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Policy Title:	Policy on Research
Department:	Division of Research
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Approved By:	**Jeffery E. Heck, MD – President & CEO**
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I. PURPOSE

Research is a critical process in the innovation of quality patient care, patient education, healthcare delivery, and population health. Research is also a vital component of medical education, contributing to the professional development of faculty and learners, to medical knowledge, community & patient engagement, and to the advancement of medical education.

II. SCOPE

This policy applies to all individuals at MAHEC engaged in research including any person paid by, under the control of, or affiliated with MAHEC, such as faculty, learners (residents, students, fellows, etc.,) or collaborative researchers. This policy outlines the procedures, which MAHEC deems appropriate and realistic to support research and scholarly activity to meet institutional goals.

III. RESPONSIBILITIES

A. Responsibility of Division of Research to Faculty and Learners.

1. MAHEC Division of Research holds a Research Forum that meets at least quarterly to review proposed on-going and completed projects.
2. The Division Director meets with Clinical Faculty to establish research priorities and agendas, ensures organizational alignment with mission, goals and objectives, and provides advisory oversight for all activities considered research, evaluation and scholarly activity.
3. Provide consultation and guidance on projects
4. Division of Research staff will ensure project activities are conducted in accordance with the defined scope of work and in accordance with ethical standards, organizational policies, and federal, state and local laws.
5. Division of Research staff will conduct periodic audits of projects to ensure compliance with policies. Audits may include, but are not limited to, observing consent processes, checking the security of data files, reviewing dissemination plans and documents, etc.

B. Rights and Responsibilities of Faculty and Learners to MAHEC Division of Research

1. Research team members have a commitment to one another to be active participants in the research process. If, for any reason, a member of the research team can no longer participate, a formal notification should be sent to all team members and an amendment should be filed with the appropriate Institutional Review Board's (IRB) providing approval and oversight.

2. Research techniques should not violate established professional ethics, organizational policies, or federal, state and local laws pertaining to the health, safety, privacy, and other personal rights of human beings, including Protected Health Information (PHI). Please refer to MAHEC's Notice of Privacy Practices form for more detail.
3. All materials created for projects should comply with MAHEC's branding guidelines (e.g., logos, templates), and should be approved by the MAHEC Marketing and Design Department.
4. Research team members are responsible for maintaining current/updated Collaborative Institutional Training Initiative (CITI) training certificates.
5. Research team members are responsible for maintaining their current/updated curriculum vitae (CV).
6. Research team members are responsible for completion of other required training such as the Research Data Security course.

IV. DEFINITIONS

A. Research
The original, careful, critical, structured, disciplined inquiry directed toward the clarification and/or resolution of problems to establish facts, principles or generalizable knowledge, or the summary and consolidation of existing knowledge.

B. Evaluation
The systematic and objective assessment of an ongoing or completed project with the aim of determining the relevance and level of achievement of project objectives, development effectiveness, efficiency, impact and sustainability.

C. Scholarly Activity
The application of systematic approaches to the development of knowledge through intellectual inquiry and scholarly communication.

D. Patient and Community Centered Research
The active engagement of patients and community members to provide unique perspectives on Research projects.

The Division of Research seeks participation of patients and community partners in human subject research, non-research, or other activities required for the success and management of projects.

E. Quality Improvement
A structured approach for identifying ways to improve work processes and achieve specific aims. Often focuses on workflow, tools, and elimination of waste.

V. GENERAL

A. Conflicts of Commitment and Interest

1. Conflict of Interest

MAHEC encourages learners and faculty to participate in research activities and to do so with the highest ethical standards. All investigators therefore have an obligation to become familiar with and abide by both MAHEC's and the relevant IRB policies on Financial and other conflicts of interest in research.

2. Violations

a. Research Misconduct - Research misconduct in any form threatens the integrity of the research and our institution. Research misconduct, therefore, cannot be tolerated at MAHEC. When

allegations of research misconduct are made, MAHEC is committed to a thorough investigation into such allegations while protecting the rights of all involved. MAHEC reserves the right to suspend or terminate all research, evaluation and scholarly activity projects under investigation for violations of written protocol, unethical conduct, serious adverse consequences or unintended problems.

b. All employees or individuals associated with MAHEC should report observed, suspected or apparent misconduct in research to the Corporate Compliance Officer

c. Any breach of PHI must be reported to the Director of the Division of Research and the MAHEC Risk Management by filing an incident report.

3. Conduct of Research

a. Research Team
   i. All research projects require a project team with appropriate expertise and access to suitable organizational resources and facilities.
   ii. The MAHEC Division of Research must review and approve the project and have input into the appropriate composition of the Research team.
   iii. In addition to the Principal Investigator (PI) with the appropriate qualifications, research teams can include, but are not limited to:
      - MAHEC faculty mentor
      - A project manager
      - MAHEC librarian
      - MAHEC Director of Data Analytics
      - MAHEC Research Scientist

b. All projects involving Mission Hospital data, employees or patients as subjects, or other Mission Health resources must include a MAHEC faculty member with privileges at Mission Hospital.

c. Interdisciplinary and intra-disciplinary research is encouraged thus teams are encouraged when appropriate to include learners and faculty from our pipeline programs (i.e., interns, medical students, residents and fellows) and with external research partners across professional specialties.

4. Principles Concerning Research

a. MAHEC will consider and support research, evaluation and scholarly activities that are consistent with MAHEC's mission, goals, and objectives, and are aligned with the organizational priorities.

b. Research activities must also meet at least one of the below criteria:

   i. Potential to inform MAHEC, local, state and/or national policy
   ii. Potential to inform clinical practice, as determined by relevant MAHEC Division or Departmental Administration and existing literature.
   iii. Potential to inform health professions education and establish curricula/training.
   iv. Potential to inform public health initiatives.
   v. Working within the constraints of funding and in accordance with strategic priorities.

5. Human Subjects Research Training (CITI)

In order to conduct research at MAHEC—including research deemed to be exempt from IRB review—individuals are required to complete an education program and become certified, and maintain

current certification, in human subject protections through the CITI Program's Mission Health System Courses. (http://www.citiprogram.org).

6. MAHEC Division of Research Approval

a. All Research requires the formal approval from MAHEC Division of Research.

The Division of Research aims to provide efficient and strategic support to those interested in conducting research at MAHEC. In order to ensure effective alignment with MAHEC's mission and organizational policies, we consider each project and carefully assess each request. Please fill out the Research Support Request Form and a Division of Research representative will follow up with you within 5 business days.

b. Additional institutional approval may include the following elements:

i. Projects involving utilization of MAHEC employees also require approval of MAHEC Human Resources.
ii. Project documentation involving dissemination of surveys to MAHEC patients requires approval from MAHEC Marketing and Design and MAHEC's Corporate Compliance and Risk Management departments.
iii. Research Division staff should ensure that templates are used and content is appropriate for research questions.
iv. Projects involving informed consent, release of protected health information, or other potential legal and/or risk management concerns require approval of MAHEC's Corporate Compliance Officer and Risk Management.
v. Projects involving provision of health care require approval of MAHEC's Corporate Compliance Officer, Risk Management, legal consultant and Professional Liability coverage carrier.
vi. The Director of the Division of Research may convene as review committee as needed in ad-hoc fashion to review research requests.

7. IRB & Other Institutional Approval

All research, program evaluation, and quality improvement project written protocols may require IRB approval and organizational approvals including:

a. The Division of Research Director can choose to accept outside IRB approval for projects conducted at MAHEC.

b. The Division of Research will provide the MAHEC Executive Board a summary of all research submitted to the applicable IRB; including but not limited to the IRB of record, the IRB decision, and the status of the project.

c. Mission Health IRB - Approval from the Mission Health IRB is needed for all Research involving Mission patients and/or data.

d. Mission Health Research Institute - Approval from the Mission Health Research Institute is also required if the research project involves the use of Mission Health data, Mission Health employees, or patients as subjects, or other Mission Health Resources.

e. UNC Healthcare Pardee Hospital - Approval from the UNC Healthcare Pardee Hospital is needed for all research conducted at or by faculty of the Hendersonville Family Health Center/Blue Ridge Community Health Services.

f. UNC School of Medicine - Research on UNC School of Medicine – Asheville students, faculty, or resources must obtain UNC-CH IRB approval

g. Other Institutions - Research in collaboration with Other Institutions may require other institutional IRB approvals.

h. The Principal Investigator of any project is responsible for determining appropriate IRB action. MAHEC Division of Research can provide support in determination of applicable IRB.

8. Research Project Implementation

a. All research, evaluation and scholarly activity projects must be conducted in accordance with the ethical, professional and legal standards and requirements.

b. All research activities must comply with the approved written protocol or approved amendments.

c. Deviations from the approved protocol as well as any unanticipated problems must be reported to the relevant IRB in accordance with the IRB's policies and shared with the MAHEC Division of Research.

d. Federal regulations require that investigators promptly (within 24 hours) report any unanticipated problems involving risk to subjects or others to the IRB using the Unanticipated Problem Involving Risk to Subjects or Others reporting form found on www.irbnet.org of Mission IRB, or appropriate similar processes of other institutional IRB's. Annual progress reports must be submitted to the Mission IRB and shared with the MAHEC Division of Research.

e. Information for patients regarding individual projects that engage patients as subjects must utilize templates for participant information letter, and participant informed consent. As required by Mission IRB, and in accordance with federal law per 45 CFR part 164, the documents must include explanations of patients' rights of refusal to participate in projects. The documents are maintained by the Division of Research in accordance with 46 CFR part 116.

f. Information regarding the use of and limits of use of clinical data including PHI for research purposes by MAHEC and the right to refuse such use will be made available to patients in the Notice of Privacy Practices.

g. The MAHEC Division of Research will conduct regular audits on all research evaluation, and quality improvement activities.

9. Data Security & Storage

a. All research data files must be kept on the MAHEC secure network in a folder accessible only by the professional researchers and the IRB approved co-investigators and project staff who will be handling data.

b. Regarding patients of MAHEC who are also involved in Research Projects:

i. Informed consent documents normally would not be stored in a health care record. Other research project documents also normally would not be stored in a health care record.

At the time of the initial IRB review, the IRB and PI will consider if the informed consent documents or any other research project documents are appropriate to place in a health care record. These documents would be relevant if a patient is receiving medication or other interventions as part of a research study protocol. Conversely, if a research

participant discloses information that is not relevant to patient care (personal sensitive information), including consent or other documents would not be appropriate. Specific safeguards should be in place to protect research data that is not relevant to patient care.

ii. If the consent form and other documents are deemed appropriate to be included in the health care record, the consent documentation and MAHEC's Notice of Privacy Practices form should state exact details of what will be share and what will not be shared with MAHEC healthcare providers.

c. All research data files are maintained in SPSS and SAS (accessible only by the Division of Research staff) or in a password protected Excel file. These files are only accessible by the Division of Research staff and approved co-investigators.

d. When individuals involved in research projects at MAHEC leave the project, access to all data files will be immediately terminated.

i. The Division Research Administrator will send an email to the following entities to terminate access if necessary:

- Information Technology
- Facilities
- Human Resources
- Sharefile Access

e. Research data must be archived for a minimum of six years after the final project closeout date or longer as deemed by other governing bodies or funders.

f. Beyond the period of retention specified, the destruction of the research record is at the discretion of the PI and the Director of the Division of Research.

g. Any and all release of research data to an outside entity must be approved by the MAHEC Division of Research and must follow MAHEC IT standards and comply with all federal laws governing the transmission of PHI. Data sharing agreements and Business Associate Agreements with the outside entity may be required and will be determined on a case-by-case basis.

10. Dissemination

Acceptable outcomes of research and scholarly activity must follow MAHEC standards for branding and dissemination including utilization of approved templates, logos, and attributions. Research products for dissemination may include:

a. Articles prepared for journals, conferences and approved public formats both internal and external. Article types include, but may not be limited to original research manuscripts, Family Physicians Inquiries Network (FPIN) Clinical Inquiries, case reports, Dermatology Photo Quizzes and white papers;
b. Posters and oral presentations prepared for external conferences and/or for MAHEC's Annual Resident Research Day;
c. Baseline and/or needs statements in grant applications;
d. Newspaper article on a health topic approved by the MAHEC Marketing and Design Department.

11. Project Termination

a. A study should be terminated in compliance with applicable IRB policies and MAHEC organizational determination. This includes but may not be limited to: when no further contact with human subjects or their individually identifiable information is planned; no subjects are or

will be treated or followed; all data are gathered and analyzed; and any final reports or publications are complete. MAHEC reserves the right to terminate all research and evaluation projects under investigation, without funding, or if they are no longer considered among the organizational priorities.

b. Termination documentation must be submitted to all institutional bodies that issued project approval.

12. Excess Revenue

If funds for a Research Project are not used in accordance to the budget submitted, the funds will be Reconciled in a manner consistent with the obligations of the funding party.