HUMAN SUBJECTS PROTOCOL

1. Title of Project:_____

   In the case of renewals, please indicate any previous title(s) under which this study may have been submitted:

2. Name of Principle Investigator:_____
   Signature of Investigator_____ Date:_____
   Address: _____
   _____

   Email:_____
   Phone Office:_____
   Phone Cell:_____
   Qualifications of the Investigator:

   In the case of renewals, please indicate any names of prior principle investigators on this proposal:_____.
   NOTE: Change of investigator requires a letter from the original investigator to the IRB requesting the change

   List the name and position of other investigators participating in this project, if any. Use a separate sheet of paper if necessary.
   None_____ Others_____

   If supervision is necessary, give the name and title of the EAMC person who will be responsible for the supervision
   Name:_____ Phone:_____

3. Status of Proposal or Activity:
   New_____ Renewal _____
   Date of last IRB approval:_____

4. If this study is part of a grant, please indicate the following:

   Grant Title:

   Principle Investigator of Grant:

5. Source of funds:

Governmental Agency or Agencies:

_____Foundation(s):

_____Corporation(s):

_____Organization(s):

_____Individual(s):

_____Other:

_____None ( )

6. Location of Study:
Name of Institution: East Alabama Medical Center

If the project is a field study, describe the community on the lines below. If the study is to be undertaken within a school, business, or other institution that does not have a review board, attach a statement of any contacts with the appropriate officials with authorization to conduct the study.

_____

_____

If the project is part of a multiple institution project that is mandated to be reviewed by a single IRB (Cooperative Research IRB), give the name and contact information for that IRB.

7. Approvals

A. Do these projects involve the use of an investigational new drug?

Yes___ No___
If yes, provide the name of the drug and the IND number: _____

Name of Drug:_____IND Number:_____

If an investigational new drug is involved, but an IND number has not been issued, what are the plans of the principle investigator for securing an IND from the FDA?

B. Do these projects involve the use of an investigational new device?

Yes___ No___

If yes, provide the name of the device and the investigational device exemption (IDE) number:_____
Name of Device:_____
IDE Number: _____

For projects involving investigational new devices which are considered non-significant risk devices, attach a letter from the sponsor discussing the reasons for the classification.

C. Do these projects involve the use of radioisotopes?

Yes___ No___

If yes, has the Radiation Safety Committee given approval?
Yes___ No___ Attach documentation of Radiation Safety Committee approval

D. Do these projects involve the use of biopsy or surgical material?

Yes___ No___

If yes, has the department providing the specimens given approvals?
Yes___ No___ Attach documentation of departmental approval

E. Do these projects involve the use of biospecimens?
Yes___No___ If yes, are they identifiable? Yes___No___

F. Have other review boards reviewed this project?
Yes___ No___

If yes, provide the name of the review board and the date of approval.

_____

If the study was rejected, give the reasons:

_____

8. Number and type of subjects and controls:

A. Number of Subjects and Controls:_____
B. Type of Subjects and Controls:_____
C. Population from which derived:_____
D. Indicate which of the following special populations will be involved in the project:

None of the following _____ , or including:

Children (under 19 yrs.)_____		Prisoners	_____
Fetuses	_____	Mentally retarded	_____
Abortuses	_____	Mentally disabled	_____

If special populations (minors, fetuses, pregnant women, prisoners, mentally retarded, or mentally disabled) are involved, state reasons for using the special populations:

List any subjects who will be at risk other than those directly involved in the study:
_____

E. Will any of the subjects be from other than East Alabama Medical Center?
Yes___ No___ If yes, where from?_____

9. Protocol Summary Narrative

A PROTOCOL SUMMARY NARRATIVE is a project abstract summarizing all the central elements of the protocol, for example rationale, objectives, methods, populations, time frame of the project and total time commitment of the subjects, data gathering, sampling methods, data analysis and protection, and expected outcomes. *Each format section must be addressed in the narrative.*

On separate sheets attach a PROTOCOL SUMMARY NARRATIVE structured in the following format: (using LAY LANGUAGE) and attach copies of any questionnaires, data templates, or images and attach proposed informed consent unless submitting a Waiver of Authorization form)

A. RATIONALE AND BACKGROUND INFORMATION

The rationale specifies the reasons for conducting the research in light of current knowledge. It should include a statement of the need or problem that is the basis of the project. It should state why the research needs to be done and what will be its relevance. The background should contain of what is known about the problem to date and any similarly research conducted (provide literature references if available).

B. STUDY GOALS AND OBJECTIVES

Goals are broad statements of what the proposal hopes to accomplish. Objectives are statements of the research question(s). Objectives should be simple and specific. Primary and secondary objectives may be stated.

C. STUDY DESIGN

The study design should include information on the type of study (e.g. prospective, retrospective , observational, interventional , controlled, non-controlled), the population of subjects and how they are recruited, inclusion and exclusion criteria, withdrawal criteria, duration of the study, total time commitment of the subjects, sampling methods and data records.

D. METHODOLOGY

The methodology section is the most important part of the protocol. It should include detailed information on the interventions to be made, procedures to be used, measurements to be taken, observations to be made, laboratory investigations to be done etc. If multiple sites are engaged in a specified protocol. methodology should be standardized and clearly defined.

Interventions should be described in detail, including a description of the drug/device/vaccine that is being tested. Interventions could also be in the realm of social sciences for example providing training or information to groups of individuals.

Procedures could be biomedical (collection of blood or sputum samples to develop a diagnostic test), or in the realm of social sciences (doing a questionnaire survey, carrying out a focus group discussion as part of formative research, observation of the participant's environment, etc.).

Standardized and/or documented procedures/techniques should be described. Instruments which are to be used to collect information (questionnaires, observation recording form (e.g. audio, video, case report forms etc.)) must also be provided.

In the case of a randomized controlled trial additional information on the process of randomization and blinding, description of stopping rules for individuals, for part of the study or entire study, the procedures and conditions for breaking the codes etc. should also be described.

A graphic outline of the study design and procedures using a flow diagram should be provided. This should include the timing of assessments.