UMES Policy on IRB Records

It is the policy of UMES that the IRB shall maintain documentation of all UMES IRB activities in accordance with federal regulations 45 CFR 46.115 and 21 CFR 56.115. All IRB records relating to research are retained for at least three years after completion of the research. All other records are retained for at least three years. If a protocol is canceled without participant enrollment, IRB records are maintained for at least three years after cancellation.

Records are accessible for inspection and copying by authorized representatives of federal agencies, UMES administration, or departments at reasonable times and in a reasonable manner.

The UMES IRB shall keep the following records:

1. Copies of all IRB applications and supporting documentation. Supporting documentation by the IRB includes: CITI certificates in addition to agency-specific training documents, signed IRB application cover page, consent documents, reports of injury, complaints, and other events (whether anticipated or unanticipated). Copies of research proposals and ancillary documentation are available from the Director of Research.
2. Minutes of IRB meetings that document pertinent discussions and decisions on research. A minute's template shall be the mechanism to document all actions and determinations made by the IRB, including:
    - Attendance at the meeting for each vote, including when an alternate member replaces a primary member
    - Momentary or permanent departure from the meeting by a committee member
    - Conflict of interest determinations
    - A summary of issues, whether controverted or minor/administrative in nature, and the correspondence to be conveyed to the investigators concerning these items
    - Drug and device issues and determinations
    - Whether the risk-to-benefit ratio is reasonable and whether the research includes sufficient safeguards
    - Approvable categories for the inclusion of children, pregnant women/fetuses, prisoners, or other identified vulnerable populations
    - Determinations concerning applications for waivers or partial waivers of privacy authorization under HIPAA
    - Justification for waiver or alteration of informed consent or documentation of informed consent
    - The basis for requiring changes in research or tabling or disapproving research
    - Summary of the discussion of controverted issues and their resolution
    - Whether the re-consent of enrolled participants is required owing to amendments to the study, problems or events that have occurred, or a pediatric subject's reaching the age of majority
    - The vote on these actions, including the number of members voting for, against, and abstaining, not voting
    - The approval period for the initial and continuing review
    - The names of IRB members who leave the meeting for the vote on an item(s) because of a conflict of interest or any other reason

- Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in a DHHS-approved sample consent document
- The minutes of convened IRB meetings are supplemented by the IRB primary reviewer's review form, in which the criteria of certain regulatory determinations are more extensively documented.

3. For the initial and continuing review of expedited research, the primary reviewer's review form is the mechanism used to document:
   - The specific permissible expedited category
   - The description of actions taken by the reviewer
   - Any findings required under the regulations or by policy
4. For exempt research, the IRB Chairperson or a designee(s) will review the form and the notice of acknowledgment generated by the reviewer documents under the specific category of exemption. In other words, to determine the exempt category stated.
5. Copies of all Continuing Review Applications, Change in Research applications, and Protocol Event Reports.
6. Copies of all correspondence between the IRB and investigators, and other entities involved in the research or UMES officials (as applicable).
7. A list of all IRB members, both primary members, and alternates. The list shall identify the member's name, earned degrees, member category (non-scientist, physician-scientist, or other scientists), research experience, experience, and expertise applicable to IRB deliberations, knowledge of or experience working with vulnerable populations, employment or other relationship with UMES, affiliation status (whether the member or an immediate family member is affiliated with UMES), and other members for whom the IRB member may alternate.
8. Written UMES IRB policies, guidance, operations procedures, and forms.
9. Statements of significant new findings are required to be provided to research participants as required by regulations.
10. Copies of reliance or research review agreements that have been executed for UMES to rely on an external IRB or for an external entity to rely on the UMES IRB.