SUBJECT: I. Statement of Principles

The Regional Medical Center at Memphis (The MED) is committed to excellence in teaching, research, and patient care. These activities are to be conducted with the highest ethical standards. For research studies involving human subjects, The MED is guided by the ethical principles regarding human subjects in research and adheres to applicable laws, regulations and guidelines, including those of the Food and Drug Administration, the Office for Human Research Protection and the State of Tennessee. Research activity is also governed by HIPAA Privacy regulations.

SUBJECT: II. Applicability

POLICY: These policies apply to all research activities, regardless of the source of funding, which in whole or in part:

1. Are conducted using any property or facility of The MED;

2. Involve the use of non-public information to identify or contact human research subjects or prospective research subjects that are patients of The MED or any of its affiliate facilities.

3. Involve human subjects in research.

Research is prohibited until the project has been reviewed and approved by both the University of Tennessee (UT) Institutional Review Board ("IRB") and The MED's Office of Medical Research. This requirement applies not only to clinical trials but also to research studies which qualify for exempt status as determined by the IRB.

A study or project approved by a non-UT IRB must be submitted to the UT IRB for review and approval prior to written approval by the MED.

PURPOSE: To assure that research conducted at The MED may attain the goals desired and complies with these policies and procedures, as well as applicable federal, state and local laws and regulations.

SUBJECT: III. Definitions (SEE APPENDIX I)

SUBJECT: IV. Office of Medical Research

POLICY: The role of the Office of Medical Research is to coordinate, encourage and facilitate research conducted at The MED; and to serve as a resource to investigators and their research teams.

The Office of Medical Research operates under the guidance and direction of the Chief Medical Officer/Senior Vice President for Clinical Affairs.

PURPOSE: To ensure that research is conducted in accordance with high ethical standards; and to ensure compliance with applicable state and federal regulations, as well as The MED's institutional policies.

PROCEDURES: The duties of the Office of Medical Research shall include:

1. Provide pricing for rate requests submitted by investigators for services to be contracted by UT from The MED;

2. Gather, review, and prepare the documents submitted for research studies for review by the Chief Medical Officer;

3. Request legal or financial review of study related documents;

4. Coordinate the evaluation of study applications, contract for purchased services, and any special arrangements required to conduct the study;

5. Provide written notification and pertinent information to the investigator regarding whether a research study is approved;

6. Provide written notification and pertinent information to the departments providing services for new research studies;

7. Provide notification to The MED's Chief Financial Officer, Accounting Office (AO), and UT Grants & Contracts Office (or other institution, when applicable) of those approved research studies for which The MED will provide services chargeable to research accounts. Arrangements and identification for these services must be made in advance by the investigator or his designee through the Office of Medical Research;

Provide to the AO a copy of the approval letter for each study (Confirmation of Approval of Research Activity) for which The MED is expected to provide research services, a copy of the contract, along with the UT contract number, account number, department, and name and address of person to whom the invoice should be directed.

8. Coordinate with research staff and The MED's department of Patient Financial Services to receive timely patient enrollment information and identification of research related tests, procedures, and other services.

9. Review Meditech Research Order Entry and Billing reports, and study coordinator reports, as applicable, to confirm that patient accounts are not charged for research tests and procedures, referring any discrepancies to Patient Financial Services for resolution.

10. For non-pharmacy services, the Office of Medical Research shall provide to the AO on a monthly basis the following information for the previous month, for each active research study, as applicable: patient identification, charges, procedure performed, service date, invoice total, IRB #, UT account number, UT contract number.

11. When contracts are to be amended, assure that prevailing rates are incorporated in the contract amendment.

12. Coordinate with research study staff and the UT IRB staff to maintain current records on all open studies being conducted at The MED.

13. Maintain copies and a computer database of research records. Copies will be maintained in compliance with The MED's Records Retention policy.

14. Provide reports to The MED's Chief Medical Officer, Administration, and departments providing research services as needed.

SUBJECT: V. Institutional Review Board

POLICY: The MED has designated the UT to review research involving The MED through the UT's Institutional Review Board (IRB). The IRB shall identify projects subject to full review, expedited review, and which are exempt from IRB review. The University will be responsible for notifying the Office of Medical Research of any IRB approved research activity which involves The MED's patients, records, services, or facilities prior to its initiation. Approval must be obtained from both the UT IRB and The MED's Office of Medical Research prior to a study's initiation.

The UT IRB shall be responsible for the general conduct of research at The MED. However, The MED reserves the right to disapprove any research activity which, in its sole discretion, (i) is not consistent with the hospital's mission; (ii) does not adequately protect the rights and welfare of human subjects; or (iii) is to involve an investigator who has failed to comply with these policies and procedures.

PURPOSE: An IRB derives its authority from federal law and local institutional policy. It has the authority to approve, require modifications in, or disapprove all research activities that fall within its authority as specified by both the federal regulations and local institutional policy. It makes an independent determination to approve or disapprove research activity based on its assessment that the following requirements are satisfied (45 CFR § 46.111):

1. Risks to subjects are minimized;

2. Risks to subjects are reasonable in relation to anticipated benefits;

3. Selection of subjects is equitable;

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative;

5. Informed consent will be appropriately documented;

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects; and

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

SUBJECT: VI. Approval of Research Activity

POLICY: All research must be approved in writing prior to initiation by The MED's Office of Medical Research which shall be responsible for obtaining the express authorization of The MED's Chief Medical Officer and any other authority required by The MED for the approval of any research. Research must be scientifically sound, have IRB approval, and be consistent with the The MED's mission. The MED reserves the right to withhold approval of any research activity. Anyone desiring to conduct research must submit the following information for each study to the Office of Medical Research at least thirty (30) days prior to the study's proposed initiation.

PURPOSE: To assure The MED is informed of all research activity conducted within its facilities and that research is in compliance with The MED's policies and procedures, as well as applicable federal, state and local laws and regulations.

PROCEDURES: To obtain approval for a research study, an investigator must submit the following:

1. Completed MED *Application for Approval to Conduct Research* (See APPENDIX II – this form can be downloaded from the MED link of the UT IRB website);

   - For research proposed to be conducted by non-credentialed physicians such as residents; non-physicians such as physician extenders and nurses, a faculty member of UT must be named as co-investigator;

   - For chart review activities in the context of research, investigators must obtain a HIPAA waiver from the IRB. HIPAA Authorization or Waiver must be obtained whenever patient charts are to be screened to identify patients who might be eligible for inclusion in a study. Also include the federal Certificate of Confidentiality, if any is involved, for the study;

2. If applicable, a study specific, written contract for clinical research hospital services between The MED and the institution (e.g. UT or InMotion Musculoskeletal Institute). If no services are to be provided by The MED, this should be stated in a cover letter (sample wording, "This will confirm our understanding that no services will be performed at The MED which are

chargeable to this Study; therefore, there will be no reimbursement to The MED from _____ for services.");
Name of Institution

3. Cover letter which clearly states the role of The MED in the study and any special arrangements to be made. If necessary, the cover letter should also clarify any of the above items;

4. Such other information or supporting documentation as may be requested by the Office of Medical Research.

The UT IRB will make available to the MED's Office of Medical Research the investigator's electronic application and all documents related to the study, the IRB letter of approval, and, if applicable, any IRB-approved documents, e.g. informed consent form or questionnaire.

Once all of the required materials have been received and reviewed by the Office of Medical Research (Completed Application), the Office of Medical Research will notify the Principal Investigator if additional information is needed or of its decision within thirty (30) days. Research studies may not be initiated, and subjects may not be enrolled, prior to written approval by The MED;

Questions concerning research activity should be directed to the Office of Medical Research, Regional Medical Center at Memphis.

All IRB approved projects will be assigned an IRB number which will then be used by The MED to identify the research protocol in the patient record, and in billing the research account for research-related tests and procedures which may have been contracted to The MED.

SUBJECT: VII. Dispensing of Drugs Administered in Clinical Trials or Other Investigative Studies

POLICY: All medications required by a research protocol must be administered through The MED's Pharmacy. This applies to inpatient and outpatient studies. Any exception to this requirement must be approved in advance by the Chief Medical Officer and the Director of Pharmacy.

PURPOSE: To comply with general hospital policy and Standards of The Joint Commission.

SUBJECT: VIII. Investigator Qualifications

POLICY:

1. Investigators applying for research or conducting research represent that they are licensed, have the appropriate skills, medical training, credentialing, experience, and privileges to conduct research at The MED. The Office of Medical Research may require investigators or those subject to an investigators' direction and control, to provide additional information and documentation that demonstrates qualifications to provide service for said research.

2. The institution represents that investigators and those subject to their direction and control are sufficiently qualified to conduct proposed research.

3. The primary investigators are responsible for the research activities of co-investigators and those participating in the research.

4. If invasive methods (e.g., blood draws) are a part of the research protocol, a co- Principal Investigator must be identified who is both a UT faculty member and a physician with privileges at The MED and credentialed to practice in the specialty where the research is to be conducted;

5. For chart reviews and non-invasive protocols, co-Principal Investigator can be an individual who is a UT faculty member at The MED; and

6. Because a MED-credentialed Principal Investigator will be identified for each research project, faculty/student investigators will not need to seek credentialing from The MED in order to conduct research at The MED.

The MED reserves the right to prohibit an investigator from performing research, if in its sole discretion, such action is necessary under the existing circumstances.

PURPOSE: To assure that investigators are fully qualified to undertake the proposed research activity.

SUBJECT IX. Investigator Responsibilities

POLICY:

1. Investigators shall submit the required documentation for research approval to the Office of Medical Research no less than thirty (30) days prior to the study's proposed initiation date and comply with all applicable laws regulations and these policies and procedures.

2. Investigators shall obtain IRB approval for study protocol, advertisements, informed consent and other applicable study documentation before initiation of study. They shall notify the IRB and The MED of changes to the study, provide progress reports as required, but no less frequently than annually, a final study report; and promptly report adverse events to the MED's Office of Medical Research, the IRB and appropriate sponsor.

3. Investigators shall assume the responsibility for training and educating personnel involved in the study including MED personnel.

4. All research staff involved in a study at The MED must be credentialed or privileged (according to their qualifications and licensing). Students / residents are not required to be privileged, but must work under the supervision of a faculty member credentialed at The MED.

5. Research personnel shall comply with existing hospital policies limiting their access to only patient records for which they have authorization, to the minimum necessary information needed, and for which the protocol has specified a need to know. This shall apply to all sources of patient information, including computer systems operated by The MED.

6. Investigators, Co-Investigators, and those subject to the investigators' direction and control shall maintain adequate and accurate medical records and case histories for each study, including recording all ordered or required tests, protocol, and procedures ordered and designated by the study. The records must identify each patient enrolled in the study at the initiation of each study, as well as the end date of that patient's participation. The information shall include the principal investigator's name, and IRB Number, and any additional information necessary to identify the applicable study, investigation, the study purpose of the research and orders for services.

7. Investigators shall ensure that any services or procedures that are ordered specifically for the study be identified individually in the medical records.

8. All orders written for research purposes, in compliance with the IRB-approved protocol, must comply with The MED's Medical Staff Bylaws, and be authenticated by the ordering practitioner, or another practitioner allowed to prescribe who is involved in the patient's care, within forty-eight (48) hours.

   Research nurses may only write orders related to the research project; physician orders for standard clinical care may not be written by a research nurse.

9. For studies requiring chart reviews, in the event that a medical record is temporarily off-site to be archived, if an investigator requires this record immediately, fees for pulling, copying, and shipping that record back to The MED are applicable; these costs will be passed along to the investigator. Investigators are encouraged to wait until the archiving process is completed and the electronic version of the record becomes available in HIM, so that they do not incur any costs.

PURPOSE: To assure The MED is fully informed of research activity in its facilities; can comply with federal and state regulations; has sufficient information to ensure patients who are research subjects are not billed for research-related tests paid for by a sponsor; and can bill the investigator or the research account for research-related services.

PROCEDURES:

1. Submit to the Office of Medical Research a completed MED *Application for Approval to Conduct Research* (see APPENDIX II) to obtain written approval before initiation of study.

   NOTE: The UT IRB office will make available to The MED's Office of Medical Research all study related documents, letter of IRB approval, and IRB-approved documents, as applicable.

2. Obtain proper written informed consent from each study subject prior to participation in the study; place copy of signed informed consent form on each patient's medical record.

3. Record enrollment of the subject in the research study in the medical record on the day of enrollment by inserting at a minimum the flowing statement:

   "Admit patient to RESEARCH PROTOCOL:' followed by the "last name of principal investigator(s)" and the "IRB# of project."

4. Submit an update of patient enrollment to the Research Office using a customized "*Verification of Patient Enrollment*" form (see APPENDIX II), within 48 hours of enrollment.

5. Document in written orders (on Physician Orders sheet) in the medical record, all research services which are to be billed to the study. The order must clearly state those tests which are to be billed to the study, indicating the IRB number and the Principal Investigator's last name, using a stamp, or written by hand. NOTE: No "Standing Orders" are to be used. Each test must be individually ordered for each day test is required.

6. Research study coordinators should enter research orders for inpatient study subjects into the Meditech Research module.

   In the event there is no study coordinator to enter orders into the Meditech Research module, the investigator may be trained to do so or must otherwise coordinate with the Office of Medical Research, submitting a completed customized "*Verification of Services for Billing*" form (see APPENDIX II) to the Office of Medical Research within 48 hours of the order, each time research services are ordered.

7. Report serious adverse events promptly to the MED's Office of Medical Research, the IRB and appropriate sponsor. A copy of the report required by the University IRB will suffice.

8. Notify the Office of Medical Research upon completion of the study and including the following information. (The UT IRB will make available to the MED's Office of Medical Research the electronic termination report.):

   a. Date of Project Termination;

   b. Number of Research Subjects Enrolled;

c. Status of Enrolled Subjects:
Number of Completing Study:
Number Discontinued Due to Noncompliance:
Number Discontinued Due to Adverse Events:
Number Lost to Follow-up:
Number Deceased:

d. Did any subjects experience any reportable unexpected adverse events? Yes *____ No ____

(* If this blank has been checked, attach explanation of same.)

e. Submit a brief narrative of overall results with respect to efficacy and safety with specific attention to the original purpose of the project.

SUBJECT: X. Informed Consent for Participation in Research Activity

POLICY: The investigator, or an IRB-approved member of the research team, must obtain signed informed consent of the subject or the subject's legally authorized representative prior to involving the subject in a research study. A signed copy of the informed consent documentation shall be included in each subject's medical record.

It is the responsibility of the investigator to discuss the research study with the subject (or legally authorized representative), to provide the required elements of informed consent, and to properly inform the subject of his/her rights as a research subject. Consent forms must indicate the name of the person providing the information and date the form is signed.

The consent form must clearly define which tests or hospital services related to the study will be paid for by the sponsor and what will be the financial responsibility of the subject. (See APPENDIX IV for *Guidelines*)

No informed consent, whether oral or written, may include exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. (45 CFR § 46.116 and 45 CFR Pts. 160 and 164).

Informed consent must embody the general requirements issued by the U.S. Department of Health and Human Services for the protection of human research subjects.

PURPOSE: To document a study subject's voluntary participation in a research study.

SUBJECT: XI. Ordering and Identification of Procedures to be Charged to Research Accounts

POLICY: Services ordered by the investigator or those subject to the investigator's direction and control and provided by The MED, including tests, pharmaceuticals and procedures shall be sufficiently identified in the patients records to ensure the proper allocation and billing for said services.

PURPOSE: To inform The MED of study-related services ordered for a research subject and to assure that a research subject's hospital account is not charged for research-related services that are funded by the study sponsor.

PROCEDURES:

1. Tests and procedures performed by The MED which must be charged to a research account of an approved study are to be identified in the patient record on a Physician Orders page by written order which states:

   "Order (name specific tests/procedures) and CHARGE TO (last name of principal investigator and IRB# of project)."

   The order must be signed by a physician.

2. If a study coordinator writes the study orders on behalf of the PI, the orders should comply with Medical Staff Bylaws governing verbal or telephone orders. If the orders are neither verbal not telephone orders, they should be documented as: "*Per PROTOCOL IRB # 1234 (PI Name)".* The study coordinator should sign, time and date the orders, which are to be co-signed by a physician.

3. The investigator or study coordinator enters the patient enrollment information in Meditech's BAR custom-designed screen (for Inpatients) and on the study-specific Verification of Patient Enrollment form. (See Appendix II for generic Enrollment form; and Appendix III for "*Research*

Subject Enrollment Process" flow chart and "*IRB Patient Research Automated Flow Process*" flow chart.)

The chart below describes how inpatients and outpatients are handled in the Meditech system.

	Research Automated Process In Meditech	
	Inpatient	**Outpatient**
1.	Investigator or Study Coordinator (I/SC) writes study-related orders on Physician Orders page in subject's Medical Record.	I/SC faxes research orders (non-Lab) to Outpatient Registration. OP Registration contacts the performing department to schedule the test(s). *NOTE: Outpatient Lab services must be contracted directly with LabCorp.*
2.	I/SC enters the patient enrollment information in Meditech's BAR custom-designed screen.	When subject arrives, OP Registration registers subject in Meditech (B/AR); if orders are for Radiology or Cardiology, subject will be registered in Order Entry.
3.	I/SC enters research orders into Research module of Order Entry	Performing department enters research orders into Research module of Order Entry
4.	Orders are received, taken/completed, and charged by performing departments.	Orders are completed and charged by performing departments.
5.	Test results are in charts and/or computer	Test results are in charts and/or computer
6.	Research Procedures are assigned to a B/AR charge category to keep charges off the claims	Research Procedures are assigned to a B/AR charge category to keep charges off the claims

SUBJECT: XII. Financial, Reporting and Billing Responsibilities

POLICY: The MED's Accounting Office (AO) will be responsible for billing for research services provided by The MED.

The AO will retain research billing records in a manner consistent with the MED's records retention policy.

PURPOSE: To assure The MED is paid for all research-related services performed for a study protocol, according to the contract executed between the institution and The MED.

PROCEDURES:

1. The Office of Medical Research shall provide the current research rates for services or procedures for a proposed research study, as requested by the research staff. The MED's pharmacist assigned to research studies shall provide Pharmacy rates.

2. When contracts are amended, the prevailing research rates shall be applied to all services covered by the contract.

2. The Office of Medical Research shall provide to the AO a copy of the approval letter for each study (Confirmation of Approval of Research Activity) for which The MED is expected to provide research services, along with the contract number, account number, and department (if applicable), and name and address of person to whom the invoice should be directed.

3. For non-pharmacy services, the Office of Medical Research shall provide to the AO on a monthly basis the following information for the previous month, for each active research study, as applicable: patient identification, charges, procedure performed, service date, invoice total, IRB #, account number, contract number.

   If Pharmacy services are utilized for a research study, the MED pharmacist assigned to research studies will submit the same information as listed above to the AO.

4. The AO shall prepare an invoice for each institution or the respective department's charges for the previous month, referencing the title of the project, the investigator's name, the IRB number, and the account number and contract number (if applicable). This invoice will be sent to the respective department or institution.

5. The AO will submit monthly statements to the responsible institution or department for payment no later than the 15th day of the month following the month in which the services were provided.

6. Subsequent notices of payment due will be forwarded if payment is not received within thirty (30) days. If payment is not received within ninety (90) days of billing, the Accounting Office will notify the Office of Medical Research.

7. When payment is received, the AO will credit the income to the department where the services were provided.

8. The Office of Medical Research shall coordinate with investigators' research staff for timely notification of patient enrollment to the Office of Medical Research; and timely identification of research related tests, procedures, and other services, to be submitted to the Office of Medical Research and the department of Patient Financial Services.

SUBJECT: XIII. Reimbursement

POLICY: Payment for services provided by The MED shall be paid to The MED promptly upon receipt of statements. Rates for the aforesaid services shall be established by The MED and should be requested by the investigator prior to initiation of the study.

PURPOSE: To fulfill obligations set forth in each study-specific contract.

SUBJECT: XIV. Compliance Audit

POLICY: The MED's department of Corporate Compliance will conduct a systematic and independent examination of research activities and related documentation.

PURPOSE: To determine whether the research-related activities were properly conducted, according to The MED's policies and procedures governing research.

Originating Division: Clinical Affairs	**Orig. Date: 1995**
Most recent review (Version # if revised): 2.0	**Effective Date:**
Oversight Approvals Required: • **Policy & Procedure Committee** • **Medical Staff** • _____ • _____	
VP signature attests that all oversight approvals have been obtained.	
Div. VP Signature:	**Date:**
CEO Signature:	**Date:**

The Regional Medical Center at Memphis
OFFICE OF MEDICAL RESEARCH

FORM 1
Application for Approval
to Conduct Research at The Regional Medical Center

Instructions for Completion of Form 1

All research activity must be reviewed and approved prior to initiation through the Office of Medical Research by the Chief Medical Officer of The Regional Medical Center. This document guides investigators through the application process.

Submissions to the Office of Medical Research must contain all required materials. Incomplete submissions will not be considered. For questions about research at The MED, please contact the Office of Medical Research at 545-7453.

Title of Project:

IRB#: IRB Approval Date:

Principal Investigator (P.I.):

Position *(please check)*: UT Faculty ☐ Fellow ☐ Resident ☐ Student ☐ Other:

Is PI credentialed at The MED?:*(please check)* YES ☐ NO ☐ *(See page 2 for requirements)*

UT College: Department:

Address: City: State: Zip:

Phone: Fax: Email:

Study Coordinator: Phone: Fax:

Study Coordinator Email:

Type of Study *(please check)*: Investigation with human subjects and/or tissue ☐ Exempt ☐

Other/Describe:

Project is funded: YES ☐ NO ☐; If Yes, Funding Source/Sponsor:

Sponsor Contact / Representative:

Sponsor Contact Phone #: Email:

Study Site(s) *(please check)*: MED ☐ MEDPLEX (MED clinics) ☐ HEALTHLOOP Clinic(s) ☐

Other:

Are there any services for which The MED will not be reimbursed? *(please check)* YES ☐ NO ☐

Services will be purchased from The MED *(please check)* YES ☐ NO ☐

If Yes, *Request For Research Rates* form has been submitted: *(please check)* YES ☐ NO ☐

If services involve interpretation of tests by specialist physicians, e.g. EKG, X-Rays, etc., provisions are in place to prevent patient from being billed *(please check)* YES ☐ NO ☐

Do you plan to use pre-printed physician order sheets for this study? YES ☐ NO ☐

Anticipated Start Date: End Date Study Duration

Signature of PI Date

The Regional Medical Center at Memphis
OFFICE OF MEDICAL RESEARCH

FORM 1
Application for Approval
to Conduct Research at The Regional Medical Center
(Cont'd)

INVESTIGATOR CHECK LIST:
(Items to be submitted / addressed with the application)

1. ☐ Form 1 (Application for Approval to Conduct Research at The Med)
2. ☐ IRB approval of HIPAA waiver has been obtained (if applicable).

   For chart review activities, investigators must obtain a HIPAA waiver from the IRB and submit such waiver letter as part of the application. HIPAA Authorization or Waiver must be obtained whenever patient charts are to be screened to identify patients who are eligible for inclusion in a study.

3. ☐ Investigator Qualifications:

   A MED-credentialed Principal Investigator must be identified for each research project. If the investigator is a student, non-faculty member, or a faculty member whose expertise is not clinical, or if invasive methods (i.e., blood draws) are a part of the research protocol, a Co-Principal Investigator must be identified who is both a UT faculty member and a physician with privileges at The MED and credentialed to practice in the specialty where the research is to be conducted. Faculty/student investigators will not need to seek credentialing from The MED in order to conduct research at The MED, provided a Co-Principal Investigator is so credentialed.

4. ☐ A contract is needed if services are required from The MED.

   If applicable, a study-specific written contract for clinical research hospital services between the institution (e.g. UT, UTMG, or InMotion Musculoskeletal Institute) and The MED is required. If no services are to be provided by The MED, this should be stated in a cover letter (sample wording: "This will confirm our understanding that no services will be performed at The MED which are chargeable to this Study; therefore, there will be no reimbursement to The MED from _____ for services.").
   (insert name of Institution)

5. ☐ There are research-related services for which The MED will not be reimbursed.

   Please provide an explanation in the cover letter.

6. ☐ If using a Pre-printed Physician Order Sheet, please submit a copy.
7. ☐ Cover letter

   The cover letter clearly states the role of The MED in the study and any special arrangements to be made. If necessary, the cover letter should also clarify any of the above items

This completed application form and required documentation should be submitted to:

Office of Medical Research
The Regional Medical Center
877 Jefferson Avenue
Memphis, TN 38103