Human Research Protection
Program Institutional Review
Board Procedure

POLICIES AND PROCEDURES IN HUMAN SUBJECTS RESEARCH:
PREPARATION, REVISION AND DISSEMINATION

DESCRIPTION

University of Cincinnati (UC) Human Research Protection (HRP) policies and procedures will be prepared and revised as needed to provide protection for the rights and welfare of human research participants.

RESPONSIBILITY

The Institutional Review Board (IRB) Chair, Office Manager or designee will prepare new or revised HRP policies and procedures as needed and submit them to the Institutional Official (IO) for review and approval. After approval, the IRB Office Manager or designee will make the new or revised policies and procedures publicly available. The IRB Office Manager or designee will provide training of IRB members and IRB office staff if there are significant changes to an HRP policy or procedure.

PROCESS

PREPARATION

I. GENERAL

- The header of each HRP policy or procedure will show:
  ○ The Policy (or Procedure) Number
  ○ The Policy (or Procedure) Title
  ○ Date adopted
  ○ Date of most recent revision
  ○ Page number (x of y)

- The footer of each HRP policy or procedure will show the path where the policy is saved electronically (i.e., the UC electronic folder in which it is saved).

- The first time abbreviated terms are used, they will be spelled out.

- When appropriate, terms will be defined.
Main section titles will be bold and all-caps.

Sub-sections, bullet lists or other formatting will be used as appropriate to enhance readability.

Applicable Regulations and Documents will be listed after all other elements of the HRP policy or procedure have been given. For HRP policies, this list will typically include federal regulations and HRP policies or procedures. HRP procedures may also list pertinent forms used by the IRB or researchers.

A table summarizing revisions will be provided after Applicable Regulations and Documents. It will be updated each time the HRP policy or procedure is revised.

Lines for Date Adopted and Signature will be the last item of every HRP policy and procedure. The IO will sign and date all HRP policies and procedures.

Approved HRP policies and procedures with original signatures will be retained by the UC Office of Research Integrity (ORI) as long as they are in effect. Deleted or replaced HRP policies and procedures will be archived electronically for three years by the UC ORI.

II. HRP POLICY FORMAT

A. Number

HRP policies will be numbered according to the following categories. The number will begin with the category's Roman numeral, then a decimal, then a two-digit Arabic numeral for each policy, consecutively in the order adopted. If a proposed HRP policy does not fall under one of the following sections, a new category may be made.

I  Authority and Institutional Commitment
II  Conduct of Research
III IRB Review
IV Investigator Responsibilities
V  Vulnerable Populations
VI  Clinical Research
VII Quality Assurance, Legal, and Compliance
B. Main Sections

1. Policy

Each HRP policy will begin with a concise statement summarizing the purpose of the policy. Policies will contain overall principles and broadly described actions that are needed to protect human research participants and document such activities. Policies will not contain step-by-step procedures or work instructions.

2. Content of Other Sections

- Elements that are needed to ensure the HRP policy is met will be identified and explained.

- When appropriate, the positions responsible for elements of the policy will be listed along with the actions they must take.

III. HRP PROCEDURE FORMAT

A. Number

HRP procedures will be numbered according to the following categories. The number will begin with the category's first digit followed by two digits given consecutively in the order adopted. If a proposed HRP procedure does not fall under one of the following sections, a new category may be made.

100 General Administration
200 Informed Consent
300 Function and Operations

B. Main Sections

1. Description

Each HRP procedure will begin with a concise statement summarizing the purpose of the procedure.
2. Responsibility

The position(s) responsible for elements of the procedure will be listed along with a brief statement of the actions they must take.

3. Process

For each element of the HRP procedure, specific actions and steps needed to ensure compliance will be listed.

DISSEMINATION AND TRAINING

I. Each new or revised HRP policy or procedure will be posted on the IRB’s website by the IRB Office Manager or designee. The document version date will be listed and a notation will be attached to indicate that it is a new document or version.

II. The IRB Chair and IRB Office Manager will identify any new or revised HRP policy or procedure that contains information that needs to be brought promptly to the attention of IRB members, IRB office staff and researchers. Examples include, but are not limited to, changes in the Adverse Event reporting policy or changes in the procedure of submitting materials to the IRB for review.

   A. The IRB Office Manager or designee will send notification of the new or revised HRP policy or procedure to researchers electronically, and put a special announcement on the IRB’s website.

   B. The IRB Office Manager or designee will inform IRB members and IRB office staff about the new or revised HRP policy or procedure and the impact on HRP activities at UC. Evidence of training will be documented and filed with the appropriate HRP policy or procedure.

   C. Researcher training will be the responsibility of the researcher’s department or affiliated Practice Corporation.

III. Each new IRB member or IRB office staff must review all applicable HRP policies and procedures prior to undertaking any responsibilities for the IRB. Evidence of training must be documented and filed with the IRB Office Manager.

U Drive Procedure 104 Policy & Procedure Prep (version 8-15-12)
Applicable Regulations and Documents:
21CFR56.108
45CFR46.103
Policy 1.05 Policies and Procedures in Human Subject Research: Preparation, Revision and Dissemination

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Date Adopted 27 August 2012 Signature [Signature]