

Michigan State University Human Research Protection Program	
<i>Subject: Renewed Approval</i>	
<i>Section: 8-7</i>	<i>This policy and procedure supersedes those previously drafted.</i>
<i>Reviewed by: IRB, URC, UGC, MSU Legal Counsel; Revision reviewed by HRP/IRB Administrative Committee</i>	<i>Approved by: Vice President of Research and Graduate Studies, 4-21-05; Revision approved by Vice President of Research and Graduate Studies on 11-2-2005</i>
<i>Related Sections: 5-5, 6, 8, 8-2, 8-6, 8-8, 8-9, 9-2, 9-3</i>	

Under federal regulations, Institutional Review Board (IRB) approval is valid for a maximum period of one year. Project investigators wishing to continue research activities, including data collection and analysis, beyond the expiration of IRB approval must submit and receive approval for renewal prior to the project's expiration. The approval period will be listed on approval letters sent to investigators, including both the approval date and the expiration date.

Like initial approval, renewed approval is for a maximum of one year. If the assessment of risk warrants it, however, the IRB may require additional review at more frequent intervals. Furthermore, approval may be withdrawn by the IRB at any time if the IRB concludes that the risk to subjects has become unacceptable.

For four years following the initial IRB approval, the responsible project investigator may complete and return to the IRB a renewal application form and other materials required for submission (see below). In the fifth year of the project a Five Year Renewal application is required. See Section 8-8, "Five-Year Renewal", of the HRP Manual for details.

Renewal reminders are sent to the Responsible and secondary investigators listed on the project approximately two months prior to the project's expiration date.

For policies and procedures on closure of projects, see Section 8-9, "Closure", of the HRP Manual. If project approval expires without renewal or closure, the noncompliance policies and procedures will be followed. See Section 9-2, "Noncompliance", of the HRP Manual.

Materials Required for Submission

A current copy of the consent form must be included with the renewal application. The consent form, however, does not need to be included if the project is undergoing data analysis only and contact with subjects is complete, or if the project involves analysis of existing data only. If there are questions of whether a current copy of the consent form is needed, the IRB staff should be consulted. The consent form will be evaluated to determine if the consent is still accurate and complete. Based on the renewal

application, the consent form will be evaluated to determine if findings that might relate to the participant's willingness to continue should be included in the consent document. The evaluation will be based on the information provided in the renewal application, including information on new findings, any changes to the project, risks and benefits. If it is determined that new information should be provided, the IRB will consider whether the information should be provided to all past participants as well as new enrollment or only to new enrollment. If information is to be provided to past participants, the IRB should consider whether an information sheet or re-consent is needed.

IRB members shall receive and review a protocol or protocol summary with sufficient information to determine whether the proposed research continued to fulfill the criteria for approval.

The renewal application completed by the investigator contains the following information:

- Subject enrollment and expected recruitment
- Subject withdrawal summary and reasons
- Unanticipated problems and adverse events
- Complaints
- Change in risk
- Summary including
 - Study progress
 - Relevant recent literature
 - Interim findings
 - Amendments or modifications
- Multi-center trial reports
- Any proposed changes in the study

Renewals that Include Revisions

If there are any changes to the protocol (e.g., title change, changes in investigators, the target population, recruiting methods, surveys or study instruments, or the study protocol) that have not yet been submitted to the IRB, a revision form and any modified documents should be submitted with the renewal documents. *Please note that any change to the protocol must be approved by the IRB before the requested revision may be implemented. See Section 8-6, "Revisions to an Approved Project", of the HRP Manual.*

Mechanism(s) for Submission

The renewal form may be submitted via email as an attachment if the email has been sent from the Responsible Investigator's MSU email account. The renewal form may also be submitted via the mail.

Submission Processing

The IRB staff checks for completeness (e.g., all questions completed, current consent form attached). Incomplete applications will be returned.

Change in Review Level

At the time of renewal, the IRB may determine that a full board project's level of review may be changed to an expedited category (2-8) if the criteria are met. See Section 8-2, "Expedited Review Procedure", of the HRP Manual.

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 renewal applications, the criteria for IRB approval must be met to approve the renewal request. If there have been any modifications, the IRB member(s) should utilize the appropriate policy in Section 6 "IRB Evaluation Criteria" of the HRP Manual to review the proposed change (e.g., informed consent section for changes to the informed consent process).

The IRB considers the following points in performing continuing review:

- Are the actual risks and benefits as anticipated?
- Have any subjects been harmed?
- Has the IRB been informed of any problems or accidents?
- Have the investigators submitted progress reports?
- Have any unanticipated problems, adverse events, or new knowledge that the protocol poses greater risk to subjects than expected when the project was previously approved been reported to the IRB and shared with subjects?
- Is the consent form still accurate and complete? Do the consent forms need to be revised?
- Have there been significant new findings that might relate to participants' willingness to continue?
- If a change is being requested, does the change alter the level of risk? See Section 8-6, "Revisions to an Approved Project" for policies and procedures relating to changes.

If information provided at the time of renewal (e.g., subject complaints, unanticipated problems, evidence of increased risk, etc) indicates that subjects may be at risk, an immediate issue to consider will be whether to:

1. Stop accrual of subjects and/or restrict activities
2. Suspend approval of the protocol
3. Notify officials who will take appropriate action (e.g., notify Contract and Grant Administration)

The IRB chair may reach this decision with consultation from other members of the IRB. At any time during the renewal process the IRB chair or IRB may determine that it is necessary to act to protect subjects by suspending the protocols. If this occurs, policy

and procedures of Section 9-3, "Termination or Suspension of Research" of the HRP Manual should be followed.

The Responsible Project Investigator must provide the following four assurances, which are embodied in the renewal application form:

- The human subjects protocol is the same as previously approved by the IRB.
- There have been no ill effects suffered by the subjects due to their participation in the study.
- There have been no complaints by the subjects or their representatives related to their participation in the study.
- There has been neither a change in the research environment nor new information that would indicate greater risk to humans than that assumed when the project was approved.

If any of the following assurances are not met (e.g., there has been a complaint), an explanation or summary must be provided in the renewal application form.

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

Research studies may require verification from sources other than the investigator that no material changes have occurred since previous IRB review. This requirement may have been imposed during the initial review of the project or at any time after initial review. To determine when further verification is needed, the IRB will consider:

- Concerns raised during the initial review due to the sensitive nature of the study (e.g., if the investigator described safeguards to assure the protection of research subjects, verification that safeguards are in place)
- High risk projects (e.g. Phase I)
- Clinical investigations where the investigator is also the sponsor
- Previous noncompliance
- Complaints