Timeframe for Submission of Changes of Protocol to the IRB

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The UW-Madison's Change of Protocol Review by Full IRB Policy describes the policies and procedures that UW-Madison IRBs and researchers are expected to follow related to the submission and review of changes of protocol. Federal regulations require researchers to obtain IRB approval of changes prior to their implementation unless to eliminate apparent immediate hazards to subjects. In addition, the federal regulations require IRBs to have written procedures to ensure prompt reporting to the IRB of proposed changes in a research activity.

Since December 2009, campus policy has defined the following timeframes to ensure prompt reporting of changes of protocol to the IRB as follows:

- **Changes implemented prior to IRB approval**: Changes in approved research initiated without prior IRB review and approval to eliminate apparent hazards to a participant must be reported to the IRB within ten (10) days of implementation, at which time an amendment to the protocol, and if needed, to the informed consent document must be submitted to the IRB. Use the Reportable Event Form in ARROW to report these potential unanticipated problems to the IRB. The report will be reviewed by the IRB to determine that the action taken by the investigator was necessary to eliminate an apparent immediate hazard to the participant(s) and the change of protocol is consistent with ensuring the participants' continued welfare. Other changes implemented prior to IRB may constitute noncompliance and should be reported to the IRB as such.

- **Changes are a result of new information**: If changes that are the result of new information, such as identification of unanticipated risks or findings that may affect a subject's willingness to take part in the study, will follow the research team must report this new information following timelines for reporting to the IRB independent of:
  - **If the change of protocol as a possible unanticipated problem within 10 business days after its discovery (or by study team receives the next business day if the new information suggests a problem that is immediately life-threatening to other subjects). This information can be submitted New Information document (e.g. action letter, revised IDB, sponsor memo) at the same time they receive the revised study documents:**
    - Submit all documents to the IRB using the Reportable Event Form in ARROW before within 60 days of receipt
  - **If the change of protocol is submitted. The research team can note in the report that a change New Information document prior to receiving the revised study documents:**
• If the study team will receive the revised study documents within 14 days of receipt of the New Information document:
  • Submit all documents to the IRB within 60 days of receipt of protocol application is forthcoming or has been submitted separately the new information document
• If the study team either does not know when they will receive the revised study documents OR knows they will NOT receive the revised study documents within 14 days of receipt of the New Information document:
  • Submit the New Information document (e.g. action letter, revised IDB, sponsor memo) with a Reportable Event: New Information SmartForm within 14 days of receipt of the new information AND submit the revised study documents with a change of protocol within 60 days of their receipt.

• Other Changes: When a change of protocol is planned it should be submitted to the IRB for review as soon as possible, especially if the changes include revisions that (1) affect the risk/benefit ratio of the study (e.g., result in a change to the protocol); (2) affect alternatives to study participation for subjects; (3) represent new information that should be provided to subjects; or (4) affect the local conduct of the study. In the case of sponsored studies that involve amendments that are externally generated, changes of protocol should be submitted to the IRB within a maximum of 60 days of their receipt by the local study team. This timeframe should allow the research team sufficient time to prepare the change of protocol application materials and obtain approval by a scientific review committee, when required, prior to review by the IRB. In the case of oncology changes with a 90 day deadline, the study team needs to account for time for both PRMC and IRB reviews submit those changes within 45 days of their receipt.

In addition to these policy requirements, the Health Sciences IRBs has further clarified timelines for reporting to help ensure prompt review and reporting of new information to subjects and compliance with external sponsor requirements (e.g., NCI deadlines for IRB approvals of changes of protocol).

Summary of Reporting Timeframes and Mechanisms

<table>
<thead>
<tr>
<th>Type of change</th>
<th>How to Report to the IRB</th>
<th>Timing of Report to the IRB</th>
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<tbody>
<tr>
<td>Changes implemented prior to IRB approval to eliminate an apparent immediate hazard to subjects</td>
<td>Reportable Event Form – Unanticipated Problem</td>
<td>10-14 business days from the implementation of the change</td>
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<td>Change of Protocol Form</td>
<td>As soon as possible, but no later than 60 days from implementation of the</td>
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<tr>
<td>Changes as a result of new information</td>
<td>Change of Protocol Form</td>
<td>4060 business days from the study team’s receipt of the new information document*</td>
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<td>*To allow the study team more time to prepare the change in these cases, the IRB will accept a Reportable Event Form – New Information to meet the 10 business day deadline in the case where the information could affect subjects’ willingness to participation (e.g., new risks); a change of protocol also must be submitted. *See above guidance on when to submit the New Information document associated with this change.</td>
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<tr>
<td>Changes issued by study sponsors/external entities</td>
<td>Change of Protocol Form</td>
<td>As soon as possible, but no later than 60 days from the study team’s receipt of the changes</td>
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<tr>
<td>“90-Day” Changes for Oncology Protocols</td>
<td>Change of Protocol Form – the study team must flag in submission notes to the IRB that the change is a “90-day change” and provide the date by which IRB approval is needed</td>
<td>As soon as possible, but no later than 45 days from the study team receiving the change</td>
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**Related Policies and Guidance:**

- [Noncompliance Policy](#)
- [Unanticipated Problems Policy](#)
- [Change of Review of Changes of Protocol by the Full IRB Policy](#)
- [Changes to Eliminate Immediate Hazards to Subjects Guidance](#)
- [Cancer Center: Submitting Changes with a 90-Day Review Deadline](#)