Department of Neurological Sciences
Additional 5% Indirect Costs on Industry-Funded Clinical Trials

Industry funded clinical trials are an important component of the academic and clinical missions of the Department of Neurological Sciences. It is essential that the Department receives funding from these trials to support required administrative services and departmental infrastructure that can then be invested across a range of academic activities.

To this end we propose the following;

- The indirect rate for industry funded clinical trials in Neurological Sciences will be 5% in addition to the indirect rate required by UVMMC. The extra 5% will be captured by existing systems and transferred to the Neurological Sciences Department quarterly. These funds will not be taken from trial operating costs.
- The 5% rate will be considered non-negotiable. If the Company refuses the 5% fee, then authority to proceed is required from by the Chair or Vice-Chair (Research)
- Those studies that do not incorporate this 5% cost will incur a tax of 10% on any profit from the study, with 90% going to the Division carrying out the trial. This tax can be individually negotiated between the PI and the Chair or Vice-Chair (Research). The funds will be taken after the trial has closed out

Prior to accepting a trial, all PI's will be expected to complete a feasibility document (see below). This document will be evaluated by the Vice-Chair (Research), or by a senior faculty member with expertise in Clinical Trials. This needs to be signed off before the trial can begin PI's with limited experience in clinical trials will require a mentor with experience. The feasibility document should be completed in collaboration and will need to be signed by both the PI and the mentor

The funds that accrue will be flexible and can be used for the following activities (the list is not exhaustive and funding can be used for other activities with approval of the Chair):

- To provide start-up funds for Divisions that are not currently carrying out clinical trials
    - e.g. to support part of a research coordinator or research nurse. The goal will be to have these Divisions self-sustaining within 24 months
- To cover losses on industry funded clinical trials
    - In the first instance these should be covered by divisional funds if available
    - The amount of departmental funding that can be used for this purpose is at the discretion of the Chair and Vice-Chair (Research)
- To contribute to research start-up funds as part of a recruitment package for new academic neurologists
    - It is likely that this fund will only be able to contribute small amounts to this type of endeavor
- To pay for publication costs when there are no other funds available
    - Divisional funds should be used in the first instance
- Bridging funds to help completion of non-industry funded studies, particularly if completion has potential to generate subsequent grants
    - These funds will be available for running costs (including salary support for study coordinators and study nurses) but not for PI salary support

Requests for funding:

- Requests of up to $3000 will be decided at the discretion of the Vice Chair (Research) or the Chair
- Requests over $3000 will go to a panel for approval
    - The panel will consist of the Vice-Chair (Research) and 2 faculty members that are PIs on current industry funded clinical trials. Final approval will be by the Chair

Instructions for Completing the Neurological Sciences Clinical Research Protocol Submission Form

SUBMITTING THE APPLICATION

1. The PI must complete this application.
2. Scientific details are meant to be synoptic and incorporate the perspective of the local PI, and their interpretation of the relevant section of the protocol, not an abridged carbon copy of the protocol.
3. It is expected that the protocol and this completed form will be reviewed by the Investigator Team at a research meeting prior to obtaining requisite endorsement signatures.
4. The PI and Vice-Chair (Research) must review and sign this form before proceeding.

UVMCC CLINICAL RESEARCH PROTOCOL SUBMISSION FORM

Trial Sponsor Name: **Sponsor's Protocol Number (i.e., S1700, AAQ786):**

Full Trial Title:

Is this a First-in-Human (FIH) trial? ☐ No ☐ Yes

A. SCIENTIFIC

1. **What preliminary data exists to support this study's aims and hypothesis/hypotheses?**

2. **Describe the patient population defined by the inclusion/exclusion criteria and describe any potential biases (e.g. age, sex,**

3. **What is the predicted outcome (e.g. expected change in primary endpoint measure) and how might it impact future patient care?**

B. SCIENTIFIC RECOGNITION &/OR STRATEGIC GOALS

Please document how your involvement as PI for this trial will provide scientific recognition/credit for you and/or the Dept of Neurological Sciences and/or support UVM strategic goals. **Please check all boxes below that apply to this protocol:**

☐ Targets disease with no good standard of care options.
☐ Targets rare disease with unmet need.
☐ Patient population for whom there is an unmet need.
☐ Based on UVM translational work.
☐ Authorship expected through involvement in the trial.
☐ Will provide a pilot data for future grants. (PI must articulate below what grant they are anticipating using it for)
☐ Other, and/or comments:

C. PROTOCOL DETAILS

Principal Investigator Name & Title:

Sub-Investigator(s) Name(s) & Title(s):

Clinical Research Category*: ☐ Interventional ☐ Observational ☐ Ancillary/Correlative

Primary Purpose of the Study*: ☐ Treatment ☐ Diagnostic ☐ Prevention ☐ Screening ☐ Supportive Care ☐ Basic Science ☐ Health Services Research ☐ Other

*(*See NCI definitions of each category/purpose on "UVMCC Clinical Research Form Addendum 1" on the last page)*

Date Study Opened (Nationally): ☐ N/A

Investigator-Initiated Trial (IIT): ☐ No ☐ Yes <u>If yes, answer questions # 1-4</u>

1. ☐ Single site (UVMMC only) ☐ Planned Multi-site
   If Multi-site, please identify Potential Participating Sites:
2. Investigator-Initiated at *another* Institution: ☐ No ☐ Yes, and the sponsor institution is:
3. Study-wide Accrual Goal:

Industry Sponsored Trial:** ☐ No ☐ Yes If yes, answer questions # 1-4:

1. Has a Pre-study Site Selection Visit (PSSV) occurred with confirmation of site-selection? ☐ No ☐ Yes
2. # of patients enrolled to date study-wide:
3. Study-wide Accrual Goal:
4. When does the sponsor plan to close the study?

*(**For assistance see CTSU.org and/or ClinicalTrials.gov & clinical coordinator)*

D. UVMMC ACCRUAL GOALS/PRIORITIZATION PLAN:

1. **Does this study compete with another active study?** ☐ No ☐ Yes If yes, answer questions a) and b):
   a) Please list other competing studies:
2. **Accrual Goals:** a) UVMMC (or Affiliate Site) Total Target Accrual (#):
   b) UVMMC (or Affiliate Site) Target Accrual per year (#):
3. **How many patients/year would likely have been eligible for this trial over the past several years?**
4. **What are the potential barriers to accrual and what preemptive steps can your research team take to minimize those barriers?**
5. **If this is an Interventional Treatment study, how do the options on this trial fit into the group's current treatment algorithm for these patients?**

E. FUNDING SUPPORT

At this time funding is anticipated to be: ☐ Complete ☐ Partial ☐ Unfunded ☐ Not Applicable (for NCTN studies)

If partial or unfunded, please list plans to obtain support:

F. RESOURCE UTILIZATION

1. **Does the protocol utilize UVM Medical Center resources (mark those that apply with an X)?**

☐ Pathology (blocks, slides, etc.) ☐ Clinical Research Center (CRC) ☐ Radiology
☐ Pharmacy ☐ Other (describe in comments)
☐ No UVMMC resources – opening at Affiliate Site only

Additional comments about any of the above Medical Center resources:
