



CLINICAL TRIALS CHECKLIST

- ✍ 1. Contact Research and Grants Administration (RGA) as soon as participation appears likely. The primary RGA contact for clinical trials is Carol Reichenbach, Director of Sponsored Projects and Intellectual Property.
- ✍ 2. RGA initiates negotiation with sponsor of business/legal details of the Clinical Trial Agreement.
- ✍ 3. Develop budget in consultation with RGA and hospital administration. When hospital or clinic services will be utilized, budgeted charges for procedures/tests must be approved by hospital accounting (Mary Genalo, Reimbursement Analysis, ext. 3938). Be sure to tell her the charges will be associated with a research project in order to get the Research discount. After these charges have been approved, submit preliminary budget to RGA for review of compliance with MUOT and sponsor policies.
- ✍ 4. Submit *IRB Application for Approval Form* (obtained from the RGA website) and complete study protocol to RGA for IRB review and approval (IRB review may run concurrently with subsequent steps). **NOTE: No patients can be enrolled in study until IRB approval is obtained.** The primary RGA contact for IRB issues is Michelle Cook, Coordinator, Clinical Research Compliance. Deadline for IRB submissions is the last Monday of each month to ensure review at the following month's IRB meeting
- ✍ 5. Finalize budget, if it is not already set by the sponsor.
- ✍ 6. Submit proposal package to RGA. This should include:
 - a) *MUOT Proposal Review and Approval Form* ("blue sheet") signed by:
 - (1) P.I. and P.I.'s Department Chair
 - (2) All Co-Investigators and their Chairs
 - (3) Hospital Administration (Hospital Administrator or designee) for budgeted hospital/clinic charges (e.g., clinical lab services, heart station services, radiology services)
 - b) Final Budget on *MUOT Detailed Budget for Clinical Trial Form* ("green sheet") signed by the P.I.
 - c) A copy of the Protocol.
 - d) Final Agreement (including Sponsor's budget)
 - (1) If P.I. signature is required on Agreement, P.I. should sign prior to submission to RGA for institutional signature
 - e) IRS tax forms (e.g. W-9).
 - f) Indemnification letter from Sponsor (if separate from Agreement).
 - g) All study-related correspondence from Sponsor.
 - h) Conflict of Interest Disclosure forms for P.I. and each Co-Investigator.
 - i) Keyword form.
- ✍ 7. RGA obtains required institutional signature(s) and sends Agreement to the Sponsor for execution.
- ✍ 8. Sponsor executes Agreement and returns it to RGA. A copy of the fully executed agreement is sent to P.I. by RGA.
- ✍ 9. RGA authorizes MUOT Accounting to assign an MUOT restricted account number for the project. **NOTE: Account number CANNOT be assigned until each of the above steps has been completed.**

**IF YOU HAVE ANY QUESTIONS CALL
RESEARCH AND GRANTS ADMINISTRATION
AT EXTENSION 4252**