ALTERATION OR WAIVER OF INDIVIDUAL AUTHORIZATION FOR DISCLOSURE OF PROTECTED HEALTH INFORMATION
(Not applicable if Informed Consent is used)

I. Title of Project:

II. Principal investigator:

III. Date of Review:

IV. Describe the Protected Health Information ("PHI") for which use and access is necessary for this research project. Protected Health Information" shall have the meaning set forth in 45 CFR 164.501, including, without limitation, any information, whether oral or recorded in any form or medium: (i) that relates to the past, present or future physical or mental condition of an individual; or (ii) the provision of health care to an individual; or (iii) the past, present or future payment for the provision of health care to an individual; and (iv) that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

V. Criteria. The following criteria must be explained in detail:

A. Explain how the use or disclosure of the PHI involves no more than a minimal risk to the privacy of individuals, based on elements (1), (2) and (3) below:

(1) Describe the plan to protect the identifiers from improper use and disclosure.
(2) Describe the plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research. If there is a health or research justification for retaining the identifiers or such retention is otherwise required by law, please explain in detail.

(3) Attach a written statement setting forth adequate assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use of disclosure of PHI would be permitted by law.

B. Explain why the research could not practicably be conducted without the alteration or waiver.

C. Explain why the research could not practicably be conducted without access to and use of the PHI.

D. Explain why if the research involves using PHI or identifiable biiospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

VI. Explain how waiver of consent will not adversely affect the privacy rights and the welfare of the individuals.

VII. Explain how the privacy risks to individuals whose PHI is to be used or disclosed are reasonable in relation to the anticipated benefits, if any, to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research.

NOW, THEREFORE, the Institutional Review Board of the East Alabama Healthcare Authority d/b/a East Alabama Medical Center after reviewing the information required by the Institutional Review Board as provided to use by the Principal Investigator for the Research Project titled _____ and determining that the Research Project meets the criteria established hereby approves the request for an alteration or waiver of individual authorization for disclosure of PHI and that said research be, and is hereby, authorized and empowered to alter or waive the individual authorization for disclosure of PHI as requested.

Alteration or Waiver of Authorization:

_____Approved on this _____ day of _____, 20___.

_____L.S.

Chairperson, Institutional Review Board
(or his/her designee)

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.

E. SAFETY PRECAUTIONS

The safety of research participants is foremost. Safety aspects of the research should always be kept in mind and information provided in the protocol on how the safety of research participants will be ensured. This can include procedures for recording and reporting adverse events and their follow-up, for example. It is useful to remember that even administering a research questionnaire can have adverse effects on individuals, too. A description of risks and benefits must be included, and how the risks will be mitigated.

F. DATA MANAGEMENT

The protocol should provide information on how the data will be managed, including data handling and coding for computer analysis, monitoring and verification. The statistical methods proposed to be used for the analysis of data should be outlined.

G. CONFIDENTIALITY

If personal health information and/or identity will be collected or accessed, there must be a description of how and who will collect or access the information, the authorization to do so, and how the data and information will be stored to protect against unauthorized access. The description must include how the information and results of the project will be used or distributed including what methods will be used to protect subjects' confidentiality.

H. INFORMED CONSENT

Unless there is an approved ALTERATION OR WAIVER OF INDIVIDUAL AUTHORIZATION FOR DISCLOSURE OF PROTECTED HEALTH INFORMATION form, attach a proposed Informed Consent containing the elements as described in the INVESTIGATOR' S GUIDE TO RESEARCH INVOLVING HUMAN SUBJECTS.