PARTICIPANT OUTREACH

DESCRIPTION

Human subject research (HSR) is a collaborative effort that includes community members, research participants, researchers and their staff and regulatory oversight personnel. Therefore it is important for the University of Cincinnati (UC) to provide information about HSR to stakeholders who do not conduct or oversee research themselves to increase their understanding and participation in HSR.

RESPONSIBILITY

The Institutional Official (IO), Institutional Review Board (IRB) Chair, researchers and other stakeholders in the research community shall identify and pursue appropriate outreach activities, as described in Human Research Protection (HRP) Policy I.06 Participant Outreach Program and in the sections below.

PROCESS

The methods used to provide information to the community about HSR at UC will vary based on the type of information being presented. They may include, but are not limited to, the following kinds of activities.

WEBSITE INFORMATION

1. Information about HSR, HRP and the IRB may be posted on publicly available UC websites.
   - Examples of general information that may be posted include, but are not limited to, the purpose of IRB review, the kinds of activities that require IRB review, HRP policies and procedures, and links to additional information.
   - The IRB Office Manager or designee will ensure that posted information is accurate and current, and make changes as needed.

2. Information about specific HSR studies may be posted on publicly available websites, either hosted by UC or by other entities.
The following study-specific basic descriptive information may be posted without IRB review.
  - Study title
  - Purpose of the study
  - Protocol summary
  - Basic eligibility criteria
  - Study site location(s)
  - How to contact the study site for further information

Information exceeding such basic descriptive information includes, but is not limited to, descriptions of risks and potential benefits, or solicitation of identifiable information. Information that exceeds the listed basic descriptive information must be approved by the IRB before it may be posted, as described in HRP Policy II.04 Recruiting Participants in Human Subject Research and HRP Procedure 203 Recruitment of Participants in Human Subject Research.

Examples of clinical trial listing services that do not need IRB approval include, but are not limited to, the National Institutes of Health (NIH) ClinicalTrials.gov website, the NIH National Cancer Institute's cancer clinical trials listing (Physician Data Query [PDQ]), and the government-sponsored AIDS Clinical Trials Information Service (ACTIS).

3. General and study specific HSR, HRP and IRB information from non-UC websites also may be made available to HSR stakeholders in the greater Cincinnati area.

- The IO and IRB Chair shall determine if links or references to such non-UC websites should be made available on UC's IRB website.

- The IRB Office Manager or designee will ensure that posted information is accurate and current, and make changes as needed.

COMMUNITY CONSULTATION

Community consultation plans done as part of a request for exception from informed consent (EFIC) require approval by the IRB as stated in HRP Policy II.01 Obtaining Informed Consent and HRP Procedure 202 Exception from Informed Consent in Clinical Trials.
Human Research Protection
Program Institutional Review
Board Procedure

Community consultation plans done as part of research involving participants who may be vulnerable to coercion or undue influence due to a psychiatric condition require approval by the IRB as stated in HRP Policy V.07 Individuals with a Psychiatric Diagnosis Who Are Able to Consent But May Be Vulnerable to Coercion and HRP Procedure 308 Institutional Review Board Review of Research Involving Vulnerable Populations.

Other consultation with community members and organizations to provide general HSR or study specific information may be arranged by a researcher or the IO or IRB Chair. These meetings may be collaborative activities with other research institutions in the greater Cincinnati area. If study-specific information only includes a basic description, as listed above, the activity does not require IRB approval.

INFORMATIONAL ACTIVITIES

The IO, IRB Chair or a researcher may arrange for UC participation in information booths, research fairs, etc., to provide general HSR or study-specific information to community members. These activities may be offered jointly with other institutions in the greater Cincinnati area. If study specific information only includes a basic description, as listed above, the activity does not require IRB approval.

FEEDBACK RESULTING FROM OUTREACH ACTIVITIES

Any comments about the participant outreach program will be forwarded to the IO and IRB Chair for evaluation. They will make sure appropriate action is taken.

If information is received that needs to be handled according to Policy II.02 Reporting to the IRB: Unanticipated Problems Involving Risks to Participants or Others, Adverse Events, and Other Problems and Procedure 320 Review of Reportable Events, the IO or IRB Chair or designee will take appropriate action.

Applicable Regulations and Documents:
Policy I.06 Participant Outreach Program
Policy II.01 Obtaining Informed Consent
Policy II.02 Reporting to the IRB: Unanticipated Problems Involving Risks to Participants or Others, Adverse Events, and Other Problems
Policy II.04 Recruiting Participants in Human Subject Research

U Drive Procedure 106 Participant Outreach (version 8-31-12)
Human Research Protection
Program Institutional Review
Board Procedure

Policy V.07 Individuals with a Psychiatric Diagnosis Who Are Able to Consent But May Be Vulnerable to Coercion
Procedure 202 Exception from Informed Consent in Clinical Trials
Procedure 203 Recruitment of Participants in Human Subject Research
Procedure 308 Institutional Review Board Review of Research Involving Vulnerable Populations
Procedure 320 Review of Reportable Events
FDA Clinical Trials Guidance on Recruiting Study Subjects (10-18-2010)
OHRP Guidance on Institutional Review Board Review of Clinical Trial Websites (9-20-2005)

<table>
<thead>
<tr>
<th>Adoption Date:</th>
<th>Created by:</th>
<th>Date of Revision:</th>
<th>Revised By:</th>
<th>Summary of Revision:</th>
</tr>
</thead>
<tbody>
<tr>
<td>8/2012</td>
<td>C. Norman</td>
<td>8-31-12</td>
<td>C. Norman</td>
<td>Add wording that was removed from Policy I.06 Participant Outreach Program. Add list of basic description, examples that exceed the list, and websites not needing IRB approval. Add reference to Policy II.04, Policy V.07, Procedure 203, Procedure 308, FDA Guidance and OHRP Guidance.</td>
</tr>
</tbody>
</table>

Date Adopted 3 September 2012  Signature Jane E. Strauss