

Policy on External Investigator Requests

Summary/Purpose: The purpose of this policy is to establish guidelines and procedures to be taken in response to requests for University of Mississippi Medical Center (UMMC) data from individuals and entities that have no prior legal or contractual rights to the data and are requesting the data for research purposes. External investigators include all non-UMMC affiliated requestors and UMMC employees, faculty and students proposing projects for non-UMMC purposes that require data gathered at UMMC.

The policy is intended to:

- provide a mechanism to review requests for UMMC data (patient, administrative, financial, etc.)
- ensure that personnel resources expended by UMMC providing data do not restrict the regular operations of UMMC and that UMMC is appropriately compensated when these resources are utilized.
- provide a standard method for deciding if external research proposals should be conducted with UMMC faculty, staff, students, alumni, patients or visitors as research participants
- balance external research requests against the survey priorities of the Institution
- limit faculty, staff, students, alumni, patients or visitors' exposure to unnecessary or irrelevant surveys through UMMC resources, e.g. e-mail

Policy: It is the policy of UMMC that external researchers must request permission from UMMC to conduct research using UMMC data and/or involving human participants (faculty, staff, employees, students, alumni, patients or visitors) at UMMC. A UMMC sponsor will be assigned to oversee each project throughout its life cycle. The UMMC sponsor must be a full-time faculty member (exceptions will be considered by the Review Committee upon written request) with relevant expertise; the sponsor should be able to answer questions about the project, serve as the campus contact for questions or concerns about the research, and be responsible for submitting a proposal to the IRB, if applicable. Individuals with potential conflicts of interest (financial or otherwise) are not eligible to serve as sponsors. Potential sponsors must receive permission from their Chair/Dean before agreeing to serve.

UMMC will not routinely grant requests to survey the entire population of any of its constituents.

This policy applies to external requests for access to data, samples, intellectual property, UMMC constituents and other work products of UMMC.

Requests from the Mississippi State Institutions of Higher Learning and/or other state and regulatory agencies requesting official or legally-mandated data are excluded from this policy.

PROCEDURES

The **External Requests Review Committee (ERRC)** will review the impact and appropriateness of all requests from external investigators to use UMMC data, samples, intellectual property, constituents and/or other work products of UMMC. The project must have

The University of Mississippi Medical Center

IRB approval, if applicable, before approval by the ERRC. The ERRC may consider such factors as scientific merit, institutional impact and alignment with UMMC's mission in its discussions. The chair of the ERRC will be appointed by the Associate Vice Chancellor for Research. The committee will meet at a frequency required by the number of data project requests and will be composed of members (or their representatives) from the following areas:

- Division of Information Systems/Office of Information Security
- Quality Improvement
- Office of Integrity and Compliance
- Office of Research
- Legal
- Public Affairs
- Risk Management
- Institutional Research
- Marketing
- Human Resources

Ad hoc members:

- Finance
- Health Information Management
- Ancillary Departments
- Department Chairs
- Radiation Safety Committee
- Institutional Biosafety Committee
- Institutional Animal Care and Use Committee
- Institutional Review Board
- Biobank

Step 1 Requests submitted through the portal by the established deadline will be compiled by administrative staff in support of the committee chair and distributed to standing and appropriate ad hoc members.

Step 2 Basing its deliberations on the criteria of the proposed research merit, impact and appropriateness to the UMMC mission, the Committee will review the Data Request Application and take one of three actions: 1) Approved; 2) Pended – further information required from the requesting investigator; or 3) Denied. External requesters should be available (via phone or in-person, upon request) to answer questions during committee deliberations.

Step 3 Each approved project will have a designated UMMC faculty sponsor. The chair of the Committee will communicate the status of the request and the decision of the Committee to the requesting investigator. Once the project is complete the external investigator should submit a final report through the portal.

REVIEW OF PUBLICATIONS

Any proposed publications resulting from an approved project will be submitted through the UMMC sponsor to the External Requests Review Committee for review at least 60 days prior to submission for publication. UMMC will delete references to Confidential Information from any Publication. In the event that the proposed publication or presentation contains patentable subject matter and needs protection, the external investigator will, upon written notice from UMMC within the 60 day review period, delay the publication or presentation for an additional 90 days to allow UMMC to file a patent application.