In this chapter:

10.1 Equitable Selection
10.2 Vulnerable Subjects
10.3 Non-English Speaking Participants
10.4 Review of Recruitment Methods, Advertising Materials and Payment
10.5 Addressing Concerns of Research Participants
10.6 Participant Education and Outreach
10.7 Involvement of Community Members in Community Based Participatory Research

10.1 Equitable Selection

<table>
<thead>
<tr>
<th>AAHRPP Std./Element</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>II.3.C</td>
<td>The IRB has and follows written policies and procedures to evaluate the equitable selection of participants.</td>
</tr>
</tbody>
</table>

Guidance and information is made available to Principal Investigators (PIs) to assist and guide them in creating recruitment and participant selection methods that are fair and equitable.

PIs are directed to enter detailed information on how participants will be identified and recruited in response to questions in the study application.

PIs are required to identify the target populations (including age range, gender, and ethnic background), the inclusion and exclusion criteria and whether payments will be made for participation. In addition, PIs are required to justify the inclusion of targeted persons (e.g., healthy participants, employees, students or participants with certain medical conditions). In determining if the selection and recruitment of participants is equitable, the IRB takes into account the purpose of the research, the setting in which the research will be conducted, whether prospective participants will be vulnerable to coercion or undue influence, the selection (inclusion/exclusion) criteria, participant recruitment and enrollment procedures, and the influence of payments to participants. The IRB also evaluates whether the study imposes fair and equitable burdens and benefits - such that one group of persons does not disproportionately receive the benefits compared to another group assuming only the risks.

IRB staff and members review this information and confirm the recruitment and selection strategies are fair, equitable, and not misleading. If recruitment strategies fail to meet these requirements, the protocol will not be approved as written and the PI will be asked to modify the recruitment plan accordingly, as a condition of approval.

10.2 Vulnerable Subjects

Investigators must provide a rationale for involvement of vulnerable subjects, such as children, prisoners, pregnant women, economically and educationally disadvantaged, and the decisionally impaired. The PI must substantiate his/her decision to involve a vulnerable population and further provide a rationale why a less vulnerable population would not serve the purpose of the research. When vulnerable populations will be targeted for enrollment, the IRB assesses the...
additional safeguards proposed by the PI to minimize the possible risks and the chance of harm to these populations. While pregnant women are considered vulnerable participants, women of reproductive age should not be arbitrarily excluded from participation in research. If women are to be excluded, such exclusion must be fully justified by the PI based on scientific rationale.

10.03 Non-English Speaking Participants
Non-English speaking participants should not be systematically excluded because of language barriers. The IRB encourages the inclusion of non-English speaking participants and permits such persons to be enrolled via a translated consent or the short form consent process consistent with 45 CFR 46.117(b)(2) and 21 CFR 50.27(b)(2).

10.4 Review of Recruitment Methods, Advertising Materials and Payment

<table>
<thead>
<tr>
<th>AHRPP Std./Element</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>II.3.C.1</td>
<td>The IRB has and follows written policies and procedures to review proposed participant recruitment methods, advertising materials, and payment arrangements and determines whether such arrangements are fair, accurate, and appropriate.</td>
</tr>
</tbody>
</table>

Recruitment tools (advertisements, etc.) are required to have IRB review and approval prior to implementation. When reviewing recruitment tools the IRB must review the final mode of its communication, including the final copy of printed advertisements and the final audio or video advertisements.

Only IRB approved advertisements, considered fair, honest and appropriate by the IRB, may be used in the conduct of subject recruitment. Recruitment materials should be included with your initial and continuing review applications. If the material is not ready at the time of the initial application, investigators may submit the material as an amendment to an already approved project. Requests for approval of recruitment materials following initial IRB review of the protocol should allow sufficient time for any necessary revisions prior to publication. Advertisements, press releases, etc., may qualify for expedited review.

When recruiting subjects from another institution with an IRB, investigators are required to gain IRB approval from that institution. In institutions without an IRB, investigators are required to obtain a letter of agreement on the facility’s letterhead indicating the research can be conducted at the site and the agency or institution will review, abide by and comply with the procedures approved by the UofL IRB.

A recruitment tool informs potential subjects of a research activity and provides them with an opportunity to contact the researcher. A recruitment tool may include, but is not limited to, post-cards, flyers, advertisements, press releases, brochures, and postings on the Internet.

Use the following guidelines when developing recruitment tools:

1. name and address of the clinical investigator and/or research facility (letterhead is acceptable).
2. the condition under study and/or the purpose of the research.
3. in summary form, the criteria that will be used to determine eligibility for the study.
4. a brief list of the benefits of study participation, (if any) i.e. a free health examination.
5. time or other commitments required.
6. the location of the research and the person or office to contact for further information;
7. in drug or device studies, no claim should be made as to the superiority, safety or effectiveness of the drug or device. Proprietary names of study products may not be used.

Chapter 10 Page 2 of 7
8. do not provide excessive monetary or other incentives that could be interpreted as inappropriate or coercive.
9. tools are consistent with protocol.

The recruitment tool should not:

1. state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
2. include exculpatory language.
3. emphasize the payment or the amount to be paid, by such means as larger or bold type.
4. promise “free treatment” when the intent is only to say subjects will not be charged for taking part in the investigation.

When following FDA regulations and guidance the recruitment tool should not:

1. make claims, either explicitly or implicitly, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling.
2. use terms, such as “new treatment,” “new medication,” or “new drug,” without explaining that the test article is investigational.
3. allow compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

Due to contractual obligations, recruitment tools should not include any proprietary identifiers, contain therapeutic or outcome claims or mention the corporate sponsor by name.

An investigator may request assistance from the HSPPO in developing UofL Today submissions to ensure that their announcement meets the above guidelines as well as the 75 word limit impose by UofL Today.

Advertisements
The IRB considers that advertisements begin the informed consent process and thus, consistent with the consent process, coercion and undue influence are prohibited during recruitment. If recruitment will be by advertisement, the mode of advertisement (flyers, radio, newspaper, or internet) and information contained in the advertisement must be approved by the IRB.

- **Audio and video tape:** The IRB may review and approve the wording prior to taping in order to preclude re-taping due to inappropriate wording. The IRB reviews the final version of the advertisement.
- **Printed advertisement:** The IRB reviews the final copy.

Telephone Screening
For protocols involving telephone screening of participants in response to an advertisement, the IRB generally requires investigators to review all the required elements of informed consent orally with prospective participants. However, investigators may request a waiver of documentation of consent limited to the screening portion (only) of the protocol if they demonstrate that the screening procedure meets regulatory criteria in 45 CFR 46.117(c)(2) or 21 CFR 56.109(c)(1).

Payment
PIs must disclose any proposed payments to participants in the protocol application form, including the method, type and timing of the payments. Payments to research participants may not be of such an amount as to result in coercion or
undue influence on the research participant’s decision to participate. If a study has multiple paid visits, payment should be prorated throughout the duration of the study to provide partial payment to persons who withdraw before completing the study. See Paying Human Subjects Policy and Guide-030 Paying Human Subjects Guidance.

**Payment Arrangement among Sponsors/Organizations, Investigators and Others**

Finder’s fees and other financial incentives paid by a sponsor or by an investigator to others related to the recruitment of research subjects are prohibited. No one may receive any incentive for the purpose of encouraging individuals to participate in research. All payment by sponsors for research conducted under the auspices of the University of Louisville must be made directly to the University of Louisville Research Foundation, Inc. (ULRF) or the University of Louisville and will be managed by the Foundation or University. Payments should never go directly to investigators, key personnel or subjects without first going through the ULRF or the University.

**10.5 Addressing Participants Concerns**

<table>
<thead>
<tr>
<th>AAHRPP Std./Element</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.4.A</td>
<td>University of Louisville has and follows written policies and procedures that establish a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives that permits them to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research protocol or plan.</td>
</tr>
<tr>
<td>III.1.G</td>
<td>Researchers and Research Staff have a process to address participants’ concerns, complaints, or requests for information.</td>
</tr>
</tbody>
</table>

**Consent Form Requirements**

The IRB requires that all consent forms include information on how to contact the investigator(s) conducting the research study. Participants are instructed to call the investigators if they have any questions about the research, about their rights as a research participant, or if they believe they have suffered a research-related injury. Each consent form must also include telephone numbers for the IRB (a local number and a toll free number). The IRB contact information affords current or past research participants or their designated representatives a means to contact an informed individual who is independent of the research team. The IRB also serves as a conduit for receiving information from any party who is not satisfied with the manner in which a study is (or was) being conducted, or if any party has any concerns, complaints or general questions about research or the rights of research participants.

Consent form templates, available on the Human Subjects Protection Program website, include instructional text and verbatim language for the inclusion of the investigator’s contact information and IRB telephone numbers under the consent form heading “Contact Information.” The IRB’s physical address is included in the consent form template to also allow for written communication.

**Recruitment Material Requirements**

The IRB requires specific contact information to be included in participant recruitment materials – flyers, newspaper ads, newsletters, and web postings.

All recruitment materials must include the appropriate contact information for the investigator(s) conducting the study. The IRB reviews all recruitment materials, and the addition of IRB contact information is required when appropriate.
Telephone (Screening) Scripts
The IRB requires investigator and IRB contact information be included in telephone scripts. Telephone scripts are often used to screen prospective participants. Like the consent forms, telephone scripts must include telephone numbers for IRB (a local number and a toll free number), as well as telephone numbers for the investigators. This contact information provides prospective participants with channels of communication to the investigators and the IRB for questions, concerns, input, information or complaints.

Responding to Contacts from Participants or Others
Concerns of research participants are investigated by the HSPPO Research Compliance Monitors. All reports of concerns received either directly by the Research Compliance Monitors or forwarded to the HSPPO by the Institutional Compliance Office or the Research Integrity Program, are shared with the HSPPO Director and/or Assistant Director. Research Compliance Monitors prepare a Contact Sheet which indicates the concerns expressed by participants or others and the actions to be taken to resolve any issues or problems. Minor concerns are generally resolved by a phone call. However, more complex concerns are followed up by the HRPP Director with the relevant IRB Chair and others in the Human Subjects Protection Program Office. Participants and others may reach the HSPPO at (502) 852-5188 or by emailing the Human Subjects Protections Program Office at hsppofc@louisville.edu.

Website
The Human Subjects Protection Program website includes participant outreach information addressing the general rights of research participants and provides links to various research resources. Additionally, the website has a toll free Compliance Hotline where current, prospective or past research participants or their designated representatives may discuss concerns and questions or offer input to an informed individual who is unaffiliated with the specific research protocol or plan. The Compliance Hotline is a 24 hour hot line answered by people who do not work at the University of Louisville. Participants may address their concerns anonymously by calling toll free at 1-877-852-1167. Information concerning the ways to contact the HSPPO with questions are contained in the following webpage: https://louisville.edu/research/humansubjects/about/questions-complaints-or-concerns-for-the-irb

10.6 Participant Education and Outreach
The University of Louisville and the Human Subjects Protection Program employ several mechanisms for communication and education to increase public awareness and educate potential research participants.

<table>
<thead>
<tr>
<th>AAHRPP Std./Element</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.4.B</td>
<td>University of Louisville conducts activities designed to enhance understanding of human research by participants, prospective participants, or their communities, when appropriate. These activities are evaluated on a regular basis for improvement.</td>
</tr>
</tbody>
</table>

Participant education materials and outreach activities are reviewed annually by the HSPPO Director, Assistant Director and the Chairs and Vice Chairs of the IRBs. That review usually takes place during the April-June fiscal year budget cycle. Suggested revisions are discussed with the appropriate Associate Vice President for Research and Innovation and the individual research deans or program directors.

On-line Resources and Human Subjects Educational Materials
The Human Subjects Protections Program website contains information for Participants in Research. A Tab for “Participants” contains the following:

General Information about becoming a research volunteer;
Information about informed consent for research volunteers;
Information about voluntary participation in research;
Questions participants are urged to ask prior to enrolling in a research study;
Information concerning the rights of a research subject which includes a toll free number for the University of Louisville;
Information concerning an anonymous Hotline to assist participants in asking questions or expressing concerns about on-going research at the University of Louisville;
A link to Clinicaltrials.gov to assist participants in finding open clinical trials;
Links to OHRP brochures: Becoming a Research Volunteer: It's Your Decision (in English and Spanish);
Links to entities and organizations where research information can be obtained (e.g. National Cancer Institute, FDA, OHRP, Cancer.net and the American Cancer Society;)
NIH Clinical Research Trials and You
Contact information for inquiries about current research at University of Louisville and their affiliated research partners:
  Norton Healthcare Office of Research Administration (NHORA) This website has information regarding all the research and clinical trials for all the Norton Hospitals and physician offices in the Louisville and Southern Indiana area.
  Brown Cancer Center Clinical Trials (JGBCC) Multidisciplinary cancer clinics with a listing of all their clinical trials according to the type of cancer.
  University of Louisville Hospital (KentuckyOne Health) Listing of departments and contact phone numbers to call University of Louisville Clinical Trials Unit Multidisciplinary listing of clinical trials.
  Just 4 Kids Information pertaining to common types of heart defects in children and research being performed at Norton Children’s Hospital.
  Kosair Charities Pediatric Clinical Research Unit (KCPCRU).

Other University of Louisville Research Resources
Colleges and Schools at the University of Louisville provide web-based information on current research or outreach opportunities.

  College of Arts and Sciences
  College of Business
  School of Dentistry
  College of Education and Human Development
  School of Interdisciplinary and Graduate Studies
  Kent School of Social Work
  Brandeis School of Law
  School of Medicine
    • Center for Environmental Genomics and Integrative Biology
    • FOAMed – Free Open Access Medical Education
    • Department of Surgery http://www.louisvillesurgery.com/downloads/ClinicalTrials_Q_A.pdf
    • Kentucky Spinal Cord Injury Research Center
  •

School of Music
  School of Nursing
    • http://harambeehealthcenter.org
  School of Public Health and Information Sciences
  Speed School of Engineering
  KBRIN – Kentucky Biomedical Research Infrastructure Network
10.7 Involvement of Community Members in Community Based Participatory Research

<table>
<thead>
<tr>
<th>AAHRPP Std./Element</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.4.C</td>
<td>University of Louisville promotes the involvement of community members, when appropriate, in the design and implementation of research and the dissemination of results.</td>
</tr>
</tbody>
</table>

Both institutional IRBs have community members who support the roles of local community participants in human subjects research. Community members are encouraged to participate in annual continuing education workshops (through PRIM&R and AAHRPP) addressing community research needs. Both the Biomedical and Social Behavioral Education IRBs include members with expertise in community based research. If necessary to review specific IRB proposals, internal University of Louisville consultants would be invited to participate in the discussion of such research proposals.