This Guidance Document is to ensure that investigators and research personnel recognize their responsibilities associated with the conduct of human subject research by outlining their responsibilities, in accordance with federal regulations, state and local laws, and institutional policies and procedures.

**Definitions:**

**Investigator:** Collective term which includes the principal investigator, co-investigator or sub-investigator (including staff, students or agents) who is responsible for the design, conduct, implementation, evaluation, participant safety, and/or reporting of the proposed or ongoing project.

**Research Staff:** Individuals (staff, student, study coordinators, research assistants or others) who are involved in the design, conduct, evaluation, participant care, and/or reporting of research for the proposed or ongoing research project.

**Responsibilities:**

**The Investigator** is responsible for protecting research participants by ensuring:

- All investigators, delegated investigators and research staff are appropriately qualified by training and experiences to conduct the research, or delegated responsibilities as outlined in the protocol. The Principal Investigator is ultimately responsible for the conduct of all persons to whom s/he delegated tasks.
- All investigators and research staff have completed the Collaborative IR Training Initiative (CITI) Program prior to any participation and refresh this training every three years.
- When required by the MMC IRB, Informed consent or permission is obtained in accordance with the relevant current protocol as approved by the MMC IRB.
- The Investigators Department chief/practice administrator or his/her designee must review and sign new protocol applications for research that involves human subjects prior to submission the MMC IRB.
- Any research that involves the administration of a drug or use of a device the Principal Investigator must be a licensed physician. (Exceptions may be made to this on a case by case basis, exceptions require a licensed physician co—investigator and approval of the department chief/practice administrator or his/her designee)
- The science of the proposed research justifies exposing participants to the level of risk associated with participation in the research.
- The design of the study must include methods and procedures that will provide answers to the research hypothesis.
- The science of the study must add to or establish a body of knowledge that is meaningful. The protocol design must minimize risks to participants while maximizing potential research benefits.
- All Investigators are in compliance with MMC Conflict of Interest Policy and Financial Conflicts of Interest (COI) which may exist are disclosed to the IRB.
There are adequate resources for the conduct of the research including but not limited to adequate number of subjects from which to recruit, research staff who are qualified and trained to conduct the research, funding, institutional resources as applicable, and time necessary to conduct the research.

A qualified physician (or dentist, when appropriate), who is an investigator or a co-investigator for the clinical trial, is responsible for all clinical trial-related medical (or dental) decisions during and following a subject’s participation in a clinical trial.

The investigator ensures that adequate medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the clinical trial.

Investigators inform subjects when medical care is needed for other illnesses of which the investigators become aware.

The investigator follows the clinical trial's randomization procedures, if any, and ensures that the code is broken only in accordance with the protocol. If the clinical trial is blinded, the investigator promptly documents and explains to the sponsor any premature unblinding.

The investigator informs the subject’s primary physician about the subject’s participation in the clinical trial if the subject has a primary physician and if the subject agrees to the primary physician being informed.

Although a subject is not obliged to give his or her reasons for withdrawing prematurely from a clinical trial, the investigator makes a reasonable effort to ascertain the reason, while fully respecting the subject’s rights.

The investigator provides written reports to the sponsor, the IRB, and, where applicable, the Organization on any changes significantly affecting the conduct of the clinical trial or increasing the risk to subjects.

If the investigator terminates or suspends a clinical trial without prior agreement of the sponsor, the investigator informs the Organization, sponsor, and the IRB.

Recruitment of research subjects is performed in a fair and equitable manner where individuals are not discriminated against based on age, race, gender or ethnicity.

Availability of medical or psychosocial resources that subjects may need as a result of participating in the research study;

Human Research Activities do not begin until you have documented IRB approval and all attributed contracts have been signed.

Research is conducted at all times in compliance with the relevant current protocol approved by the MMC IRB and all applicable federal regulations, state and local laws, Institutional, MMC HRPP policies and procedures, and the ethical principles outlined in the Belmont Report; including research which is exempt from federal regulations and other requirements.

Initiation of changes in approved research do not commence without prior IRB approval, except when necessary to eliminate apparent immediate hazards to participants. If the investigator believes that a proposed change is so trivial that IRB review is not required, the investigator must contact IRB Administration for confirmation before initiating the change;

Participants are notified of all changes or new information that would affect an individuals’ willingness to continue their participation in the research. Where the
change in IRB-approved research is necessary to eliminate apparent immediate hazards to participants, investigators must report the change to the IRB within five (5) business days to enable the IRB to determine the change was consistent with ensuring the participants’ continued welfare;

- Continuing review and approval of the research is secured in a timely fashion, prior to expiration of the current approval period
- Closure of the research study which has concluded by submitting a final report for MMC IRB review and approval
- The IRB is notified promptly of unanticipated issues such as:
  - An interim analysis, safety monitoring report, publication in the literature, or revised investigator brochure that indicates an increase in the frequency or magnitude of harm, uncovers a new risk, or provides more information about the benefits of the Human Research.
  - Change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a Human Research protocol.
  - Protocol violation that harmed participants or others or that indicates participants or others might be at increased risk of harm.
  - Complaint of a participant that indicates participants or others might be at increased risk of harm or at risk of a new harm.
  - Local/internal adverse event which in the opinion of the investigator are unexpected and at least probably related to the study procedures.
  - A harm that is “unexpected” when its specificity and severity are not accurately reflected in the consent document.
  - A harm that is “at least probably related to the study procedures” if in the opinion of the investigator, the research procedures more likely than not caused the harm.
  - External adverse event which in the opinion of the sponsor or investigator requires changes to the protocol or informed consent form.
  - Finding of Non-Compliance or Allegation of Non-Compliance.
  - Audit, inspection, or inquiry by a federal agency.
  - Failure to follow the protocol due to the action or inaction of the investigator or study staff.
  - Breach of confidentiality.
  - Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a participant.
  - Incarceration of a participant in a protocol not approved to enroll prisoners.
  - Complaint of a participant that cannot be resolved by the research team

- All research records are maintained, including original signed consent documents after closure of the study by the study team according to IRB, sponsor, and federal
Research Staff

Every member of the research team is responsible for protecting human participants. Co-Investigators, Study coordinators, nurses, research assistants, faculty sponsors, student/staff investigators and other research staff have the following strict obligations to:

- Strictly adhere with the federal regulation, state and local laws and HRPP policies and procedures for the conduct of human subjects research
- Comply with all IRB determinations and procedures
- Adhere rigorously to all protocol requirements
- Inform investigators of all unanticipated problems involving risks to subjects or others
• Ensure adequacy of the Informed consent process
• Take necessary measures to protect the safety rights and welfare of participants
• Notify the IRB promptly of serious and/or continuing noncompliance with applicable regulatory requirements or determinations of the designated IRB of which they become aware, whether or not they are involved in the research.
• Disclose any financial COI which may exist according to MMC Policy
• Maintain current certification for human research protection education as outlined MMC HRPP.