CLINICAL STUDY APPROVAL ELEMENTS

All Clinical Studies

- **Confidentiality Agreement**: Email to Billie Moore, PhD, in Tech Transfer (bmoorescott@gru.edu). Include a copy of the agreement, the faculty member’s name, department, campus address, telephone number as well as the information to be disclosed (i.e., a study protocol) and the contact information of the other party.

- **Contract**: Email to OCIS along with a completed Contract Coversheet. The Contract Coversheet is located on OCIS website. OCIS will route the documents to the Office of Legal Affairs and email a confirmation notice to the research site.

All Studies that will use Hospital Services and Resources

- **Hospital Budget**: Be sure to click “Yes” in eIRB and eSPROUTE if the study will use hospital services or resources. Hospital services and resources include radiology, pathology, pharmacy, electronic medical record and patients. OCIS can obtain hospital research prices for a study budget. Complete and upload the “MCG HI Internal Budget (electronic route)” form located on the Department of Sponsored Programs Administration (DSPA) website. If using Radiology or Pathology, complete the forms found on OCIS website. Upload these forms to eSPROUTE. If using an external IRB, be sure to email OCIS a copy of the protocol, IRB approval letter and approved ICD. OCIS will obtain hospital approval for your study.

- **Billing Grid**: A billing grid is required for all studies that will use a billable hospital service or need Patient Accounting to bill insurance for routine care that is part of the study. (See detailed information on this topic on the OCIS website.)

- **Institutional Review Board (IRB)**: All IRB submissions are completed online.

- **Request for Application (RFA) or Request for Proposal (RFP)**: OCIS can help obtain hospital research prices for a study budget. Hospital approval is required after the notice of funding is received. When the funding notice is received, the researcher should submit the appropriate internal budget documents through eSPROUTE.

- **PowerTrials**: All studies that use hospital services are required to use this online program EXCEPT chart reviews and case studies. Basic information on a study is entered in PowerTrials by OCIS personnel. The hospital account number (CPI#) and study labels are provided when the study contract is fully executed (signed by both parties).

- **New Faculty**: Contact the Division of Sponsored Programs and the OCIS when a new faculty member plans to transition a clinical study from another institution.