Submission and Approval Process Guidelines for Human Studies Research Performed at a University Medical Center, Inc. facility d/b/a University of Louisville Hospital and James Graham Brown Cancer Center
September, 2012

Disclaimer: These are guidelines organized in an outline format for informational purposes only. Formal policies are currently in revision.

GUIDELINES:

- Notification: Investigators are responsible for notifying the University of Louisville Hospital Research Integrity Office (ULH RIO) of any study they wish to submit for consideration and approval.
    - Investigators have the option to submit study documents to the RIO for preview before submitting to the Institutional Review Board (IRB) if they wish feedback prior to IRB submission. We provide this at no charge prior to IRB submission.

- Minimum Documentation Required:
    - Research Protocol:
    - Consent Document: either a Preamble or Informed Consent Form (ICF), or a Complete Waiver when applicable
    - IRB Protocol/Application:
    - Partial Waiver when applicable
    - Billing Compliance Table (exceptions: chart reviews)
    - Curriculum Vitas (CVs) of all Research Personnel
    - Miscellaneous documentation required, as applicable:
        - Advertisements, recruiting fliers
        - Scripts
        - Cover letters, email language
        - Questionnaires, surveys
        - Letters of support from collaborating faculty, departments, outside institutions, or other involved entities
        - For chart reviews, a Data Collection Sheet is required

- Tracking Number: the assigned IRB number.

- Missing Documents: RIO staff will review the submission to ensure the submission is complete.
    - If documents are missing, RIO staff will contact the Investigator and Regulatory Coordinator/Study Coordinator
    - ULH RIO review of the study will not commence until all required documents have been received.

Review of New Submissions may take one of two review paths:

- Full Committee Review: Studies requiring a signed ICF will go before the Research Review Committee (RRC) for formal review.
    - The RRC meets every Tuesday at 1:00 pm. and consists of 9 representatives from the ULH and James Graham Brown Cancer Center.
    - Four dispositions are possible: 1) approve as submitted; 2) approve pending changes; 3) defer with return to expedited review; and 4) defer with return to full committee.
    - Comments from the entire RRC are captured in a write up

- Expedited Review: Studies not requiring a signed informed consent form (ICF) will generally be reviewed via an Expedited Review Process
    - Four dispositions are possible: 1) approve as submitted; 2) approve pending changes; 3) defer with return to expedited review; and 4) (rarely) defer with return to full committee. Comments from the entire committee are captured in a write up
    - Comments from the Expedited Review committee are captured in a write up

- Write Ups: The write up sent to the PI and Study Coordinator will be in the form of a WORD document and will contain a list of all questions, concerns, or changes which must to be addressed in order for the study to comply with all University Medical Center, Inc. (UMC) policies, requirements and/or standards before site approval may be granted.

- Revised Documents: Responses from the Investigator should be submitted directly to the Research Integrity Office via email with revised documents attached and any additional explanations provided.
    - For studies deferred by the RRC with return to full committee, revised documents will be submitted to the RRC for full review per the schedule outlined above.

- Hospital Departments Affected by the Research Study: During the review process, the RIO may forward a copy of the research protocol and any other study documents to the affected hospital department(s) for their review and input. Examples: radiology, laboratory, pathology, nuclear medicine, etc.

- Final Stages: The RIO will begin the final stages of the approval process when the following have occurred:
    - all questions, concerns, or requested changes from the RIO have been addressed
    - IRB approval for the study has been granted
    - IRB amendments (which are required in order to make changes requested by the RIO) are approved by the IRB
    - UofL's clinical trial agreement is fully executed (when applicable)

- UMC's letter of indemnification/facility agreement is fully executed (when applicable)

- The Final Stages of the approval process include, in this order:
  - Regulatory Review
  - Billing Compliance Review and Finalization
  - T account assignment
  - Issuance of the hospital approval letter

Contact Information
ULH Research Integrity Office 2012
September, 2012

Contact Information ULH RIO:

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