

Electronic Versions of HSC Submission Documents October 2008

The Human Subjects Committee (HSC) now requires **electronic versions** of submission documents, in addition to the paper copies. We are making this change in order to manage the convened HSC meetings through the SharePoint system. Obtaining electronic versions also will result in significant savings on printing costs. At this time, items that are not being reviewed by the convened committee will remain as paper submissions.

The electronic versions will be sent to a special email account: HSCsubmissions@kumc.edu.

NOTE: If the KUMC Research Institute is managing your study, please continue to submit all study-related information directly to the RI. RI staff will email the electronic documents to HSC on your behalf.

ANY TYPE of electronic document is acceptable: (Word, Excel, PDF, etc.)

**** Please Do Not Use Staples on Paper Submission Items ****

HSC submissions for **New Studies-Full-Committee Review** should include documents listed below:

HSC Application Form	1 Signed Paper Original; 2 Paper Copies; Electronic version (signed or unsigned)
Protocol	3 paper copies; Electronic version
Consent Form(s)	3 paper copies; Electronic version
Other applicable documents such as: Scientific Review Checklist, Sponsor's consent template, Investigator's Brochure, Device Brochure, Grant Application, Advertisements, DSMB Charters	3 paper copies; Electronic version
When emailing to HSCsubmissions@kumc.edu, please identify the submission as a New Study and the PI's name [i.e., New Study – Jones].	

Submissions for **New Studies-Expedited and Exempt Studies:**

HSC Application Form	1 Signed Paper Original
Protocol	1 paper copy
Consent Form(s)	1 paper copy
Scientific Review Checklist (Expedited Studies only)	1 paper copy
Other applicable documents such as data collection sheets, surveys, assessment instruments, etc.	1 paper copy

Responses to Provisos – Chair Review:

Cover letter from the PI	1 Signed Paper Original
Revised Protocol, if applicable	1 paper copy
Revised Consent(s), if applicable	1 paper copy
Other revised documents	1 paper copy

Responses to Provisos – Deferred or Tabled:

Cover letter from the PI	1 Signed Paper Original; 2 Paper Copies; Electronic version (signed or unsigned)
Revised Protocol, if applicable	3 paper copies; Electronic version
Revised Consent(s), if applicable	3 paper copies; Electronic version
Other revised documents	3 paper copies; Electronic version
When emailing to HSCsubmissions@kumc.edu, please identify the submission as HSC #, PI, Proviso Response [i.e., HSC# 12345- Jones Proviso Response].	

FULL COMMITTEE Amendments, such as Revised Protocol and/or Revised Investigator’s Brochure that necessitate a Revised Consent Form

Request for Amendment Form	1 Signed Paper Original; 2 Paper Copies; Electronic version (signed or unsigned)
Revised Protocol (if applicable)	3 paper copies; Electronic version
Revised Consent Form (if applicable)	3 paper copies; Electronic version
Investigator’s Brochure (if applicable)	3 paper copies, Electronic version
When emailing to HSCsubmissions@kumc.edu, please identify the submission by HSC#, PI and type of submission [i.e., HSC# 12345- Jones Revised Consent]	

MINOR Amendments, such as changes to the protocol or consent form that do not increase risk or add new procedures.

Request for Amendment Form	1 Signed Paper Original
Revised Protocol (if applicable)	1 paper copy
Revised Consent Form (if applicable)	1 paper copy
Any supporting documentation	1 paper copy

FULL COMMITTEE CONTINUING REVIEWS (*Item III on the application is A – C*)

Continuing Review Form	1 Signed Paper Original and 1 Paper Copy; Electronic version (signed or unsigned)
Current Stamped Consent Form(s)	2 paper copies
Current Protocol	1 paper copy; Electronic version
Clean Consent Form(s) -- not stamped	1 paper copy; Electronic version
Other required documents such as AE summary, FDA report, DSMB report, etc.	2 paper copies; Electronic version
When emailing to HSCsubmissions@kumc.edu, please identify the submission by HSC#, PI and type of submission [i.e., HSC# 12345- Jones Continuing Review]	

EXPEDITED CONTINUING REVIEWS (*Item III on the application is D -F*)

Continuing Review Form	1 Signed Paper Original
Current Stamped Consent Form(s)	1 paper copy
Current Protocol	1 paper copy
Clean Consent Form(s) -- not stamped	1 paper copy
AE summary, FDA report, DSMB report, if applicable	1 paper copy

Paper Documents Only are accepted for all other submissions, such as:

Changes to study personnel

Recruitment materials

Problem reports