

Demonstration Project: Two Year Approval Periods

Overview

Under the current federal regulations for human research, studies are required to undergo continuing review of the research at least annually, depending on the degree of risk to the subjects. Many research studies under the oversight of IRB BehavSci and IRB Health (IRBs) pose no more than minimal risk to the subjects. Thus, it is unlikely that IRB determinations about potential benefits, informed consent, or risks to subjects would be affected by new information gathered from the research or from other sources if the approval period were lengthened beyond one year.

To exercise existing flexibility in the application of federal regulations to non-federally funded studies, the IRBs will undertake a demonstration project (i.e., pilot) to assess the feasibility of issuing *two year* approval periods for certain types of studies. The longer approval period will eliminate the need for principal investigators to submit scheduled continuing reviews on an annual basis. This demonstration will begin on September 10, 2007.

To qualify for two-year approval studies must:

- Pose *no more than minimal risk* to subjects and

Must *not* include any of the following:

- Federal funding or federal training grants
- FDA regulated components
- Sponsor or other contractual restrictions
- Clinical interventions (including clinical behavioral interventions)
- Prisoners as subjects
- Receipt of an NIH issued Certificate of Confidentiality to protect identifiable research data

IRB applications granted a two-year approval may not be used to support proposals or future awards involving federal funding. Contact the IRB office for instructions if federal funding is anticipated.

Why undertake this demonstration?

The University of Michigan maintains a federalwide assurance (FWA00004969) with the Department of Health and Human Services (HHS) in which it pledges to comply with federal regulations for all federally supported research and also to follow the ethical principles of the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research). This commitment allows the IRB some flexibility in its application of federal regulations to studies that are not federally funded. While continuing to apply the highest ethical standards for the protection of human subjects, this initiative will decrease the administrative burden on investigators.

What does this mean?

New or renewing applications meeting the criteria cited above will be reviewed by the IRBs to determine that subject protections comply with federal regulations. If appropriate protections are in place, and there are no additional extenuating circumstances, the IRBs can issue a two year approval. All other regulatory requirements, including amendments and adverse event and ORIO reporting, remain unchanged.