Michigan State University
Human Research Protection Program

**Subject:** Renewed Approval

**Section:** 8-7

This policy and procedure supersedes those previously drafted.

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**Approved by:**
- Vice President of Research and Graduate Studies, 4-21-2005. Revision 1 approved by VP Research & Graduate Studies on 11-2-2005. Revision 2 approved by VP Research & Graduate Studies on 3-9-2008. Revision 3 approved by VP Research & Graduate Studies on 5-6-2008. Revision 4 approved by VP Research & Graduate Studies on 9-3-2009. Revision 5 approved by VP Research & Graduate Studies on 7-22-2011. Revision 6 approved by Assistant VP Regulatory Affairs on 4-5-2014.

**Related Sections:** 5-5, 6, 8, 8-2, 8-3, 8-5, 8-6, 8-8, 8-9, 9-3

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(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research. 45 CFR 46.109(e), 21 CFR (f)

Institutional Review Board (IRB) approval is valid for a maximum period of one year, with limited exceptions specified in the Human Research Protection Program (HRPP) Manual 8-8 “Demonstration Projects.” Principal investigators (PI) who would like to continue research activities, including data collection and / or analysis of identifiable private data, beyond the expiration of IRB approval must submit and receive renewed approval prior to the research study's expiration. The approval period will be listed on approval letters sent to researchers, including both the approval date and the expiration date.

Like initial approval, renewed approval is valid for a maximum of one year, with limited exceptions specified in HRPP Manual 8-8 “Demonstration Projects.” However, the IRB may require additional review at more frequent intervals if the assessment of risk warrants it. Approval may also be withdrawn by the IRB at any time if the IRB concludes that the risk to subjects has become unacceptable.

Continuing review is required so long as remaining activities include data collection, analysis of identifiable private information, or the research remains active for long-term follow-up of subjects, even when the research is permanently closed to the enrollment of new subjects and all subjects have completed all research-related interventions.

**Renewal Reminders**
Renewal reminders are routinely sent by the IRB to researchers to assist in meeting the continuing review requirement. Such renewal reminders include research study specific information (e.g., title, expiration date) as well as a reminder to investigators that research activities may not occur if a renewal is not approved by the IRB.

Approximately two months before the expiration month, the IRB staff will routinely send a renewal reminder to the PI and if applicable, the secondary investigator and/or the study coordinator. This renewal reminder will alert the researchers that an application
for renewal or closure must be completed. The renewal application should be submitted at least one month prior to the expiration date.

If a renewal application is not received, approximately one month prior to the expiration date, a second renewal reminder will routinely be sent, stating that a renewal application must be submitted immediately to apply for renewed approval or a closure application must be submitted before the expiration date to apply for closure of the research study.

If a renewal or closure is not received, approximately one week prior to the research study's expiration, a final email notification will routinely be sent from the IRB to the PI and if applicable, the secondary investigator and/or the study coordinator, copying the appropriate supervisor (chair, director, or dean). This notification will alert them that the research study will be expiring in the upcoming week, and they need to renew or close the study. This email will state that the research must stop and no research activities (e.g. data collection, analysis) may occur after the expiration date.

Renewal reminders are sent via email and the IRB cannot ensure successful delivery or receipt. Ultimately, it is the responsibility of the PI to ensure a renewal application is submitted prior to the research study's expiration date.

Failure to Obtain Renewed Approval
If a PI does not provide continuing review information to the IRB or the IRB has not approved a renewal application by the expiration date:

- All research activities must stop. Stopping all research activities includes recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and analysis of identifiable private data.
- Interventions and interactions on current subjects can continue only when the IRB finds an over-riding safety concern or ethical issue involved such that it was in the best interests of individual subjects.
- Under no circumstances can the IRB allow the enrollment of new subjects into expired research studies.

For policies and procedures on closure of research studies, see HRPP Manual 8-9 “Closure.”

Materials Required for Submission
To apply for renewed approval of a research study, the PI must submit a renewal application and if appropriate, a current copy of the consent form and data and safety monitoring reports.

The renewal application (i.e. status report) completed by the PI contains the following information:

- Number of subjects accrued, subject enrollment, and expected recruitment
- Summary since the last IRB review of:
  - Adverse events, untoward events, and adverse outcomes experienced by subjects
Unanticipated problems involving risks to subjects or others
Subject withdrawal summary and reasons
Complaints about the research
Study progress
Any relevant recent literature
Any interim findings
Amendments or modifications
- The PI’s current risk-potential benefit assessment based on study results
- Any relevant multi-center trial reports
- Any proposed changes in the study
- Data safety monitoring board report
- A protocol summary document that describes the current research study and incorporates all revisions that have been approved by the IRB

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 research study is closed to accrual and only undergoing data analysis. If there are questions of whether a current copy of the consent form is needed, the IRB staff should be consulted.

If there are any changes to the research study (e.g., consent form, target population, recruiting methods, surveys or study instruments, study protocol) that have not yet been submitted to the IRB, a revision form and any modified documents (e.g. newly proposed consent form, revised survey) should be submitted with the renewal documents. Any change to the research study must be approved by the IRB before the requested revision may be implemented. See HRPP Manual 8-6 “Revisions to an Approved Research Study.”

Mechanism(s) for Submission
MSU IRB renewal applications must be submitted via the MSU IRB online system. The renewal application must be completed in full; all questions must be completed. The MSU IRB online system will not allow submission of an incomplete application.

The PI must log in to the MSU IRB online system and check that s/he has read the signature assurance language to submit the renewal application. Only the PI may submit a renewal application, and such submission constitutes an electronic signature.

Submission Processing
The IRB staff checks for completeness (e.g., all questions completed, current consent form attached). Incomplete applications will be returned. IRB staff verifies current training for all researchers listed on the research study. IRB staff will notify the PI of any individuals without current training and those individuals must have current training before the renewal approval letter can be issued.
Change in Review Level
At the time of renewal, the IRB or IRB chair may determine that a research study’s level of review may be changed. See HRPP Manual 8-2 “Expedited Review Procedure” or 8-3 “Full Board Review Procedure.”

Materials Provided to IRB Members
The assigned reviewer will access the renewal application, current consent form (if applicable), and any supporting documents via the MSU IRB online system. The reviewer will also have access to the complete IRB file for review, including any protocol modifications previously approved by the IRB. The reviewer accesses and reviews the research study and any proposed modifications previously approved by the IRB.

How Review is Conducted
IRB members shall receive and review the full protocol, application, or protocol summary with sufficient and relevant information necessary to determine whether the proposed research continues to fulfill the criteria for approval.

For requirements on the materials to be distributed to IRB members and review procedures for expedited and full board renewals, see the following sections of the HRP Manual:
5-5 Meetings
8-2 Expedited Review Procedure
8-3 Full Board Review Procedure

IRB Member Considerations
The IRB member(s) is required to review and approve protocols using the criteria at federal regulations 45 CFR 46 and, for FDA research studies, 21 CFR 56. The criteria for IRB approval must be met to approve or recommend approval of the application. The IRB member(s) should utilize HRPP Manual 6 “IRB Evaluation Criteria.” If there have been any modifications, the IRB member(s) should utilize the appropriate policy in HRPP Manual 6 “IRB Evaluation Criteria” 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:
- Assessment of actual risks and benefits against anticipated risks and benefits
- Whether there have been any:
  - Harm to subjects
  - Problems or accidents
  - Unanticipated problems, adverse events, change in the research environment, or new knowledge that the research study poses greater risk to subjects than expected when the study was previously approved and if so, whether shared with subjects
  - Significant new findings that might relate to subjects’ willingness to continue and if so, has or will the information be provided to subjects or will subjects re-consent
Complaints by the subjects or their representatives related to their participation in the study

- Progress reports
- Accuracy of consent form and need for revision
- Alteration of risks level as a result of requested changes; see HRPP Manual 8-6 “Revisions to an Approved Project” for policies and procedures relating to changes

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 subject’s willingness to continue should be included in the consent form. The evaluation will be based on the information provided in the renewal application, including information on new findings, any changes to the research study, 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 subjects as well as new enrollees or only to new enrollees. If information is to be provided to past subjects, the IRB should consider whether an information sheet or a re-consenting process is needed.

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

- Stop accrual of subjects and/or restrict activities
- Suspend approval of the protocol
- 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 protocol. If this occurs, the policy and procedures of HRPP Manual 9-3 “Termination or Suspension of Research” would be followed.

Additional Considerations
See HRPP Manual 8-5 “Initial Review” for consideration of when review may be required more often than annually.

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 research study 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 research studies (e.g. Phase I)
- Clinical investigations where the investigator is also the sponsor
• Previous noncompliance
• Complaints
• Others as the IRB sees fit