Center for Clinical and Translational Science

Accelerating discoveries to improve health℠

Non-indemnified Clinical Study Approval Process

Non-Indemnification Policy

The University of Kentucky (UK) Healthcare Risk Management Committee (UKHC RMC) administers a self-insurance program to protect its physicians from medical malpractice claims, which could result from their participation in the conduct of clinical studies. UKHC RMC review is required for all clinical studies that are investigator initiated, studies where the sponsor does not provide indemnification or limits time or dollar amount of indemnification for medical malpractice liability, with the exception of studies that meet the exclusion criteria detailed below. UKHC RMC review assesses the medical malpractice liability for conducting a clinical study. UKHC RMC review also determines whether the protection of this program will be given to a clinical researcher for medical malpractice claims that may arise from participation in a particular clinical study. Medical malpractice liability protection is **contingent** on UKHC RMC review and approval of proposed clinical studies.

It is the responsibility of the principal investigator to initiate the non-indemnification review process for all eligible clinical trials, as defined below.

If an investigator does not forward a study for review that qualifies for Inclusion in the Indemnification Process and a problem occurs and a claim is made, the University is not obligated to defend the investigator.

NOTE: Email nonindemnification@uky.edu for any questions regarding protocol eligibility or the nonindemnification submission/review process.

I. Features of Clinical Studies requiring UKHC RMC Review

Inclusion criteria for UKHC RMC Review:

1. All non-indemnified human clinical research that is not IRB exempt or expedited regardless of the funding source. Type of IRB review should be determined by the reviewing IRB rather than the relying IRB. This means that if UK IRB is ceding reliance to an external/ central IRB, then the external/ central IRB type of review is what determines if non-indemnification review is needed.
2. Surveys and medical record chart reviews are included if they require Full IRB review.

3. All human clinical research for which a drug, device, investigative procedure or financial support are provided by an external sponsor, but full indemnification is not provided (i.e. limitation on time or dollar amount). This will require a review of the CTA (Clinical Trial Agreement).
4. All VA cooperative studies utilizing UK services (i.e. VA Merit Awards).
5. Any study utilizing AI (Artificial Intelligence).
6. Studies in which there is no physical risk to the subject but there could be risk to the institution based on social, political or ethical issues.

Exclusion criteria:
The following studies do not require review by UKHC RMC.

1. Industry supported clinical studies that provide full indemnification.
2. IRB review was Expedited
3. IRB review was Exempt

Expedited Review:
Low risk studies may qualify for expedited review by RMC.

II. Instructions for submission:

The Principal Investigator (PI) is responsible for reviewing the inclusion/exclusion criteria for the review process. The PI can ask for legal advice on the requirements by contacting Katie Haagen at katie.haagen@uky.edu.

If a study qualifies for review then the PI should initiate the process described below:

To submit an application for review, send the following items to nonindemnification@uky.edu:

a. Completed Clinical Project Risk Assessment Evaluation Form (sections I, II and III), available at www.ccts.uky.edu/non-indemnification.

b. Research Description (Form B) or study protocol

c. IRB Approval letter(s) from all reviewing IRBs. This includes UK eIRB, Central IRBs (i.e., CIRB, Advarra, Western, etc.) as applicable

d. IRB Approved Consent document(s)

e. Clinical Trial Agreement (CTA) or study contract for sponsored/ externally funded studies if no indemnification is provided or if indemnification is limited.

After the UKHC RMC review, the PI will receive notification of approval. Upon receipt of this approval, the PI may proceed with the steps necessary to initiate the protocol.

Even though IRB approval has been obtained, if the Risk Management Committee has not given approval, **THE STUDY MUST NOT BE STARTED**.

IV. Reconsideration Process

If the protocol does not receive UKHC RMC approval, the PI can make revisions to address the UKHC RMC's concerns and resubmit to the UKHC RMC for reconsideration. However, the decision of the UKHC RMC is final.

V. Modification to Protocol

During the course of the study **if a modification to the protocol results in an increased risk level** then legal counsel should be notified at (nonindemnification@uky.edu). Submit a summary of changes and revised documents, along with IRB approval. Legal counsel will determine whether or not the protocol will need to be reviewed in order to continue coverage. If the study requires review a summary of the changes being made along with the revised documents and IRB approval should be sent to (nonindemnification@uky.edu) for review. The protocol will ONLY need to be resubmitted for review if there is an increased risk level (a change in the risk/benefit ratio) of the study with a modification.

VI. Change in Principal Investigator

If there is a change of principal investigator during the study, notify nonindemnification@uky.edu so that the records can be updated to reflect this change. Revised documents and IRB approval should also be included.