MAHEC Research Policy Key Points

1. **This policy applies to:**
    a. MAHEC Staff and Faculty
    b. Anyone otherwise paid by, or under the supervision of/affiliated with MAHEC:
        i. Residents, Fellows, student, interns, etc.
2. **Research includes:**
    a. A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge
    b. Requires IRB review if involves or uses data collected from or about human subjects/patients, or animal subjects, including medical students, residents, employees at MAHEC
    c. May include Educational Projects, Evaluation or Quality Improvement. (Click here for more information.)
3. **Research-like activities:**
    a. Subject to the same ethical and confidentiality standards as in formal research
    b. May include Educational Projects, Evaluation or Quality Improvement
4. **Institutional Review Board (IRB):**
    a. Mission's IRB is the IRB of record according to MAHEC's Federal Wide Assurance registration with the Office of Human Research Protection. Click here for Mission IRB resources.
    b. There are cases when we may "rely on" the UNC IRB, or accept a determination from an external IRB (non-Mission IRB). Click here for IRB Reliance guidance.
    c. All proposals for studies using data from or about human subjects must be reviewed by an IRB before the project starts; exemption from IRB oversight cannot be determined by the investigator(s)
    d. The IRB will determine whether certain CITI and/or GCP modules are required for those listed on the proposal
5. **Data Use:**
    a. Anyone involved in research must follow MAHEC protocols for data sharing, storage, and security to ensure compliance with HIPAA, other federal, state and local laws, and organizational policies pertaining to the health, safety, privacy, and other personal rights of human beings, including Protected Health Information (PHI)
    b. Data use agreements must be executed in order to use/share MAHEC data
    c. Having access to data for healthcare operations alone (e.g., data collected or maintained for clinic and program operations and improvement) including as a learner through an internship or practicum, does not mean that the data may be used for research or educational assignment purposes or publicly presented
6. **Principal Investigator/Project Lead Responsibilities:**
    a. Complete and/or ensure the completion of a thorough literature review.
    b. Ensure selection of appropriate and feasible research methods.
    c. Design and adhere to an appropriate study protocol.
    d. Ensure relevant study team members have completed human subjects protection training as required under this policy and by the IRB of record; and ensure all study team members submit required Financial Conflict of Interest disclosures
    e. Obtain relevant approvals
    f. Obtain and maintain IRB review/approval from the appropriate institution
    g. Oversee study team member's research activities, appropriate to and consistent with their designated role on the project
    h. If the project is funded: ensure that all funds are appropriately spent consistent with the requirements of the funding agency

Please contact research@mahec.net with any questions!