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Author: Research Compliance Committee Research Integrity Office	Effective Date: 11/02	Revised Date: 1/03 09/08

Purpose: To define the process of how research studies are received and reviewed for evaluation by the Research Integrity Office.

Policy Statement: The Research Integrity Office shall receive and review all research protocols in a consistent and confidential manner that will allow for appropriate tracking, evaluation, storage, and retrieval of all protocols conducted at University of Louisville Hospital.

Departments Affected: Research Integrity Office

Guidelines:

- Attach “Study Review Checklist” to study material packet
- Stamp top right corner with the date of receipt of study packet.
- “Study Review Checklist” is update as the documents are received.
- Study protocol are reviewed and assessed in terms of risk involved, safety, feasibility, availability of resources, conflict of interest, in-kind costs, staff requirements
- Assess contract for the following:
 - Identification and responsibilities of parties are clearly defined
 - Indemnification clauses are stated
 - Insurance reimbursement is discussed
 - Costs are identified
 - Sponsor’s financial commitment is outlined, eg, payments for drugs, labs, procedures, etc.
 - Device trials are evaluated regarding Medicare reimbursement, preferably category B. Information is obtained from sponsor and submitted to FI./ CMS.
- Discuss necessary issues with appropriate departments involved
- Attach and complete “Research Tracking Form”
- Document missing information and follow-up needed on “Research Tracking Form”

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- Determine research related costs involved and complete T-Account request if not already done. Remember to include pharmacy set up fee if hospital based drug study or if utilizing ACB pharmacy, laboratory fees, and Health Information Management fees as necessary.
- Determine if excessive staff time is involved and discuss with investigator.
- Forward approval notice to affected departments including study title, Investigator, Coordinator and contact information)
- Final approval letter along with a T-account number will be provided to study team. The assigned T- account number must be used for charging research related procedures.
- Request that departments to arrange inservice (at site training pertinent to protocol for staff involved in clinical care of research subject), accountability log must be placed in the unit reflecting the completion of inservice signed by the charge nurse of the unit. Also, make available a copy of study synopsis, any special instructions pertinent to protocol and consent form in the unit where the study will be conducted.
- Reminder to report any serious adverse events (SAE's) to RIO and Risk Management
- Reminder to utilize out-patient registration form
- Reminder to forward email of enrolled subjects to Research Office on a weekly basis
- Note that overall time line goal of 10 working days starts when ALL information has been received