POST-AWARD Administration of Clinical Research Projects:

Administration of *Investigator-Initiated* Research Projects at UVM

Roles/Responsibilities:

** Principal Investigator (PI):*
The PI has final responsibility for overseeing all aspects of the research study with duties including but not limited to:

-providing oversight of study personnel, including UVMMC staff;
-reviewing grant finances in PI Portal (https://www.uvm.edu/spa/pi-portal);
-obtaining IRB/IACUC approval and implementing research protections and protocols;
-providing patient care when appropriate;
-analyzing and interpreting study data;
-writing and submitting progress reports;
-communicating with other PIs or Sub PIs;

** Research Coordinator:*
Research Coordinator duties vary between divisions and across research studies. Typical Research Coordinator duties would include:

-submitting protocols to IRB;
-reporting patient data to sponsor in accordance with agreement;
-invoicing sponsor for patient visits as they occur and providing all required paperwork;
-enrolling patients and collecting data in accordance with IRB-approved protocol;
-maintaining patient data;
-scheduling follow-up visits;
-facilitating incentive payments to study subjects, including completion of the check request and Payment Acknowledgement Form;
-fielding study subject questions or inquiries;
-reporting monthly time commitments to Shannon Ghostlaw resulting in generation of UVMMC invoices.

**Grant Management Specialist (GMS) - Bridget Brisson:*
GMS duties include but are not limited to:

-creating internal award modifications such as requests for cost-share, carry-over, and/or no cost extensions;
-processing UVM salary distribution changes to allocate personnel effort at UVM;
-paying UVMMC invoices associated with coordinator time;
-processing cost transfers when appropriate;
-reviewing expenses on UVM projects at least quarterly;
-scheduling quarterly meetings with PIs to review finances and personnel effort;
-assisting the PI with annual reporting (e.g. RPPR);
-sending reminders when deadlines are approaching;
-requesting transfer of remaining balance to UVM residual balance fund.

**Business Manager (BM) - Daniel Mills:*
Business Manager duties include but are not limited to:

-processing changes in UVM FTE when needed to account for grant-funded effort;

-reviewing, approving, and submitting payments to research subjects;
-reviewing and approving monthly MRI invoices from LCOM Dean's Office;
-providing oversight, training, and guidance to GMS.

** Sponsored Projects Administration (SPA):*
In collaboration with the PI and GMS, SPA is responsible for:

-setting up the award in Click and assigning chartstrings in PeopleSoft;
-creating subawards in accordance with the proposal and sending to subawardees for partial execution;
-invoicing sponsors as study milestones are met and/or study expenses are incurred with the exception of payments associated with patient visits, which are invoiced by the coordinator, as described above;
-communicating with sponsor when institutional approval or concurrence is required;
-negotiating contract language on behalf of UVM.

** Office of Clinical Trials Research (OCTR):*
OCTR involvement in investigator-initiated research is typically limited to assistance with pre-award budgeting as described above. However, expert research coordinator services are available through OCTR at an hourly rate. PIs may contact OCTR directly using the Request for Support tool available here: https://www.med.uvm.edu/clinicaltrials/requestforoctr

Administration of Clinical Trials at UVMMC:

Roles/Responsibilities:

** Principal Investigator (PI):*
The PI has overall responsibility for all aspects of the clinical trial including:

-providing oversight of study personnel including UVMMC staff;
-obtaining and implementing research protections/protocols such as IRB;
-providing patient care when appropriate;
-analyzing and interpreting study data;
-overseeing project closeout and reporting final study data.

** Research Coordinator:*
Research Coordinator duties vary between divisions and across research studies. Typical Research Coordinator duties would include:

-reviewing IRB information and submitting updates as needed;
-enrolling patients and collecting data in accordance with approved protocol;
-maintaining patient data and scheduling follow-up visits;
-reporting patient data to sponsor in accordance with contract/protocol;
-reviewing study finances in Financial Edge and providing information to PI;
-invoicing sponsor for patient visits as they occur and providing all required paperwork;
-fielding study subject questions or inquiries concerning their participation in the study;
-reporting monthly time commitments to Shannon Ghostlaw in UVMMC billing;
-performing study closeout activities.

**Grant Management Specialist (GMS) - Bridget Brisson:*
UVM GMS involvement in clinical trials is minimal with duties including:

-scheduling quarterly meetings with clinical PIs to review active studies and finances;
-running reports in Financial Edge prior to quarterly meetings;
-assisting with study closeout and transfer of balance to appropriate sundry fund;
-preparing paperwork to request new sundry funds when needed;
-providing sundry fund balance information at quarterly meetings or upon request.

**Business Manager (BM) - Daniel Mills:*
UVM BM involvement in clinical trials is minimal with duties including:
-Reviewing and approving monthly MRI invoices from LCOM Dean's Office;
-Allocating MRI expenses to study budget via monthly commitment reconciliation.

** OCTR - Mark Tomase, Greg Barrows:*
OCTR is responsible for **reviewing new protocols and negotiating contracts**. Per department policy Mark Tomase **requests an additional 5% in indirect costs** to be paid into a department discretionary account. After study concludes, Greg Barrows works with PI, RC, or GMS to closeout study and transfer remaining balance to the appropriate sundry fund.

** Sponsored Projects Administration (SPA):*
SPA has no involvement in clinical trials at UVMMC.