Workflow for industry-initiated clinical trials

Industry-initiated clinical trials are reviewed, negotiated, and administered by the Hospital/Medical Group in consultation with the Office of Clinical Trials Research (OCTR)

Industry sponsor provides PI and/or Research Coordinator (RC) with a copy of study protocol, following execution of a CDA.

PI **sends the study protocol and completed feasibility assessment to Clinical Research Supervisor** to determine feasibility, given available resources and characteristic of the patient population at UVMMC.

If you will require access to CRC resources including clinical research space or expert nursing services

PI or RC submits a request for CRC support using online form here.

Following feasibility assessment, proposed studies will be discussed within each division.

If the decision is to proceed with the study…

PI contacts Mark Tomase in OCTR and provides a copy of the protocol and payment schedule.

PI may need to request budget quotes from CRC and IDS Pharmacy.

OCTR negotiates the contract on behalf of the PI requesting mandatory 5% departmental overhead in addition to UVMMC overhead rates.

While the contract is being negotiated…

PI works with Clinical Research Coordinator (RC) to finalize protocol and **submit to IRB.**

If your division does not have a designated clinical research coordinator (RC)

PI submits a request for coordinator services by emailing Kimberly Luebbers at Kimberly.Luebbers@med.uvm.edu

IRB perform review and issue approval and/or request revisions when necessary.

After IRB approval is in place…

RC and PI **initiate study enrollment** in accordance with IRB-approved protocol.

Contacts:
NSCI = Bridget Brisson
OCTR = Mark Tomase
CRC = Kim Luebbers
Clinical Research Supervisor, Neurology= Emily Houston