

**BAPTIST MEMORIAL HEALTH CARE CORPORATION
INSTITUTIONAL REVIEW BOARD**

6025 Walnut Grove Road
Suite 404
MEMPHIS, TENNESSEE 38120

J. CAMERON HALL, M.D., CHAIRMAN

PROTOCOL SUBMISSION PACKET TABLE OF CONTENTS

<u>Section</u>	<u>Document</u>	<u>Last Revision</u>
1	Table of Contents	10/25/06
2	IRB Meeting Schedules – 2006 & 2007	10/06
3	IRB Letter	4/06
4	IRB Contacts	4/06
5	Simplified Assurance (FWA)	4/06
6	Contracts and Budgets	8/05
7	BMH Contract/LOI Information	6/04
8	Application for Evaluation of New Research Protocols	9/05
9	Progress/Termination Report Form	9/05
10	Policy On Internal Review of Research Proposals	11/00
11	Document Submission Guidelines	4/06
12	Code of Federal Regulations: Title 21, Part 50, Sec. 50.25	4/1/02
13	Informed Consent Guidelines	2/06
14	Informed Consent Template (Sample)	4/7/06
	HIPAA Privacy Regulations and Medical Research: BMHCC-IRB Guidance & Procedures	3/9/06
15.0	HIPAA Guidelines Appendix A, B	
15.1	HIPAA Guidelines Appendix C	
16	BMHCC-IRB Standard Operating Procedures (SOP)	3/9/06

**BAPTIST MEMORIAL HEALTH CARE CORPORATION
INSTITUTIONAL REVIEW BOARD
2006
MEETING SCHEDULE**

Jan 12	June 22
Jan 26	July 13
Feb 9	July 27
Feb 23	Aug 10
Mar 9	Aug 24
Mar 23	Sept 14
Apr 13	Sept 28
Apr 27	Oct 12
May 11	Oct 26
May 25	Nov 16
June 8	Dec 14

Deadline for all submissions is
two weeks prior to the next scheduled IRB meeting.

**BAPTIST MEMORIAL HEALTH CARE CORPORATION
INSTITUTIONAL REVIEW BOARD
2007
MEETING SCHEDULE**

Jan 11	June 28
Jan 25	July 12
Feb 8	July 26
Feb 22	Aug 9
Mar 8	Aug 23
Mar 22	Sept 13
Apr 12	Sept 27
Apr 26	Oct 11
May 10	Oct 25
May 24	Nov 15
June 14	Dec 20

Deadline for all submissions is two weeks prior to the next scheduled IRB meeting.

**BAPTIST MEMORIAL HEALTH CARE CORPORATION
INSTITUTIONAL REVIEW BOARD**

6025 Walnut Grove Road
Suite 404
MEMPHIS, TENNESSEE 38120

J. CAMERON HALL, M.D., CHAIRMAN

April 7, 2006

Dear Doctor:

Please find attached the "BMHCC-IRB Policy on Internal Review of Research Proposals."

When submitting a protocol, please include relevant **BACKGROUND INFORMATION** and **BIBLIOGRAPHY** to the experimental drug(s), device(s) and/or experimental design.

The BMHCC-IRB meets approximately twice per month, the second and fourth Thursday of the month, January - October, and the third Thursday of the month, November and December.

Send **1** original and **20** copies of protocol packet and **4** copies of the Investigators Brochure to the IRB office, 6025 Walnut Grove Road, Suite 404, Memphis, TN 38120. (See **PROTOCOL SUBMISSION GUIDELINES** included with this packet.) Protocols should be submitted to the IRB office 14 days prior to the meeting date. Protocols are submitted to the committee for review by the order in which they are received. An average of six to eight protocols are reviewed at each meeting.

Sincerely,

J. Cameron Hall, M.D.
Chairman

JCH:sms

**BAPTIST MEMORIAL HEALTH CARE CORPORATION
INSTITUTIONAL REVIEW BOARD**

6025 Walnut Grove Road
Suite 404
MEMPHIS, TENNESSEE 38120

J. CAMERON HALL, M.D., CHAIRMAN

IRB CONTACTS

J. Cameron Hall, M.D., IRB Chairman **226-1677**
e-mail address - jhall3@midsouth.rr.com

Leigh Jackson, Vice-Chairman **226-1675**
e-mail address – leigh.jackson@bmhcc.org

Sandra M. Scott, Administrative Coordinator **226-1677**
e-mail address - sandra.scott@bmhcc.org

IRB Office Fax **226-1680**

BAPTIST MEMORIAL HEALTH CARE CORPORATION INSTITUTIONAL REVIEW BOARD

6025 Walnut Grove Road
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MEMPHIS, TENNESSEE 38120

SIMPLIFIED ASSURANCE (FWA)

All physicians/investigators submitting protocols/renewals to the BMHCC-IRB are required to complete the OHRP Human Subject Assurance Computer-based training course and receive a certificate of completion that is to be submitted to the IRB for inclusion into the appropriate file.

The Federal Wide Assurance has taken the place of Single, Multiple and Cooperative Project Assurances.

HUMAN SUBJECT ASSURANCE TRAINING

It is recommended that all three modules be completed to better give an overview of the entire process.

Be sure to log-in on the first page in order for your name to appear on your certificates.

Send copies of the three HUMAN SUBJECT ASSURANCE TRAINING Certificates to the IRB office at your earliest convenience or include with your protocol submission/renewal documents.

The web site for the HUMAN SUBJECT ASSURANCE TRAINING is:

<http://ohrp-ed.od.nih.gov>

Please do not hesitate to call or contact the IRB office at 226-1677 if assistance is needed.

BAPTIST MEMORIAL HEALTH CARE CORPORATION INSTITUTIONAL REVIEW BOARD

6025 Walnut Grove Road, Suite 404
MEMPHIS, TENNESSEE 38120

J. CAMERON HALL, M.D., CHAIRMAN

August 15, 2005

Re: Contracts and Budgets

Dear Principal Investigator:

The Baptist Memorial Health Care Corporation (BMHCC) and the BMHCC IRB have added two new requirements for IRB submission and approval.

When a protocol that involves any BMHCC facility is submitted to the BMHCC IRB, the preliminary contract and budget for the study must be included. The BMHCC Research Financial Review Committee will review the study and budget to assure that the hospital's involvement is financially sound. The BMHCC attorney will review the contract. The contract should include Baptist Memorial Hospital (*specify BMH facility, i.e., Collierville, DeSoto, Memphis, etc.*) if at all possible; if not, we will attempt to set up another agreement with either you and/or the sponsor. The BMHCC IRB cannot issue an approval letter until these steps are completed and all budgets and contracts are approved.

Additionally, the BMHCC IRB has begun requesting payment from industry sponsored research studies as follows: \$1500 for initial review and approval, and \$500 per year thereafter for safety reports, annual review, etc. If a sponsor has a problem with this, please do not hesitate to contact the IRB office at 226-1677.

Sincerely,

J. Cameron Hall, M.D.
Chairman

BAPTIST MEMORIAL HOSPITAL CONTRACT / LOI INFORMATION

Thank you for choosing Baptist Memorial Hospital for your research study site. If your protocol will involve BMH patients that will be treated on our premises (inpatient or outpatient, excluding private physician's offices), it is required that a letter of agreement for indemnification be submitted for signatures. This can be incorporated into the investigator's site/research agreement or developed as a separate document. Please submit a draft to the Baptist Clinical Research Center office to be processed through the BMH Legal counselor before final signatures are obtained.

The Administrator that should be named on the document for signatures is :
J. Stuart Mitchell, III, Vice-President, Market Leader
Baptist Memorial Hospital, Metro Memphis.

Please add the following items substituting the company's name for **THE SPONSOR**, (if applicable to maintain consistency) and maintain consistency in references to BMH if indicated as "INSTITUTION" in main body of contract.

INDEMNIFICATION SECTION:

1. **SPONSOR** agrees to indemnify, defend and hold harmless Institution and its officers, directors, employees, agents, and subcontractors including without limitation, any of Institution's personnel working under the supervision of Sponsor's approved clinical investigator(s), Institution's Patient Participation Committee, and any of Institution's affiliates involved in the Study, and their officers, directors, shareholders, owners, employees, agents, and subcontractors (hereinafter referred to as the "Indemnified Parties") against any causes of action, claims, demands, suits, costs, liabilities, expenses, damages, and attorney fees (hereinafter referred to as a "Claim") brought against any one or all of the Indemnified Parties based on a personal injury, disease, sickness or death allegedly resulting from the conduct of the Study in accordance with the Protocol, or the use of any drug, device or product submitted by Sponsor. Institution shall promptly notify Sponsor, upon receipt of notice of a Claim. Sponsor shall thereupon assume the defense and costs of such Claim, utilizing attorneys chosen by Sponsor with the consent of Institution, which consent shall not be unreasonably withheld. Sponsor's duty to indemnify, defend and hold harmless shall also include an obligation on the part of Sponsor to reimburse Institution for any medical expenses incurred by research subjects for acute medical care, including hospitalization, in the treatment of any adverse reaction arising from the subject's participation in the Study. Sponsor's obligation to indemnify, defend and hold harmless the Indemnified Parties shall survive any termination of this Agreement.

2. This indemnity shall not apply to any Claim that is attributable to (I) the failure of Institution's personnel to adhere to all material terms of the Protocol or any written instructions relative to the use of any product(s) used in the performance of the Study (deviations arising out of necessity and not contributing to the injury or affecting Study validity shall not be considered a failure to adhere to the Protocol); or (ii) any grossly negligent, willfully malfeasant or intentionally wrongful act of Institution or Institution's personnel directly involved in the Study.
3. **SPONSOR** agrees to maintain throughout the term of this agreement, comprehensive general and/or professional liability insurance providing at least one million dollars (\$1,000,000) coverage per occurrence. If the Study involves a drug, device or product, Sponsor will additionally obtain products liability insurance providing at least three million dollars (\$3,000,000) coverage per occurrence. Sponsor agrees to provide Institution with a certificate or certificates of insurance evidencing this coverage. In the event that any of Sponsor's insurance is on a claims-made basis, Sponsor agrees to provide for appropriate coverage for prior acts when such insurance is no longer in effect. Sponsor agrees to name Institution as an additional insured on its policies of insurance and provide Institution with at least sixty (60) days prior written notice of any non-renewal or cancellation.

INDEMNITY OR CONFIDENTIALITY SECTION:

4. ***THE SPONSOR** and Baptist Memorial Hospital agree to make disclosure of records to the US Department of Health and Human Services. If, as and to the extent required by law, until the expiration of four years after the furnishing of services under this Agreement, **THE SPONSOR** shall make available upon request to the US Department of Health and Human Services, and the US Comptroller General and their representatives, this Agreement and all other books, documents and records as are necessary to certify the nature and extent of service provided under this Agreement.

INDEMNITY OR CONFIDENTIALITY SECTION:

5. ***THE SPONSOR** and Baptist Memorial Hospital in this agreement agree to amend and/or sever the non-conforming part to the extent that the remaining sections reasonably reflect the initial intentions of the parties if either the IRS or HCFA rule that any part of this agreement violates any rules or regulations of the IRS or HCFA.

COMPLIANCE WITH LAW SECTION:

6. **THE SPONSOR** represents and warrants that all necessary approvals and authorizations have been obtained to conduct the study and that the Protocol meets and was developed in compliance with all applicable laws and standards of care.

FORCE MAJEURE SECTION:

7. No party shall be liable for the failure to perform its obligations under this Agreement if such failure is occasioned by a contingency or occurrence beyond such party's reasonable control, including, but not limited to: strikes or other labor disturbances, lockouts, riots, wars, fires, floods, earthquakes, or storms. A party claiming a right to excused performance under this Section shall immediately notify the other party in writing of the extent of its inability to perform, which notice shall specify the occurrence beyond its reasonable control that prevents such performance.

GOVERNING LAW SECTION:

8. This agreement shall be governed by and construed in accordance with the laws of the State of Tennessee. **THE SPONSOR** agrees to comply with all applicable federal, state and local laws, rules and regulations in its performance hereunder.

*absolute requirement for patients who may incur non-study related charges while hospitalized. Audit by third party payors sometimes require full review of patient therapy (including investigational studies) while hospitalized.

**APPLICATION FOR EVALUATION OF NEW RESEARCH PROTOCOLS BY
BAPTIST MEMORIAL HEALTH CARE CORPORATION
INSTITUTIONAL REVIEW BOARD**

DATE: _____

TITLE: _____

PRINCIPAL INVESTIGATOR:	SIGNATURE:
NAME: _____	_____
ADDRESS: _____	PHONE: _____
_____	FAX: _____
_____	E-MAIL: _____

PARTICIPATING INVESTIGATORS:	SIGNATURE(S):
NAME(S): _____	_____ Date _____
_____	_____ Date _____
_____	_____ Date _____

Attach additional signature page(s) if more than 3 Participating Investigators.

NOTICE: The OHRP Human Subject Assurance Training Certificates of Completion (3 modules) located at (http://ohrp-ed.od.nih.gov) must be on file in the BMHCC-IRB office for <u>all</u> investigators participating in this research study prior to final approval or renewal. Certificates included: YES___ NO___ ON FILE___

SPONSOR OR COLLABORATING GROUP:	
NAME: _____	PHONE: _____
ADDRESS: _____	FAX: _____
_____	E-MAIL: _____

LOCAL PROTOCOL COORDINATOR:	
NAME: _____	PHONE: _____
ADDRESS: _____	FAX: _____
_____	E-MAIL: _____

LOCATION OF RESEARCH: BMH Memphis _____ OTHER (specify) _____

APPROVALS: (Yes, No, N/A)	FDA (IND or IDE number): _____
	NIH _____
	Collaborating Group: _____
	Other IRB (specify): _____

**BAPTIST MEMORIAL HEALTH CARE CORPORATION
INSTITUTIONAL REVIEW BOARD**

6025 Walnut Grove Road, Suite 404
MEMPHIS, TENNESSEE 38120

PROGRESS/TERMINATION REPORT

Date: _____

BMH-IRB#: _____

Principal Investigator: _____ Sponsor: _____

Title of Protocol: _____

1. This is a _____ termination report. Skip to item 4.
This is a _____ status report for continuing review approval.

**SUBMIT 1 COPY
SUBMIT 4 COPIES**

4 copies of the most recent IRB approved informed consent must be included for reapproval.

2. Has the protocol been modified in any way since the last review approval? Yes _____ No _____

If yes, please check and submit documentation or summary of the following:

- _____ Amendments/changes affecting treatment.
_____ Amendments/changes affecting patient eligibility.
_____ Amendments/changes affecting patient monitoring.
_____ Amendments/changes regarding serious adverse events* or side effects.

3. Has the informed consent been modified to reflect these modifications?

Yes ___ No ___ NA ___

4. Please complete this status report on the progress of research.

- a. _____ Has this study been conducted? If not, justify continuing approval.
b. _____ # of patients accrued at BMH since last review.
c. _____ # of patients accrued studywide including all centers.
d. _____ # of serious adverse events*, unexpected problems, including deaths. (list on back of page)
e. _____ # of complaints about research. (list on back of page)
f. _____ # of subjects withdrawn or discontinued from study.
f.1. _____ patients withdrew consent, refused further protocol treatments. (specify on back of page)
f.2. _____ patients experienced intolerable expected serious side effects*. (specify on back of page)
f.3. _____ patients had a serious adverse event/complication*. (specify on back of page)
f.4. _____ patients died.
f.5. _____ patients had other reasons. (specify on back of page)

5. Has BMHCC IRB, company sponsor, and/or the FDA been notified about all serious adverse side effects* and serious adverse events* experienced by any patients treated under this protocol?
Yes_____ No_____ NA _____ If no, specify:
6. Have the results of your studies or of similar studies by others changed your estimate of the benefit risk ratio? Yes_____ No_____ If yes, specify:

NOTES FROM ITEM 4 (d, e, f.1, f.2, f.3, f.5) ON FRONT OF PAGE:

(Note: f.1. through f.5 equals the number of patients identified in "f.")

***Definition of Serious Adverse Event (SAE):** Any experience that suggests a significant hazard, contraindication, side effect, or precaution. This includes, but is not limited to, any experience that is fatal, life-threatening, permanently or significantly disabling, requires inpatient hospitalization or prolongation of hospitalization. In addition, congenital anomaly, occurrence of malignancy and overdose are always regarded as serious.

PLEASE RETURN THIS DOCUMENT, FOUR (4) COPIES OF THE MOST RECENT IRB APPROVED INFORMED CONSENT, AND DOCUMENTATION OR SUMMARY OF AMENDMENTS AND/OR CHANGES AS SOON AS POSSIBLE TO THE BAPTIST MEMORIAL HEALTH CARE CORPORATION INSTITUTIONAL REVIEW BOARD FOR CONTINUING REVIEW. DELAY COULD RESULT IN PREMATURE TERMINATION OF THIS PROTOCOL.

NOTICE: The OHRP Human Subject Assurance Training Certificates of Completion (3 modules) located at (<http://ohrp-ed.od.nih.gov>) must be on file in the BMHCC-IRB office for all investigators participating in this research study prior to final approval/renewal of the study. Certificates included: YES__ NO__ ON FILE__

Principal Investigator's Signature

Date

BMHCC IRB POLICY ON INTERNAL REVIEW OF RESEARCH PROPOSALS

1. The **APPLICATION** - Application - must be completed and signed by both the Principal Investigator and the Participating Investigator(s). Investigators may be physicians on the BMH Medical Staff or BMH affiliates with acceptable credentials.
2. **INFORMED CONSENT** - does the informed consent document address those areas specifically required by the BMHCC IRB and FDA? (see attachments)
3. The **SUBJECT** - objectives of the study (what is it all about?).
4. The **PURPOSE** - generally one of three, i.e., an efficacy, toxicity, or comparison study.
5. The **BACKGROUND** - any previous experiments in animals or humans and their results.
6. The **DESIGN** - what are the investigators going to do, how are they going to select patients, what patients are going to be excluded, what procedures will be performed on study patients, how is the information going to be analyzed, etc.
7. **BENEFITS** - a list of specific benefits, not a repeat of the purpose.
8. **RISKS** - include all major risks, especially those of low frequency but serious in nature.
9. The **DURATION** of the study.
10. The **NUMBER** of patients that the investigator anticipates entering.
11. **RECORDS** - what records will be kept, who will keep them, how will the data be evaluated, method of follow-up.

BMHCC-IRB

DOCUMENT SUBMISSION GUIDELINES

Protocols (new) Original signed application page(s) + 20 copies,
20 copies of the protocol **and** 21 copies of the Informed
Consent + 4 copies of the Investigator's Brochure

Each "protocol packet" must be stapled together as one unit in the following order:

- (1) Application page + OHRP Certificates for each investigator (see application page)
- (2) Additional signature page(s) when applicable
- (3) Protocol
- (4) Informed Consent Document
- (5) Investigator's Brochure, when applicable. (This may be attached to the back of the protocol with a rubber band due to the size of most brochures.)

Amendments Original + 4 copies
Informed Consent Original + 4 copies + 5 copies of the latest
BMHCC-IRB approved consent

Informational Amendments 1 original (mainly administrative/editorial changes
to protocol and/or consent document not requiring
IRB approval)

Please use a highlighter (a yellow marker is preferred) or another recognizable means such as italicization, bold type and/or strikethrough to indicate any additions, changes and/or corrections made to the protocol and/or the informed consent document to facilitate review and approval.

Reapprovals 1 original (signed) copy of the Progress Report +
3 copies **and**
4 copies of the latest BMHCC-IRB approved
consent (for comparison)
\$500 annual renewal fee

Terminations 1 original (signed) Termination Report

Adverse Event Reports 1 copy of report with cover letter

Investigator's Brochure 1 copy of brochure with cover letter

BAPTIST MEMORIAL HEALTH CARE CORPORATION

INSTITUTIONAL REVIEW BOARD

6025 Walnut Grove Road, Suite 404
MEMPHIS, TENNESSEE 38120

J. CAMERON HALL, M.D., CHAIRMAN

April, 2006

The following are the most current IRB guidelines for document submission. The guidelines should assist in the processing of all correspondence to the Baptist Memorial Health Care Corporation Institutional Review Board. If you have any questions, please do not hesitate to call the BMHCC-IRB office at (901) 226-1677.

PROTOCOL ADDITIONS, REVISIONS, CHANGES

When additions/changes are made to a protocol, an informed consent or any protocol related document, please state as such in the cover letter and include a brief description of the current change(s) to the document. These changes need to be highlighted in all copies of the document, preferably with a yellow marker, or by another recognizable means such as italicization, bold type and/or strikethrough in order to facilitate review and approval. Additionally, include a statement as to whether or not IRB approval of the document is required.

Submit five (5) copies of Amendments, Addendums, Revisions and/or Informed Consent documents requiring IRB approval and five (5) copies of the most recent approved Informed Consent document.

Include the original date and the date of each revision of the Informed Consent document in the header or footer of the signature page and preferably in the header or footer of each page. The revision date should reflect the date of any change made to a document regardless of the nature of the change, i.e., requested change, typographical correction, etc. A smaller font may be used for headers or footers if desired.

Submit four (4) copies (1 original and 3 copies) of the Progress Report and four (4) copies of the most recent approved Informed Consent document and any additional documentation necessary.

Progress Reports should be submitted at least one month prior to the expiration date. The study must be renewed **prior to** the expiration date, if the study is ongoing, or the study will be terminated. Notification of termination will be sent to the Participating Investigators, Sponsor/Company of the protocol and the FDA (if applicable). Protocols more than three months delinquent must be resubmitted to the Baptist Memorial Health Care Corporation Institutional Review Board for review (investigator will provide the 20 copies).

The continuation of research after expiration of IRB approval is a violation of FDA regulation [21 CFR 56.103(a)]. If the IRB has not reviewed and approved a research study by the study's current expiration date, i.e., IRB approval has expired and research activities should stop. No new subjects may be enrolled in the study. When a protocol is terminated, appropriate follow-up care should be continued so as not to jeopardize patient safety/welfare.

ADVERSE EVENT REPORTS

The following guidelines should assist in the submission of Adverse Events to the BMHCC-IRB. When available, please include a copy of the original report or the MedWatch report with (not in place of) the cover letter summarization. Each Adverse Event should be "briefly summarized" in a cover letter attached to the AE report(s) document stating the following:

BMH-IRB Number

Title of Protocol

Principal Investigator

Clinical Evaluation

Patient: "Patient ID number or initials"

Study Site: "Local or non-local"

Type of Report: "Initial, Follow-up, etc."

Date of onset: "Date of Adverse Event"

Event: "Brief description of Adverse Event"

Outcome: "Brief summary"

Assessment of Relationship: "None, unlikely, possible, probable, unknown, not assessable, etc." as determined by the Principal Investigator, physician, or sponsor.

This Adverse Event "**will/will not**" necessitate a revision to the informed consent document for this study.

OR this table format may be used

Date/ Report No.	Report Type	Patient	Event	Outcome	Relationship
Usually date of cover letter	Initial/FU , etc.	Age/gender			
05-26-05 0000 -00000	F/u #3 – non-local	50 yom	Renal Failure Acute Right ventricular failure asthma	Recovered/Resolved	Possible

On September 26, 1996, the Baptist Memorial Health Care Corporation Institutional Review Board voted that "it is expected that patients enrolled in this study who have identified adverse events will have these events reported to the Adverse Events Committee of the Baptist Memorial Hospital. The PI is responsible for reporting adverse events and should follow hospital guidelines using the ADE collection form in the front of each patient's chart. **This is in addition to the required reporting of adverse events to the IRB.**"

Please do not include multiple documents such as SAEs, Progress Reports, Amendments, etc., under one cover letter. Each type of document requires individual processing. Multiple Adverse Events for the same study may be submitted together but each must follow the above guidelines.

Code of Federal Regulations Revised as of April 1, 2002

**TITLE 21--FOOD AND DRUGS PART 50--PROTECTION OF HUMAN SUBJECTS
Table of Contents Subpart B--Informed Consent of Human Subjects**

Sec. 50.25 Elements of informed consent.

- (a) Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject:
- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
 - (2) A description of any reasonably foreseeable risks or discomforts to the subject.
 - (3) A description of any benefits to the subject or to others which may reasonably be expected from the research.
 - (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
 - (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.
 - (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
 - (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
 - (8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- (b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:
- (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
 - (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
 - (3) Any additional costs to the subject that may result from participation in the research.
 - (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
 - (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
 - (6) The approximate number of subjects involved in the study.
- (c) The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective. [[Page 285]]
- (d) Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local law.

BAPTIST MEMORIAL HEALTH CARE CORPORATION INSTITUTIONAL REVIEW BOARD

INFORMED CONSENT GUIDELINES

1. When informed of persons to contact with questions concerning the research project, the BMHCC IRB should not be specifically listed.
2. Concerning additional elements of Informed Consent, the IRB requires that patients be informed that:
 - a. there may be unforeseeable risks;
 - b. there may be circumstances under which the subject's participation is terminated by the investigator;
 - c. the patient may have responsibility to maintain certain procedures related to the research even if he/she decides to withdraw from the project itself.
3. Patients should be specifically informed of any additional costs for their care which are directly related to the research project. A statement acknowledging that increased costs directly related to the research study should be explained to the patient must be included in the Informed Consent.
4. The informed consent needs to be written in layman's language, i.e. 9th grade reading level. Clearly define all medical terminology and if necessary, attach a glossary containing definitions of terms in layman's language.
5. Please have all possessive case pronouns be consistent throughout the document. Example "I, me, my" or "you, your".
6. Surrogate Consent - Mentally incompetent patients may not enter protocols without durable power of attorney for healthcare unless confronted with a life-threatening situation necessitating the use of the test article.
7. The following Ombudsman Statement is to be included in the Informed Consent:

"If questions arise regarding the ethical aspects of my participation and/or my rights as a research subject, I may contact Rev. Anthony Burdick, Baptist Memorial Hospital, at (901) 226-5025."
8. The following statement is to be included in the Informed Consent:

"A copy of this signed consent form is required to be present on my medical chart throughout my hospitalization at Baptist Memorial Hospital (*specify BMH facility, i.e., Collierville, DeSoto, Memphis, etc.*), and on subsequent charts should I have to be readmitted while on this particular study. This copy will become a permanent part of my medical record."

BAPTIST MEMORIAL HEALTH CARE CORPORATION INSTITUTIONAL REVIEW BOARD

INFORMED CONSENT GUIDELINES *continued*

9. The following disclaimer statement must be included in the Informed Consent:

"I understand that in the event of physical or psychological injury from this research procedure, Baptist Memorial Hospital (*specify BMH facility, i.e., Collierville, DeSoto, Memphis, etc.*) does not have funds for patient compensation either for lost wages or for treatment. Therefore, Baptist Memorial Hospital (*specify BMH facility, i.e., Collierville, DeSoto, Memphis, etc.*) does not provide reimbursement for such injuries. Baptist Memorial Hospital (*specify BMH facility, i.e., Collierville, DeSoto, Memphis, etc.*) will provide the medical and ancillary services ordered by my physician at the established charges for those services."

10. In the Patient Confidentiality section, include the Baptist Memorial Health Care Corporation Institutional Review Board as one of the parties having access to the patient's medical records related to this study.

11. Before the signature lines, include the following:

"I understand that taking part in this research project is voluntary. I have read and understand the nature of this research project and have been given the opportunity to ask any questions that I may have. My signature indicates I voluntarily agree to participate in this research project. I understand that upon signing this consent document, I will be given a signed and dated copy for my records."

12. The Signature of the person obtaining consent and a Date/Time line, as illustrated below, are required by the IRB to be on all informed consents utilized in the BMH system to assure compliance with JCAHO.

Signature of person obtaining consent

Date/Time

INFORMED CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

Title of Study:

Protocol No.:

Sponsor:

Investigator:

Participating Investigators:

Telephone:

INTRODUCTION

You are being asked to participate in a research study. Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed procedures. This document describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study.

PURPOSE

PROCEDURES

POSSIBLE RISKS

Any treatment has possible side effects. The treatments used in this study may cause all, some, or none of the side effects described.

POSSIBLE BENEFITS

There may or may not be any medical benefit to you from participating in this study. The information gained from this study may be used scientifically and may be helpful to others.

ALTERNATIVE TREATMENTS

NEW FINDINGS

COSTS

COMPENSATION FOR INJURY

(Required):

I understand that in the event of physical or psychological injury from this research procedure, Baptist Memorial Hospital (specify BMH facility, i.e., DeSoto, Collierville, etc.) does not have funds for patient compensation either for lost wages or for treatment. Therefore, Baptist Memorial Hospital (specify BMH facility, i.e., DeSoto, Collierville, etc.) does not provide reimbursement for such injuries. Baptist Memorial Hospital (specify BMH facility, i.e., DeSoto, Collierville, etc.) will provide the medical and ancillary services ordered by my physician at the established charges for those services.”

COMPENSATION FOR PARTICIPATION

CONFIDENTIALITY (HIPAA)

insert HIPAA section here

(Required):

*“A copy of this signed consent form is required to be present on my medical chart throughout my hospitalization at Baptist Memorial Hospital (specify BMH facility, i.e., DeSoto, Collierville, etc.), and on subsequent charts should I have to be readmitted while on this particular study. This copy will become a permanent part of my medical record.”
(This statement is not required when the study is a patient survey, and not a treatment study.)*

CONTACT FOR QUESTIONS

(Required):

“If questions arise regarding the ethical aspects of my participation and/or my rights as a research subject, I may contact Rev. Anthony Burdick, Baptist Memorial Health Care Corporation, at (901) 226-5025.”

VOLUNTARY PARTICIPATION

CONSENT TO PARTICIPATE

The research study, procedures, risks and benefits have been explained to me. I have read and understand all of the above, been given the opportunity to ask questions, and my questions have been answered to my satisfaction. I voluntarily agree to participate in this research study. I will be given a copy of this signed and dated consent form for my own records. I do not give up any of my legal rights by signing this consent form.

Name of Participant (printed)

Signature of Participant

Date/Time

Name of Investigator (printed)

Signature of Investigator

Date/Time

Name of Person Obtaining Consent (printed)

Signature of Person Obtaining Consent

Date/Time

**THIS SPACE HAS BEEN
INTENTIONALLY LEFT BLANK**

**BAPTIST MEMORIAL HEALTH CARE CORPORATION
INSTITUTIONAL REVIEW BOARD**

**HIPAA PRIVACY REGULATIONS
AND MEDICAL RESEARCH:
BMHCC-IRB GUIDANCE AND PROCEDURES**

REVISION OF IRB POLICIES AND PROCEDURES

In 2003, implementation of the privacy regulations required revision in IRB policies and procedures. These changes affected all new applications and previously approved studies, provided that at least some of the subjects would be accrued on or after April 14, 2003. In addition, the provisions of the privacy rule must be satisfied for both studies in which informed consent is required and those in which informed consent has been altered or waived.

New Applications

For all new studies received in the IRB office, the application must specify in the section on confidentiality either that the research use and disclosure of PHI will be undertaken with authorization, or that the research use or disclosure satisfies one of the conditions under which subject authorization is not required under the privacy regulations.

For studies in which subject authorization for the use and disclosure of PHI is required, the confidentiality section of the subject consent form must include the required authorization disclosure. The required disclosure is provided in appendix A. The authorization language must either mirror the language in Appendix A or must otherwise meet the requirements outlined in the HIPAA Privacy and Security regulations. The model confidentiality section, as revised to include the authorization for the use of PHI, is provided in Appendix B. The investigator will receive approval for the authorization language in a separate paragraph of the final approval letter for the study.

For studies in which the use or disclosure of PHI may satisfy one of the conditions under which subject authorization is not required under the privacy regulations, the investigator must submit the BMHCC-IRB, "Request for Research Use and Disclosure of Protected Health Information Without Subject Authorization" (see Appendix C). The investigator will receive a separate approval letter for the use and disclosure of PHI without subject authorization. This approval letter must be presented to the Health Information Management Department (HIM) of the entity maintaining the PHI to establish that the IRB has reviewed the proposed use

and disclosure of PHI without subject authorization and has determined that it satisfies the regulatory requirements. If the PHI is maintained by the investigator, the letter should simply be retained as confirmation that the regulatory requirements have been satisfied for using or disclosing PHI in research without subject authorization.

**BAPTIST MEMORIAL HEALTH CARE CORPORATION
INSTITUTIONAL REVIEW BOARD**

**SUBJECT AUTHORIZATION
TO USE AND DISCLOSE INDIVIDUALLY IDENTIFIABLE
HEALTH INFORMATION IN MEDICAL RESEARCH**

**TEMPLATE FOR HIPAA PORTION
OF THE CONFIDENTIALITY SECTION
OF THE STUDY CONSENT FORM**

APPENDIX A

**SUBJECT AUTHORIZATION
TO USE AND DISCLOSE INDIVIDUALLY IDENTIFIABLE
HEALTH INFORMATION IN MEDICAL RESEARCH**

**TEMPLATE FOR HIPAA PORTION
OF THE CONFIDENTIALITY SECTION
OF THE STUDY CONSENT FORM**

The subject authorization language provided below should be inserted at the appropriate location in the confidentiality section of the study consent form (see Appendix B). The authorization language must either mirror the language in Appendix A or must otherwise meet the requirements outlined in the HIPAA Privacy and Security regulations. The material in block form is the required authorization language. The *italicized* material in parentheses provides directions for including material that may or may not be relevant for particular studies.

Under federal privacy regulations, you have the right to determine who has access to your personal health information (called “protected health information” or PHI). PHI collected in this study may include your medical history, the results of physical exams, lab tests, x-ray exams, and other diagnostic and treatment procedures, as well as basic demographic information. By signing this consent form, you are authorizing the researchers to have access to your PHI collected in this study (*if the study will use PHI in the possession of another covered entity, add*) and to receive your PHI from (*either*) your physician (*and/or*) facilities where you have received health care. (*If any of the following individuals or entities will also be reviewing the PHI collected or received for the study, then add the following sentence.*) In addition, your PHI may be shared with other persons involved in the conduct or oversight of this research, including (*if the study is multi-institutional, add*) researchers at (*name of the institutions*); (*if a cooperative group study, add*) the (*name of the cooperative group*); (*if the research involves an FDA-regulated drug, device or biologic, add*) the Food and Drug Administration (FDA); and (*if claims for some of the procedures performed during the study will be submitted to third party payers, add*) your medical insurance carrier. (*If the research is sponsored, add*) Your PHI may also be shared with (*name of sponsor*), which sponsors and provides funds for this research; (*name of CRO, if applicable*) which has been hired by the sponsor to coordinate the study; and a Data and Safety Monitoring

Committee (if applicable). (If the previous sentence was used, add the following sentence as well.) However, these latter organizations may not have the same obligations to protect your PHI. The Baptist Memorial Health Care Corporation Institutional Review Board (IRB) may review your PHI as part of its responsibility to protect the rights and welfare of research subjects. Your PHI will not be used or disclosed to any other person or entity, except as required by law, or for authorized oversight of this research study by other regulatory agencies, or for other research for which the use and disclosure of your PHI has been approved by the IRB. Your PHI will be used only for the research purposes described in the Introduction of this consent form. Your PHI will be used (either) until the study is completed (or if the research is FDA regulated) for as long as the sponsor reports study data to the FDA (or if the research is without a foreseeable end-point, such as a repository or a registry) indefinitely. (**PLEASE NOTE: CHOOSE ONLY ONE OF THESE, NOT ALL THREE**)

You may cancel this authorization in writing at any time by contacting the principal investigator listed on the first page of the consent form. If you cancel the authorization, continued use of your PHI is permitted if it was obtained before the cancellation and its use is necessary in completing the research. However, PHI collected after your cancellation may not be used in the study. If you refuse to provide this authorization, you will not be able to participate in the research study. If you cancel the authorization, then you will be withdrawn from the study. Finally, the federal regulations allow you to obtain access to your PHI collected or used in this study. (If the research study includes treatment of subjects, add the following sentences.) However, in order to complete the research, your access to this PHI may be temporarily suspended while the research is in progress. When the study is completed, your right of access to this information will be reinstated.

**BAPTIST MEMORIAL HEALTH CARE CORPORATION
INSTITUTIONAL REVIEW BOARD**

**REVISED TEMPLATE FOR THE CONFIDENTIALITY SECTION
OF THE CONSENT FORM**

APPENDIX B

**BAPTIST MEMORIAL HEALTH CARE CORPORATION
INSTITUTIONAL REVIEW BOARD**

**REVISED TEMPLATE FOR THE CONFIDENTIALITY SECTION
OF THE CONSENT FORM**

CONFIDENTIALITY:

1. Provide a statement explaining how individual identifiers will be used in maintaining the research records. (E.g., “Your research record will be labeled with your name.” or “Your research record will be labeled with a code number. A master key that links your name and the code number will be maintained in a separate and secure location.”)
2. Insert the HIPAA authorization portion of the confidentiality section.
3. If the study involves the use of a federal Certificate of Confidentiality, provide the information about the certificate and how it protects subject information from re-disclosure.
4. If information about the subject’s participation in the study or the results of procedures performed in the study will be placed in the subject’s medical record (as contrasted with the research record), then this should be explained. Indicate that information placed in the medical record may be available to the subject’s employer or insurer.
5. State that individual subjects will not be identified in any presentations or publications based on the results of the research study.

**BAPTIST MEMORIAL HEALTH CARE CORPORATION
INSTITUTIONAL REVIEW BOARD**

6025 Walnut Grove Road, Suite 404
MEMPHIS, TENNESSEE 38120

J. CAMERON HALL, M.D., CHAIRMAN

**Request for Research Use and Disclosure of Protected Health Information
Without Subject Authorization**

APPENDIX C

BAPTIST MEMORIAL HEALTH CARE CORPORATION INSTITUTIONAL REVIEW BOARD

6025 Walnut Grove Road, Suite 404
MEMPHIS, TENNESSEE 38120

J. CAMERON HALL, M.D., CHAIRMAN

Request for Research Use and Disclosure of Protected Health Information Without Subject Authorization

Researcher's Name: _____

Address: _____

Phone: _____ Fax: _____

Email: _____

Location of Research: _____

1. Purpose of the request to review protected health information:

2. Do you plan to record any patient identifiers? Yes _____ No _____

(Examples of identifiers: name, address, telephone number, social security number, date of birth, race, sex, hospital admission number, medical records number, physician, diagnosis).

(a). If you answered Yes to the above question, please list the identifiers you will be recording:

(b). If you will be recording patient identifiers, please describe how you will secure and protect the recorded identifiers from improper use and/or disclosure:

(c). If you will be recording patient identifiers, please list the methods you will use to destroy the identifiers and the expected time frame for destruction:

(d). If you will not be destroying the patient identifiers, please list your justification:

BAPTIST MEMORIAL HEALTH CARE CORPORATION INSTITUTIONAL REVIEW BOARD

6025 Walnut Grove Road, Suite 404
MEMPHIS, TENNESSEE 38120

J. CAMERON HALL, M.D., CHAIRMAN

Please read the following statements and confirm your acceptance and agreement to abide by the conditions by signing and dating below:

1. I am seeking to review protected health information solely for the purpose of preparing a research protocol or for similar purposes preparatory to research.
2. I will not remove any protected health information from the covered entity during the course of the review.
3. It would not be practical to obtain authorizations from each patient whose information may be accessed during the proposed review of protected health information.
4. It is not practical to prepare a research protocol without accessing and/or using protected health information.
5. I will take all reasonable steps to protect the patient identifiers, if any are recorded.
6. I will not reuse or disclose protected health information obtained as a result of my review of protected health information, other than to the extent required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by law.

Signature of Researcher

Date

Please complete and return to BMHCC IRB via mail at the above address or you may fax the documents to 226-1680. Please call the IRB office at 226-1677 if you have any questions.

**Baptist Memorial Health Care Corporation
Institutional Review Board
Information Sheet**

Overview of policy: The purpose of the Institutional Review Board (IRB) Policies is to provide BMHCC investigators and staff with an educational resource that can be used in the preparation and submission of research proposals, including informed consent forms, for review by the IRB. The policies are also designed to provide information on the ethical and legal duties of investigators during the conduct of human subject research. The policies, which serve as the official governance document for human subject research, reflect both the recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and the Federal Regulations (45 CFR 46, 21 CFR 50, 21 CFR 56) which govern human subject research as amended to incorporate the Common Rule (FR 56. No.117, 28002). Also, included in these policies, as an addendum, are the guidance and procedures to assure HIPAA compliance in research.

All research conducted in any BMHCC facility will require BMHCC Institutional Review Board approval. Nothing in the IRB Policies and/or the Federal Regulations governing human subject research is intended to limit the authority of a physician or any other health care personnel to provide emergency medical care to the extent the individual is permitted to do so under applicable Federal, State, or Local law.

Primary owner of policy: Henrietta Davis, Director Clinical Research and IRB Vice-Chairperson

Questions: Sandra Scott, BMHCC Institutional Review Board Administrative Coordinator

Recommended minimum distribution: Should include any department involved in clinical research conducted at any Baptist facility, including, but not limited to the following:

Administration (high level overview)
Board of Directors (high level overview)
Business Office
Clinical Ancillary Departments
Health Information Management
Medical Staff Services
Nursing
Pharmacy

Policy approval process:
BMHCC Institutional Review Board
Privacy and Security Committee
Administrative Leadership Team
Board of Directors

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Institutional Authority/Purpose/Policy
Last Revision: 06/05	
Reference #: S.IRB.1101	

I. Institutional Authority

The Baptist Memorial Health Care Corporation Institutional Review Board (BMHCC IRB) is empowered by the Baptist Memorial Health Care Corporation (BMHCC) to function independently as an Institutional Review Board (IRB) while incorporating the mission and purpose of BMHCC. [21 CFR 56.109(a)]

II. Purpose

The purpose of the BMHCC IRB is to facilitate clinical research by the review and approval of research protocols and their associated forms, assuring the scientific merit of the protocols and safeguarding the rights and welfare of the clinical research subjects. [21 CFR 56.101(a)]

III. Policy

The BMHCC IRB policies and procedures are standardized in structure, format, process and communication to facilitate uniformity in compliance with U.S. Food and Drug Administration regulations. The principles, which govern the BMHCC IRB, are the International Conference on Harmonisation Good Clinical Practice Consolidated Guidelines for the assurance for protection of the rights and welfare of research subjects.

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Standard Operating Procedures Glossary of Terms
Last Revision: 06/05	
Reference #: S.IRB.1102	

I. Standard Operating Procedures

The Standard Operating Procedures (SOP) provides definitions and guidelines for IRB personnel, board members, investigators and hospital administrations.

II. Maintenance

The SOP is housed in the IRB office and is available to all authorized persons. A copy of the SOP is given to each IRB member and alternate.

III. Review

The SOP is reviewed and revised annually.

IV. Definitions

A. Clinical Trial

The systematic investigation of the effects of materials (i.e., investigational drugs, devices) or methods (i.e., surgery, radiation) on a disease state conducted according to a formal study plan (protocol). Generally, a clinical trial refers to the evaluation of treatment methods (drugs, surgery, etc.) although methods of prevention, detection or diagnosis may also be the object of a clinical trial.

B. Food and Drug Administration (FDA)

The federal agency responsible for regulating the sale of food, drugs and cosmetics in the United States.

C. Institutional Review Board (IRB)

An independent body of medical and non-medical members established according to requirements outlined in Title 21, part 56 of the U.S. Code of Federal Regulations (21CFR56). The IRB, usually institution-specific, is responsible for the initial and continuing approval of research involving human subjects, as well as for verifying the protection of safety and rights of those human subjects.

D. Investigator (Principal Investigator, PI)

As the leader of the investigational team, this individual (usually a physician or dentist) is responsible for conducting the clinical trial and ensuring the safety and welfare of the study subjects. For studies conducted for a commercial sponsor or government grant, the investigator signs the FDA Statement of Investigator form (1572), per 21CFR312.3, "means an individual

who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject). In the event a team of individuals conducts an investigation, the investigator is the responsible leader of the team. ‘Participating-investigator’ indicates any other member of that team.”

E. Investigator’s Brochure

Collection of all relevant information on the investigational product known prior to the start-up of a particular clinical trial including pre-clinical data such as chemical, pharmaceutical, toxicological, pharmacokinetic and pharmacodynamic data in animals and in man; and the results of earlier clinical trials. The data should support the justification for the proposed trial and evaluate safety or precautions. The brochure should be updated on a continual basis as new information is gathered.

F. Sponsor

Individual or organization, which takes responsibility for initiation, organization and management of a clinical trial. Per 21CFR312.2, “means a person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, government agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator, and the employees are investigators.”

G. Subject

A human being (patient or non-patient volunteer) participating in a clinical trial. They may be:

1. a healthy person volunteering in a trial,
2. a person with a condition unrelated to the use of the investigational product,
3. a person whose condition is related to the use of the investigational product,
4. either a recipient of the study drug being tested, or a control. Per 21CFR312.2, “means a human who participates in an investigation, either as a recipient of the investigational new drug or as a control.

A subject may be a healthy human or a patient with a disease.”

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Scope of Authority/Relationships
Last Revision: 06/05	
Reference #: S.IRB.1103	

I. Scope of Authority

- A. The BMHCC IRB has the authority to recommend modifications to, disapprove, or approve all research protocols, which are presented to the BMHCC IRB based upon consideration of human subject protection. [21 CFR 56.109(a)]
- B. The BMHCC IRB has the authority to require regular accurate progress reports from the investigators, and to oversee the conduct of the study at such time that the BMHCC IRB feels it is necessary. [21 CFR 56.108(a)(1) and 56.109(f)]
- C. The BMHCC IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements listed in these operating procedures, or that is associated with unexpected serious harm to subjects or allegations of possible serious harm. Any such suspension or termination, including a statement of the reasons for the IRB's actions, shall be reported promptly to the investigator, appropriate institutional officials, and the Food and Drug Administration (FDA). [21 CFR 56.108(b)(3) and 56.113]
- D. The BMHCC IRB adheres to the following statements: Research institutions bear primary responsibility for prevention and detection of research misconduct and for the inquiry, investigation and adjudication of research misconduct alleged to have occurred in association with their own institution. Research institutions will notify the funding agency of an allegation of research misconduct if 1) the allegation involves Federally funded research and meets the Federal definition of research misconduct, and 2) the institution's inquiry into the allegation determines there is sufficient evidence to proceed to an investigation. When the investigation is complete, the research institution will notify the agency in writing of all decisions and actions taken or planned. [From the Federal Policy on Research Misconduct, Federal Register, December 6, 2000, Volume 65, Number 235]
- E. The BMHCC IRB has the authority to place restrictions on any study that the IRB has reason to believe is not being conducted in accordance with the requirements of the IRB or the FDA. [21 CFR 56.108(a)(1), 56.109(a) and 56.113]

II. Relationships

- A. The BMHCC IRB is an independent board but is ultimately accountable to the Vice President, Metro Memphis, BMHCC.
- B. The BMHCC IRB provides informational guidelines to research investigators to aid in protocol submission. The chairperson and members of the IRB are available to receive questions and concerns from investigators. The BMHCC IRB expects the principal investigators to be familiar with Good Clinical Practice guidelines and FDA requirements as set forth on Form 1572. [21 CFR 50 and 21 CFR 312.60]
- C. The BMHCC IRB does not accept the review of a protocol by any other IRB.
- D. The BMHCC IRB is participating in the OHRP IRB registry.

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Membership
Last Revision: 06/05	
Reference #: S.IRB.1104	

I. **Membership**

- A. Members of the BMHCC IRB are selected and retained as long as it is mutually acceptable to the IRB, the chairperson, and the institution's administration. The BMHCC IRB has at least five members with varying backgrounds. [21 CFR 56.107(a)] (See membership list)

- B. The BMHCC IRB is sufficiently qualified through the experience and expertise of its members to safeguard the rights and welfare of human subjects. [21 CFR 56.107(a)]

- C. The BMHCC IRB ensures diversity of membership [21 CFR 56.107(a)] by including representation by:
 - 2. members not all of the same gender or profession [21 CFR 56.107(a)(b)]
 - 3. at least one member whose primary concerns are in scientific areas [21 CFR 56.107(c)]
 - 4. at least one member whose primary concerns are in nonscientific areas [21 CFR 56.107(c)]
 - 5. at least one member who is not affiliated, or related to someone who is affiliated, with the institution [21 CFR 56.107(d)]

- D. Members recommend alternates of similar background and expertise to the IRB for approval and these alternates attend meetings when the member is unable to attend. Potential alternates are voted into the board by unanimous agreement prior to their becoming alternates. When alternates attend the same meeting with the member that they represent, only one of them votes.

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Chairperson/Vice-Chairperson/Members
Last Revision: 08/05	
Reference #: S.IRB.1105	

I. Chairperson

Selected based on qualifications with appropriate medical background, he/she retains the position as long as it is mutually acceptable to the chairperson, the board, and the institution's administration. The duties include, but are not limited to: facilitating and presiding at the meetings, acting as a resource person, directing expedited reviews or delegating this task to an experienced reviewer, and directing all IRB correspondence and business. The chairperson does not receive compensation for serving as chairperson, other than regular salary from his/her employer.

II. Vice-Chairperson

A vice-chairperson is similarly appointed by the board and serves in the chairperson's absence.

III. Members

Persons become members by either indicating an interest in serving on the board or by being asked to become a member. Potential members are voted into the board by unanimous agreement prior to their becoming a member. Members are retained as long as it is mutually acceptable to the board, the chairperson, and the institution's administration. Duties include: reviewing protocols prior to the meetings, reporting at the meeting on protocols specifically assigned to the member, voting for approval or disapproval of protocols, amendments and other reports regarding studies. It is required that the member or their alternate attend the majority of meetings scheduled within a six-month period or be removed from the membership.

Alternate members are selected and approved for each member in the same manner as are members. Alternates receive the same training as members and attend at least two meetings before being listed as an alternate.

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Training of Members
Last Revision: 06/05	
Reference #: S.IRB.1106	

I. Orientation

At the time of induction of a new member, the member or alternate is introduced to the staff of the BMHCC IRB office, familiarized with the content, security and location of study files. The new member receives a new member packet to review, which includes the information given to investigators submitting protocols. New members attend several meetings before being assigned as a reviewer. Members and alternates are requested to complete the NIH computer-based Training Module for Assurances (<http://ohrp-ed.od.nih.gov>).

II. Continuing Education

A symposium on human rights in general, ethical and safety issues involving human subject research, and FDA requirements for IRB members and alternates is offered yearly.

III. Reference Materials

Reference materials are available in the BMHCC IRB office for review by any member or alternate.

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Compensation/Liability/Consultants
Last Revision: 06/05	
Reference #: S.IRB.1107	

I. Compensation

No member, including the chairperson, is monetarily compensated above his/her regular salary for serving on the BMHCC IRB. A luncheon is provided during each meeting.

There is a charge of \$1500 for IRB initial review and approval for commercially sponsored trials, and a subsequent charge of \$500 per year (for annual review, amendments, adverse events, etc.) There is no charge for government sponsored trials or locally initiated trials.

II. Liability Coverage For Members and Alternates

Members and alternates who are employees or associates of BMHCC are covered for liability. The community representative is covered as a volunteer after filling out a volunteer application.

III. Consultants

Individuals with competence in specific areas are invited to attend a meeting and assist in the review of a complex issue, which requires expertise beyond or in addition to that available among IRB members. Such individuals attend only the discussion of that particular study, and are not able to vote. [21 CFR 56.107(f)] (Use of consultants is not a requirement of the FDA.)

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Administrative Coordinator/Resources/ Conflict of Interest
Last Revision: 06/05	
Reference #: S.IRB.1108	

I. Administrative Coordinator

The BMHCC IRB administrative coordinator is an employee of the BMHCC, and is accountable to the IRB chairperson and the institution's administrative department director. Duties include: preparation for and scheduling of IRB meetings, arranging for luncheon service and meeting room, facilitating the recording of minutes, producing IRB correspondence under the direction of the chairperson, maintaining the study files, recording IRB budget expenses and filing notices in compliance with other regulatory duties.

II. Resources

- A. BMHCC IRB files are kept in locked file cabinets in a locked office.
- B. The IRB administrative coordinator has a computer which is networked with BMHCC, access to a facsimile machine, a copier and a document shredding service.

III. Conflict of Interest

- A. No IRB member is selected by investigators.
- B. Principal investigators do not participate in IRB deliberations and voting. If an IRB member is professionally involved with the protocol being discussed, he/she is not a reviewer, abstains from voting, and only takes part in the discussion by providing clarification to questions. [21 CFR 56.107(e)]

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Initial Review
Last Revision: 02/06	
Reference #: S.IRB.1109	

- A. Any investigational research which is conducted within the premises of any BMHCC facility, or which may involve treatment of the subject(s) within the premises of any BMHCC facility, is reviewed and approved by the BMHCC IRB before such research can occur. (Exception: see “emergency use)
- B. New protocols are submitted with:
- A. One original and 20 copies of the BMHCC IRB application page
 - B. 21 copies of the protocol
 - C. 21 copies of the informed consent with the following required statements included:
 1. “If questions arise regarding the ethical aspects of my participation and/or my rights as a research subject, I may contact Rev. Anthony Burdick, Baptist Memorial Health Care Corporation, at (901) 226-5025.”
 2. “A copy of this signed consent form is required to be present on my medical chart throughout my hospitalization at Baptist Memorial Hospital (*specify BMH facility, i.e., DeSoto, Collierville, etc.*), and on subsequent charts should I have to be readmitted while on this particular study. This copy will become a permanent part of my medical record.” (This statement is not required when the study is a patient survey, and not a treatment study.)
 3. I understand that in the event of physical or psychological injury from this research procedure, Baptist Memorial Hospital (*specify BMH facility, i.e., DeSoto, Collierville, etc.*) does not have funds for patient compensation either for lost wages or for treatment. Therefore, Baptist Memorial Hospital (*specify BMH facility, i.e., DeSoto, Collierville, etc.*) does not provide reimbursement for such injuries. Baptist Memorial Hospital (*specify BMH facility, i.e., DeSoto, Collierville, etc.*) will provide the medical and ancillary services ordered by my physician at the established charges for those services.”
 4. Include a line in the footer of each page of the Informed Consent document for the patient's initials.
(Example: Patient's initials _____)
 5. All pages of the Informed Consent document must be numbered as Page 1 of 5, Page 2 of 5, etc.

6. The original date and the most current revision date must be included in the informed consent document in the footer of the signature page and preferably in the footer of each page. The revision date should reflect the date of any change made to the document regardless of the nature of the change, i.e., requested change, typographical correction, etc. A smaller font may be used in the footer if desired.
7. The Signature of the person obtaining consent and a Date/Time line, as illustrated below, are required by the IRB to be on all informed consents utilized in the Baptist system to assure compliance with JCAHO.

Signature of person obtaining consent

Date/Time

8. A copy of the 1572 (for drug studies) (All revisions to the 1572 are submitted at the time of revision.)
 9. 4 copies of the investigator's brochure.
- D. Protocols are presented to the board in the chronological order in which they are received.
- E. All advertisements or publications for recruitment of study subjects connected with a study are reviewed by the full board at a convened meeting and cannot be used until they are approved. Any advertisement which involves Baptist is also reviewed and approved by the marketing department of the hospital before it can be used.

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Duplicate Review
Last Revision: 06/05	
Reference #: S.IRB.1110	

For Principal Investigators (PI) who wish to conduct a study already approved by the IRB for another investigator, a duplicate review is requested.

- I. The PI checks with the IRB administrative coordinator to make sure that his/her protocol and informed consent is a duplicate of another approved protocol.
- II. The PI contacts the PI/coordinator of the approved protocol to ensure that the application is identical. The only changes allowed are in the consent and application page for the PI and local ombudsman (if the duplicate study is not in the metro Memphis area).
- III. The PI submits 4 copies of the application page, Duplicate Review Tracking Sheet, informed consent document, protocol and Investigator's brochure, along with a cover letter indicating that this protocol is for duplicate review.
- IV. The IRB administrative coordinator distributes the packets to the reviewers of the original protocol and presents the protocol to the full board, which follows regular approval guidelines.
- V. Although the protocol documents are identical (except as stated above for the informed consent), the IRB files are kept separate, duplicate reviews protocols are assigned a new BMH-IRB number, and *are* treated as separate studies.

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Continuing Review [21 CFR 56.109(a-f)]
Last Revision: 06/05	
Reference #: S.IRB.1111	

- I. At any time following the approval of a study that any of the following actions occur, they are reported immediately to the IRB:
 - A. Changes in the research proposal
 - B. Protocol violations
 - C. Changes in the consent
 - D. Any exceptions made by the sponsor
 - E. Unexpected or serious adverse events, either local or otherwise
 - F. Withdrawal from the study
- II. Five copies of amendments/revisions are submitted to the board for review by the three original reviewers before a convened meeting (one copy is for the chairperson and one copy is for the IRB file). Changes to the protocol in the form of the amendment/revision are not initiated until the investigator is informed of board approval by phone and/or letter from the IRB. If it is deemed by the investigator to be necessary to initiate the amendment/revision before board approval in order to eliminate apparent immediate hazards to the subjects, he/she may do so, but a written report to the IRB is submitted explaining this action and the reasons behind it.
- III. Safety reports are reviewed by a member of the IRB who is clinically trained and appointed by the chairperson. Safety reports are reviewed in the context of other reports regarding this particular study, and other reports involving this investigational product. After review, the reviewer initials and dates the report to indicate that the report has been reviewed. These reports are added to the IRB agenda as informational reports.
- IV. At the time of approval, the IRB approval letter indicates the frequency that study progress reports are to be submitted to the board. The progress report is received by the IRB office, and approved at a convened meeting, before the anniversary date of the initial approval or reapproval. If progress reports are not received at the appointed date, the study will be terminated, but a progress report is still to be received by the IRB. Progress reports received within three months of the termination date will be presented to the IRB and the study reinstated if the report

is satisfactory. Progress reports received later than three months from the termination date are added to the file, but the protocol is resubmitted by the investigator, as if it is a new protocol, in order to be reinstated. No new subjects are to be enrolled to these terminated studies until reapproval.

Studies that are not renewed by the appropriate time are considered closed. Investigator should not be enrolling patients during the time that the study is not reapproved.

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Communication with Investigators
Last Revision: 06/01	
Reference #: S.IRB.1112	

- I.** The BMHCC IRB notifies investigators and the institution of its decision to approve or disapprove the proposed research activity, or suggested modifications required to secure such approval; included in that communication is a statement of the reasons for its decision. [21 CFR 56.109(e)] The date of the protocol approval is the latest date of full IRB review of that protocol before approval.

- II.** The investigator is then given three months to respond in writing. In the case of suggested modifications, if the investigator does not respond within the three month period, the protocol will be considered withdrawn, and in order for the investigator to receive IRB approval for that protocol, he/she must resubmit the protocol as if it were a new protocol, with the requested modifications.

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Frequency of Review
Last Revision: 06/05	
Reference #: S.IRB.1113	

The BMHCC IRB requires that locally conceived and/or funded studies, and studies which are deemed by the IRB to be high-risk be reviewed semi-annually. [21 CFR 56.108(a)(2)]

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Authority/Suspension/Investigation/ Supervision of Research
Last Revision: 06/01	
Reference #: S.IRB.1114	

I. Authority

The BMHCC IRB has the authority to request verification from sources other than the investigator that no material changes have occurred since the last review. [21 CFR 56.108(a)(2)]

II. Suspension

If the BMHCC IRB has reason to believe that the following guidelines are not followed, the study is suspended pending correction of the deficiencies:

- A. The investigator is responsible for assuring that changes in research activities are reported promptly to the BMHCC IRB. [21 CFR 56.108(a)(3)]
- B. The investigator does not initiate changes in approved research without IRB review and approval, except where necessary to eliminate immediate hazards. [21 CFR 56.108(a)(4) and 56.115(a)(1)]
- C. The investigator is responsible to promptly report the following data to the BMHCC IRB, the BMH Adverse Drug Event Committee, the FDA and the sponsor:
 1. Unanticipated problems involving risks to subjects or others. [21 CFR 56.108(b)(1) and 56.115(a)(1)]
 2. Serious or continuing noncompliance with 21 CFR 50 and 56, or the requirements of the BMHCC IRB. [21 CFR 56.108(b)(2)]
 3. Suspension or termination of IRB approval, FDA approval of the study, or sponsor approval. [21 CFR 56.108(b)(3) and 56.113]
(The BMH Adverse Drug Event Committee is a hospital committee, and not related to the BMHCC IRB. We request reporting to this committee to assist them in receiving this information.)
- D. The BMHCC IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB requirements or that has been associated with unexpected serious harm to subjects. Such action is reported promptly to the investigator, appropriate institutional officials, the FDA, and the sponsor. [21 CFR 56.113]

III. Investigation

A. The BMHCC IRB will initiate investigation and report to the institution and the Office of Human Research Protection (OHRP) any and all instances of alleged scientific misconduct discovered, including:

1. fabrication, falsification or plagiarism of research data and information
2. attempts to prevent reporting of misconduct or mistakes.

B. A finding of research misconduct requires that:

1. There be a significant departure from accepted practices of the relevant research community; and
2. The misconduct be committed intentionally, or knowingly, or recklessly; and
3. The allegation be proven by a preponderance of evidence.

IV. Supervision of Research

The BMHCC IRB has the authority to observe or have a third party observe the consent process, and the research conducted by the investigator. [21 CFR 56.109(f)]

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Device Studies
Last Revision: 06/05	
Reference #: S>IRB.1115	

- I.** The BMHCC IRB follows 21 CFR 812.3(m)(1-4) to determine which investigational devices pose significant or non-significant risk.
- II.** The same guidelines for drug studies apply for approval of device studies, except that the Investigational Device Exemption (IDE) is usually not granted by the FDA until after IRB approval, therefore, the IRB will not have this number until after the FDA grants the IDE. The investigator will submit this number for the IRB file upon receiving it. [21 CFR 812.60, 812.62 and 812.64] The study cannot begin until the IRB receives this number.
- III.** If the IRB determines that a device study that had been presented for approval as a non-significant risk actually does present a significant risk, they notify the investigator and/or the sponsor. [21 CFR 812.66]

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Scheduling of Meetings/Pre-Meeting Guidelines
Last Revision: 06/05	
Reference #: S.IRB.1116	

I. Scheduling of Meetings

- A. The BMHCC IRB meets at 12 noon, the second and fourth Thursday of each month, except November and December, when only one meeting is held on the third Thursday. Should the agenda for a meeting be extremely light, a meeting is cancelled, and the activity projected to the following meeting. Should the agendas in November and December be extremely heavy, another meeting may be scheduled in those months as well.

- B. Occasionally there is a need for a called meeting of the entire IRB, or a few members. These meetings are reported in minutes of the IRB.

II. Pre-Meeting Guidelines

At least one week prior to each scheduled meeting, a packet is sent to every member or their alternate including: amendments and progress reports to primary reviewers, new protocols and other relevant reports/materials to each member of the IRB. An agenda of the imminent meeting is also included. The minutes of the prior meeting and agenda informational items are e-mailed to members prior to the meeting. The IRB members are notified in this packet or via e-mail of the location of the next meeting if it is changed from the regular meeting room.

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Review Process [21 CFR 56.108(a)(1)]
Last Revision: 06/05	
Reference #: S.IRB.1117	

- I. All members receive each new protocol; however, there are three reviewers who are primarily responsible for detailed review of the protocol, and who also receive the investigator's brochure. The first and/or second reviewers are usually clinically trained, and at least one reviewer is chosen for either statistical, ethical, or layperson's perspectives, according to the protocol being reviewed.

- II. In order for the BMHCC IRB to approve research, the IRB determines that all of the following requirements are satisfied:
 - A. Risks to subjects are minimized and are reasonable in relation to anticipated benefits.

 - B. Selection of subjects is equitable.

 - C. Informed consent is sought from each prospective subject or legally authorized representative, and is appropriately documented.

 - D. Provision is made for monitoring data for the safety of subjects, when appropriate.

 - E. Provision is made to protect the privacy of subjects.

 - F. Safeguards are in place to protect vulnerable subjects. [21 CFR 56.110]

- III. Following the presentation by the primary reviewers, the board discusses the protocol and then votes on the approval/disapproval of the submission. The board votes in one of the following ways:
 - A. Approved as submitted.

 - B. Not approved/minor: minor questions, clarifications or changes requested from the board. The study is not in effect until these questions are satisfactorily addressed. Minor corrections are reviewed by the chairperson, his/her appointee, or the original reviewers and at the next board meeting. Occasionally, studies with minor changes need to be brought to the full board for re-review.

 - C. Not approved/major: there are significant concerns about the protocol and/or informed consent. The study is not in effect until these questions are satisfactorily addressed. The protocol/informed consent is resubmitted with

corrections by the investigator, and the three original reviewers review it and present it at the next scheduled IRB meeting.

- IV. Any member having a conflicting interest in a particular protocol does not present the protocol to the board and abstains from voting, but may answer clarification questions.
- V. A BMH-IRB number is assigned to each protocol submission and this number is used in all correspondence.
- VI. Emergency use of a test article must follow FDA guidelines:
 - A. The use of an investigational drug or biologic requires an Investigational New Drug (IND) approval by the FDA. [Exception: 21 CFR 312.36]
 - B. Emergency use is defined as “a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval.” [21 CFR 56.102(d)]
 - C. Such use is allowed for one emergency use of the test article. Subsequent use on another subject requires IRB review and approval, unless there has not been sufficient time to present the protocol to the IRB before the subsequent subject presents
 - D. Emergency use of a test article must be reported in writing to the IRB within five working days, including a copy of the protocol, informed consent, subject’s name, condition, explanation of the emergency situation. [21 CFR 56.104(c)]
 - E. The IRB chairperson or his/her representative must be notified prior to emergency use of a test article, but this notification is not to be considered as IRB approval. The purpose of this notification is to track the five days required for a written report to the IRB. [21 CFR 56.108(a)(1) and (b)(1)] This report is filed in the IRB office.

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Expedited Review [21 CFR 56.108(a)(1), 56.110(a-c), and 45 CFR 46.110]
Last Revision: 06/05	
Reference #: S.IRB.1118	

The IRB chairperson, or his/her designee, review studies involving minimal risk, or modifications to ongoing studies involving minor changes. This review is presented in the agenda and minutes of the board and voted on. The BMHCC IRB has the right to re-review this decision.

- I.** Expedited review is allowed for protocols involving minimal risk as listed in the Federal Register, and including that amount of risk that is already encountered in the daily life of the individual. Minimal risk lists are found in the above citations.

- II.** Amendments or modifications to a previously approved protocol or consent form, which provides for a procedural change or decreased risk to a subject, and can be designated as minor changes, are reviewed by the chairperson or his/her designee.

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Voting Requirements/Institutional Review
Last Revision: 02/06	
Reference #: S.IRB.1119	

I. Voting Requirements

- A. Review of proposed research is at convened meetings. [21 CFR 56.108(c)]
- B. A quorum consists of a majority of the active members (who are eligible to vote). Members with real or remote interest in an item will abstain from voting. [21 CFR 56.108(c)]
- C. At least one physician is present at each meeting.
- D. At least one member whose expertise is in nonscientific areas is present at each meeting. [21 CFR 56.108(c)]
- E. Approval/disapproval of a protocol is based upon a majority vote. [21 CFR 56.108(c)]
- F. All active members (and their alternates when substituting for a member) have full voting rights in all business transacted.
- G. Members attending by conference telephone vote audibly, other members attending in person vote by show of hands.
- H. No member votes by proxy.

II. Institutional Review

Research approved or disapproved by the IRB may be subject to further review by institutional officials. However, those officials may not approve research, which has not been approved by the IRB. [21 CFR56.112]

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Communication
Last Revision: 06/05	
Reference #: S.IRB.1120	

- I.** All communications to and from the BMHCC IRB involving a study are kept in the IRB file. [21 CFR 56.115(a)(4)]
- II.** The BMHCC IRB communicates to the investigator in writing all requests for modification or clarification regarding a protocol. [21 CFR 56.108(a)(1) and 56.109(a)]
- III.** The BMHCC IRB communicates to the investigator in writing the approval or disapproval of proposed research, giving reasons for the decision, and allowing the investigator three months to respond. [21 CFR 56.108(a)(1) and 56.109(e)]
- IV.** The BMHCC IRB submits copies of the meeting minutes conveying IRB decisions to the institutional administrator of record, the Pharmacy Director and the Medical Staff Office.
- V.** The BMHCC IRB communicates with the sponsor of research and the FDA whenever a study is suspended or terminated by the IRB. [21 CFR 56.113]

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Appeal of IRB Decisions
Last Revision: 06/05	
Reference #: S.IRB.1121	

I. Appeal of IRB decisions

- A. The investigator may submit a response to the action recommended by the IRB, addressed to the chairperson. The response contains adequate reasons or data in asking the IRB to reconsider its recommendation.

- B. This information is submitted to the full board, and the initial reviewers recommend to accept or reject the appeal. The full board votes on the appeal unanimously.

- C. The decision of the IRB to approve a research study may be overruled by the institutional officials, but the institution does not have the authority to overrule IRB rejection of a research activity. [21 CFR 56.112]

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Record Requirements
Last Revision: 06/01	
Reference #: S.IRB.1122	

- I.** A current list of IRB members and their qualifications, earned degrees, certifications and licensure, and institutional relationship (if applicable) is maintained and updated as needed by the IRB administrative coordinator. [21 CFR 56.115(a)(5)]
- II.** Operating guidelines for the functioning of the IRB are maintained and reviewed on an annual basis. Revisions to the operating rules and procedures are by unanimous vote of the IRB. [21 CFR 56.108(a-b)]
- III.** Minutes of the IRB meetings are in sufficient detail to show: the attendance (names of members and guests) at the meetings; a written summary of discussion of substantive issues and their resolution; action taken by the IRB; the vote on these actions, including names of persons abstaining from voting; and the basis for requiring changes in or disapproving research. [21 CFR 56.115(a)(2)]
- IV.** Copies of all protocols, consent forms, progress reports (continuing review), amendments, safety reports (adverse reaction reports), correspondence and any other pertinent data are kept in the IRB files for five years after termination of the research, or longer as required by the sponsor. These records are accessible for inspection and copying by authorized representatives of the FDA at reasonable times and in a reasonable manner. [21 CFR 56.115(a)(1)(3) and (4), and (b)]
- V.** Statements of significant new findings regarding a study which are reported to test subjects are submitted to the IRB and retained in its study file. [21 CFR 56.115(a)(7)]
- VI.** Emergency use of a test article requires a report to the IRB from the investigator within five (5) working days. [21 CFR 56.115(a)(4) and 56.104(c)]

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Investigator Information
Last Revision: 06/05	
Reference #: S.IRB.1123	

The principal investigator (or at least one participating investigator) is affiliated with a hospital within the Baptist Memorial Health Care Corporation.

I. Study Protocol [21 CFR 56.103(a) and 56.115(a)(1)]

A. Application (to the IRB) page includes:

1. Title of study
2. Name, address, contact numbers (email if applicable) of the principal investigator, and original signatures of the principal investigator and participating investigators, with twenty copies.
3. Name, address and contact numbers (email if applicable) of the sponsor.
4. Name, address and contact numbers (email if applicable) of the local protocol coordinator.
5. Location(s) of the research.
6. Approval numbers from organizations (FDA, National Institute of Health (NIH), etc.)

B. Protocol includes:

1. Title of study.
2. Purpose of study.
3. Sponsor of study.
4. Results of previous related research.
5. Subject inclusion/exclusion criteria.
6. Justification (if needed) for inclusion of any special/vulnerable populations.
7. Study design.
8. Description of procedures to be performed.
9. Provisions for managing adverse reactions.
10. Compensation to subjects (if any).
11. Compensation for injured research subjects.
12. Protection of subject's privacy.
13. Explanation of which costs of the research are paid for by whom (subject, third party payer, sponsor).

C. Informed Consent document

1. Containing all requirements of 21 CFR 50.25.
 - a. Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
 - A description of any reasonably foreseeable risks or discomforts to the subject.
 - A description of any benefits to the subject or to others which may reasonably be expected from the research.
 - A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
 - A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.
 - For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
 - An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
 - A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- b. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:
- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.
 - Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
 - Any additional costs to the subject that may result from participation in the research.
 - The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
 - A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
 - The approximate number of subjects involved in the study.

- c. The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective. [[Page 285]]
 - d. Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local law.
- 2. If there is a majority of subjects to be enrolled in a study with language needs other than English, the consent form will be presented in a document translated by a certified interpreter.
 - 3. Protected Health Information guidelines are followed for release of information, as below:
 - a. A description of the information to be used or disclosed.
 - b. The name of the person or entity authorized to request use or disclosure.
 - c. The name of the person to whom the request is made.
 - d. An expiration date (or event) of the use or disclosure.
 - e. A statement of the individual's right to revoke this authorization and/or the exceptions to the right to revoke with a description of how to revoke authorization.
 - f. A statement that information used or disclosed may be subject to redisclosure and no longer protected by this rule.
 - g. Signature and date of individual or representative (and description of relationship/authority to act for the individual.)
 - h. Written in plain language.

II. Investigator's Brochure

The investigator's brochure (when one exists) or drug insert (if the drug is approved) is provided. [21 CFR 56.111(a)(2), 56.115(a)(1) and 21 CFR 312.55]

III. Investigator guidelines

- A. The investigator obtains a legally effective informed consent allowing sufficient opportunity to consider whether or not to participate without any coercion. The information must be presented in a language understandable to the subject and without exculpatory language and without releasing the sponsor, institution or investigator of any liability. [21 CFR 50.20]
- B. Any changes in the study made following initial approval must be approved by the IRB before implementing them. [21 CFR 56.108(a)(4) and 56.115(a)(1,3 and 4)]

- C. All unexpected and/or serious adverse events occurring to subjects in the study, whether local or non-local, are reported to the IRB promptly. [21 CFR 56.108(b)(1), 56.115(a)(1, 3 and 4), and 56.113] These are reviewed by a person with a clinical background appointed by the IRB chairperson.
- D. Progress reports on the study are submitted to the IRB in sufficient time before the anniversary date from the initial review or reapproval to be presented at a full IRB meeting. Progress reports received after that date result in the study being terminated. [21 CFR 56.108(a)(1) and 56.115(a)(1, 3 and 4)]
- E. Final reports are submitted to the IRB at the end of the study. The final report from the sponsor is also submitted when it is received by the investigator.
- F. Institutional forms and reports: All adverse drug reactions (serious or not) experienced by hospitalized patients are reported on an Adverse Drug Reaction (ADR) form which is present on all patient charts.

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Exemptions from Prospective Review (Emergency Use, Review by other IRB)
Last Revision: 06/05	
Reference #: S.IRB.1124	

I. Emergency Use

- A. Emergency use of a test article is done in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval. Emergency use is done at the discretion of the investigator. [21 CFR 56.102]

- B. The IRB does not grant emergency approvals, but requires notification of emergency use of a test article at the time of use (usually by phone call to the IRB chairperson), and written notification within five working days. [21 CFR 56.104(c)] This written notification includes explanation of the emergency situation, a copy of the protocol (if applicable), and a copy of the informed consent.

- C. Subsequent use of this test article requires full IRB review. [21 CFR 56.104(c)]

II. Admission of a subject to BMH on a study reviewed by another IRB

- A. If admission is predicted and there is enough time, the investigator submits the protocol to the BMHCC IRB in the regular manner. This procedure is followed when it is expected that more than one subject will be admitted to the hospital while on the study.

- B. If the admission is not predicted, or there is not enough time for regular submission:
 - 1. The attending physician notifies the IRB of the intent to continue the patient on treatment while hospitalized. This is not obtaining approval, but a notification only.
 - 2. The attending physician notifies the pharmacist and investigator of the patient's admission.
 - 3. A copy of the subject's informed consent is obtained and placed on the subject's hospital chart.
 - 4. A copy of the protocol (or information from the protocol containing treatment procedures, risks and emergency procedures) and a copy of the outside IRB's approval letter are filed in the pharmacy.

BAPTIST

POLICY MANUAL

Effective Date: 04/94	Emergency Research Consent Exception [21 CFR 50.24]
Last Revision: 06/01	
Reference #: S.IRB.1125	

- I.** When the IRB finds that all the requirements listed in 21 CFR 50.24 have been met, research is allowed without subject consent. [21 CFR 56.109(c)(2)]
- II.** The IRB notifies the investigator in writing when it determines that it cannot approve a 21 CFR 50.24 study.
- III.** These studies are subject to the same review criteria as all other studies.

BAPTIST

POLICY MANUAL

Effective Date: 04/94	HIPAA Privacy Regulations and Medical Research: BMHCC-IRB Guidance and Procedures
Last Revision: 03/06	
Reference #: S.IRB.1126	

I. Revision of IRB Policies and Procedures

In 2003, implementation of the privacy regulations required revision in IRB policies and procedures. These changes affected all new applications and previously approved studies, provided that at least some of the subjects would be accrued on or after April 14, 2003. In addition, the provisions of the privacy rule must be satisfied for both studies in which informed consent is required and those in which informed consent has been altered or waived.

II. New Applications

For all new studies received in the IRB office, the application must specify in the section on confidentiality either that the research use and disclosure of PHI will be undertaken with authorization, or that the research use or disclosure satisfies one of the conditions under which subject authorization is not required under the privacy regulations.

For studies in which subject authorization for the use and disclosure of PHI is required, the confidentiality section of the subject consent form must include the required authorization disclosure. The required disclosure is provided in appendix A. The authorization language must either mirror the language in Appendix A or must otherwise meet the requirements outlined in the HIPAA Privacy and Security regulations. The model confidentiality section, as revised to include the authorization for the use of PHI, is provided in Appendix B. The investigator will receive approval for the authorization language in a separate paragraph of the final approval letter for the study.

For studies in which the use or disclosure of PHI may satisfy one of the conditions under which subject authorization is not required under the privacy regulations, the investigator must submit the BMHCC-IRB, "Request for Research Use and Disclosure of Protected Health Information Without Subject Authorization" (see Appendix C). The investigator will receive a separate approval letter for the use and disclosure of PHI without subject authorization. This approval letter must be presented to the Health Information Management Department (HIM) of the entity maintaining the PHI to establish that the IRB has reviewed the proposed use and disclosure of PHI without subject authorization and has determined that it satisfies the regulatory requirements. If the PHI is maintained by the investigator, the letter should simply be retained as confirmation that the regulatory requirements have been satisfied for using or disclosing PHI in research without subject authorization.

APPENDIX A

SUBJECT AUTHORIZATION TO USE AND DISCLOSE INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION IN MEDICAL RESEARCH

TEMPLATE FOR HIPAA PORTION OF THE CONFIDENTIALITY SECTION OF THE STUDY CONSENT FORM

The subject authorization language provided below should be inserted at the appropriate location in the confidentiality section of the study consent form (see Appendix B). The authorization language must either mirror the language in Appendix A or must otherwise meet the requirements outlined in the HIPAA Privacy and Security regulations. The material in block form is the required authorization language. The *italicized* material in parentheses provides directions for including material that may or may not be relevant for particular studies.

Under federal privacy regulations, you have the right to determine who has access to your personal health information (called “protected health information” or PHI). PHI collected in this study may include your medical history, the results of physical exams, lab tests, x-ray exams, and other diagnostic and treatment procedures, as well as basic demographic information. By signing this consent form, you are authorizing the researchers to have access to your PHI collected in this study (*if the study will use PHI in the possession of another covered entity, add*) and to receive your PHI from (*either*) your physician (*and/or*) facilities where you have received health care. (*If any of the following individuals or entities will also be reviewing the PHI collected or received for the study, then add the following sentence.*) In addition, your PHI may be shared with other persons involved in the conduct or oversight of this research, including (*if the study is multi-institutional, add*) researchers at (name of the institutions); (*if a cooperative group study, add*) the (*name of the cooperative group*); (*if the research involves an FDA-regulated drug, device or biologic, add*) the Food and Drug Administration (FDA); and (*if claims for some of the procedures performed during the study will be submitted to third party payers, add*) your medical insurance carrier. (*If the research is sponsored, add*) Your PHI may also be shared with (*name of sponsor*), which sponsors and provides funds for this research; (*name of CRO, if applicable*) which has been hired by the sponsor to coordinate the study; and a Data and Safety Monitoring Committee (*if applicable*). (*If the previous sentence was used, add the following sentence as well.*) However, these latter organizations may not have the same obligations to protect your PHI. The Baptist Memorial Health Care Corporation Institutional Review Board (IRB) may review your PHI as part of its responsibility to protect the rights and welfare of research subjects. Your PHI will not be used or disclosed to any other person or entity, except as required by law, or for authorized oversight of this research study by other regulatory agencies, or for other research for which the use and disclosure of your PHI has been approved by the

IRB. Your PHI will be used only for the research purposes described in the Introduction of this consent form. Your PHI will be used (*either*) (1) until the study is completed (*or if the research is FDA regulated*) (2) for as long as the sponsor reports study data to the FDA (*or if the research is without a foreseeable end-point, such as a repository or a registry*) (3) indefinitely. **(PLEASE NOTE: CHOOSE ONLY ONE OF THESE, NOT ALL THREE)**

You may cancel this authorization in writing at any time by contacting the principal investigator listed on the first page of the consent form. If you cancel the authorization, continued use of your PHI is permitted if it was obtained before the cancellation and its use is necessary in completing the research. However, PHI collected after your cancellation may not be used in the study. If you refuse to provide this authorization, you will not be able to participate in the research study. If you cancel the authorization, then you will be withdrawn from the study. Finally, the federal regulations allow you to obtain access to your PHI collected or used in this study. (*If the research study includes treatment of subjects, add the following sentences.*) However, in order to complete the research, your access to this PHI may be temporarily suspended while the research is in progress. When the study is completed, your right of access to this information will be reinstated.

APPENDIX B

REVISED TEMPLATE FOR THE CONFIDENTIALITY SECTION OF THE CONSENT FORM

Confidentiality

1. Provide a statement explaining how individual identifiers will be used in maintaining the research records. (E.g., “Your research record will be labeled with your name.” or “Your research record will be labeled with a code number. A master key that links your name and the code number will be maintained in a separate and secure location.”)
2. Insert the HIPAA authorization portion of the confidentiality section.
3. If the study involves the use of a federal Certificate of Confidentiality, provide the information about the certificate and how it protects subject information from re-disclosure.
4. If information about the subject’s participation in the study or the results of procedures performed in the study will be placed in the subject’s medical record (as contrasted with the research record), then this should be explained. Indicate that information placed in the medical record may be available to the subject’s employer or insurer.
5. State that individual subjects will not be identified in any presentations or publications based on the results of the research study.

APPENDIX C

Request for Research Use and Disclosure of Protected Health Information Without Subject Authorization

**BAPTIST MEMORIAL HEALTH CARE CORPORATION
INSTITUTIONAL REVIEW BOARD**

6025 Walnut Grove Road, Suite 404
MEMPHIS, TENNESSEE 38120

J. CAMERON HALL, M.D., CHAIRMAN

Researcher's Name: _____

Address: _____

Phone: _____ Fax: _____

Email: _____

Location of Research: _____

1. Purpose of the request to review protected health information:

2. Do you plan to record any patient identifiers? Yes _____ No _____
(Examples of identifiers: name, address, telephone number, social security number, date of birth, race, sex, hospital admission number, medical records number, physician, diagnosis).

a. If you answered Yes to the above question, please list the identifiers you will be recording: _____

b. If you will be recording patient identifiers, please describe how you will secure and protect the recorded identifiers from improper use and/or disclosure:

c. If you will be recording patient identifiers, please list the methods you will use to destroy the identifiers and the expected time frame for destruction:

d. If you will not be destroying the patient identifiers, please list your justification:

**BAPTIST MEMORIAL HEALTH CARE CORPORATION
INSTITUTIONAL REVIEW BOARD**

6025 Walnut Grove Road, Suite 404
MEMPHIS, TENNESSEE 38120

J. CAMERON HALL, M.D., CHAIRMAN

Please read the following statements and confirm your acceptance and agreement to abide by the conditions by signing and dating below:

1. I am seeking to review protected health information solely for the purpose of preparing a research protocol or for similar purposes preparatory to research.
2. I will not remove any protected health information from the covered entity during the course of the review.
3. It would not be practical to obtain authorizations from each patient whose information may be accessed during the proposed review of protected health information.
4. It is not practical to prepare a research protocol without accessing and/or using protected health information.
5. I will take all reasonable steps to protect the patient identifiers, if any are recorded.
6. I will not reuse or disclose protected health information obtained as a result of my review of protected health information, other than to the extent required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by law.

Signature of Researcher

Date

Please complete and return to BMHCC IRB via mail at the above address or you may fax the documents to 226-1021. Please call the IRB office at 226-1677 if you have any questions.