Sponsored Research/ Trials Feasibility Form

To ensure consistency in clinical trials, equal access to clinical trial resources, and participation in research efforts that align with the institutional values of MVHS, the Research Department /CTO has been created. The CTO will assist in assessing clinical trial feasibility, regulatory submissions, communication with sponsors and other regulatory authorities, and clinical trial operations- if requested.

Any appropriately credentialed research trained MVHS faculty can submit an application to lead a research study as a Principal Investigator (PI). The PI has the ultimate responsibility for the conduct and execution of the study and the personnel working on the study. Residents and fellows may not act as a PI of a study at MVHS. To submit and execute a study, they will need to collaborate with current faculty in good standing. These personnel will be listed under collaborator, if applicable.

This feasibility form is for Sponsored research projects and trials. In Sponsored trials the study is conceived and executed by the government, federally funded agency, private organization, or pharmaceutical company. If this is an Investigator Initiated Trial or internal research project, please use the IIT/ internal projects feasibility form. Completed forms can be submitted to research@mvheathsystem.org. Answer all questions to the best of your ability and if you have any questions, contact the CTO.

1. **General Information:**
   Name of the Principal Investigatory (PI):

   Investigator Qualifications (MBBS, MD, NP, etc):

   Therapeutic Area:

   Contact Number:

   Email Address:

   Note that anyone proposing a research study must be in good research standing to initiate a research study. Please attach medical license, current CITI certification for Good Clinical Practices (GCP), and signed/ dated curriculum vitae (signature must be within two years).

2. **Professional Details of Investigator**

Medical Experience (Yrs/ Months)

Clinical Experience (Yrs/ Months)

How much time will you be able to dedicate to this study?

How many trials has the investigator lead as PI (this will not affect consideration of this study/ project):

How many trials has the investigator participated in as a Co-Investigator or Sub-Investigator:

Has the PI ever been barred by the FDA from participating or leading a study? Has the PI ever received an FDA Warning Letter? Yes ☐ No ☐
If yes, please explain:

Will anyone else in your department be able to participate in this study in any capacity (screening, consenting, and/or performing any additional study responsibilities)? **

** All personnel that participate in the research study, must have appropriate licensure, CVs, CITI training and any protocol training, as applicable

3. **Study Details:**

Name of Study:

Sponsor:

Funder (if different from Sponsor):

ClinicalTrials.gov identifier (if available):

Study Type (Check all that apply):
Observational Study ☐ Interventional Study ☐
Drug Study ☐ Device Study ☐ Genetic Testing ☐
Quality Assurance/ Case Study Preparation/ Internal Data Review ☐

Will samples need to be taken/ stored: Yes ☐ No ☐
If yes, please elaborate:

Will devices/ drugs need to be stored with appropriate chain of custody documentation?
Yes ☐ No ☐

Will you use any of the following services/ resources: Laboratory, Dry Ice, Pathology, Imaging, Pharmacy (include any additional equipment as well)?

Yes ☐ No ☐
If yes, please explain.

To your knowledge is there a similar or competing study at MVHS that is ongoing that targets the same population or has similar research goals:

Does the protocol align with the accepted standard of care or will additional procedures/ treatments occur (this includes additional blood draws, imaging, etc.)?

Is specialized equipment required? (comment if this equipment is currently in the department, will need to be borrowed from another department, purchased, or provided/ loaned from the sponsor?

Will assessments occur outside of regular clinic hours?

Are there specific faculty requirements or training (device, drug, imaging, etc.)?

Are frequent and severe adverse events/ safety events?

Will you need study documentation in another language other than English? What languages?

What external or satellite sites will be used for this study (recruiting and/or additional procedures)?

4. **Study Population:**
Please describe the study population:

What is the study inclusion/ exclusion?

How will you screen for this study? Will EPIC/ MyChart be used? In a preliminary EPIC search, how many potential subjects were listed?

How many subjects will be enrolled at this site?

5. **Study Materials/ Communication:**
Provide your clinical trials contact (Name, position, company, phone, email):

Has the sponsor provided you with any preliminary materials (Consent, protocol, Case Report Forms, Budget, Clinical Trials Agreement (CTA)? Yes ☐ No ☐
If yes, please indicate which materials have been received and attach them to the submission.

Will there be any other contracts/ agreements that need to be investigated?

6. **Sponsor Expectations:**
   Provide your clinical trials contact (Name, position, company, phone, email):

Additional Comments:

Principal Investigator	**Dept. Chair or Program Director/GME Designee (required if faculty/resident)**
_____	_____
Signature Date	Signature Date
_____	_____
Name	Name
_____	_____
Title	Title