

Date:  
CPHS#:

**OPHS WORKSHEET - 45 CFR 46.111 and 21 CFR 56.111**  
**CRITERIA FOR IRB APPROVAL OF RESEARCH**

The Committee for Protection of Human Subjects may approve research involving human subjects, provided that the Committee finds that all of the criteria below are met:

- A. Risks to subjects are minimized:
- By using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
  - Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
  - *Points to consider include:* (1) Are research staff qualified? (2) Are subject numbers adequate/inadequate? (3) Are procedures that would answer the scientific question being done anyway and, if so, can the data from these procedures be used to reduce the likelihood and magnitude of harm?

Protocol-specific comments:

- B. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.
- In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) among those research risks that fall within the purview of its responsibility.
  - *Points to consider include:* (1) Is the research likely to achieve its proposed aims? (2) Is the importance of the aims clear? (3) Are there direct potential benefits to the participants?

Protocol-specific comments:

- C. Selection of subjects is equitable.
- In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, people with physical or developmental disabilities, or economically or educationally disadvantaged persons.
  - *Points to consider include:* (1) Are the burdens of the research distributed fairly? (2) Are the benefits distributed fairly? (3) Is a population unfairly targeted? (4) Is a population unfairly excluded?

Protocol-specific comments:

- D. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by appropriate local, state and federal regulations.
- *Per 45 CFR 46.116, one of the following is true:* (1) Informed consent including the required elements of informed consent will be sought from each prospective participant or the participant's representative. (2) The informed consent process will be waived or altered.
  - Or, if FDA-regulated, informed consent will be sought in accordance with and to the extent required by *21 CFR 50*.

Protocol-specific comments:

- E. Informed consent will be appropriately documented as required by local, state and federal regulations.
- *Per 45 CFR 46.117, one of the following is true:* (1) Informed consent will be documented. (2) The requirement for written documentation will be waived. (3) The informed consent process will be waived.
  - *Per 21 CFR 50.27, one of the following is true:* (1) Informed consent will be documented. (2) The requirement for written documentation will be waived.

Protocol-specific comments:

- F. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- *Points to consider include:* (1) Is the research greater than minimal risk? (2) Is the research likely to result in safety reports to the sponsor or IRB? If so, what data are reviewed? When? By whom?

Protocol-specific comments:

- G. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- **Privacy** refers to persons and their interest in controlling access to themselves.
  - **Confidentiality** refers to agreements with the participant about how their data are to be handled.
  - *Points to consider include:* (1) What are the participants' expectations of privacy? (2) Will data release cause risk of harm? (3) Are there legal or ethical requirements? (4) What measures will be in place, if any, to protect subject confidentiality?

Protocol-specific comments:

- H. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally or physically disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study and in the IRB review process to protect the rights and welfare of these subjects.
- *Points to consider include:* (1) Who is vulnerable to coercion and undue influence? (2) Is there a power differential? (3) Are there excessive motivating factors? (4) Are there decisional issues? (5) Does the subject have the capacity to consent?

Protocol-specific comments: