Recruitment of Human Participants

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Overview

Purdue University (PU) Institutional Review Boards (IRBs) and investigators share the responsibility for creating a recruitment environment that is not only effective but is also ethical and complies with federal regulation and guidance. The identification, initial contact, screening and recruitment of potential human participants is the beginning of the informed consent process. The screening and recruitment process should demonstrate respect for the dignity and autonomy of potential participants by avoiding any potential undue influence and by protecting both the privacy of the individual and the confidentiality of any information obtained for recruitment and/or screening.

Definitions

Coercion is the persuasion of an otherwise unwilling person to do or agree to something by use of obvious or implied force or threats.

Compensation is payment, merchandise, class credit or other gift or service provided to research participants or their legally authorized representatives to reimburse them for their time, effort, and/or for any out-of-pocket expenses associated with research participation. Note: Compensation is sometimes distinguished from an *incentive* or *inducement*, which is generally thought of as a payment or other offering that is "over and above" reimbursement and intended to encourage research participation.

Finder's Fee is a payment made by an investigator or sponsor to an organization or individual (including non-research personnel or a research participant) for identifying and/or referring potential participants for research.

Recruitment Bonus is a payment, merchandise, or other gift or service offered by an investigator or sponsor as an incentive or reward to an organization, investigator or key personnel conducting research designed to accelerate recruitment that is tied to enrollment rate, timing, or numbers.

Recruitment Database is a data set including private identifiable information collected for the specific purpose of identifying and recruiting potential participants.

Recruitment Materials are announcements; advertisements; flyers; posters; scripts for telephone or other oral communication; letters and email messages; bulletin board tear-offs; internet postings; newspaper, radio, television, or video broadcasts, or other media used to attract potential participants for research.

Recruitment Methods are materials, incentives, and other practices or procedures used to inform potential participants about research.

Student Subject Pools are usually comprised of undergraduate students enrolled in particular courses requiring participation in one or more research projects (i.e., PSY 12000). Occasionally colleges or departments create subject pools to communicate research opportunities to students.

Undue Influence/Undue Pressure is excessive or inappropriate reward or other incentive in which a person is induced to act otherwise than by their own free will or without adequate consideration of the consequences.

Ethical Concerns and IRB Review

The IRB reviews the recruitment methods and materials for all studies in consideration of the purpose of the research, the setting in which the research will be conducted and participant population. Investigators should consider the following ethical issues when planning their recruitment strategies. These are the same considerations the IRB uses to evaluate studies.

- **Equitable selection of participants:** The recruitment plan ensures the selection of research participants is equitable and appropriate for the study.
- **Respect for persons:** The recruitment plan ensures appropriate procedures are used for the study population, especially if the population presents any special problems requiring specific safeguards. Such populations may include vulnerable populations such as children, prisoners, pregnant women, economically disadvantaged persons and cognitively impaired persons or those lacking of decision-making capacity. Other populations (e.g., employees, students, etc.) may be considered a vulnerable population depending on their circumstances in relation to the research.
- **Lack of pressure:** The study is introduced to potential participants in a way that allows them ample time to consider, with no undue pressure because of the ***timing*** of the request, ***who*** makes the request, ***how*** the request is made, or the offering of excessive inducements. Consider if adolescents whose parents give them permission to be in the study will feel they cannot say "no". Will students be hesitant to say "no" to a professor or teacher? Will employees be placed in a situation where they may be hesitant to say "no" to an employer or manager? How will such pressure be minimized?
- **Respect for privacy:** Recruitment plans should respect an individual's reasonable expectations for privacy. Will potential participants identified using confidential information such as school, employee or patient records, have given permission beforehand for this use of their

information? If investigators ask screening questions, will the questions be asked in a private setting where others will not overhear the answers?

- **Unbiased presentation:** All information used for recruitment should be accurate, balanced, and free of misleading emphases that make the study excessively attractive. Is the information as complete as is appropriate for each stage of recruitment?
- **The "Therapeutic Misconception":** Patients tend to believe anything proposed by health care providers will benefit them, even if they are told there is no assured benefit. This "misconception" can also affect the decisions of individuals participating in social, behavioral and education research. This misconception can occur any time participants believe that they will directly benefit from participation in a research study, even if they are told there is no assured benefit. Does the recruitment plan work to counteract this misconception?

Using Records to Identify Potential Participants

- **The review of student records** for the purpose of identifying, contacting and recruiting participants is subject to the rules set forth in the Family Educational Rights and Privacy Act (FERPA). See HRPP Policy **Research Involving Student Education Records**.
- **Use of medical records** for the purpose of identifying, contacting and recruiting participants is subject to HIPAA regulations. Access to medical records and identifiable health information by people not directly involved in a patient's care is highly restricted.
- **Use of Personally Identifying Information (PII)** should limit the amount of identifiable information gathered or obtained and the number of people who have access to identifiable information must be minimized.

Information to Include in the IRB Application

The IRB needs to understand the details of all recruitment activities that will be used in a study. The IRB application must reflect all of those activities and their related details. Below is a list of questions often asked of investigators about their studies. This list is not exhaustive nor do all of these questions pertain to every study. Nevertheless, even when relevant, IRB applications frequently lack these pertinent details. Including a complete description in IRB applications goes a long way towards helping investigators avoid delays in the IRB review process.

- If your IRB application proposes multiple study populations, address all applicable questions for each participant group. An example of this is a study in which both students and their teachers are research subjects. Another example would be a study in which both teenagers and their parents are research subjects.
- How will potential participants be initially identified for this study? Who will identify them?
- How and when will potential participants be approached/contacted about study participation? Who will conduct these activities and where will they occur?

- If your recruitment plan involves contacting individuals multiple times in an effort to secure their initial enrollment in the study, describe how frequently and in what manner individuals will be contacted.
- Identify all recruitment methods that will be used. If your recruitment plan involves using any email, address and/or telephone lists, how will those lists be obtained?
- Describe any provisions to protect the privacy and/or confidentiality of potential participants? This is particularly important when conducting research on sensitive topics, health-related issues, controversial issues, etc. Such provisions are as simple as sending a recruitment letter in an envelope rather than sending a post-card or, if recruiting students in a K-12 school, the school may send recruitment materials to parents rather than giving investigators access to their contact information.
- Will you use screening procedures? If so, who will conduct the screening procedures?
- Will you collect any information/data from potential participants during the recruitment and/or screening process? How will it be collected (i.e., what procedures will be used)? Identify all data points that will be collected prior to their enrollment in the study.
- Will any identifying data collected during the recruitment and/or screening process be retained without consent from individuals who failed to qualify for, or declined to participate in, the study? If yes, identify all retained data points and provide a justification for the retention. If not, will those data be destroyed and how will they be destroyed?

Acceptable Recruitment Methods

The following methods of recruiting subjects are generally acceptable. In reviewing recruitment activities, the IRB reviews the mode of communication as well as the content and how it is presented. There may be circumstances in which one or more of the methods may not be appropriate for a particular study. This is not an exhaustive list but it is an outline of the most commonly used methods for recruitment and includes both behavioral and biomedical recruitment strategies. One study may employ more than one method of recruitment. The method(s) of recruitment should be discussed in the IRB application.

- **Advertisements, flyers, information sheets, notices, internet postings on electronic bulletin boards and/or web pages.** The text of these needs to be included within or as an attachment to the IRB Application. ***The IRB must approve the text to be used***. Prospective participants who respond to these will contact the study investigators directly. See the **Recruitment Materials** section of this guidance for suggested text for ads and notices.
- **Direct contact with potential study participants.** Study team members may directly contact potential participants either in person (face-to-face), by giving a presentation to a group, over the phone, or on the internet through chat rooms or instant messaging. Considerable care must be taken when using any of these methods so that the person contacted does not feel pressured to participate.
- **Recruitment letters and/or emails.** Ideally the recruitment letter or email would come from someone or some agency or clinic known to the prospective participant informing them about

the study. Preferably, the letter or email would ask the person to call for additional information, return a post card or send an email if interested in participating in the study.

The recruitment letter or email can be brief but it should include:

- information about how the person was identified to be sent the letter,
- who is doing the study and why,
- what is involved if the person participates,
- an overview of any risks or potential benefits,
- information about how to contact the study team if interested in participating,
- where to get answers to additional questions, and
- when using email, proper notification about the confidentiality issues associated with email communication.

- **Random or other probability sampling.** This could include snowball sampling, random digit dialing, or other methods used primarily in the social and behavioral sciences.
- **Referrals.** Referrals may be from non-investigator healthcare providers, snowball sampling, participants referring other participants. Investigators may provide their colleagues with a "Dear Potential Study Participant" letter describing the study. Or researchers may provide information sheets to colleagues or associates who can pass them on to potential participants.
- **Participant pools.** These are pools for which potential research participants have given permission for future contact.
- **Another IRB-Approved Screening Protocol, Recruitment Protocol and/or Recruitment Database.** This protocol describes how potential research participants will be asked for and will give permission for future contact. Investigators contact these potential participants about particular studies according to their approved protocol and the consent of the prospective participant. In many cases prospective participants will have given permission to be contacted for future studies by means of a check-off box in a consent form for a previous study.
- **Review of medical records to identify potential research participants.** Such procedures must be conducted in accordance with HIPAA requirements.
- **Review of education records.** Such procedures must be conducted in accordance with FERPA requirements.
- **Review of publicly available records.**
- **Review of other records.** Such procedures must be conducted in accordance with applicable rules and regulations.

Unacceptable Recruitment Methods

- **Use of Incentives, Finder's Fees or Bonuses** of any type in exchange for referral of potential participants or tied to the rate or timing of enrollment is prohibited. Such payments may encourage recruiters to put inappropriate pressure on prospective participants.

- **Sharing of Participant Names and Contact Information:** Researchers may not share names and/or contact information of previous research participants with other researchers without permission from those participants.
- **Medical Record Access:** When protected health information is involved, investigators who are not the health care providers or part of the clinic providing health care are prohibited from having access to patient names, addresses, phone numbers, medical record numbers or any other form of protected health information. Patients must initiate contact unless there is documented permission from the patient (i.e., a note in the medical record that the primary care provider spoke with the patient who agreed to be contacted) that the patient agreed to be contacted.
- **Student Education Records:** Use of identifiable student education records other than directory information for research purposes without either the student's consent (or parent's consent if student is under age 18) or receipt of an exception to FERPA granted by the Records Custodian of the institution owning the records, is prohibited.

Who May Recruit

Prospective research participants should be contacted by someone who is

- Thoroughly knowledgeable about the study,
- Able to answer questions,
- Trained in the voluntary nature of research participation, and
- The most appropriate person to contact prospective participants

When treatment or medical care is involved, first contact should be made by persons directly involved in prospective participants' care, rather than unknown researchers. For example, a nurse may hand out, or the clinic may mail out, study information to eligible patients allowing them to directly contact the investigators. This procedure notifies patients of the opportunity to participate in the research study while simultaneously protecting their privacy and confidentiality.

Payments to Participants

All human subjects research studies that offer payment or other incentives for participation must adhere to Purdue University policies and procedures as well as IRB requirements. IRB review and approval is conducted to ensure payments and other incentives are appropriate and do not exert undue influence on a participant's decision to take part in a research study. For further information please see HRPP Guidance **Compensation for Research Participation**.

Recruitment Using Telephone

Use of non-public phone number lists may be used with permission of the list owner. This procedure must be detailed in the IRB application. Investigators are not required to submit a copy of the list owner's permission, but are required to retain it and make it available upon request.

When using telephone calls to recruit potential participants, a script should be included in the IRB application describing the information that will be conveyed to and obtained from potential participants. Scripts should include:

- Verification that the correct person is on the phone line. This is especially important when announcing the study name or other information that could breach participants' confidentiality or otherwise place them at risk should the correct person not answer the phone.
- An introduction identifying the caller, the study, and the person(s) responsible for the study, if not the caller, along with their Purdue University affiliation.
- A statement about, or reminder of, how the potential participant's name was obtained.
- A general description of the study and a description of the types of questions that will be asked.
- An estimate of the time commitment.
- A question that allows the potential participant to opt out or schedule a more convenient time (e.g., "Are you interested in hearing more about this study? Is this a good time to talk?").
- Information about scheduling participants for study procedures or next step of the study.
- A closing that includes a contact name and telephone number if the potential participant should have any further questions about the study.
- If a message will be left for potential participants who are not available to take the call, provide the text of the message, indicating how breach of confidentiality will be avoided when leaving it. This may require ensuring that if someone other than the potential participant calls the researcher back, they do not hear a greeting that itself breaches the confidentiality of the potential participant.

If recruitment procedures conducted via phone involve consenting participants to proceed with data collection for the study (e.g., interviews conducted over the telephone), investigators may want to request a waiver of signed consent in their IRB application for that part of the research study.

Recruitment Using Electronic Media

Recruitment conducted using electronic media creates new challenges for both investigators and those charged with maintaining protections for research participants. Examples of electronic media used for recruitment include advertising on a website or electronic bulletin board, text messages, email solicitation, chat rooms, instant messaging, banner ads, discussion forums, blogs, Amazon Mechanical Turk, YouTube and other social media sites (e.g., Facebook, Twitter, etc.) to name a few. Although technology grows swiftly, the requirements for research recruitment remain steadfast.

- ***Recruitment procedures and materials used with electronic media must follow the IRB guidelines that apply to traditional media such as recruitment letters and flyers.*** Procedures should consider strategies to avoid perceptions of undue influence and maintain participant privacy. Materials must be written in clear, direct lay terms, at a level likely to be readily understood by potential participants, be clearly presented as recruitment material, and cannot be published until they have received appropriate IRB review and approval.

- ***Recruitment announcements on websites should be clearly identified as a recruitment ad for a voluntary research study.*** Such ads and announcements cannot be located or positioned in such a way that they could be easily mistaken for, or confused with, something else. For example, an investigator wanting to recruit students might use a recruitment plan that involves instructors notifying their students of that research opportunity. Oftentimes this is allowable so long as it is done so the instructor is merely passing on the information while making it clear to students the research is not related to the course and interested students contact the investigator directly. Instructors using Blackboard should be certain to place any recruitment information on the Blackboard Announcement page and make it clear the research opportunity is unrelated to the course.

  Similarly investigators may have a designated webpage on their website used exclusively for study recruitment. Large studies may even have their own websites. In some cases it may be important that such websites and pages not be merged with an academic site to avoid confusion particularly when participants are students or patients. Such websites should be written at a reading level appropriate to the potential participants.
- ***Email invitations*** to potential participants should include the same elements as a recruitment letter. If potential participants are asked to contact researchers by email, the invitations should also contain proper notification of the confidentiality issues associated with email communication.
- ***Use of non-public email list-serves and distribution lists*** may be used with permission of the list owner. This procedure must be detailed in the IRB application. Investigators are not required to submit a copy of the list owner's permission with the IRB application, but should keep a copy of that permission on file with the study's research records and make it available upon request.
- ***When recruitment activities are conducted through internet forums or other web-based communities***, investigators are expected to conduct their activities in accordance with that sites terms of use and/or privacy policy or, where such communities have a moderator or administrator, permission should be obtained in accordance with that community's requirements. These procedures should be detailed in the IRB application. Investigators are not required to submit a copy of a forum's or community's requirements, permissions, terms of use statements or privacy policy, with the IRB application. However they should maintain such with their research records and make it available upon request. Additionally, depending on the specific circumstances of a particular research project, the IRB may require submission of such information in order to evaluate the proposed study.

Employee Recruitment

General concerns involving employees as research participants. Employees who participate in research are particularly vulnerable to undue influence and coercion. Such research also raises concerns about confidentiality. Employee participants may feel unable to exercise free choice due to a belief that the decision to participate may affect performance evaluations or job advancement. The circumstances and concerns about retribution, even subtle cues of compromise, can place employees in a position of involuntary participation in a research study. Even when informed their research information will not be shared with their employer, employees may feel compromised by the possibility their employer will know of their participation in the study.

Investigators can mitigate these risks by employing the following guidelines and procedures in their recruitment plan.

- Provide justification for their selection in the IRB application.
- Outline procedures to be followed to minimize the appearance of coercion or undue influence of the employees.
- The investigator or study team must not indicate to any potential participants that research participation imparts any competitive occupational advantage, direct or implied, over other individuals who do not volunteer for research, and investigators.
- The investigator or study team must not impose any occupational penalty, direct or implied, on those individuals who do not volunteer.
- Avoid the involvement of anyone in the recruitment process who may be in the employee's chain of command.
- Recruitment through methods not requiring initial direct contact, such as flyers, bulletin board or internet postings or other methods that allow volunteers to initiate contact about the study.
- Recruitment through a third party who is not in an authoritative relationship with the employee can be used.

The above is by no means an exhaustive list, but it does identify some common procedures used successfully with employee research studies.

Research involving Purdue University Employees. Investigators who include University employees, such as office staff, lab technicians, and post-doctoral fellows, colleagues or subordinates as research participants must give particular consideration to their recruitment methods. Such populations are vulnerable to perceived, even if not intended, pressures to appear to supervisors and/or colleagues as cooperative and supportive of their unit's work. Such pressure may manifest itself with respect to both the initial decision to participate and any subsequent decisions to continue or discontinue participation. Participation in research conducted by one's unit may also pose unique confidentiality considerations.

In order to reduce the likelihood of these pressures, investigators who wish to recruit University employees, especially if potential participants are from their own lab or office, should follow the recommendations outlined above in addition to all applicable Purdue University requirements. See Purdue University **Policy on Sending Campus-wide Electronic Mail (V.A.1)**

Student Recruitment

PU IRBs consider all students, not just Purdue University students, to be a vulnerable population and closely examines research that requests their recruitment. Investigators need to consider that student participation in such research may not be truly voluntary because of a desire on the part of students to appear cooperative or highly motivated or because participation in research is a course requirement. The IRB requires that investigators use recruitment procedures that minimize the possibility of undue influence and coercion.

Ethical Considerations involving Recruitment of Students

- ***Students' participation must be entirely voluntary.*** Instructors cannot mandate or require student participation in research as part of a course requirement. Measures must be built into

the research to assure students that their participation is strictly voluntary and that they may withdraw their participation at any time without penalty.

- ***The investigator must not indicate to any potential participants that research participation imparts any competitive academic or occupational advantage***, direct or implied, over other students who do not volunteer for research, and investigators must not impose any academic or occupational penalty, direct or implied, on those students who do not volunteer.
- ***Students have the right to have class time devoted to classroom activities appropriate to meeting the objectives for the scheduled course.*** The IRB disallows recruitment of potential participants during class time. The instructor and all others associated with the conduct of the class (e.g., teaching assistants, etc.) must not be present during announcement of the research opportunity or any recruitment activity. Rather an announcement should be made in advance indicating that class will either start later than usual or end earlier than usual so the recruitment activity can occur. It should be emphasized that attendance at the announcement and recruitment are voluntary and students' attendance and enrollment decision will not be known by those administering the course.
- ***Investigators* who propose enrolling their own students in research** should carefully consider the appropriateness of enrolling individuals they directly supervise or instruct and will require explicit justification. Additionally investigators may be required to engage in additional procedures to ensure against actual or perceived undue influence or coercion

Investigators Recruiting Students

Various procedures may be used to minimize the possibility of unintended undue influence or coercion while still permitting students to participate in research. These include:

- Avoid recruitment methods involving direct contact with potential participants.
- Use recruitment methods such as postings, flyers, information sheets, etc. that allow potential participants to initiate contact.
- Provide a number of research projects and equal alternative assignments from which students can choose for meeting course credit (or extra credit) requirements.

Family Member Recruitment

In cases when a family member is asked to recruit another family member or members into a research study, the investigator should consider how best to protect and respect the privacy of family members who may be identified as potential participants.

One way to respect and preserve the privacy of family members is for the researcher to develop a plan that allows the family member who is already in the study to provide information sheets that explain the study to other family members. This allows the potential participants to initiate contact with the study team to express interest. There are other methods to protect the privacy of family members. Whatever method is used should be carefully considered and described in the IRB application.

Recruitment Materials

Investigators must submit all recruitment materials for IRB review and approval prior to implementation and the IRB application must describe how the materials will be used. Recruitment materials may include, but are not limited to, flyers, letters, emails, newspaper, radio or television advertisements, posters, brochures, press releases and website postings.

General Requirements – Recruitment materials must meet the following criteria:

- Purpose indicates that the activity is research.
- Free of deception and exculpatory language (e.g., releasing the investigator or sponsor from liability).
- Language and terminology is appropriate for the intended audience. In most cases this means the material should be written in clear, direct lay terms, at a level likely to be readily understood by potential participants, and must be clearly presented as recruitment material.
- Font size or other visual effect is not misleading or presents undue influence/coercion.
- Compensation is not overly emphasized, misleading or presents undue influence/coercion.
- Potential benefits of participation are not misleading or present undue influence/coercion.

Information to be Included – Recruitment materials (including oral recruitment scripts) should generally be limited to information potential participants need to determine their eligibility for, and interest in, the study. This typically includes the following criteria.

- Name and contact information of the investigator and the organization conducting the study.
- Brief description of the condition or concept being studied and/or the purpose of the research.
- Summary of criteria that will be used to determine study eligibility or exclusion.
- Time or other commitment required of the participants.
- Person or office to contact for further information.
- If compensation is offered:
  - statements about payment should not be emphasized by LARGE or **bold** type relative to other statements (if in writing); and
  - the amount of payment should be preceded by "up to" (e.g., "up to $100") if not all participants will receive the full amount.

The IRB must review copies of final versions of recruitment materials, however investigators are not required to submit non-amended materials when the only change is the advertisement appearing in a different version of the same medium (e.g. newspaper ad reappearing as a flyer – two versions of a print medium). Should an investigator want to use the same advertisement in a different medium for which they have not obtained approval, an amendment to the study should be submitted to the IRB for review and approval. An example would be an investigator who is approved for print media, but not electronic media, wants to post the IRB-approved advertisement in a flyer to an electronic bulletin board or webpage. Another example of a change requiring an amendment is an

investigator approved to post recruitment ads on web pages who wishes to now send these ads via email.

When advertisements are taped for broadcast and are produced from an IRB-approved template or script (such as a newspaper, television or radio advertisement), investigators are not required to submit the final product for IRB review **UNLESS the study is subject to FDA regulations**. However, for non-FDA regulated studies, investigators are responsible for ensuring that the final product matches the IRB-approved template or script. Investigators are responsible for maintaining copies of the final product as part of their research records for possible post-approval monitoring.

Listings of IRB-approved studies, including internet registries, do not require IRB review when the information provided in the listing is limited to basic information, such as title of the study, basic eligibility criteria, study site location(s) and information on how to contact the site/investigator for further information all of which has already received IRB approval.

Recruitment materials must NOT include any of the following:

- Any direct or implied claim that the purpose of the study is to provide treatment for a condition or disease, or that the research will improve a participant's medical condition
- Any direct or implied claim that a certainty of cure or other benefit beyond what is contained in the IRB application and the informed consent document.
- Any claim (direct or implied) that a drug, biologic or device being studied is safe and effective, or equal or superior to, an existing treatment
- Any claim (explicit or implicit) about a drug, biologic, or device being studied that is inconsistent with FDA labeling
- Any statement (direct or implied) that the research is approved by the FDA
- Statements that promise "free medical treatment" when the intent is that participants will not be charged for their participation
- Use of terms such as "new treatment", "new medication", "new drug", or "new device" without explaining that the drug, biologic or device is investigational
- For studies involving a placebo, descriptions of study design, drug allocation, or potential benefits without acknowledging the possibility that participants may receive a placebo
- Exculpatory language (e.g., releasing the investigator or sponsor from liability).

Screening Activities

All screening procedures are part of the IRB review of proposed research. Although screening activities do not necessarily result in data that are used to evaluate study outcomes, such procedures occur because of the research are reviewed by the IRB as part of the study application. Screening activities are reviewed as part of the overall recruitment and consent process and evaluated with respect to the protection of privacy and confidentiality of those who are screened.

Screening procedures may include:

- Any interaction or intervention with the participants to determine eligibility that would not otherwise have been performed if not for the study, or
- Accessing the results of interventions that were performed for purposes other than the study.

In other words, collecting data directly from participants through written screening tools, oral responses to questionnaires, or accessing private information, i.e., grades, medical test results, legal records, or any other non-public information linked to a potential participant, for purposes of eligibility. Screening constitutes a research intervention or interaction that must be reviewed and approved by the IRB.

The IRB application should include:

- All screening material(s) that may be used,
- Identification of data points, if any, that will be collected or acquired,
- Whether data will be retained from participants who are ineligible upon screening, and if so
- Why and how data collected during the screening procedures will be stored.

Additional Issues to Consider

- **Protecting Privacy**: In order to protect the privacy of potential participants, collect only the minimal information necessary for screening purposes.
- **Keeping Information Confidential:** Often the greatest risk of obtaining information during the recruitment and/or screening process is the loss of confidentiality. The investigator must consider and describe how the confidentiality of this data will be maintained. Whenever possible, information obtained during this process should not be linked with subject identifiers. As noted above, the amount of data collected should be limited. Once collected it should be kept secure.
- **Screening Procedures and Informed Consent**
  - If screening procedures will take place **prior to the participant providing informed consent** for participation in the research, the investigator may request a waiver of signed informed consent or informed consent for screening activities in the IRB application.
  - If an oral informed consent process is used, use of a screening script may be necessary.
  - If screening activities will take place only **after the subject has provided informed consent** for participation in the research, then the waivers described above are unnecessary.
- **HIPAA regulations apply to the screening process if it involves review of medical records.** Investigators must obtain prospective HIPAA authorization or apply for a waiver of HIPAA authorization and informed consent.
- **Telephone Scripts.** When conducting the screening process over the telephone, the script should include:
  - Identification of the study, the caller and his/her affiliation with Purdue University.
  - The names of persons responsible for the study.
  - An estimate of the time to complete the interview
  - A question that allows the potential participant to opt out of the telephone interview, or schedule a more convenient time (e.g., "Are you interested in hearing more about this study? Is this a good time to talk?").

- A description of the types of questions that will be asked especially of the most personal and sensitive a participant can expect to be asked accompanied by the statement, "You are free not to answer any questions you do not wish to answer".
- A request for verbal consent before proceeding with the questions, and a statement about what will be done with the screening data if the potential participant is not enrolled in the study.
- The arrangement of an appointment or next step for those eligible potential participants who wish to continue.

Regulations and References

DHHS Regulations and References

- 45 CFR 46.111
- 45 CFR 46.116
- 45 CFR 46.117
- OHRP, *Guidance on Institutional Review Board Review of Clinical Trial Websites*, September 20, 2005.

FDA Regulations and References

- 21 CFR 50.20
- 21 CFR 56.111
- FDA, *IRB Information Sheets: Recruiting Study Subjects*, 1998 Update.
- FDA, *IRB Information Sheets: Screening Tests Prior to Study Enrollment*, 1998 Update.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report - Ethical Principles and Guidelines for the Protection of Human Subjects of Research, April 18, 1979.