Michigan State University Human Research Protection Program	
Subject: Demonstration Projects	
Section: 8-8	*This policy and procedure supersedes those previously drafted.*
Approved by: Vice President of Research and Graduate Studies, 9-3-2009. Revision 1 approved by VP Research & Graduate Studies on 7-22-2011.	
Related Sections:8-1, 8-2, 8-5, 8-7	

The Michigan State University (MSU) Human Research Protection Program (HRPP) is embarking upon a systematic attempt to identify (and prioritize for action) existing HRPP policy or process constraints that constitute a burden on investigators and on the institution above and beyond what is reasonable and responsible considering risks to human subjects.

Policy or process changes may be innovations which are changes made outright or "demonstrations" which are temporary policy or process changes made with an eye to demonstrating at some future checkpoint that the policy alteration or process streamlining or reduction has not inappropriately increased risks to human subjects nor otherwise adversely impacted subjects' rights or welfare.

In pursuing this initiative, it is acceptable to consider departing from process standards incorporated in federal regulations (and associated guidance by federal regulatory agencies) for those categories of research that meet the criteria specified in this policy for each demonstration project.

Two Year Approvals

MSU Institutional Review Boards (IRB) will undertake a demonstration project to assess the feasibility of issuing two year approval periods for certain types of studies.

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
- 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

Research studies which could be granted a two year approval will be reviewed and approved by an IRB member. See the following HRP Manual section for review procedures: HRPP Manual 8-2 “Expedited Review Procedure.”

Additionally, any proposed change or revision to an approved research study that affects human subjects that has been granted a two year approval (with certain limited exceptions must be reviewed and approved by the IRB prior to implementation of the change. See HRPP Manual 8-6 “Revisions to an Approved Research Study” and 9-5 “Unapproved Change in Protocol.”

The investigator must submit an initial application or renewal application to the IRB. Review procedures as defined in the HRPP Manual will be followed for applications under consideration for a two year approval. See HRPP Manual 8-2 “Expedited Review Procedure,” 8-5 “Initial Review,” and 8-7 “Renewed Approval.”

IRB staff will review the application and initially determine if the research meets the criteria for a two year approval. If the research study appears to meet the criteria for two year approval, IRB staff will notify the IRB member(s) assigned to review the research study. The assigned IRB member(s) will make the determination of whether to grant a two year approval period.

IRB staff will process research studies granted a two year approval by IRB members in accordance with HRPP Manual 8-2 “Expedited Review Procedure”.

In addition, a demonstration project worksheet will be used to document the two year approval determination. The completed worksheet will be placed in the file.

Exemption Category (7)

MSU will undertake a demonstration project that evaluates the addition of a new exemption category. Exemption category (7) allows research studies that are limited to analysis of a previously existing identifiable data to be classified as exempt and thus not required to obtain continuing IRB review of the protocol in certain circumstances.

To qualify for exemption category (7), studies must use existing sets of identifiable data and pose no more than minimal risk to subjects and must not include any of the following:

- Federal funding or federal training grants
- Sponsor or other contractual restrictions
- Previous restrictions on data use (e.g., data use agreements, previous informed consent restrictions)
- FDA regulated research
- Receipt of an NIH issued certificate of confidentiality to protect identifiable research data
- Research subject interactions and interventions

Research studies which meet the above criteria for exempt category (7) will be evaluated and determined exempt by IRB staff/chair when appropriate. See the following HRP Manual section for review procedures: HRPP Manual 8-1 “Exemptions.”

The investigator must submit an exempt application or renewal application to the IRB. Review procedures as defined in the HRP Manual will be followed for applications under consideration for exempt category (7). See HRPP Manual 8-1 “Exemptions.”

IRB staff will review the application and determine if the research meets the criteria for exempt category (7). If the research study meets the criteria for exempt category 7, the exempt determination will be documented and processed in accordance with HRPP Manual 8-1 “Exemptions.”

In addition, a demonstration project worksheet will be used to document the exempt category (7) determination. The completed worksheet will be placed in the file.