

February 6, 2008

Health Sciences IRB Informed Consent Template Revised

The Health Sciences Informed Consent template has been revised and is available online: [Template and Instructions for Adult Informed Consent](#). Please use this updated template for all NEW studies. It is not necessary to replace already approved Informed Consent Forms.

The following is a summary of the revisions:

1. The word "subject" was replaced with "research participant".
2. Added an introductory statement in front of "WHY IS THIS STUDY BEING DONE?"
3. Updated the risks for genetic testing or genetic research under "WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?"
4. Added a description of the IRB under "WILL YOUR INFORMATION BE KEPT PRIVATE?"
5. Updated the template language in the "WHAT ARE THE COSTS?" section. Now the examples are provided depending on the studies sponsored by either pharmaceutical company or non-pharmaceutical sponsored
6. Updated the information regarding study-related injuries under "WHAT HAPPENS IF YOU GET INJURED OR NEED EMERGENCY CARE?" Also added to the instructions for pharmaceutical sponsored studies the following: "The language in this section must match the contract."
7. Updated the template language in "UNDER WHAT CIRCUMSTANCES CAN YOUR PARTICIPATION BE TERMINATED?", and added the following
8. Clarification: "This section may not apply if the participation is one-time only."
9. Under the section "Whom do you call if you have questions or concerns?", the use of the word "Dr." was clarified in the instructions, when it appears in the informed consent. Also, updated the template language in this section.