

Principal Investigator Responsibilities When Other Institutions Are Relying on the UK IRB*

The University of Kentucky and another institution (*Relying Site*) are entered into a Reliance Agreement ceding IRB review to the University of Kentucky IRB. When this arrangement is made it is important for investigators at both sites to understand their responsibilities. This document is intended to review the responsibilities for the PIs at each site to ensure compliance with all applicable regulations and protocol responsibilities.

**Please note: There may be additional responsibilities for researchers utilizing SMART IRB, IREx, or conducting cooperative research with Norton Healthcare.*

The University of Kentucky (UK) Principal Investigator will:

- 1) Collect information from the Relying Site PI for the protocol application, including but not limited to the information listed below, and information regarding any special local considerations to be made by the UK IRB. Provide the information to the UK IRB.
- 2) Include in the UK IRB protocol application the following:
 - the list of the Relying Site PI and other research personnel involved in the study at the Relying Site;
 - documentation of human subjects protection training for the Relying Site PI and research personnel at the Relying Site;
 - and any financial conflict of interest disclosure for the Relying Site PI and each research personnel involved in the Study at the Relying Site, and any associated management plans, if applicable.
- 3) Promptly provide the Relying Site PI with:
 - current approved protocol and consent documents;
 - approved modifications, amendments or changes to the protocol;
 - approval of continuing reviews, reviews of unanticipated problems involving risk to subjects or others, and serious or continuing noncompliance;
 - and any other information required by the UK IRB to be provided to the Relying Site.
- 4) Notify the Relying Site PI of the standards and guidelines of the UK IRB regarding reporting of any post IRB-approval events, such as those listed below. The UK PI should collect these reports from the Relying Site PI and submit them to the UK IRB for review:
 - proposed amendments or changes in study activities;
 - injuries, adverse events or unanticipated problems involving risks to subjects or others;
 - serious or continuing noncompliance;
 - protocol violations;
 - or findings from Federal inspections or Quality Improvement inspections.

(For assistance with reporting requirements, please refer to the "[University of Kentucky Investigator Quick Guide to IRB Reporting Requirements](#)".)

- 5) Collect required information from the Relying Site PI in order to complete the continuing review submission form. The UK continuing review must cover information from all Relying Sites.
- 6) Notify the Relying Site PI of any lapses of approval. Forward to the UK IRB, any request from the Relying Site PI for continuation of a specific patient on a research protocol during a lapsed period of approval.

The Relying Site PI

The Relying Site PI understands that the Relying Site has ceded IRB review to UK and, therefore, IRB responsibilities for the study will be assumed by the UK IRB. The Relying Site PI has direct responsibilities to the UK IRB, as described below.

The Relying Site PI will:

- 1) Notify the UK PI about any special local considerations that must be considered by the UK IRB for the Relying Site (e.g. applicable state laws).
- 2) Provide to the UK PI:
 - the list of all research personnel involved in the study at the Relying Site;
 - documentation of human subjects protection training for the Relying Site PI and all research personnel involved in the study at the Relying Site;
 - assurance(s) of the qualifications of relying site personnel to conduct the research as approved by the UK IRB;
 - any conflicts of interest/financial interest disclosures for the relying site personnel and any associated management plans, if applicable;
 - and any other information required by the UK IRB regarding the Relying Site PI and/or research personnel involved in the study.
- 3) Assure that any additional local requirements for ancillary human research protection reviews (pharmacy, nursing, radiation safety, etc.) are obtained and followed at the Relying Site.
- 4) Assure that research activities at the Relying Site are not initiated until all UK and Relying Site requirements for the study regarding funding and clinical trial agreements are finalized and the protocol has been reviewed and approved by the UK IRB.
- 5) Conduct the protocol and obtain informed consent as approved by the UK IRB.
- 6) As requested on a continuing basis provide the UK PI with any information necessary for the continuing review process. This may include, but is not limited to, information regarding:
 - subject recruitment;
 - summary of all enrolled subjects;
 - minor violations;
 - screen failures;
 - summary of adverse events;
 - and subject complaints or withdrawals.

- 7) If at any time study approval lapses, cease all human subject research work related to the protocol at the Relying Site. If the Relying Site determines that subjects who are already enrolled on the trial may be harmed if research ceases, notify the UK PI about the individual subject(s) and the justification for remaining on the trial.
- 8) Consistent with UK policies, report to the UK PI all post-IRB approval events such as:
 - proposed amendments;
 - deviations;
 - subject injuries;
 - serious or continuing noncompliance;
 - unanticipated problems involving risks to subjects;
 - protocol violations;
 - or findings from Federal inspections or Quality Improvement inspections.

(For assistance with reporting requirements, please refer to the "[University of Kentucky Investigator Quick Guide to IRB Reporting Requirements](#)".)

- 9) Promptly cooperate with any UK or Relying Site investigation regarding serious or continuing noncompliance or an unanticipated problem upon request.
- 10) Promptly cooperate with any UK or Relying Site quality assurance/quality improvement review or monitoring of the Study protocol upon request.
- 11) In the event of the need for an audit, allow the UK PI and reviewing UK institutional officials access to research related records.
- 12) Maintain records of all research and related activities conducted under the Agreement for at least six years, and longer if required by law, after completion of any study.
- 13) Promptly respond to all requests for information from the UK PI or UK IRB, including but not limited to the information set forth in the Agreement.

Questions? Please contact:

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For questions about the rights and welfare of subjects in research, contact the staff in the Office of Research Integrity between the business hours of 8am and 5pm EST, Mon-Fri at the University of Kentucky at 859-257-9428 or toll free at 1-866-400-9428.

Adapted from the Boston Children's Hospital/Susan Kornetsky