

Worksheet to Guide an Ethical Review of a Research Project

This worksheet is designed to be completed by the research investigator to provide reviewers with the information they need to evaluate whether a proposed research study is consistent with ethical principles. As a guide to both investigators and reviewers, the worksheet begins with a description of three well-established guiding principles of ethical research. The worksheet is *annotated* throughout to guide reviewers (and investigators) about application of the ethical principles. The content of the worksheet is based on the content of several universities' Institutional Review Board application forms.

Guiding Principles of Ethical Research

The following three ethical principles of research are drawn from the Belmont Report, issued in 1978 by the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research and posted at:

<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>.

Respect for Persons

Respect for Persons entails the notions that individuals are treated as autonomous agents, and persons with diminished autonomy receive protection. Following from these ethical principles are requirements that individuals must provide voluntary informed consent to participate in research, individuals have the right to withdraw from research, and investigators must protect participants' privacy and confidentiality.

Beneficence

Beneficence is the obligation to protect the well-being of the research participant. To assess beneficence, reviewers can ask themselves "Is the research participant being treated as I would like to be treated?" Beneficence also involves the requirement that the study be well-designed and likely to be successfully implemented and disseminated so it can produce useful knowledge, and the requirement that the benefits of the study to the individual and/or society outweigh the risks to the participants.

Justice

The principle of Justice requires that the burdens and risks of the research are shouldered equally by all the groups in society who will benefit from the research. That means, for example, that researchers must not collect data that will benefit all members of society only from vulnerable disadvantaged populations.

NAME OF PROJECT:

PRINCIPAL INVESTIGATOR (PI):

(name, affiliation, and contact information)

CO-INVESTIGATORS/COLLABORATOR(S):

(name, affiliation, contact information, and role in study)

RESEARCH ASSISTANTS OR OTHER SUPPORT STAFF:

(name, affiliation, contact information, and role in study)

TRAINING IN HUMAN RESEARCH

For each individual above, list the date (within the last 5 to 10 years at most) the person obtained a certificate of training in human research.

CONFLICTS OF INTEREST

Following the principle of Beneficence, the information in this section helps investigators and reviewers evaluate whether the project is likely to produce unbiased data that can produce a benefit to society and/or the individual that outweighs the risks and costs to the participants in the research.

Please describe any conflicts of interest (financial or intellectual or other) and how they will be managed. Researchers are not expected to eliminate all conflicts of interest, as this is generally impossible. However, they must recognize and manage any conflicts.

PROJECT DESCRIPTION

Following the principle of Beneficence, the information in this section helps investigators and reviewers evaluate whether the project is likely to produce data that can produce a benefit to society and/or the individual that outweighs the risks and costs to the participants in the research.

- 1. What are your research questions/what is the purpose of your study?**

2. Give a brief non-technical, step-by-step description of your study. Be sure to describe exactly what is expected in terms of subject participation, including its duration.
3. List all surveys, interviews, tests, procedures, and interventions the participant must undergo in the research.
4. How many participants do you plan to enroll?
5. Describe the inclusion and exclusion criteria for the research.
6. What research methods will you use? Give a brief non-technical explanation that includes a description of the study design, the statistical analysis methods, and the rationale for the sample size.
7. Do you have a plan to publish the research? What journals are you considering?
8. Do you have a plan to present the research at a professional or other conference? What conferences are you considering?

HUMAN SUBJECT PARTICIPANT INFORMATION

In this section, the principles of Respect for Persons, Beneficence, and Justice apply.

1. Please describe the study population you are targeting by checking all that apply:
☐ Males
☐ Females
☐ Individuals from the community
☐ Students
☐ Other: _____
2. Are you targeting a specific ethnic group?
☐ No
☐ Yes (If yes, please describe the group)

3. Please state what age range you are targeting in your research.

4. Will you be studying any of the vulnerable populations listed below?

- ☐ Your employees or individuals over whom you have direct or indirect oversight
- ☐ Your students
- ☐ Children (under age 18)
- ☐ Patients you or your colleagues or trainees treat
- ☐ Persons who are economically, educationally, or otherwise disadvantaged
- ☐ Individuals with diminished mental/physical capacity
- ☐ Pregnant women
- ☐ Other: _____

5. Please state your scientific rationale for studying the vulnerable population.

BENEFITS AND RISKS

In this section, the principles of Respect for Persons, Beneficence, and Justice apply.

1. What benefits, if any, do you expect the participants to get from this study?

2. What risks are your participants exposed to? Check all that apply.

- ☐ Physical
- ☐ Legal
- ☐ Psychological
- ☐ Social
- ☐ Economic
- ☐ Risks from disclosure of personal or medical information
- ☐ Other: _____

3. Describe how you will minimize the risks to participants, including any vulnerable participants described in the previous section (e.g., screening to ensure appropriate selection of participants, monitoring of participants' experience during the research procedures, procedures for voluntary and involuntary withdrawal of participants, procedures to protect participants' identity and to keep their data confidential and safe from disclosure and loss).
4. When will you destroy or discard the data?
5. As the investigator, what is your analysis of the potential risk versus benefits to society/participants to participating in this study?

RECRUITMENT

In this section, the principles of Respect for Persons, Beneficence, and Justice apply.

1. How will you initially contact and select the participants? Please provide a copy of all recruitment materials.
2. Please describe whether participants will be compensated for their participation in the research and if so, how (i.e., no compensation, cash, gift cards, etc.)
3. Please offer some rationale or evidence that the number of participants needed to successfully carry out the project can be recruited within a reasonable time period.

INFORMED CONSENT

In this section, the principle of Respect for Persons applies.

1. Please describe the informed consent process for the study (i.e., when/where potential participants will be approached, how much time they will have to decide about participating, how you will minimize risks of coercion to participate).
2. Please certify that your participants will provide written informed consent, and provide copies of any consent documents that your participants will sign, including a copy of any assent form that minors will sign.
3. Please describe procedures you will use to verify that your participants have the opportunity to ask questions about the study and understand the consent document they are signing.

HIPAA

Please provide copies of any HIPAA authorization that your participants will sign.

If your practice/organization is considered a “covered entity” under HIPAA and you will be collecting Personal Health Information (PHI) (as defined by HIPAA) in your research, then you likely need to obtain a HIPAA authorization that is specific to research from all participants. Information about HIPPA regulations governing research can be found here:

https://privacyruleandresearch.nih.gov/pdf/hipaa_privacy_rule_booklet.pdf

MODIFICATION AND ADVERSE EVENTS

_____ The PI’s initials here certify that s/he will seek additional review if s/he wishes to make any significant modifications to study procedures or experiences any adverse events during the conduct of the research.

Signature of the Principal Investigator asserting that the information provided above is correct.
