways to simplify descriptions of complicated study interventions... test your ideas on an 8<sup>th</sup> grader! Use the term "You" when referring to the prospective participant. Do **not** use the phrase "You understand" as you cannot confirm it is true.

The IRB office staff is equipped to offer support and suggestions for writing ICFs. Please feel free to make a call and get some assistance.

## Reporting Adverse Events (AEs)

The IRB processes and reviews a large number of Adverse Event (AE) reports. Often these reports are incomplete and/or incorrectly submitted. This kind of error can slow down the review process, and increase the overall review time for other IRB projects. Please use the information below to guide your future AE reports.

The UF policy for reporting AEs is guided by Federal regulations. Accordingly, the IRB classifies AEs into two (2) types, and each must be reported in a specific way. The first type of Adverse Event is Serious AND Unexpected and the second type is Serious OR Unexpected.

- Serious **AND** Unexpected Adverse Events must be reported within 5 days of their occurrence if local, or within 5 days from the time the PI is notified about it if non-local. Use the Serious and Unexpected Adverse Event Safety Report.
- Serious **OR** Unexpected Adverse Events should be reported using the Adverse Event Table, which is a cumulative list of AEs that is submitted at the time of continuing review or upon study closure.

The appropriate forms and instructions for reporting AEs are available at the IRB website. Confirm your use of the correct form; complete each question on the form; use N/A (not applicable) *only* when appropriate; and make sure there is an original PI signature on the reporting form.

## Links of Interest

- National Institute of Health (NIH)  
<http://www.nih.gov/health/>
- Office for Human Research Protections  
<http://ohrp.osophs.dhhs.gov/>

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