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:** 2/17/09
Oversight Approvals Required: • Policy & Procedure Committee • Medical Staff • _____ • _____	
VP signature attests that all oversight approvals have been obtained.	
Div. VP Signature: Jack D McCabe MD	**Date:** 1/6/09
CEO Signature: Donald D. Waters	**Date:** 2/17/09

APPENDIX I

DEFINITIONS

APPENDIX I

Definitions

Adverse Event / Effect (AE) – An unintended, although not necessarily unexpected, result of therapy or other intervention (*e.g.*, headache following spinal tap or intestinal bleeding associated with aspirin therapy).

Any untoward medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research. See ***Serious Adverse Event***

Amendment – A written description of a change(s) to, or formal clarification of, a contract between The MED and the institution (e.g. University of Tennessee, InMotion Musculoskeletal Institute, etc.). See ***Protocol Amendment; Revision***

Approval (in relation to Institutional Review Boards) – The affirmative decision of the IRB that the clinical trial has been reviewed and may be conducted at the institution site within the constraints set forth by the IRB, the institution, good clinical practice (GCP), and the applicable regulatory requirements. Approval is specifically granted for the study itself; consent form(s), surveys or questionnaires, or promotional material to be used, as applicable; changes in protocol, consent form, or investigators involved; and continuation of the study beyond the period originally approved.

Audit – A systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory requirement(s).

Authorization for Personal Health Information (PHI) Uses and Disclosures – A valid Privacy Rule Authorization is an individual's signed permission that allows a covered entity to use or disclose the individual's PHI for the purpose(s) and to the recipient(s) stated in the Authorization and as defined in the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations set forth in 45 CFR §§ 160 and 164. When an Authorization is obtained for research purposes, the Privacy Rule requires that it pertain only to a specific research study, not to future, unspecified projects. If an Authorization for research is obtained, a covered entity's uses and disclosures must be consistent with what is

stated in the Authorization. An Authorization differs from an informed consent in that an Authorization is an individual's permission for a covered entity to use or disclose PHI for a certain purpose, such as a research study. An informed consent, on the other hand, is the individual's permission to participate in the research. An informed consent provides research subjects with a description of the study and of its anticipated risks and/or benefits, and a description of how the confidentiality of records will be protected, among other things. An Authorization can be combined with an informed consent document or other permission to participate in research.

Clinical Research Coordinator (CRC) – Person who handles most of the administrative responsibilities of a clinical trial, acts as liaison between investigative site and sponsor, and reviews all data and records before a monitor's visit. *Synonyms: investigational study coordinator, trial coordinator, study coordinator, research coordinator, clinical coordinator, research nurse, protocol nurse.*

Clinical Trial – A clinical trial is a research study to answer specific questions about vaccines or new therapies or new ways of using known treatments. Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people. Trials are in four phases: Phase I tests a new drug or treatment in a small group; Phase II expands the study to a larger group of people; Phase III expands the study to an even larger group of people; and Phase IV takes place after the drug or treatment has been licensed and marketed.

The most commonly performed clinical trials evaluate new drugs, medical devices, biologics, psychological therapies, or other interventions on patients in strictly scientifically controlled settings, and may be required for regulatory authority approval of new therapies. Trials may be designed to assess the safety and efficacy of an experimental therapy, to assess whether the new intervention is better than standard therapy, or to compare the efficacy of two standard or marketed interventions. The trial objectives and design are usually documented in a clinical trial protocol.

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one of more investigational medicinal product(s), and /or to identify any adverse reactions to one or more investigational medicinal product(s), and/or to study absorption, distribution, metabolism and excretion of one of more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy.

Co-investigator – one who assists the principal investigator in the conduct of research and is identified in documentation as a co-investigator.

Compliance –

1. Adherence of subjects to following medical advice and prescriptions. Primarily applied to taking medicine as directed, but also applies to following advice on diet, exercise, or other aspects of a subject's life.
2. Adherence of investigators to following a protocol and related administrative and regulatory responsibilities.
3. Adherence of Sponsors to following regulatory, legal, and other responsibilities and requirements relating to a clinical trial.

Confidentiality – Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information, or a subject's identity or protected health information.

Consent form – see ***Informed Consent Document***

Contract – A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

Data – Representations of facts, concepts, or instructions in a manner suitable for communication, interpretation, or processing by humans or by automated means.

Device – An instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part or accessory, which is intended for use in the diagnosis, cure, treatment or prevention of disease. A device does not achieve its intended purpose through chemical action in the body and is not dependent upon being metabolized to achieve its purpose.

Drug – Any chemical compound that may be used on or administered to humans as an aid in the diagnosis, treatment, cure, mitigation, or prevention of disease or other abnormal conditions.

Experimental – Term often used to denote a therapy (drug, device, procedure) that is unproven or not yet scientifically validated with respect to safety and efficacy. A procedure may be considered "experimental" without necessarily being part of a formal study (research) to evaluate its usefulness. See ***Research; Investigational New Drug or Device***.

Good Clinical Practice (GCP) – A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule – The first comprehensive Federal protection for the privacy of personal health information defined in the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191 and accompanying amendments) and its implementing regulations set forth in 45 CFR §§ 160 and 164 . See ***Personal Health Information*** **(PHI)**

Human Subjects – Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information

Informed Consent – An ongoing process that provides the subject with explanations that will help in making educated decisions about whether to begin or continue participating in a trial. Informed consent is an ongoing, interactive process, rather than a onetime information session. NOTE: Under 21 CFR 50.20, no informed consent form may include any "language through which the subject or the 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."

Informed Consent Document – A document that describes the rights of the study participants, and provides a summary of a clinical trial (including its purpose, the treatment procedures and schedule, potential risks and benefits, alternatives to participation, etc.) and explains an individual's rights as a subject. It is designed to begin the informed consent process, which consists of conversations between the subject and the research team. If the individual then decides to enter the trial, s/he gives her/his official consent by signing the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time. *Synonym: informed consent form; see also informed consent.*

The informed consent document should outline any additional costs that will be billed to study subjects or their insurance company as a result of participation in the study. Any such charges should be appropriate and equitable.

Institution – Any public or private entity or agency or medical or dental facility which is contracted to perform the clinical trial or study, e.g. University of Tennessee, InMotion Musculo-skeletal Institute, etc.

Institutional Review Board (IRB) – An independent body constituted of medical, scientific, and non-scientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving,

and providing continuing review of trial protocol and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects. All research must be approved by an IRB before they begin.

Investigational Device Exemption (IDE) – Application for exemption from the Food Drug and Cosmetic Act to study investigational medical devices

Investigational New Drug or Device – A drug or device permitted by FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing. The FDA regulations apply to ALL medical device studies, whether the device is marketed or not. See ***Device; Medical Device*** A pharmaceutical form of an active ingredient or placebo or device being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

Investigator – A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator (see definition below). The individual "under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team and may be called the ***principal investigator***."

Investigator's Brochure – Relevant clinical and non-clinical data compiled on the investigational drug, biologic or device being studied. An Investigator's Brochure must contain:

1. A description of the drug substance and the formulation,
2. A summary of the pharmacological and toxicological effects,
3. A summary of information relating to safety and effectiveness in humans, and
4. A description of possible risks and adverse reactions to be anticipated and precautions or special monitoring.

Monitor – Person employed by the sponsor or contract research organization who reviews study records to determine that a study is being conducted in accordance with the protocol. A monitor's duties may include, but are not limited to, helping to plan and initiate a study, and assessing the conduct of studies. Monitors work with the clinical research coordinator to check all data and documentation from the study.

Personal Health Information (PHI) – Individually identifiable health information as defined under the Health Insurance Portability and Accountability Act of 1996 that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. See ***Authorization for PHI Uses and Disclosures***

Principal Investigator – The Principal Investigator (PI) is the individual responsible and accountable for conducting and monitoring a protocol at his/her site. The PI shall hold a professional medical doctoral degree in the specialty in which research is to be conducted, and conducts clinical research and under whose immediate direction research services, including the administration of investigational drugs, devices and procedures are administered. See ***Investigator***.

Protocol – A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline the term protocol refers to protocol and protocol amendments. NOTE: Present usage can refer to any of three distinct entities: 1) the plan (i.e., content) of a protocol, 2) the protocol document, and 3) a series of tests or treatments.

Protocol Amendment(s) – A written description of a change(s) to or formal clarification of a protocol. See ***Revision*** and ***Amendment.***

Protocol Deviation. A variation from processes or procedures defined in a protocol. Deviations usually do not preclude the overall evaluability of subject data for either efficacy or safety, and are often acknowledged and accepted in advance by the sponsor.

Research – A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Includes Clinical Research. This includes the development of research repositories and databases for research. The MED's research policies shall apply to all research activity conducted at The Med involving patients, patients' records, patients' specimens, the clinics, or other hospital facilities. This includes the use of investigational products or procedures, chart reviews, surveys, recruitment activity or any other activity which requires access to inpatients or outpatients, or to their records.

Research Staff / Team – Principal investigator, co-investigator(s), clinical research coordinator, and all staff involved with the conduct of a research study.

Revision – A change or clarification in the original study documents (Protocol, Informed Consent Form). All changes (no matter how minor) in study

procedures, consent forms, questionnaires, advertisements, personnel, etc. must be submitted to and approved by the IRB before they are implemented. See ***Amendment***

Risk – In clinical trials, the probability of harm or discomfort for subjects. Acceptable risk differs depending on the condition for which a product is being tested. A product for sore throat, for example, will be expected to have a low incidence of side effects. However, unpleasant side effects may be an acceptable risk when testing a promising treatment for a life-threatening illness.

Serious Adverse Event (SAE) – Any untoward medical occurrence that at any dose:

- Results in death,
- Is life-threatening,

  NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
- Requires inpatient hospitalization or prolongation of existing hospitalization,
- Results in persistent or significant disability/incapacity, or
- Is a congenital anomaly/birth defect.

See ***Adverse Event***

Site – This refers to the physical location where a clinical trial is conducted. A physician who has offices and sees subjects in three separate locations is viewed as having one site. A physician who is on the staff of four hospitals could be viewed as having one or four sites, depending on how similar or different the subject populations are and whether the data from these four locations will be pooled and considered a single site. For example, a single physician who enrolls groups of subjects at a university hospital, private clinic, community hospital, and Veterans Administration Hospital should generally be viewed as having four sites, since the subject populations would be expected to differ at each site.

Sponsor – An organization that supports research activity through provision of financial assistance, contribution of any drug/product, device, equipment, or other intervention to be utilized or evaluated in the course of research ; individual, company, institution or organization taking responsibility for initiation, management and financing of study.

The sponsor is the individual, company, institution, organization or other entity who takes responsibility for and initiates a clinical investigation. The sponsor may be a pharmaceutical company, a private or academic

organization, or an individual. The sponsor assumes responsibility for compliance with applicable laws and regulations. The sponsor, for example, is responsible for obtaining FDA approval to conduct a trial and for reporting the results of the trial to the FDA.

Sponsor-Investigator – An individual who both initiates and conducts a clinical investigation and under whose immediate direction the investigational drug is being administered or dispensed.

Standard of Care – Treatment regimen or medical management based on state of the art participant care. The currently accepted treatment or intervention considered to be effective in the treatment of a specific disease or condition. A guideline for medical management and treatment.

Study Protocol – See ***Protocol***

Study – See ***Research***

Subject / Research Subject / Trial Subject – See ***Human Subjects***

Web-based Reference Sources for Definitions:

1. CenterWatch Clinical Trials Listing Service – Patient Resources Glossary (http://www.centerwatch.com/patient/glossary.html)
2. Applied Clinical Trials - CDISC Clinical Research Glossary. Version 5.0. (http://www.cdisc.org/glossary/CDISCGlossaryV5.pdf)
3. Clinical Trials.gov – A Service of the National Institutes of Health: Glossary of Clinical Trials Terms (http://clinicaltrials.gov/ct2/info/glossary)
4. WebMD Clinical Trial Services (http://www.webmd.com/content/pages/13/65826.htm)
5. ClinDev Global, Inc. (http://www.clindev.com/glossary.php?c=4)
6. U.S. Department of Health & Human Services – Office for Human Research Protections (OHRP) (http://www.hhs.gov/ohrp/irb/irb_glossary.htm)
7. U.S. Department of Health & Human Services – U.S. Food and Drug Administration (FDA) (http://www.fda.gov/cder/guidance/iche2a.pdf)

APPENDIX II

FORMS

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

The Regional Medical Center at Memphis

RESEARCH SERVICES

REQUEST for RESEARCH RATES

NAME OF PROJECT: _____

_____

_____

IRB # : _____

Project Sponsor: _____ **Anticipated Start Date:** _____

Principal Investigator: _____ **Phone:** _____

Study Coordinator: _____ **Phone:** _____

	TESTS OR PROCEDURES REQUESTED	Approved Research Rate	CPT Code #	Mnemonic Code #
Item # 1				

APPROXIMATE NUMBER OF SUBJECTS TO BE ENROLLED: _____

Request prepared by: _____ **Date:** _____

Rates approved by: _____ **Date:** _____

The Regional Medical Center at Memphis
RESEARCH SERVICES

VERIFICATION of PATIENT ENROLLMENT

PROJECT TITLE: <<_____>>

PRINCIPAL INVESTIGATOR: <<_____>>

IRB #: <<_____>> **UT ACCOUNT #:** <<_____>>

RESEARCH STUDY COORDINATOR: <<_____>> **PHONE #:** <<_____>>

STUDY DURATION: <<_____>> *(start date)* **TO** <<_____>> *(end date)* **ACTUAL COMPLETION DATE:** <<_____>>

Please list below all patients enrolled in this research protocol. If a patient is removed from the protocol, indicate date and reason. Use this list as your original and update as patients are enrolled, for the duration of the project. This is a requirement for all research protocols. Attach additional pages as necessary. This form should be submitted within 2 days after enrollment.

Patient's Name	Medical Record #	Patient Account #	Date Enrolled	Date Terminated / Reason

FAX list to Office of Medical Research at 515-9938

The Regional Medical Center at Memphis

RESEARCH SERVICES

VERIFICATION of SERVICES for BILLING

IRB # : _____ **Patient Name:** _____ **Medical Record #:** _____

Account #: _____

NAME OF PROJECT: _____

_____

UT Contract #: _____ **UT Account #:** _____

PRINCIPAL INVESTIGATOR: _____ **PHONE #:** _____

RESEARCH STUDY COORDINATOR: _____ **PHONE #:** _____

A copy of this completed form must be submitted *as research services are performed for the duration of the project. Forms must be submitted within 2 days of the earliest services date to ensure any adjustments to the patient's account. Charges for these research-related services MUST NOT appear on the patient's account.*

Study Procedure	Date of Service (1)	Date of Service (2)	Date of Service (3)	Date of Service (4)	Date of Service (5)	Date of Service (6)	Date of Service (7)	Date of Service (8)	Unit Price	Total Price
										$ -
										$ -
										$ -
										$ -
										$ -
										$ -
										$ -
										$ -
										$ -
										$ -
										$ -
										$ -
										$ -
										$ -
TOTAL										$ -

FAX completed form to Office of Medical Research Office at **515-9938**

(For Departmental and Research Office Use Only; This is Not an Invoice)

PRINCIPAL INVESTIGATOR CERTIFICATION AND AGREEMENT OF COMPLIANCE

(Title of Research Study, Principal Investigator, IRB#)

The undersigned hereby certifies that he/she has reviewed the policies and procedures of the Regional Medical Center at Memphis concerning the conduct of research at the facility and agrees to comply with them fully in the conduct of the above referenced research project. Included in the policies are the following provisions and obligations which the undersigned agrees to comply with:

1. **Enrollment of the subject in the research study must be recorded in the medical record on the day of enrollment.**
2. **Upon enrollment, a copy of the subject's signed written informed consent must be attached to the medical record.**
3. **Research services which are to be billed to the study are to be identified in written orders in the medical record.** The order must clearly state those tests which are to be billed to the study, indicating the IRB number and the PI's last name, using a stamp, or written by hand. For example: "Charge CBC to (Principal Investigator's Last name) IRB#1234." (The study's IRB number is cross-referenced with the UT Account number to be certain that the correct research account is invoiced.)
4. ***A completed "Verification of Services for Billing" form (or an alternative mutually agreed-upon documentation of services) must be submitted to the Office of Medical Research within 48 hours of the order, each time research services are ordered.***
5. **An update of patient enrollment is to be forwarded to the Office of Medical Research using the "Verification of Patient Enrollment" form, within 48 hours of enrollment.**
6. **Adverse events must be reported to the Office of Medical Research**.
7. **The Office of Medical Research must be notified of any revisions in the protocol or consent form.**
8. **Upon completion of the study, the Office of Medical Research must be informed of the end date.**

Moreover, I acknowledge that I understand the laws and regulations governing research with human subjects and will fully comply with them. I understand that the conduct of research at The Regional Medical Center is contingent upon my complying with the policies and procedures of the facility, as well as all applicable laws and regulations governing research with human subjects. Further, I understand that I must submit adequate records upon request of the Office of Medical Research so that the research contemplated hereby may be monitored and audited.

_____ _____

Signature of Principal Investigator(s) *Date*

NOTE: SIGNED FORM MUST BE SUBMITTED PRIOR TO ANY ENROLLMENT OF SUBJECTS
(Items #3 and #4 apply only to those studies which have contracted services with the MED.)

DB Project # _____

PI / IRB # _____

The Regional Medical Center

RESEARCH CHECKLIST

COLLEGE / DEPARTMENT: _____

PI: _____ **Study Coord:** _____ **Phone #:** _____

PROJECT TITLE: _____

_____

____ Protocol / Proposal

____ IRB # _____ IRB Approval Date _____

____ IRB-Approved Consent Form

____ Sponsor / Funding: _____

____ Contractual Arrangements: _____

____ Device for Biomed Inspection: _____

____ Research Tests in Meditech ____ Research OE ____ IRB # added into Meditech for OE

____ Research Coordinator has profile to use Meditech Research OE

____ Memo to Medical Director/CMO

____ (Draft) Letter of Approval from Medical Director/CMO

Chart Review only?____ Questionnaire?____ Recruitment only?____ Other: _____
Start Date: _____ End Date: _____
Classification (circle): Industry Federal Other:_____
Services Required: Yes ___ No ___
Contract Needed: Yes___ No___ ; with _____
Services (Circle): Pharm Lab EKG Radiology Other:_____
Rates Requested? _____ Confirmed? _____
UT Account # _____ UT Contract # _____

_____

File complete ____ Prepared for review ____ Reviewed by Research Office ____

____ Date Approved by Medical Director/CMO ____ Contract signed

____ Date Approval letter sent *Copies to:* _____

____ Date Confirmation memo sent *Copies to:* _____

____ UT Contract *Copies to:* Accounting __ Pharmacy __ Legal __ Other: _____

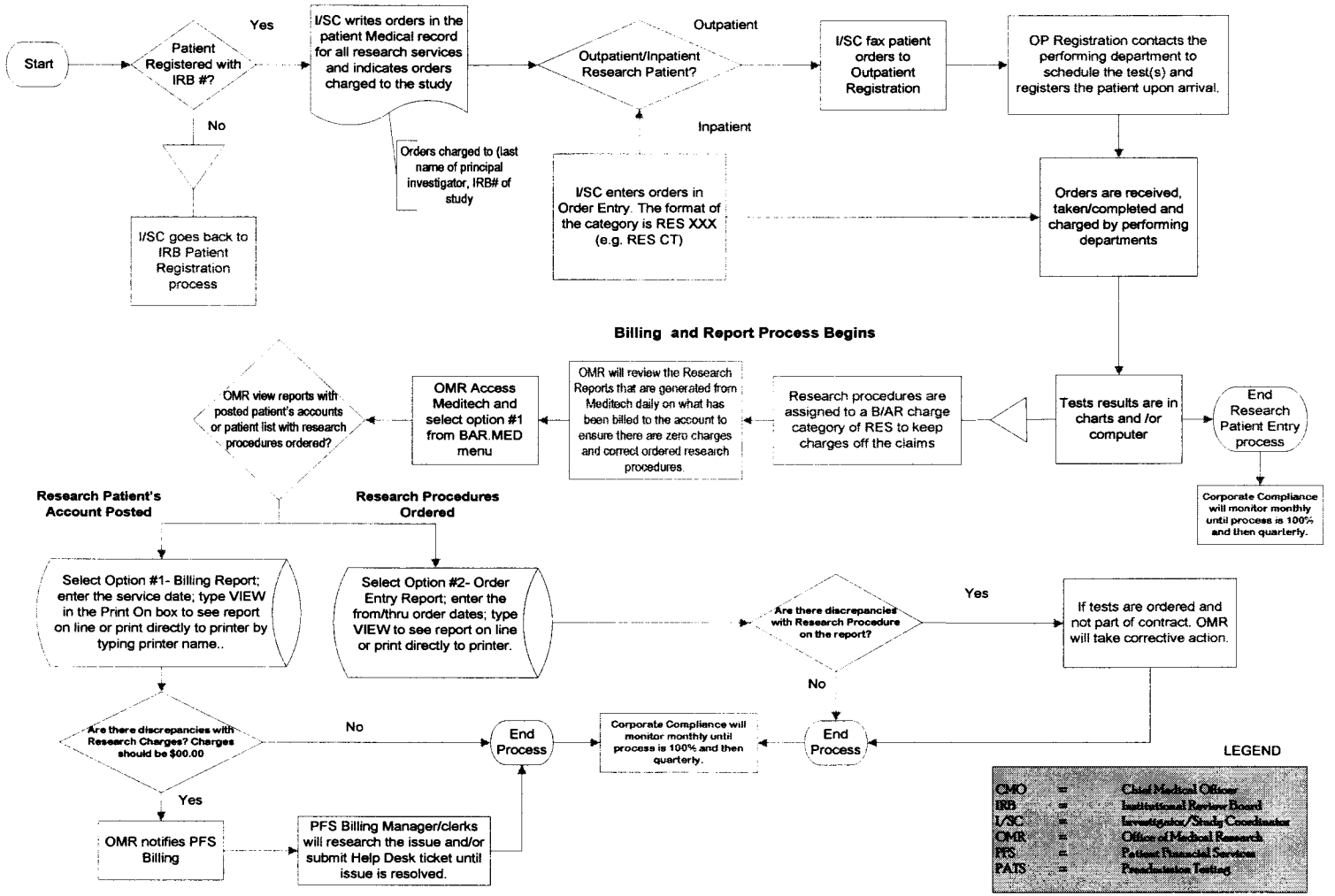
____ Entered into Database

COMMENTS / ISSUES:

APPENDIX III

MEDITECH AUTOMATED RESEARCH FLOW PROCESS

IRB Patient Research Automated Process Flow



APPENDIX IV

GUIDELINES
TO
FINANCIAL OBLIGATIONS LANGUAGE
IN
RESEARCH APPLICATION AND
INFORMED CONSENT FORMS

GUIDELINES
FOR
"FINANCIAL OBLIGATIONS" / "COST OF PARTICIPATION" LANGUAGE IN THE APPLICATION AND INFORMED CONSENT FORMS FOR STUDIES AT THE MED

Investigators and The Regional Medical Center have a shared responsibility to comply with federal regulations and hospital policy regarding research subjects' financial obligations, and to ensure that subjects are informed of any additional costs to the subject that may result from participation in the research.

The MED is seeking greater clarity in the language employed in Application documents and Informed Consent forms for studies to be conducted at The MED, pertaining to who will be responsible for the costs for tests and procedures done solely for research. Our goal is to advise investigators planning to seek approval to conduct clinical trials at The MED, on acceptable language so they can avoid delays due to having to submit revisions to a sponsor and the IRB before a study can proceed at The MED.

Essential elements

Below are listed some guidelines for the **"Financial Obligations" / "Cost Of Participation"** statements found in the Application and the Informed Consent Form submitted to the IRB:

- Clearly state who will be responsible for paying for study-related tests/procedures.
- If feasible, list the tests that will be paid for by the study sponsor.
- When applicable, use a statement along the line of "any orders written by the study coordinator for this study will not be billed to the patient or their insurer".
- Do not use phrases like "standard of care". This phrase is too subjective, varying regionally, from institution to institution, and between physicians. Instead, use words like "routine care", "tests/services not related to research", etc. This eliminates the ambiguity inherent in attributing some tests to "standard of care".
- Do not use statements containing contingencies, requiring denial of payment by subject's insurance before Sponsor will pay for study-related tests or procedures, e.g. *"Sponsor will reimburse the costs of any study related tests, visits and procedures, which are required for study purposes, and are not covered by your medical insurance or another party."*

Examples

The following examples contain language that is acceptable in IRB-approved research applications and consent forms that will be submitted for approval by The MED:

CONSENT FORM

COST OF PARTICIPATION

EXAMPLE 1.

There should be no additional cost to you as a result of your participation in this research study. However, you will continue to be responsible for medication, assessments, and procedures required for your routine medical treatment. The following tests will be performed solely for the study: _____[list tests/procedures]____ . Any test or procedure orders written by the research study nurse for this study will be done at no charge to you and will be paid for by the sponsor of this study, _____[name of sponsor]_____.

EXAMPLE 2.

Neither the subject not the subject's insurance carrier will be responsible for any procedures that are done only for this study. The following tests will be performed solely for the study: _____[list tests/procedures]____ . Any test or procedure orders written by the research study nurse for this study will be done at no charge to you and will be paid for by the sponsor of this study, ____[name of sponsor]____.

~~~~~~

APPLICATION

FINANCIAL OBLIGATIONS

EXAMPLE 1.

No charges will be incurred by the patient for any tests or procedures over and above those deemed necessary for routine treatment for the condition(s) of the patient. The following tests will be performed solely for the study: _____[list tests/procedures]____ . All study medications ordered by the investigator or nurse will be provided or paid for by the sponsor at no charge to the patient or to the institutions involved. Procedures that are part of routine care will be billed to the patient or his insurance carrier. Procedures that are ordered by the PI or nurse for the study and paid for by the sponsor will be billed directly to the study.

EXAMPLE 2.

The study drug, study doctor's visits and laboratory tests related to this study will be provided at no cost to the subject. Neither the subject nor their insurance company will be charged for the services provided in the normal course of the conduct of this study. Costs related to these services will be paid by the study sponsor.
~~~~~~