IRB Number: Date received by IRB:

NORTH MISSISSIPPI HEALTH SERVICES
INSTITUTIONAL REVIEW BOARD
Submission Form

**** If this is a hospital-based study, be sure to attach a clinical trials billing submission form (Attachment A)***

Listing number on ClinicalTrials.gov (please put N/A if not listed):

Title of Investigation:

Phase II: **Phase III:** **Phase IV:** **Not Applicable:**

Acronym (if any):

Protocol Number:

Principal Investigator (PI):

Sub-investigator(s):

Investigator(s) address, phone and e-mail:

PI's Signature _____ **Date**:_____

Study type:

biomedical:	☐ drug	☐ device	☐ other _____
behavioral:	☐ written survey	☐ interview	☐ other _____
other:	☐ human device exemption	☐ registry	☐ other _____

If a drug study, provide IND number: _____ * Also include documentation from the sponsor or FDA verifying the IND number.

If a device study, provide IDE number: _____

If no IDE number, provide sponsor's risk assessment: ☐ Non-significant risk ☐ Significant risk

Sponsor (include address, contact, phone and e-mail):

Funding Agency (include address, contact, phone and e-mail):

NIH or other federal Grant Number (when applicable):

Collaborating Organization(s) (include address, contact, phone and e-mail):

Healthcare Professional Study Summary (Intranet):

Projected duration of study:
Enrollment period:
Follow-up period:

Maximum number (please do not include a range) of human subjects to be studied:
NMHS site____ total____
*Please note that if this maximum number is met at your site, approval from the IRB must be obtained prior to enrolling any more subjects.

Research Sites: ☐ hospital ☐ clinic ☐ both

The following departments will be affected:

☐ Pharmacy ☐ Surgery ☐ Laboratory

☐ Medicine ☐ Billing ☐ Other _____

If any of the above departments will be affected, have they been contacted: ☐ Yes ☐ No

If the study involves a questionnaire, has it been submitted to the IRB? ☐ Yes ☐ No

Age range of human subjects:

Criteria for subject selection:

Beneficial effect to human subject arising from investigation:

Potential adverse effects (psychological) arising from investigation:

Potential or established side effects of drugs used in investigation:

Brief justification of research where immediate benefit to specific human subject is absent:

Accountability for data and safety monitoring:

☐ Individual Investigator ☐ Sponsor ☐ Data Safety Monitoring Board (DSMB)

☐ Other _____

Planned frequency of safety data analysis (per time versus per subject and/or in response to specific events):

Description of stopping rules (what event(s) would warrant stopping the study):

List significant information that emergency care providers of patients on this study should know (state "None" if no emergency information is necessary):

If study is biomedical and requires the investigator(s) be contacted when patient is admitted to the hospital, please provide the following information for at least 2 contacts.
Investigator name:
Investigator alphanumeric pager:
Investigator e-mail address:

Research Coordinator name:
Research Coordinator alphanumeric pager:
Research Coordinator e-mail address:

If the study is biomedical and requires any inpatient or outpatient billing for study-related tests, procedures, medications or devices, please provide billing information for the guarantor.
Name:
Address:

IRB Office Information – pre-IRB approval

Status of review: administrative expedited full

Cost benefit analysis necessary: no yes if yes, date submitted:

Training plan necessary: no yes if yes, date submitted

Charge status: full sub-study

none: in-house study student compassionate use registry

Vulnerable patient population: not applicable children pregnant women

prisoners other