

Top 10 Things to Know About Human Participant Research (before AAHRPP visits!)

Q1: What is the Belmont Report?

A: The *Belmont Report* identifies three basic ethical principles on which the Federal Regulations and institutional compliance programs are based. The three principles are:

1. Respect for Persons

The principle of respect for persons means respecting an individual's autonomy (his/her right to make decisions for him/herself). This means that individuals should participate in research voluntarily and be given enough information to make an informed decision about whether or not to participate.

2. Beneficence

The principle of beneficence requires that the investigator protect individuals from harm and make efforts to secure their well-being. Investigators should consider the best ways to maximize benefits and minimize harms.

3. Justice

The principle of justice means that the benefits and burdens of the research are fairly distributed. Investigators should ensure that they employ fair procedures and outcomes in the selection of research participants. It is a violation of the principle of justice to select a class of participants (e.g., welfare patients, an ethnic minority, institutionalized persons) simply because of easy availability rather than for reasons directly related to the problem being studied.

Q2: What is informed consent?

A: Informed consent is the process of informing potential research participants about the research, what they will be asked to do, the benefits, and the risks. While the initial process is prospective and takes place prior to any research activity, consent should also be viewed as an ongoing educational interaction between the investigator and the research participant that continues throughout the study. The most important things to remember about informed consent are:

1. Specific information must be conveyed in the informed consent process, including:

- a. Purpose of the research
- b. Inclusion and exclusion criteria
- c. Study procedures in which the participant will be involved

- d. Risks
 - e. Benefits
 - f. Alternative options (when medical treatment is involved in the research)
 - g. How to ask questions and opt out of the research at a later date
2. **Potential participants must be able to understand the information.** Consent documents should be written without the use of jargon or technical terms when possible. Writing usually should target an 8th grade reading level to ensure comprehension.
 3. **The decision to participate in the research must be voluntary.** If an investigator has a relationship with potential participants (e.g., physician-patient, instructor-student, employer-employee), care should be taken to avoid recruitment methods that may be seen as coercive due to the special relationship between parties.

Informed consent documents are usually signed, unless the study involves minimal risk or the IRB has specifically approved a waiver of signed informed consent.

Q3: How does consent differ from assent?

A: Consent is a legal concept. Only legally competent adults can give legally effective informed consent.

Assent is a knowledgeable agreement to participate in the study and is used when the investigator recruits participants who, by age or circumstance, are not able to give legally effective informed consent. Children and decisionally impaired adults cannot give legal consent. When legally effective informed consent cannot be obtained, the investigator should obtain the "assent" of the child or decisionally impaired adult. This form documents the child's or decisionally impaired adult's knowledgeable agreement, or assent, to participate in a research study.

In cases where assent is obtained from a child or decisionally impaired participant, permission must also be obtained from an authorized representative (e.g., parent, legal guardian). In studies involving children, the authorized representative is the parent or court-appointed guardian. In studies involving decisionally impaired adults, the authorized representative is a designated proxy (such as a Durable Power of Attorney for Health Care), court-appointed guardian, spouse, adult child, parent, or adult sibling, in that order.

In order for the individual to participate in the research study, the potential research participant must "assent" to the research AND the guardian or representative must give permission. The potential participant may not be enrolled if one of the parties does not approve of the participation.

Q4: What is the difference between confidentiality and anonymity?

A: Anonymous data is data that has no identifying information. When you collect anonymous data you do not collect names, social security numbers, addresses, or any other information that could be used to identify the research participants.

Confidential data is data that is not disclosed outside of the immediate research team. Confidential data is not necessarily anonymous; it may have some identifiers associated with it.

It is expected that researchers will maintain the confidentiality of research data. You should have sound plans to protect the participant's identity as well as the confidentiality of the research records. It is important to carefully explain the strategies that will be used to protect confidentiality, such as the use of numbering or code systems or safely locked files in private offices. Furthermore, you should describe who has access to the data and under what circumstances a code system may be broken.

Q5: What is meant by balancing risks and benefits?

A: When the investigator and the IRB perform a systematic risk/benefit assessment, they are applying the principle of beneficence.

1. Risk is evaluated by considering both the chance or probability of harm and the severity or magnitude of the possible harm. When evaluating risk, consider possible psychological, physical, legal, social, and economic harm.
2. Benefit is the anticipated positive value of the research to either the participant directly or to society in terms of knowledge to be gained.

When designing the research, the principle investigator must not only consider the benefits of the research, but also carefully consider the potential risks. These risks must be clearly communicated to potential research participants so that they have the ability to make an informed decision about participating in the research. Typically, the welfare of the research participants will outweigh benefits for the greater good, except in extreme circumstances.

Much of the IRB's evaluation of proposed research will focus on the risks and the benefits. The IRB will carefully consider whether the research involves "minimal risk" or "greater than minimal risk".

Minimal Risk: "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." [45CFR46.102(i)]

Q6: What information must be included in recruitment materials?

A: The following information is required on materials that will be used to recruit potential research participants:

- A clear statement that volunteers are being recruited for *research* purposes
- Identification that the research is a Penn State study
- Name and contact information of the person responsible for the study
- Inclusion/exclusion criteria in summary form, if applicable
- A brief list of what participants will be asked to do
- Time or other commitment required (number of visits, total duration to include follow-up visits, etc.)
- Compensation/reimbursement – the dollar amount may be included
- If recruiting children, inclusion of a statement regarding parental consent requirements for participation

Additional important considerations:

- Language must not be coercive.
- Do not over emphasize monetary compensation. While the dollar amount may be included, the materials should not, for example, have “EARN CASH” or “\$\$\$\$” throughout the ad.
- Avoid the use of catchy words like “free” or “exciting”.
- Clearly indicate that research participation is being solicited.
- Avoid misleading information about the purpose of the research.

Advertising is considered the beginning of the informed consent process. Any recruitment processes and advertising materials aimed at recruiting potential participants into a study (including audio or video tapes) must be reviewed and approved by the IRB prior to being used.

Q7: When do I need to submit information to the IRB about changes I want to make to my study?

A: All changes you want to make to your study must be submitted to the IRB for approval before you implement the changes, except when the change is necessary to eliminate apparent immediate hazards to participants. Modifications include, but are not limited to:

1. procedural changes to a study
2. adding or removing investigators/research personnel
3. changing the title of the study
4. requesting additional participants beyond the original approved number
5. new funding sources
6. new or revised advertisements
7. changes to Informed Consent Forms
8. changes to surveys, questionnaires, or correspondence with potential or current participants

Modifications to an approved study can be submitted via the Modification Request Form. Minor modifications, such as title changes, changes in investigators, and changes in funding source, may be approved by the ORP staff, the IRB Chair or his/her designee using the expedited review procedure. More extensive modifications may require full board review, if the study was initially reviewed by the full board. In either case, revisions or clarifications may be required.

Q8: What is a continuing review and what does it mean for my study?

A: A continuing review is re-review of your study by the IRB at specific intervals, which is required by Federal regulations [45 CFR 46.109(e)]. Full review and expedited review studies are reviewed annually by the IRB. Exempt studies are reviewed every three years.

The continuing review process requires you to complete a Continuing Progress Report (CPR) prior to the expiration date of the study. Reminder emails are sent from the ORP to investigators to help you remember to complete the CPR with enough time for review by the IRB before your study expires.

If you do not submit a CPR form by the continuing review date, approval of your study will lapse. You must discontinue work on the study until you submit a new application and it is approved by the IRB.

Q9: What records related to my study and IRB approval should I keep?

A: You should keep in a readily accessible location all correspondence with the IRB/ORP and all records of interactions with participants in your study. Specifically, you should maintain:

1. copies of applications to the IRB
2. approval notices from the IRB
3. copies of email exchanges with the IRB/ORP
4. copies of modification requests and approvals
5. signed Informed Consent Forms
6. records documenting interactions with participants

All records of human participant research are subject to inspection by Federal authorities, the Penn State IRBs, and ORP staff. Generally, Penn State requires that copies of all research records must be kept for three years after the close of the study. Other specific Federally mandated retention requirements are:

1. Studies that involve drugs or devices seeking FDA approval must be kept for two years after the FDA has taken final action on the marketing application.

2. Studies that involve Protected Health Information (PHI) and are subject to the Health Insurance Portability and Accountability Act (HIPAA), must be kept for six years after the close of the study.
3. Records for studies funded by the Public Health Service should be maintained for three years following the submission of the final budget report.

Q10: What categories of research participants are considered “vulnerable populations” requiring special protections in research?

A: Federal regulations identify the following groups at vulnerable populations:

1. children (45 CFR 46, Subpart D)
2. pregnant women and fetuses (45 CFR 46, Subpart B)
3. prisoners (45 CFR 46, Subpart C)

Additionally, the Penn State IRB includes decisionally impaired individuals in the “vulnerable populations” category.

If your research involves any participants from these categories, please refer to additional Q/A documents related to that population.