

## INSTRUCTIONS FOR AGENDA SUBMISSIONS

### 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 extra materials
- 3 paper copies of the HIPAA Authorization
- 6 paper copies of the consent form(s)

\*\* Email all above referenced materials to [scrihs@siumed.edu](mailto: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 **clean** paper copy of the amended protocol
- 3 paper copies of consent form(s) showing tracked changes
- 2 paper copies of the **clean** 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 any additional materials (i.e. questionnaires, advertisements, flyers, etc.)

\*\* Email all above referenced materials to [scrihs@siumed.edu](mailto:scrihs@siumed.edu)

### Continuing Reviews

- 2 paper copies of the Continuing Review form
- 5 paper copies of the consent form(s)
- 4 paper copies of the HIPAA Authorization
- 1 paper copy of the protocol
- 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 all above referenced materials to [scrihs@siumed.edu](mailto: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.

**NO MORE AMENDMENT SUMMARIES WITH CONTINUING REVIEWS!!**