

Full Board Protocol Review

The IRB has the authority to approve, require modification in, or disapprove, all research activities that fall within their jurisdiction. The decisions and requirements for modifications by the IRB will be promptly conveyed to investigators in writing by the IRB Chairperson. Written notification from the IRB Chairperson of decisions to disapprove a protocol will be accompanied by the IRB's reasons for the decision and an invitation for an opportunity for reply by the investigator, either in person or in writing. Copies of all correspondence of this type will be maintained in the IRB file for that project in the Chairperson of the Oakwood University IRB.

The IRB may only approve an application when its decision is based on consideration of the following:

- a. Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- b. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably 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 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) as among those research risks that fall within the purview of its responsibility.
- 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, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- 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 federal regulation.
- e. Informed consent will be appropriately documented, in accordance with, and to the extent required by federal regulation.
- f. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- g. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Once approved, full-board protocols are continually reviewed by the IRB, usually on an annual basis. The Chair of the IRB or designee will notify the principle investigator in writing of the IRB decision and the continuing review date.

Submission Deadlines

Full Board protocols must be submitted to the OU IRB for review at least three weeks prior to the date on which investigators plan to start data collection and include requirements identified in

previous section Initial Review.. Human subjects may not be recruited or research initiated until final IRB approval has been received in writing. If the investigators wish to begin collecting data during a long break (e.g. winter break or summer break), then the protocol should be submitted for review at least three weeks prior to the start of the break.

Full Board research is approved for a maximum period of one year. Renewal requests must be submitted at least three weeks prior to the approval expiration date. The approval expiration date is clearly noted on all OU IRB certifications sent to the principal investigator and must be strictly adhered to. If the approval expiration date occurs during a long break (e.g. winter break or summer break), then the request for continuing review should be submitted at least three weeks prior to the start of the break.