Clinical Research Policies and Processes: PRE-AWARD

Creating and Submitting a Clinical Research Proposal:

Determine the appropriate recipient organization:

* ***Investigator-initiated*** **research projects are submitted and administered by the University using UVMClick and the PI Portal. This includes requests for federal (NIH, DOD), foundation (AHA, MGFA), and even industry funding *provided the research is investigator-initiated*.**

Submission contacts: Bridget Brisson, Grant Management Specialist (GMS), Department Neurological Sciences; Daniel Mills, Business Manager, Department of Neurological Sciences

* ***Industry-initiated*** **clinical trials are reviewed, negotiated, and administered by the Hospital/UVMMG.**

Submission contacts: Mark Tomase, Administrative Coordinator, Office of Clinical Trials Research (OCTR); Kim Luebbers, Assistant Dean for Clinical Research and Director, OCTR

Investigator-initiated research projects:

Any submission requiring institutional approval or signatures must be routed prior to submission. This includes all grant proposals and subcontracts. Preproposals, letters of intent, and internal grant submissions generally do not need to be routed unless institutional signatures are required.

1-3 months prior to deadline, the PI should:

Contact the OVPR Office of Research Development if they anticipate requesting proposal development/review services through the Office of the Vice President for Research. Priority is given to complex proposals including multi-site studies such as U01 proposals. PIs may contact the RD Office directly via the "Request for Support" tool available here: https://www.uvm.edu/ovpr/research-development

Work with Mark Tomase in OCTR to devise a draft budget in accordance with the clinical requirements of the project, including expenses such as study coordinator time, investigator time, research subject study payments, MRI, etc.

Contact the Clinical Research Center (CRC) if they anticipate making use of CRC space or services including expert nursing support. An overview of CRC services can be found online here: http://www.med.uvm.edu/clinicalresearch/home

Identify all subcontracting organizations involved with the proposed study and request the following information/documentation, below. This information should be returned to the PI no later than 2 weeks prior to submission. GMS can assist with this process if needed.

* Signed Subrecipient Commitment and Audit Certification Form: https://www.uvm.edu/sites/default/files/Sponsored-Project- Administration/subrecipientcommitmentform.pdf

* Scope of Work statement describing the actual work to be performed at the study site;

* Budget and Budget Justification in sponsor format (e.g. R&R);

* Other documents if/when required by sponsor e.g. Biosketches, Facilities/Resources, Equipment.

For multi-site studies requiring single IRB approval: **contact WCG-IRB** and request a quote. WCG-IRB contact = Charles Eibeler, ceibeler@wcgclinical.com, phone 919-244-9887.

2 weeks prior to deadline:

PI informs GMS of upcoming submission and provides GMS (1) link to funding opportunity announcement or request for proposals; (2) all necessary budgeting materials including estimates from Mark Tomase, WIRB, subcontractors, etc; and (3) draft budget justification.

GMS creates draft proposal and budget in Click. Generates comprehensive budget document incorporating expenses at UVM, UVMMC, and subaward sites and sends to PI for review.

1 week prior to deadline:

PI provides the GMS with a complete draft proposal incorporating all grant sections.
For System-to-System proposals to federal sponsors such as NIH or DOD, the PI should send every grant section as a separate attachment (Word format preferred) via email or the large file transfer system.
For all other submissions, a single PDF file containing the complete proposal is acceptable.

GMS finalizes budget, compiles all grant sections in Click, and routes draft proposal for internal approvals.

PI signs into Click and certifies proposal.

SPA reviews draft proposal and suggests edits. GMS incorporates edits into draft, informing PI of any changes.

No later than 2 days prior to deadline:

PI provides GMS with final proposal. For system-to-system submissions send final files via email or file transfer. For other proposals a single PDF is sufficient.

GMS uploads final files to UVM Click and creates a final PDF for the PI to review and approve. GMS confirms the proposal is ready to submit.

SPA performs final review. If no changes are needed SPA will either (a) submit to the sponsor (for system-to-system submissions) or else (b) provide formal approval or signed documentation for the PI to submit to the sponsor directly.

Industry-Initiated Clinical Trials:

Sponsor provides PI with study protocol. PI and RC review protocol to determine clinical feasibility.

If the decision is to proceed, **PI contacts Mark Tomase in OCTR** and provides a copy of the protocol and payment schedule.

Mark negotiates clinical agreement with sponsor including indirect rates.

Once study is approved, RC and PI work together to **obtain IRB approval** in advance of project setup.