GUIDELINES FOR WRITING INFORMED CONSENT FORMS

I. INTRODUCTION

This document supersedes the previous Guideline for Writing Informed Consent Forms, issued September 25, 2001, which was developed by The George Washington University, Committee on Human Research, Institutional Review Board (GWU IRB). Like its predecessor, this revised document provides guidance to all GWU affiliated investigators, including GWU, MFA and GWU Hospital investigators, regarding how to draft an informed consent form (ICF) that meets Federal, regulations and GWU IRB requirements. This document includes general guidance regarding how to write an ICF as well as a sample ICF for clinical research trials.

The sample ICF includes the following changes:

1. INTRODUCTION Section – New bulleted language;
2. PROCEDURES Section - New language for genetic research activities (i.e., use of an ICF addendum); and new detail regarding use of tissues/specimens for non-genetic research activities (in response to HIPAA);
3. PREGNANCY/CONTRACEPTION/BREASTFEEDING Section – Condensed the language and modified accordingly;
4. CONSENT FOR USE/DISPOSAL OF TISSUE/SPECIMEN(S) Section – Revised to reflect modifications made to PROCEDURES section;
5. COMPENSATION Section – Included non-exculpatory language;
6. PAYMENT FOR INJURY OR HARM Section – Revised language to take into account study specific agreements and further clarify when a subject would be responsible for payment for injury or harm resulting from study participation;
7. RIGHT TO WITHDRAW FROM THE STUDY Section – Explained what will happen to tissue/specimens when subject withdraws from study;
8. CONFIDENTIALITY OF MEDICAL AND RESEARCH RECORDS – Revised language to reflect certain regulatory agencies’ unfettered access to research and medical records and includes language to be used when a Certificate of Confidentiality is issued for a particular study;
9. SIGNATURES Section – Clarified what the subject is affirming;
10. PRINCIPAL INVESTIGATOR SIGNATURE Section - Clarified that only the PI is eligible to sign this section of the ICF; and
11. Added an ICF ADDENDUM FOR GENETIC RESEARCH.

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Revised November 2004
Please note that if you propose to conduct research on a population, the majority of which is not proficient in English, the ICF requirements outlined below must be translated into a non-English ICF. For further guidance regarding translation and back-translation of an ICF, please refer to the GWU Medical IRB Manual.

II. BASIC REQUIREMENTS

A. An ICF must be written on GWU/MFA department letterhead (title page only), with 1-inch margins on both sides and the bottom and with 1.5 inches at the top.
   - Use a type size of 12 point.
   - Number all pages.
   - Use a footer with the IRB number and revision date with a type size of 8-10 point.
   - Letterhead should not include names of department members who are not associated with the study.

B. An ICF should address the subject with the pronoun, "you" (third person), rather than "I" (first person), e.g., "You are invited to take part in a research study."

C. An ICF should be written for the subjects in an informative, understandable manner.

D. An ICF should be written at the eighth-grade reading level.
   - Use one or two syllable words whenever possible.
   - Write short sentences and paragraphs.
   - Define all medical terms in lay language. Avoid medical terminology where possible and define medical terms when they need to be used, e.g., leukocytes vs. white blood cells vs. blood cells which fight infection.
   - Use headings to break up the information.
   - Avoid contractions such as "don't."

E. An ICF should be organized as follows:
   - The first item on the ICF should be the heading “Informed Consent Form;”
   - The second item on the ICF should be "Research Study" followed by the title of the research study. Include the IRB# immediately after the protocol title;
   - The third item on the ICF should be "Investigator:" followed by the investigator's name and phone number. The name and telephone number of a sub-investigator or research coordinator (contact person) may be included.
in addition to the investigator's name and telephone number if appropriate for the study;
• The headings and numbering system noted in the sample Biomedical ICF, available at www.gwumc.edu/research/forms.htm, should be used in each consent document;
• The footer for each page of the ICF should include the IRB#, which is always 6 digits; the date (revision) of the ICF; and the page numbers for the ICF, preferable page 1 of ##;
• The enclosed box text found in the sample ICF must be included in all ICFs. If a particular section does not apply, please write “Not Applicable” under that heading;
• Detailed information, complex drug dosing instructions, and concomitant medication lists may be provided for subjects in a separate Information Sheet. This Information Sheet will also need approval by the GWU IRB prior to use.

F. The Code of Federal Regulations, specifically 45 CFR 46.116 and 21 CFR 50.25, require that the following 8 elements of information, at a minimum, be provided to each prospective subject or the prospective subject’s legally authorized representative (LAR) prior to enrolling into a study unless the GWU IRB has determined that a waiver of or alteration to informed consent may be granted for a particular study:

• **Purpose of the Study.** A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation in the research, a description of the procedures to be followed, and identification of any procedures that may be experimental;
• **Potential Risks or Discomforts.** A description of any reasonably foreseeable risks or discomforts to the subject. Such risks/discomforts include physical risks as well as breach of confidentiality risks;
• **Anticipated Benefits.** A description of any benefits to the subject or to others which may be reasonably expected from the research;
• **Disclosure of Alternative Procedures.** A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
• **Confidentiality of Records.** A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
• **Compensation and Injury Explanation.** For research involving more than minimal risk, an explanation as to whether any compensation will be provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
• **Contact Information.** An explanation of whom to contact for answers to pertinent questions about the research and research subject’s rights, and whom to contact in the event of a research-related injury to the subject; and

• **Voluntary Participation Statement.** A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

G. In addition, federal regulations provide that the following information be provided to subjects, where appropriate:

• A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant or the subject could make a woman pregnant) that is currently unforeseeable;

• Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

• Any additional costs to the subject that may result from participation in the research;

• The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

• A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

• The approximate number of subjects involved in the study (at GW and the total number from all sites).

The GWU IRB has determined that the additional elements stated above (as appropriate) should be included in all clinical trial consents used at GWU.

A sample Biomedical ICF, is available at [www.gwumc.edu/research/forms.htm](http://www.gwumc.edu/research/forms.htm). This sample ICF is provided by the GWU IRB to enable the investigator to meet the above federal regulations and GWU IRB requirements.