Non-indemnification Clinical Trial RMC Approval Process

Non-Indemnification Policy Statement

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 may result from their participation in the conduct of clinical trials. UKHC RMC review is required for all clinical trials where the sponsor does not provide indemnification for medical malpractice liability, with the exception of trials that meet the exclusion criteria detailed below. UKHC RMC review assesses the medical malpractice liability for conducting a clinical trial. 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 trial. Medical malpractice liability protection is **contingent** on UKHC RMC review and approval of proposed clinical trials.

It is the responsibility of the principal investigator to initiate the non-indemnification review process for all eligible clinical trials, as defined below, by directing the proposed clinical trial protocol to **one** of the following three review committees: (1) the Markey Cancer Center Protocol Review Committee (PRC) for cancer clinical trials; (2) the CR-DOC Protocol Review Committee for investigator-initiated NIH-sponsored clinical trials, which are not multicenter cooperative clinical trials; and (3) the Non-indemnified Non-cancer Protocol Review Committee for all other non-indemnified trials. Electronic submissions via email are preferred and may help expedite this process.

NOTE: Contact Dr. John S. Thompson (Tel: 859.281.4927; Email: jsthom1@uky.edu) for any questions regarding protocol eligibility or the non-indemnification submission/review process.

I. Features of Clinical Trials requiring UKHC RMC Review

Inclusion criteria:

1. All clinical trials (investigator-initiated and industry-sponsored) for which a drug, device, investigative procedure or financial support are provided but indemnification is not provided.
2. Investigator initiated NIH-supported clinical trials that are not cooperative clinical trials.
3. Orphan drug trials that are not indemnified.
4. Clinical trials for which the PI is a UK/VA employee, which also involve the participation of non-UK/VA health care providers.
5. Clinical trials that present no/minimal physical risks to the study subjects but have the potential for institutional legal liability based on prevailing social, political or ethical issues.

Exclusion criteria:

1. All NIH/NCI/VA multicenter cooperative clinical trials.
2. Other multicenter clinical trials, including industry sponsored trials, which have an external Data Safety Monitoring Board.
3. All protocols that have been granted an IRB exemption.
4. All protocols that have been granted an expedited IRB approval.
5. All protocols that do not require IRB review.
6. Industry supported clinical trials, where the sponsor provides indemnification.

II. Instructions for submission to the appropriate review committee:

The Principal Investigator (PI) is responsible for assessing whether or not a clinical trial needs to undergo review by the UKHC RMC.

A scientific review needs to be completed by the appropriate one of the following three committees.

Scientific Review Committees

Non-indemnified Non-cancer Protocol Review Committee
Chairperson: John Slevin, MD
This committee reviews clinical trials that do not have to go through the Markey Cancer Center Protocol Review committee or the CR-DOC Protocol Review committee. For questions regarding submitting to this committee contact John Slevin (Chairperson) Email: jslevin@uky.edu; Phone: 859.281.4920.

The Clinical Project Risk Assessment Evaluation Form and the Routing Form are located on the CCTS web site: www.ccts.uky.edu (UK Research Policies) or see OSPA: www.research.uky.edu/ospa/site.html (Non-indemnified Trials).

To submit an application for review:

1. Complete sections I, II, III of the Clinical Project Risk Assessment Evaluation Form.
2. Complete Investigator Name/Date and protocol title on the Routing Form.
3. Submit the completed Clinical Project Risk Assessment Evaluation Form, Routing Form, study protocol and draft informed consent to Dr. John Slevin via email to jslevin@email.uky.edu.
4. Once Dr. Slevin has completed his review, he will sign and date the routing form and forward the routing form and the Clinical Project Risk Assessment Evaluation Form to Dr. John Thompson.

Markey Cancer Center Protocol Review Committee
Chairperson: Jeff Moscow, MD Phone (859) 323-0239 Email: jmoscow@email.uky.edu
This committee reviews all cancer-related clinical trials. For questions regarding submissions to this committee contact Katie Bugg (PRC Coordinator) Email: Katie.bugg@uky.edu Phone: (859) 257-8213.

The New Protocol Registration Form is located at markey.uky.edu/crcc/documents/PRCSubmissionForm.pdf. The Routing form is located on the CCTS web site: www.ccts.uky.edu (UK Research Policies) or see OSPA: www.research.uky.edu/ospa/site.html (Non-indemnified Trials).

To submit an application for review:

1. Complete the New Protocol Registration Form.
2. Complete the Investigator Name/Date and protocol title on the Routing Form.
3. Submit the completed New Protocol Registration Form, the Routing Form, draft informed consent and an electronic copy of the protocol via email to Katie.Bugg@uky.edu.
4. Once the Committee has completed their review and assigned a Risk Assessment score, the PRC Coordinator will complete the PRC memo, routing form, Risk Assessment and obtain the

appropriate signatures from the Chair or his designee. (Sections I and II of the Risk Assessment form will be sent to the PI for review and approval).

5. Upon full completion and approval of the Risk Assessment form, the PRC Coordinator will submit the following to Dr. John Thompson: protocol, PRC memo(s), Risk Assessment form, routing form, and draft consent form.

CR-DOC Protocol Review Committee

Chairperson: Tom Getchell, PhD

This committee reviews all clinical trials that utilize the CR-DOC. For questions regarding submissions to this committee contact Tom Getchell (Chair) Email: tgetche1@uky.edu Phone: (859) 257-1412, ext. 321.

A link to the Clinical Project Risk Assessment form and Routing form are located at www.mc.uky.edu/gcrc/Home.aspx under "application process".

To submit an application for review:

1. Complete sections I, II, III of the Clinical Project Risk Assessment Evaluation Form.
2. Complete the Investigator Name/Date and protocol title on the Routing Form.
3. Submit the completed Clinical Project Risk Assessment Evaluation Form, study protocol and draft informed consent to: alcose0@uky.edu (Abby Cosentino).
4. Once Dr. Getchell has completed his review, he will sign and date the routing form and forward the routing form and the Risk Assessment to Dr. John Thompson.

The PI should forward a copy of the IRB approval and the IRB approved, stamped consent form to Dr. Thompson upon receipt. The Review process cannot continue until Dr. Thompson has received these documents. Dr. Thompson will communicate any necessary changes or initial concerns to the Principal Investigator via email.

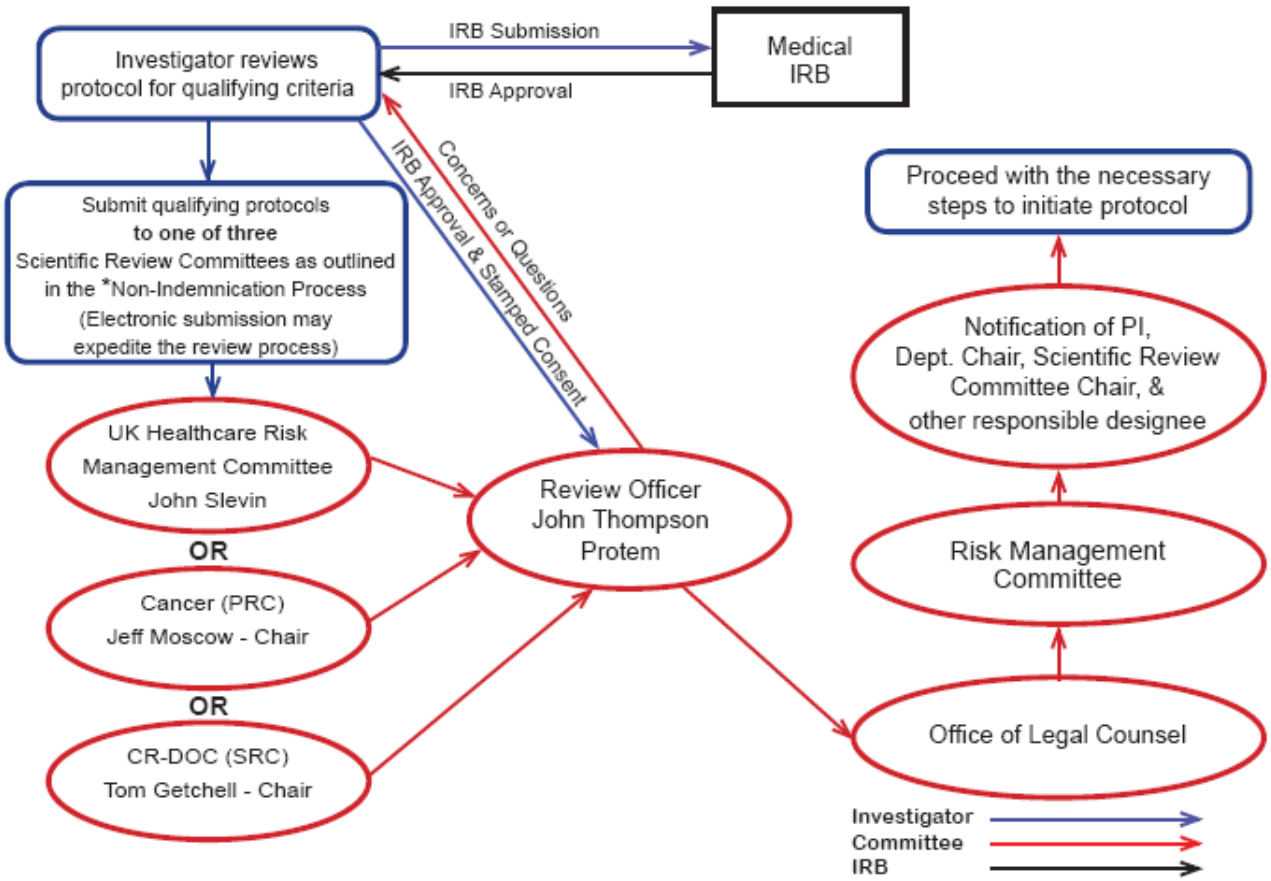
Dr. Thompson will review the Scientific Review Committee's assessment, the routing form, protocol, IRB approval letter, stamped consent, and will prepare a summary and recommendation and forward to legal counsel. Legal counsel will assess the submission and recommend either an expedited or full review by the Risk Management Committee, which meets monthly.

After the UKHC RMC review, legal counsel will notify the Principal Investigator and/or their designee (if applicable), Department Chair and Scientific Review Committee Chairperson of the status of their protocol via email. Legal counsel will send the original signed routing form to the Principal Investigator and/or their designee for filing in the regulatory file. 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 TRIAL MUST NOT BE STARTED**.

If an investigator does not forward a trial 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.

Required Approval Process for All Non-indemnified Clinical Trials



III. Flow Chart Points to Consider:

1. If a clinical trial meets the criteria for UKHC RMC review, start the process outlined in the flow chart immediately so that this proceeds in parallel with the IRB approval and Contract (if applicable).

2. Although there are occasions when Sponsored Projects may eventually obtain indemnification, do not delay your protocol by waiting for this to occur. This may happen on rare occasions and on these occasions the work by the Scientific Review Committees will have been unnecessary — but this is worth the effort to generally move the process forward as quickly as possible.

3. Electronic submission to the appropriate scientific review committee will help expedite this process.

IV. Appeal 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.