

**ADULT HEALTH
INSTITUTIONAL REVIEW BOARD
SUBMISSION REQUIREMENTS & GENERAL INFORMATION**

PROTOCOL SUBMISSIONS

Submission Timeline:

New Protocol Submissions must be submitted to the IRB two weeks prior to the next meeting. For a list of meeting dates and submission deadlines, please go to: http://www.umkc.edu/research/ors/irb/ah_meetings.html

Incomplete Submissions:

If your protocol submission is found to be incomplete during pre-review by the IRB, the submission will be returned to you. The protocol will not be reviewed by the Board until all documents are submitted for review. The submission date will then be the date of complete submission.

Hand Written Submissions:

Hand written submissions will be returned without pre-review or review. The application form is a word document and can be saved to your computer for completion.

Required for a New Protocol Submissions:

For new submissions, please submit **one** signed original and **three** copies of the following:

- Application form signed by the PI or Co-I/Sub-I
- Investigators Brochure and/or Drug Package Insert (if applicable/FDA only)
- Protocol
- Copy of all Study Measures
- 1572 Form (if applicable/FDA only)
- Informed Consent Form
- Certificate of confidentiality (if applicable)
- Advertisements or subject handouts (if applicable)
- Data collection forms (if applicable)
- HIPAA documentation (dental protocols)
- **ALSO REQUIRED: One complete copy of the grant with a budget summary (for funded projects)**

Progress Reports:

(Please submit **one** signed copy only)

Please submit **one** completed Progress Report sixty (60) days prior to the expiration date to continue your research. IF you are closing the protocol, please complete and submit the progress report any time prior to the expiration date. All reports must have PI or Co-I/Sub-I signature or they will be returned as incomplete.

Documents Required for Continuing Review:

(Please submit **one** signed copy only)

- One completed Progress Report
- One copy of the original application or revised and approved application form
- One copy of the approved consent form
- One clean consent for approval

Documents Required for Protocol Closure:

- One completed Progress Report

AMENDMENTS

All amendment/modifications/revisions to a project must be received and approved by the appropriate IRB before they are initiated except where necessary to eliminate apparent immediate hazard to the subject. Requests for approval of modifications/changes may be submitted at any time by an investigator.

“Major” modification requests are reviewed through the full board review process. Examples of “major” modifications include, but are not limited to, escalation in the drug(s) dosage(s), the introduction of an additional drug(s); the addition of a new invasive procedure. Major modifications may impact the risk/benefit ratio in the study. “Minor” modification requests are reviewed through the expedited review process.

Amendment to an existing Consent Form:

- Application form signed by the PI or Co-I/Sub-I
- New Consent with revisions marked (underlined, bold or highlighted)
- One Copy of the most recently approved consent form

Amendment/revision to an existing Protocol or Investigators Brochure:

(Please submit **one** signed copy only)

- Application form signed by the PI or Co-I/Sub-I
- New Protocol or Investigators Brochure with revisions marked (underlined, bold or highlighted)

Advertisement submission or amendment/revision:

(Please submit **one** signed copy only)

- Application form signed by the PI or Co-PI
- New advertisement or revised ad with revisions marked (underlined, bold or highlighted)

SPECIAL CIRCUMSTANCES

Fellow/Resident or Graduate Student PI's

A fellow, resident or a graduate student can be listed as a PI, IF they have permission from their resident advisor. The advisor MUST be listed as a CO-I/Sub-I, sign submission documents and will be copied on all correspondence between the IRB and PI.

Protocols involving Minors:

For research protocols involving minors you must submit your initial research proposal to the UMKC IRB. The UMKC IRB will contact Children's Mercy Hospital (CMH), Office of Research Integrity for a consultant review. . If you will be enrolling subjects from Truman Medical Center (TMC), you must also submit your research protocol to TMC, Office of Research Administration. Consent form and assent forms are necessary for review.

TMC: <http://www.trumed.org/tmc/Default.aspx?alias=www.trumed.org/tmc/research>

BIOLOGICAL MATERIALS

Protocols involving biological materials and teeth obtained from non-UMKC affiliated locations are required to submit the following:

- A list of materials to be obtained (teeth, tissue, etc.)
- What information will be provided with the specimens
- A list of agencies providing materials (Institution name and address)
- Documentation from the site outlining the procedure by which they notify patients that their specimen which is normally discarded will be used for research and the patient may refuse to allow the use of their specimen for research.
- Signed site location approval letter from an authorized official on letterhead