THE UNIVERSITY OF KANSAS
CANCER CENTER

Protocol Review and Monitoring Committee
Submission Requirements for Initial and Continuing Review

The Protocol Review and Monitoring Committee would like to encourage investigators and their study personnel that only complete submissions can be accepted.

To streamline the application process for investigators and to reduce redundancy, the PRMC is adopting several of the HSC's forms to act as our application as well as some other minimal form requirements that the PRMC has.

Initial Review
Full Committee Review, Expedited Review and Exempt Review Applications
Required Forms:

- Full HSC application and related required documents (ie, Institutional Research Safety Form…)
- PRMC Addendum
- NOTE: PRMC does not review the consent form.

Please ensure that all required sections of each application are completed and signatures are obtained on each.

PRMC requires all submissions be sent electronically only (signed or unsigned, to the PRMC Coordinator, email address: PRMC-KUCC@kumc.edu

All original hard copies (signed), including consent(s) will remain with the PI, the appropriate study personnel/study coordinator, and/or CTSR Regulatory Coordinator until after PRMC review and approval. Once the PI or appropriate study personnel/coordinator or Regulatory Coordinator has received the PRMC Approval letter, they can then submit to the HSC per the HSC submission requirements.

Human Subjects Committee (HSC) now requires electronic versions of submission documents (signed or unsigned, in addition to the signed hard copies.

- **Upon receipt of a PRMC approval letter from the PRMC Coordinator**, *it is the responsibility of the PI, appropriate study personnel/coordinator or CTSR Regulatory Coordinator to submit all relevant documentation electronically (signed or unsigned) and hard copies (signed), simultaneously to HSC, including the PRMC approval letter and consent(s), to HSC.*

HSC email address: HSCsubmissions@kumc.edu
HSC address below:
KUMC Human Subjects Committee
G006 Sudler, MS 1032
3901 Rainbow Blvd.
Kansas City, KS 66160

Access to the appropriate forms can be found at PRMC forms page, @ http://prmc.kumc.edu

Protocol Types Requiring Full Committee Review:
(1 physician, 1 basic scientist, 1 biostatician, 1 oncology nurse)

1. Investigator-initiated prospective trials
2. Industry sponsored prospective trials

ALL TRIALS MUST HAVE A QUALIFIED BIOSTATICIAN.

Protocol Types Requiring Expedited/Exempt Review:
(Administrative review)

1. National cooperative group studies
2. Non-interventional studies
   a. Observational
   b. Epidemiological
   c. Ancillary or Companion
   d. Correlative
3. Retrospective Chart Reviews*
   Please see template located at http://prmc.kumc.edu/prottemp.aspx

   A qualified biostatician is not required but recommended.

   *All retrospective chart reviews must contain the following minimal elements:
   1) Hypothesis, 2) Rationale, 3) Methods, 4) Statistical Analysis, 5) Reference

Continuing/Annual Review
Required Forms:

- HSC Continuing Review Form and related required documents
- PRMC Serious Adverse Event Summary
- Consent Form (HSC requirement only, if applicable)

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