



CHECKLIST FOR KCMC ETHICS COMMITTEE APPLICATIONS

Circle type of submission: *Initial* *Amendment* *Annual Renewal* *Other*

Protocol # and Title: _____

(Tick all that apply)

- ☐ Cover Letter
- ☐ Protocol synopsis in requested KCMC Ethics Committee Format
- ☐ Curriculum Vitae of Principal Investigator(s)
- ☐ Complete protocol, version # _____, date _____ (ddMONyear)
- ☐ Main study informed consent form (ICF) based on protocol v. _____, date _____. ***Check any applicable boxes below and record ICF date.***
 - ☐ English, consent version date: _____
 - ☐ Kiswahili, consent version date: _____
 - ☐ Back Translation, consent version date: _____
- ☐ Other study ICF (such as database/specimen repository, controls or other sub-groups, etc): List each ICF, including language and version date.
 - ☐ _____
 - ☐ _____
 - ☐ _____
 - ☐ _____
 - ☐ _____
 - ☐ _____
- ☐ Questionnaires (*If applicable*) List type of questionnaire, version # and date:
 - ☐ _____
 - ☐ _____
 - ☐ _____
- ☐ Other (*If applicable*) Such as annual review, letter of amendment, SAE reporting, safety reports, etc.) List specifics of what was submitted, including version/date. If more space is required, attach separate sheet and note here that sheet attached.
 - ☐ _____
 - ☐ _____

- ☐ Patient diary cards (*If applicable*). List type, version # and date:
☐ _____
- ☐ Product information (Package Insert; *If applicable*) List type, version # and date:
☐ _____
☐ _____
☐ _____
- ☐ Advertisement (*If applicable*): Posters, Fliers, Handouts, etc. List all types and versions submitted:

- ☐ Protocol Budget
- ☐ Fee paid Amount: _____

The KCMC IEC requires 3 complete bound packages of all material submitted. How many copies of this complete package were submitted? # ____ confirmed by _____

Declaration:

I have reviewed the list of Materials and it is complete and complied to the prerequisites. All of the required elements have been compiled and check boxes ticked.

KCMC-Duke University Collaboration Staff Member/Date

Staff Member, KCMC Ethics Committee/Date

The following KCMC EC certificate of clearance, No. _____ corresponds with this submission. If this is the initial submission of this proposal, enter the certificate number once approval has been granted.

This study received initial clearance from the KCMC EC on _____.
 (ddMONyear)

This submission checklist togethr with the KCMC Certificate of Clearance serve to document all components of what has been reviewed and approved by the KCMC IEC. The KCMC-Duke University Collaboration requires this checklist to be filed within the protocol specific regulatory files to meet essential documentation requirements.