**Investigator’s Assurance:** By submitting this protocol, I attest that I am aware of the applicable principles, policies, regulations, and laws governing the protection of human subjects in research and that I will be guided by them in the conduct of this research.

**INSTRUCTIONS:** To submit a protocol application please complete the following.

For **exempt** protocols: Submit **two** copies of this application, **two** copies of the consent form and **two** copies of the protocol (including questionnaire or survey if applicable).

For **expedited** protocols: Submit **three** copies of this application, **three** copies of the consent form, and **three** copies of the protocol (including questionnaire or survey if applicable).

For **full board** review: Submit **thirty(30)** copies of this application, **thirty(30)** copies of the consent form and **four** copies of the protocol. Sponsored drug studies also require **four** copies of the investigator’s brochure, **one** copy of the FDA Form 1572, and **three** copies of the drug summary sheet.

In the following judgment of the Principal Investigator, this research qualifies for which of the following:

(please note: protocols involving children <19 years of age cannot be submitted as exempt)

**Exempt _______**
Category ________
(See Guidelines Part V)

**Expedited ________**
Category _________
(See Guidelines Part IV)

**Full Board ________**
(See Guidelines Part III)

Date of submission

Title of Research

Principal Investigator
Dept/College/Bldg. Room # Phone Email

Other Investigator
Dept/College/Bldg. Room # Phone Email

Other Investigator
Dept/College/Bldg. Room # Phone Email

Site(s) of Human Subject Data Collection (If sites are separate from the University, please submit approval letter)

Funding Agency (if applicable)

**NOTE:** If this study is to be funded with federal funds, provide 1 copy of the grant with this application

IRB Application Revised: 8/2005
PURPOSE OF RESEARCH:

Relevant Background and Rationale for the Research:

Subject Population:  NOTE: Federal guidelines require selection of subjects be equitable within the exclusions, and subjects meeting the criteria cannot be discriminated against for gender, race, social or financial status, or any other reason.

Approximate number of subjects _________   Male/Female Ratio _________

Vulnerable Subjects: Identify all categories of vulnerable subjects to be recruited - (check only if applicable):

☐ Minors < 19 years … *Attach Investigator Checklist for Research Involving Children*
☐ Pregnant Women
☐ Fetuses
☐ Prisoners …. *Attach Investigator Checklist for Research Involving Prisoners* (adjudicated youth / adolescents detained in a juvenile detention facility is considered a prisoner). The federal regulations for inclusion of prisoners as research subjects and investigator checklist are located on IRB website at: http://southmed.usouthal.edu/com/research/IRB.html
☐ Cognitively Impaired Persons
☐ Economically or educationally disadvantaged persons
☐ Other vulnerable population (identify): ________________________________
Procedures and Agents (if applicable) to be Used:

The Experimental Design and Methodology:

*Please limit this description to the portions dealing directly with the use of human subjects.*

What incentives will be offered, if any?

Risk/Benefits to participants and precautions to be taken:

*Identify possible risks to subjects. These may be of a physical, psychological, social or legal nature. If subjects are vulnerable populations, or if risks are more than minimal, please describe what additional safeguards will be taken.*
**Participant Recruitment:** Describe the sources of potential participants, how they will be selected and recruited and how you will contact them.

**In your opinion, do benefits outweigh risks?**

Yes _____ No _____

**Privacy/Confidentiality:**

*Please describe whether the research would involve observation or intrusion in situations where subjects have a reasonable expectation of privacy. If identifiable existing records are to be examined, has appropriate permission been sought, i.e. from institutions, subjects, and physicians? What provision has been made to protect the confidentiality of sensitive information about individuals?*

**HIPAA: Research Requirements**  
*The Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rule provides additional protection for protected health information (PHI), which is defined as "individually identifiable health information" including demographic information collected from an individual.*

**HIPAA Training:** Compliance with the HIPAA’s Privacy and Security Rule requires that each institution "must train all members of its workforce on the policies and procedures with respect to protected health information, as necessary and appropriate for the members of the workforce to carry out their function within the covered entity." This education requirement applies to investigators and research staff (research coordinators, research assistants and other personnel having access to PHI) who are conducting human subjects research that involves access, use, or generation of protected health information within a “covered entity.” The USA Health System has been designated as an Organized Health Care Arrangement (OCHA) which includes: USA Hospitals, USA Physician’s Group, USA Diabetic Foot Clinic, USA Speech and Hearing Center, USA Psychology Clinic, USA Cancer Research Institute, and USA Office of Emerging Health Technologies. Employees of the covered entity who have not previously read the HIPAA Privacy Compliance Plan for Research policy and returned the training certification sheet must complete the online HIPAA research tutorial at: [http://www.southalabama.edu/com/research/humansubjects/hipaa.shtml](http://www.southalabama.edu/com/research/humansubjects/hipaa.shtml)
1. Does your research occur within the USA Health System or other Covered Entity? (see sentence above)
   - Yes
   - No (if no, skip the HIPAA section and proceed to the next section)

2. Does your research use health information that contains ANY of the following identifiers (check all that apply):
   - Names
   - Geographic subdivisions smaller than a State
   - Elements of dates (except year) related to an individual
   - Device identifiers and serial numbers
   - Telephone numbers
   - Fax numbers
   - Social security numbers
   - Medical record numbers
   - Health plan beneficiary numbers
   - Account numbers
   - Certificate/license numbers
   - Vehicle identifiers and serial numbers
   - Biometric identifiers
   - Web universal resource locators (URLs)
   - Email addresses
   - Internet protocol address numbers
   - Full-face photographic images
   - None (If none, skip to question #4, data security)

3. Is the health information obtained from ANY of the following (check all that apply):
   - USA Hospitals
   - USA Physician’s Group
   - USA Speech and Hearing Center
   - USA Office of Emerging Health Technologies
   - None (if PHI is not obtained from any of the above sources (within USA’s covered entity), HIPAA privacy rule does not apply to human subjects research)

4. You are: (check applicable box)
   - Obtaining Subject Authorization to use the health information in research
     (Include Subject Authorization to Use/Disclose PHI in the confidentiality section of the informed consent document – use USA authorization template language)
   - Requesting a Waiver of Subject Authorization
     (Attach Request for Waiver of Subject Authorization Form)
   - HIPAA does not apply to this human subjects research study

5. Data Security
   Do you plan to maintain electronic identifiable health information specific to this study? (ie, research databases, spreadsheets, computing applications)
   - Yes
   - No (if no, skip to next section on consent form process)

   a. Please indicate how study data will be kept secure. Check all that apply:
      - Data coded; data key is destroyed at end of study
      - Data coded; data key is kept separately and securely
      - Data kept in locked file cabinet
      - Data kept in locked office/suite
      - Electronic data protected with a password
      - Data stored on a secure network
      - Portable storage (e.g., laptop, flash drive)
      - Other – describe: ____________________________
b. Complete and submit a separate application for the establishment of a research database or repository with this IRB new projects application.

<table>
<thead>
<tr>
<th>Consent Form Process:</th>
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<tbody>
<tr>
<td>a. Will consent be obtained for this study? ☐ Yes ☐ No</td>
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<tr>
<td>If no, please justify:</td>
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<tr>
<td>b. Explain how consent will be obtained.</td>
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<td>c. Who will obtain consent?</td>
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<tr>
<td>d. Will more project-specific instruments be used in the consenting process? ☐ Yes ☐ No</td>
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<tr>
<td>If yes, attach patient information sheets or other such instruments.</td>
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<th>Human Subjects Protection Training:</th>
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<tr>
<td>As a condition of the University’s Federal Wide Assurance of Protection for Human Subjects, principal investigators and key research personnel are required to complete appropriate training before conducting human subject research</td>
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There are several acceptable options for fulfilling the human participant research requirement. Options include completion of an NIH on-line training program available at http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp

Other acceptable on-line modules are available through UCLA at http://www.ucla.edu/research (click on “Research”, then go to “Protection of Research Subjects” for the certification program) or University of Michigan at http://www.irb.research.umich.edu/ (click on non-UM Faculty and Staff and Students).

Once you have finished, a computer generated certificate is provided. Preferably, a copy of the certificate should be attached with submission of this application form. However, you may also fax a copy to 461-1595 or forward to the IRB Office at CSAB 138. NOTE: Investigators will not receive final approval for human subjects’ research until the human subjects and HIPAA training requirement is completed. List all study team members (sub-investigators, coordinators, and other key personnel involved with the conduct of the study. |

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<th>Name</th>
<th>Role</th>
<th>Human Subjects Training Current Status</th>
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</table>
Other Requirements *(if applicable)*

A Disclosure of Financial Conflict of Interest Form is to be submitted with each proposal for funded research.

If x-rays or isotopes are to be used specifically in support of the research, approval of the Radiation Safety Committee must be obtained.

If a biological hazard exists for either subjects or investigators, approval of the Biohazards Committee must be obtained. Under Federal Regulations, this includes all handling of human blood or other tissues for research (not clinical) purposes.

If a medical procedure is to be performed in the hospital using human subjects, the investigator must have been approved for such procedures by the Office of the Senior Hospital Administrator.

Consent for Participation Instructions *(see Guidelines Part IX)*
The University of South Alabama Clinical Trials Database is accessible via the world-wide web at http://southmed.usouthal.edu/com/trials/ and serves as a useful tool to recruit subjects for the study protocols, enhance physical referral, and address patient inquiries. **NOTE:** Completion of this form and listing of your trial in the database is mandatory for all clinical research studies.

**Indicate Category of Research:**
Clinical Research: ___________   Non-Clinical Research: ___________

**NOTE:** Please explain below if you wish to exclude your clinical research project from the USA trials database:

______________________________________________________________________________

**IRB Protocol Number:** ___________
(to be filled in by IRB administrator)

**Trial Registration Data:**
Anticipated Trial Start Date: ___________
Anticipated Number of Subjects to be recruited:
   USA site: ___________
   Nationally: ___________

**Title of Protocol**

______________________________________________________________________________

**Principal Investigator**

______________________________________________________________________________

**Sponsor**

______________________________________________________________________________

**Participants:**

    Male/Female    ____/____  Age range ____

    Who is Eligible to Participate:

    Major Exclusions:

______________________________________________________________________________

**Brief description of research in lay terms (including therapeutic intervention, if any, primary and secondary outcome variables).**

______________________________________________________________________________

8
Primary Disease Category ________________

Keyword(s): ___________________ ___________________ ________________

Experimental Drug/Device: __________________________________________

Contact/Referral Information

Physician referrals are encouraged   Yes ____   No ____
Patient inquiries are encouraged   Yes ____   No ____

For additional information about this research please contact:

______________________________________________________________________________

Title (eg, Research Coordinator)

______________________________________________________________________________

Address

______________________________________________________________________________

Phone                Email                Fax
Title of Research

Principal Investigator

Department/Campus Address

Sponsor

Sponsor’s Agent (if applicable)

Will this protocol use hospital staff, resources or facilities? Yes _____ No _____

If no, please sign and obtain department chair’s signature and submit protocol to the IRB.

If yes, review is required by the Office of the Senior Hospital Administrator prior to review by the IRB. Note: Please answer the following questions and attach to this application.

1. Please provide a detailed description of the hospital resources to be used (e.g., lab studies, radiology studies, cardiology studies, etc.)
2. Who will be financially responsible for hospital charges incurred as part of this study? Is there separate funding or is the patient’s insurance responsible?
3. Approximately how many subjects will be enrolled in this study within the USA Hospital System?

My signature, as Principal Investigator, certifies that I will:

► Conduct all aspects of the project as approved by the IRB,
► Promptly report any revisions or amendments to the research activity for review/approval by the IRB prior to commencement of the revised protocol, with the only exception to this policy would be to eliminate apparent, immediate hazards to the subject,
► Promptly report any unanticipated problems or adverse advents,
► Assume full responsibility for selecting subjects in strict accordance with the inclusion/exclusion criteria outlined in the application materials, and,
► Where consent form(s) have been approved for the research activity, only IRB-approved, stamped consent forms will be used in the consent process.

Signature, Principal Investigator       Date

Signature, Departmental Chair       Date

Signature, Senior Hospital Administrator      Date

This signed form and investigator checklist (next page) must accompany your protocol submission to the IRB.
Investigator Checklist for Expedited and Full IRB Submission

The purpose of the checklist is to facilitate the application approval process and is intended to be utilized as a pre-review evaluation which may help identify and resolve issues that may delay approval.

- New Projects Application for Human Subjects is filled out in its entirety, including the Clinical Trials Database form for clinical research studies. This also includes signatures of the Principal Investigator, Department Chair and Hospital Administrator, if applicable.
- Completed human subjects protection training and HIPAA training in research.
- Are risks greater than “minimal risk”? If so, has the investigator cited appropriate references listing potential adverse reactions?
- If data is acquired at site other than USA, is permission statement included?
- Is subject selection equitable (e.g., subject population included/excluded; risk of coercion in recruitment)?
- Is informed consent appropriately documented? All basic elements, and additional elements as appropriate, for informed consent as specified by federal regulations –
  - Research purpose and procedures
  - Risks and Discomforts
  - Potential Benefits
  - Alternative Procedures or Treatments
  - Provisions for Confidentiality
  - Research-related injury
  - Contacts for additional information
  - Voluntary participation and the right to discontinue participation without penalty

When appropriate, the consent document should include the following additional information:

- Unforeseeable risks
- Termination of participation by the investigator
- Additional Costs
- Consequences of discontinuing research participation
- Notification of significant new findings
- Approximate number of subjects

- The consent document should include a statement “you will be given a copy of this consent”.
- Is clear, concise, non-technical language uses throughout the informed consent document?
- Are the provisions for maintaining confidentiality adequate?
- Have additional safeguards for subjects vulnerable to coercion or undue influence been included?
- Does the research setting (e.g., location of research, facilities) provide adequate safeguards for protection of human subjects?
- Are children (under the age of 19) involved? If so, include the investigator checklist for research involving children. If a separate assent form is not used, a assent line for minors must be included in the main consent form.
- Consent should be printed on USA departmental letterhead or formatted with a header to include institution, name of investigator, address and contact information.
- If applicable, the tissue banking form should be incorporated within the informed consent document prior to the final signature page.
- All supporting documents have been attached, including protocol, survey instruments, interview schedules, solicitation letters, advertisements, consent forms, etc. Supporting documents must be in final form as you intend to distribute them. Your application will be returned if these documents are in outline or first draft form.

I have reviewed the relevant items above. I understand that the IRB Office can not accept incomplete packets and will not forward them to the IRB for review. In addition, studies are not to be implemented prior to receiving an IRB approval letter.

Investigator Signature __________________________ Date __________________________