Clinical Trials Office: Frequently Asked Research Questions

Listed below are commonly asked questions regarding conducting research at MVHS and affiliated institutions:

What type of research projects are supported?

Clinical Trials/ research projects are clinical investigations that answer a scientific question. Clinical research improves our understanding of disease, assists with the new development of drugs/ devices/ treatment therapy, and increases the general field of knowledge. Research projects include but are not limited to Case Reports, Case Series, Quality Improvement (QI) projects, Phase I or II or III studies, Post Approval/ Phase IV studies, and Registry Studies.

Do I need training to perform research? What training is needed?

Yes, you need to complete research training to conduct research trials. The type of training required for your research study, depends on the nature of the research. Documented protocol training of the study staff will be required. This demonstrates that everyone on the study has read the protocol, has a certain level of understanding of the study, and is prepared to execute what is needed to complete the study.

Another required training module is the "Collaborative Institutional Training Initiative (CITI) platform (http://about.citiprogram.org). This website hosts various self-paced training material with an assessment required at the end. There is numerous training material present that can be personalized based on the type of study you will be participating in and your role.

Why do I need to go through the Clinical Trials Office to submit a research study?

To ensure consistency in clinical trials, equal access to clinical trial resources, and participation in research efforts that align with the institutional values of the MVHS, the 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. Studies need to go through the CTO to ensure that they are appropriately routed to the IRB with all necessary submission materials. Additionally, the CTO works with both the IRB and Graduate Medical Education (GME) offices to ensure that there are no duplicate projects and projects are appropriately registered.

What is the Informed Consent process?

An informed consent is a legal document that has been drafted by the IRB/ Study Sponsor/ Investigator that explains the research study to the subject. The document will let the potential subject know that participation is voluntary and they may leave at any time without forfeiting any rights or treatments; explain why the study is being performed and what is expected of the subject if they intend to participate; explain any risks or benefits; let the subject know what information will be used/ collected and whom it may be shared with. Potential research subjects should be given adequate time to review the form and no study procedures are to be conducted until the form is completely reviewed and signed.

What is the Institutional Review Board?

The Institutional Review Board (IRB) is a group that review research studies involving human subjects to ensure that the studies comply with regulations, ethical standards, and institutional policies. IRBs ensure that the rights and welfare of subjects are protected. IRBs may be located at the research study site (local IRBs) or centrally located. IRBs are made of scientists, doctors, clergy, patient advocates, and lay people.

How are research studies reviewed by the IRB?

Once a study is submitted to the IRB, the study is reviewed according to risk in the following categories. *Exempt review* is for studies that have minimal risk and fit within a set of established exemption categories. Some of the categories include educational tests, surveys, interviews, observation of public behaviors, secondary research for which consent is not required. *Expedited Review* is for studies involving no more than minimal risk. Identification of the subject's/ responses wont place them in harm and the research is not classified. Some of the categories include collection of biological specimens by non-invasive means and research that involves materials that have been collected (retrospective) or will be collected solely for non-research purposes. *Full Review* is any study that does not qualify for expedited or exempt review. This includes research with any protected/ vulnerable populations, research procedures that may cause harm, and collected information on sensitive subjects.

Please note that while you may indicate what risk level and the desired type of review; the IRB has the ultimate say on what type of review will be conducted.

What is a protocol? Do I need one?

A protocol is a document that outlines the research question and the steps needed to answer that question. In IIT studies, this may be created by the principal investigator (PI) or other members of the study team. In Sponsored studies, the protocol is created and distributed by the Sponsor. The protocol acts as reference document for the study team and ensures that the study is executed properly. Important elements of the protocol include the research question (hypothesis), study goals (objective), how the study will be conducted (procedures), and who will be included (study population and inclusion/exclusion criteria). Additional elements may include statistical considerations (how many people will participate to get the needed data and how will this data be analyzed) and safety elements (description of risk and any anticipated adverse events).

Yes, you do need a study protocol. The presence of a protocol will ensure that the study goals are met and the study question is answered completely. The protocol will also serve as a training guide for study members and ensure study procedures are consistently implemented across all study personnel and subjects. This study protocol will be used by the CTO to determine the classification of study, what training will be necessary, and any additional resources may be needed; and the IRB will determine what submission and informed consent is needed (if any). If you do not have a study protocol, questions from the feasibility questionnaire should help generate the necessary components. If you have further questions regarding the protocol, please contact the CTO.

Who can lead a research study?

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.

Can MVHS employees participate in research?

MVHS employees can participate in research studies. For clinical trials research, due to concerns of coercion, MVHS employees may only participate in clinical trials in certain circumstances with an exemption from the IRB.

What is healthy volunteer?

A volunteer subject with no known significant health problems who participates in research to test a new drug, device, or intervention is known as a "healthy volunteer" or "Clinical Research Volunteer." We need to study healthy volunteers for several reasons: When developing a new technique such as a blood test or imaging device, we need clinical research volunteers to help us define the limits of "normal." These volunteers are recruited to serve as controls for patient groups. They are often matched to patients on such characteristics as age, gender, or family relationship. They are then given the same test, procedure, or drug the patient group receives. Investigators learn about the disease process by comparing the patient group to the clinical research volunteers.

What are Phase I, Phase II, Phase III studies?

Phase I Studies are implemented in healthy volunteers and the focus is on patient safety. Patient volunteers are followed primarily for side effects and not how the drug affects their disease. Phase 1 studies typically offer little to no benefit to volunteer subjects.

Phase II Studies are implemented in a small patient population that has the disease/ condition of interest. Research is conducted to determine side effects in that particular population, how it behaves in the body and if it improves the condition of that population.

Phase III Studies are implemented in a larger expanded patient population that as the disease/ condition of interest. There may be a comparison to other therapies that are currently on the market.

What are the main types of studies?

There are two main types of trials or studies - interventional and observational.

Interventional trials aim to find out more about a particular intervention, or treatment. A computer puts people taking part into different treatment groups. This is so that the research team can compare the results.

Observational studies aim to find out what happens to people in different situations. The research team observe the people taking part, but they don’t influence what treatments people have. The people taking part aren’t put into treatment groups.

Are there research studies involving protected populations at MVHS?

Protected populations in clinical trials are groups of people that are identified by federal regulations as needing additional protections. This groups include (but may not be limited to): children, prisoners, pregnant women, neonates, disadvantaged individuals, and people with physical handicaps or mental disabilities. There are special considerations for these groups and what types of trials they may participate in. These studies will be reviewed by the MVHS IRB on a case by case basis to ensure all subjects are appropriately protected.

Will subjects be paid for participating in research studies?

Dependent on the research study, participants may be compensated for their time. There are standard compensation rates for the participant's time and the study PI determines inconvenience rates.