

INSTRUCTIONS FOR FULL BOARD AGENDA SUBMISSIONS

Both paper copies and electronic submissions for monthly SCRIHS meetings must be received at the SCRIHS office by the agenda deadline. Deadlines are posted on the SCRIHS website.

New studies

- 3 paper copies of the Application for Approval**
- 4 paper copies of the protocol**
- 4 paper copies of the Investigator's Brochure or Instructions for Use**
- 4 paper copies of any recruitment materials or additional materials**
- 3 paper copies of the HIPAA Authorization**
- 4 paper copies of the consent form(s)**
- 3 paper copies of NIH grant application (if applicable)**
- 1 paper copy of all PI and Co-PIs Conflict of Interest forms

** Email each of the above documents to scrihs@siumed.edu

Full-Board Amendment Summaries

- 2 paper copies of the Amendment Summary form**
- 3 paper copies of the amended protocol showing tracked changes**
- 1 **untracked** paper copy of the amended protocol**
- 3 paper copies of consent form(s) showing tracked changes**
- 2 paper copies of the **untracked** amended consent form(s)**
- 3 paper copies of HIPAA Authorization showing tracked changes (if applicable)**
- 1 clean paper copy of amended HIPAA Authorization (if applicable)**
- 3 paper copies of Investigator's Brochure or Instructions for Use (if applicable)**
- 3 paper copies of any additional materials (i.e. summary of changes, questionnaires, advertisements, flyers, etc.)**

** Email each of the above documents to scrihs@siumed.edu

Continuing Reviews

- 2 paper copies of the Continuing Review Statement**
- 4 paper copies of the consent form(s) (These copies should be void of any SCRIHS stamps)**
- 3 paper copies of the HIPAA Authorization **
- 1 paper copy of the protocol**
- 1 paper copy of the Investigator's Brochure or Instructions for Use (If new within the last year, even if already approved by SCRIHS)**
- 3 paper copies of any additional materials (i.e. adverse event information, annual reports, DSMB reports, etc.)**
- 1 paper copy of the last two patient signed consents (ONLY if there have been new enrollments since the last continuing review)

** Email each of the above documents to scrihs@siumed.edu

****Please follow these instructions for email submissions:**

The SUBJECT LINE of the email should contain the following:

1. Type of Submission (i.e. CR for continuing review, AS for amendment summary, or NP for new protocol)
2. Agenda Month
3. Protocol Number

EXAMPLE: NP for January #06-209

The TEXT of the email should contain the Principal Investigator's name and the Protocol Title.

AMENDMENT SUMMARIES CANNOT BE SUBMITTED WITH CONTINUING REVIEWS

INSTRUCTIONS FOR EXPEDITED SUBMISSIONS

New Studies

Application for Approval

Protocol

Consent form(s) (if applicable)

Request for waiver of consent/authorization (if applicable)

HIPAA authorization (if applicable)

Any recruitment materials, data collection forms, or additional materials

NIH grant application (if applicable)

NOTE: These materials must be submitted electronically to scrihsexpedited@siumed.edu

There is no submission deadline for expedited studies.

Any changes or modifications to the study need to be submitted to SCRIHS via an Amendment Summary Form.

INSTRUCTIONS FOR EXEMPT SUBMISSIONS

New Studies

1 paper copy of the Investigator Request for Exemption form

1 paper copy of the protocol

1 paper copy of the Investigator Request for Waiver of Authorization form (if applicable)

1 paper copy of any recruitment materials, data collections forms or additional materials

NOTE: These materials do NOT need to be submitted electronically.

There is no submission deadline for exempt studies.

Any changes or modifications to the study need to be submitted to SCRIHS via a letter addressed to the SCRIHS chair.

INSTRUCTIONS FOR ADMINISTRATIVE AMENDMENT SUMMARY SUBMISSIONS

Consent Form(s) and/or HIPAA Authorizations:

- 1 paper copy for the SCRIHS file
- 1 paper copy to be returned to the Investigator
- 1 paper copy for each participating hospital (SJH and/or MMC)
- 1 paper copy showing tracked changes

Protocols, Investigator's Brochures, Instructions for Use or any other supporting documentation:

- 1 paper copy for the SCRIHS file
- 1 paper copy for each participating hospital
- 1 paper copy showing tracked changes or

1 paper copy of the signed Amendment Summary Form

NOTE: These materials do NOT need to be submitted electronically