requests substantive modifications to the IRB submission that are relevant to the meeting the criteria for approval as required by the federal regulations.

A project that lacks sufficient information to conduct an adequate review and confirm the

research project, transfer to another researcher, and continuation in the research project under independent monitoring)
   c. Whether current subjects need to be informed of the suspension
   d. Any adverse events, UPIRSOs, or outcomes that have been reported to the IRB.
2. Suspensions not initiated by the IRB Committee must be reported to and reviewed by the convened IRB as a reportable event in accordance with *IRB SOP: Requirements for Reporting to the IRB.*
3. ***Suspension*** of a project means the following activities will cease immediately:
   Enrollment of new subjects
   Screening and recruiting of new subjects
   Presenting or publishing any data or results

The following activities may continue only at the direction of the IRB:
   Submission of amendments
   Follow-up on enrolled subjects (evaluate continuation of all enrolled subjects on a case by case basis)
   Treatment of enrolled subjects

The following activities may continue:
   Submission Continuing Progress Reports
   Submission of Reportable Events requiring prompt reporting

4. If the IRB Chair or IRB Committee suspends approval of a project due to the Investigator's failure to comply with the requirements of the approved protocol or institutional policies and procedure, the HRPP Director shall notify the Associate Provost for Research, who shall provide written notice to the Dean, applicable Institutional Officials, Institutions where the project is being conducted and where MCW is serving as the IRB of Record, OHRP and/or the FDA and/or the head of the supporting Federal Agency.

Termination

1. Termination will ordinarily be initiated by an IRB Chair or an IRB Committee, but may also be initiated by the HRPP Director or the Associate Provost for Research. A single project or multiple projects for a single Investigator may be terminated to eliminate immediate risks to the subjects, or the institution.
2. When study approval is terminated, the following will be considered:
   a. What actions, if any, may be needed to protect the rights and welfare of currently enrolled subjects
   b. Whether procedures for withdrawal of enrolled subjects take into account their rights and welfare (e.g. making arrangements for medical care outside of a research project, transfer to another researcher, and continuation in the research project under independent monitoring)
   c. Whether current subjects need to be informed of the termination
   d. Any adverse events, UPIRSOs, or outcomes that have been reported to the IRB
3. Terminations not initiated by the IRB Committee must be reported to and reviewed by the convened IRB as a reportable event in accordance with *IRB SOP: Requirements for Reporting to the IRB.*
4. ***Termination of Approval*** of a project means the following activities will cease immediately:
   Enrolling new subjects into the project(s)
   Screening and recruiting of new subjects
   Presenting or publishing any data or results
   Submission of Amendments
   Submission of Continuing Progress Reports

The following activities of the project may continue at the direction of the IRB:
   Follow-up on enrolled subjects (evaluate continuation of all enrolled subjects on a case by case basis)

Treatment regimen for currently enrolled subjects to end participation on project safety

Development of a plan to notify subjects of termination of the project, and describe how the Investigator will safely withdraw subjects from the project, and transfer into clinical care

The following activities may continue:

Submission of Reportable Events requiring prompt reporting that occurred prior to termination.

5. If an IRB Committee terminates approval of a project due to the Investigator's failure to comply with the requirements of the approved protocol or institutional policies and procedure, or due to identification of immediate harm or risk to subjects, the HRPP Director shall notify the Associate Provost for Research, who shall provide written notice to the Dean, applicable Institutional Officials, Institutions where the project is being conducted and where MCW is serving as the IRB of Record, OHRP and/or the FDA and/or the head of the supporting Federal Agency.
6. The Investigator must submit a final report for the project to the IRB within 90 days from the date of the IRB termination of approval.

Expedited Review of Submissions

The same procedures as described will apply to studies that meet criteria for Expedited review. The actions will either be performed by a single designated expedited reviewer or may be performed by a convened Full Committee; if a submission is deemed to warrant review by a convened Full Committee as determined by the IRB Chair of either the Expedited Committee or any one of the Full Committees.

Appeal Process

1. Investigators have the right to appeal an IRB determination and/or decision.
2. The appeal be written and addressed to the IRB Chair and the HRPP Director.
3. The appeal must contain the following information:
    Reason for the appeal including new information which was not initially provided or considered by the IRB.
    Scope of the appeal including the activities, length of time, and limitations
4. The appeal will be evaluated by the IRB Chair and the HRPP Director and/or Institutional Officials as deemed necessary by the MCW IRB Office.
5. The IRB Chair will provide the Investigator with a response to the appeal to the appeal that includes;
    The decision
    The rational for the decision
    Any additional action required

SUPPORTING DOCUMENTS:
N/A

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