Internal Research Projects/ Investigator Initiated Trials (IIT) Feasibility Form

To ensure consistency in clinical trials, equal access to clinical trial resources, and participation in research efforts that align with the MVHS institutional values the Research Department/CTO has been assists 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 research conceived by MVHS faculty and staff. If this is a Sponsored study, please use the Sponsor 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.

If you do not have a study protocol, the form will help generate responses that may be used to assist in protocol creation.

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:

3. **Collaborator's Qualifications** (if applicable)
Is there a collaborator for this study? Yes ☐ (Answer questions below) No ☐
Collaborator's Qualifications (MBBS, MD, NP, etc):

Therapeutic Area:

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

Contact Number:

Email Address:

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

4. Study Details:
Name of Study:

How will data be collected:
Retrospectively ☐ (The study will analyze existing data, such as medical records)
Prospectively ☐ (The study actively collect data and follow participant over time)

Study Type (Check all that apply):
Case Report ☐ Case Series ☐ Registry ☐

Quality Improvement (QI) ☐ Post Approval/ Phase IV ☐

Other, Please describe: ☐

Will you use any of the following services: Laboratory, Pathology, Imaging, Pharmacy (include any additional equipment as well)?
Yes ☐ No ☐
If yes, please explain.

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

Will imaging be involved: Yes ☐ No ☐
If yes, please elaborate:

Is there funding available?: Yes ☐ No ☐
If yes, please elaborate:

How will you obtain/ review patient records?

Will a safety board be necessary? Yes ☐ No ☐
If yes, please elaborate:

Will you need/ require a statistician?

To your knowledge, are there any competing studies?

5. **Study Protocol:**
If there is a present study protocol, please attach. If not please proceed to the questions below:

Research Question/ Hypothesis (What are you looking to investigate)**:**

Research Procedures (How will you answer your research question. You may also include the study design and methodology)**:**

Study Population/ Number of individuals that will participate/ Number of charts to be reviewed:

Study Duration:

Background/ Significance (Why is this significant/ Previous studies in the field)**:**

Safety/ Risks/ Benefits (Will safety events be collected? Could there be any risks to patients? Will there be any benefits to patients)?

Statistical Analysis Plan (How do you plan to analyze the data you collect):

Publication and Presentation Plan (List any meetings/ conferences/ journals where you will present the results of this study):

Comments:

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