

ATTACHMENT 22

POLICY ON RESEARCH

It is the policy of UMMC that all basic and clinical research activities adhere to the guidelines established for research related activities by government and non-government agencies that provide funds for these activities. Research activities funded through external sources are subject to the funding agency's policies and procedures in addition to UMMC policies and procedures.

Business Issues

It is the policy of UMMC for all projects and activities to comply with all applicable government, non-government, and institutional regulations. These regulations include, but are not limited to: cost transfers; cost sharing (both voluntary and involuntary); cash management; certification of effort; allowability and reasonableness of expenditures. Research activities shall be separately accounted for and budgeted. It is the policy of UMMC not to cost share unless required by the awarding agency or deemed advantageous by the UMMC administration.

It is the policy of UMMC to comply with the Office of Management and Budget Cost Accounting Standards (OMB Circular A-21) with regard to consistency in estimating, accumulating, and reporting cost. These standards will apply regardless of funding source.

It is the UMMC policy that only those experimental and investigational devices (category B) which are identified by the Food and Drug Administration as items that are safe to the patient and are covered under Medicare during the clinical trial stage of the investigation may be billed to Medicare. The patient must be in an approved clinical trial for a device to be covered.

The University Hospital and Clinics will not underwrite research. In cases where the study does not pay for hospital charges, an advanced beneficiary notice will be obtained from the patient and the patient will be billed for the hospital charges.

Conflict of Interest

It is UMMC policy to avoid any real or potential conflicts of interest and that faculty and staff will disclose to UMMC, to the fullest extent possible, any significant proprietary, financial, or compensation interest in any organization with which UMMC does business (as defined in, but not limited to, the Mississippi Code of 1972, Sections 25-4-10 through 25-4-119, and the UMMC Faculty and Staff Handbook, and Personnel Procedures).

All research, service, teaching and the use of available resources must be carried out in a manner consistent with the pursuit of academic achievement.

Faculty and staff members often participate in extramural professional activities, such as consulting and similar activities that advance the dissemination of knowledge. Each faculty or staff member, by virtue of employment, accepts the responsibility to refrain from activities or commitments that are inconsistent (such as those leading to conflicts of interest) with their Medical Center duties or the integrity of their research.

Research Integrity

It is the policy and responsibility of all investigators to conduct their professional activities according to high standards of scholarship. Their responsibility to the community at large demands that they be honestly and sincerely devoted to the ideals of discovery and dissemination of knowledge. Fraud in research undermines the academic enterprise. The following principles for the conduct of research will be followed. All data and research products will be accessible by principal investigators and collaborators involved in a given research endeavor. Data will be recorded accurately. A review of the research activities, scientific content, and research methods will be performed by the principal investigators and collaborators prior to submission of the work for publication. The format of this review can be individualized for each research group. Authorship will follow normal academic standards.

Human Subjects

It is the policy of UMMC that research conducted at UMMC involving the use of human subjects will adhere to the guidelines established by the Institutional Review Board (IRB). UMMC has provided a formal guarantee [Multiple Project Assurance (MPA) M1045-01] to the Department of Health and Human Services (DHHS) that it will follow procedures that will assure protection of human subjects involved in research. This guarantee applies to all human subject research conducted by anyone on the premises of UMMC and to research conducted elsewhere by faculty, students, staff, or other representatives of UMMC in connection with their institutional responsibilities.

In order to comply with this assurance, UMMC has established an institutional committee to review projects that involve human subjects. Under the provision of DHHS Regulations for the Protection of Human Subjects (45 CFR 46) and FDA regulations (21 CFR 50 and 21 CFR 51), this committee has been designated the Institutional Review Board. The IRB consists of representatives from a variety of scientific disciplines and community members. The primary function of the IRB is to assist the investigator in the protection of the rights and welfare of human subjects. Investigators, however, carry the primary responsibility for assuring that research protocols measure up to the standards established by federal regulations and the IRB. The IRB also serves to facilitate the conduct of research that is beneficial to humanity as well as protect the investigator and the institution through a comprehensive review process.

Before a human subject research project is initiated, it must first be reviewed and approved by the IRB, and then conducted in full compliance with IRB guidelines. There can be no exceptions to this requirement.

Use of Animals in Research and Teaching

It is the policy of UMMC that all activities conducted at UMMC involving the use of live animals in research, research training, experimentation, and biological testing will comply with the *Animal Welfare Act* (Public Law 99-158), the *Public Health Service Policy on Human Care and the Use of Laboratory Animals*, and the *Guide for the Care and Use of Laboratory Animals*. UMMC acknowledges and accepts responsibility for the care and use of animals involved in activities covered by these federal statutes.

A qualified veterinarian directs the UMMC animal care and use program. An Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures has been established in accordance with federal regulations. The specific duties and responsibilities of the IACUC in overseeing animal care and use program and described in the UMMC Animal Welfare Assurance which is submitted to the Public Health Service and is on file in the Office of Research.

Biohazardous Materials and Recombinant DNA

It is the policy of UMMC that all activities involving the use of recombinant DNA, microbiological agents, and activities utilizing non-human primates are reviewed and approved by the Institutional Biohazards Committee.

Biohazards are divided into two broad categories, recombinant DNA and other microbiological agents. The manipulation or propagation of recombinant DNA molecules must be done in accordance with current *National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules*. Manipulation or propagation of microbiological organisms (including parasitic, fungal, bacterial, rickettsial, and viral agents) that pose a potential health risk must be done in accordance with procedures described in the current Centers for Disease Control manual *Biosafety in Microbiological and Biomedical Laboratories*.

Radioactive Materials

It is the policy of UMMC that all activities involving the use of radioactive materials are reviewed and approved by the Radiation Safety Committee. Radioisotope users employed by UMMC operate under Mississippi State Department of Health (MSDH) Radioactive Material Medical Board License #MS-MBL-01 effective July 1, 1983. This license is issued by the MSDH Division of Radiological Health as the agency solely responsible for licensing.