

| Michigan State University Human Research Protection Program | |
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| <i>Subject: Initial Review</i> | |
| <i>Section: 8-5</i> | <i>This policy and procedure supersedes those previously drafted.</i> |
| <i>Reviewed by: IRB, URC, UGC, MSU Legal Counsel; Revision reviewed by HRPP Director, Sr. Asst. VP Regulatory Affairs, VPRGS.</i> | <i>Approved by: Vice President of Research and Graduate Studies, 4-21-2005. Revision approved by the Vice President of Research and Graduate Studies on 4-5-2006. Revision approved by the Vice President of Research and Graduate Studies on 2-10-09.</i> |
| <i>Related Sections: 4-3, 4-6, 5-4, 5-5, 8-1, 8-2, 8-3, 8-4</i> | |

Policy

If an activity requires review by a Michigan State University (MSU) Institutional Review Board (IRB), research may not be conducted until the IRB has reviewed and approved the project and the investigator has received the approval letter and stamped consent form (if applicable). See Section 4-3, "Determination of Human Subject Research", of the HRP Manual for the policies and procedures on when a project must be submitted to the IRB.

To apply for approval of a research project, the responsible project investigator must submit an Initial Application for review to the IRB. In order to submit an initial application, the responsible project investigator, co-investigators and study coordinator (if applicable) must have current training through the online tutorial available at the humanresearch.msu.edu website. See Section 11-1-A "Education of Investigators, Coordinators and Research Staff", of the HRP Manual for requirements.

Materials Required for Submission

To evaluate the research study, the IRB members must have all applicable attachments. The following attachments must be included whenever applicable:

- Signed coversheet
- Instruments or measures (e.g. surveys, interview questions, questionnaires, etc)
- Consent form or script for verbal consent (unless requesting waiver of consent)
- Assent form
- Recruitment materials (including advertisements)
- Contract or Grant application for externally funded projects
- Debriefing form
- Translations of instruments and consents provided to non-English speaking subjects
- Permission from school administration to allow researchers to conduct research in individual schools
- HIPAA Authorization form
- Investigator brochure
- DHHS-approved sample informed consent and complete DHHS approved protocol (for DHHS sponsored multi-center clinical trials)

- If submitted to other IRB(s), that institution(s) approval letter
- Package insert if using FDA approved drug/device/diagnostic test
- FDA form 3454 or 3455, if applicable
- Any other pertinent documents related to the proposed study

Mechanism(s) for Submission

For projects submitted to the Biomedical and Health Institutional Review Board (BIRB) and the Social Science / Behavioral / Education Institutional Review Board (SIRB), the initial application must be completed and submitted using the online application and review system. For projects submitted to the Community Research Institutional Review Board (CRIRB), the current version of the initial application available at the humanresearch.msu.edu website must be submitted. CRIRB applications may be submitted by mail or by email from the Responsible Project Investigator's MSU email account.

The initial application must be completed in full; all questions must be completed. The BIRB / SIRB online system will not allow submission of an incomplete application. Incomplete CRIRB applications will be returned. An approval letter will not be issued until the IRB office is in receipt of a coversheet signed by the Responsible Project Investigator. By signing the coversheet, the Responsible Project Investigator accepts responsibility for the research study. For CRIRB applications sent through email, the email from the Responsible Project Investigators email account constitutes an electronic signature.

Submission Processing

The IRB staff assigns the application an Institutional Review Board (IRB) log number, which is sent to the Responsible Project Investigator for reference in future communication with the IRB. The IRB staff checks for completeness (e.g., appropriate documents attached) and appropriate category for review. Incomplete applications will be returned.

Change in Review Level

Investigators indicate on the application which category (exempt, expedited or full board) they believe the project falls into, but the IRB staff, chair or members may change the category if the selection is not appropriate. See *Section 8 "Types of IRB Review" of the HRP Manual for policies and procedures related to change in review level and/or category.*

How Review is Conducted

See the following HRP Manual sections for review procedures: Section 8-2, "Expedited Review Procedure", or Section 8-3, "Full Board Review".

IRB Member Considerations

When reviewing initial applications, the criteria for IRB approval must be met to approve or recommend approval of the application. The IRB member(s) should utilize Section 6, "IRB Evaluation Criteria" of the HRP Manual.

In addition, IRB members should utilize the additional criteria for approval if research subjects include vulnerable populations such as pregnant women, human fetuses, neonates, children or prisoners, as well as if investigators have requested a waiver or alteration of informed consent or waiver of documentation.

Additional Considerations

An IRB may not approve a project for more than one year. Typically, the approval period is 364 days. However, in projects where any of the following conditions are likely to prevail, the IRB will require review more often than annually:

- Phase I trials
- Any clinical studies where risks to health are considered life threatening
- Any behavioral studies where stress to subjects could threaten health
- Any study where data monitoring and security issues may warrant more frequent review
- Others as the IRB sees fit