1.0 POLICY

1.1 Background.

1.2 Federal regulations require that adequate provisions are made to maintain the privacy of research participants and confidentiality of identifiable data collected in research.

1.3 **Privacy** is defined as the interest of persons (participants) in controlling the access by others (including the investigator) to themselves. Preferences regarding privacy depend on the individual and can vary with such characteristics as age, gender, ethnicity, socio-economic status, education, health, legal status, and the individual’s relationship with the investigator.

1.4 **Confidentiality** is defined as the agreement between the investigator and participant about the disclosure, management and use of data.

1.4.1 Disclosure means the release, transfer, provision of access to, or divulging in any manner of information data outside the entity holding the information.

1.4.2 **Use** means the sharing, employment, application, utilization, examination, or analysis of individually identifiable information within the entity that maintains such information.

1.5 The University of Alabama is subject to the HIPAA Privacy Rule (Protected Health Information or PHI). It is both a Covered Entity and a Hybrid Entity. See [http://hipaa.ua.edu/#what](http://hipaa.ua.edu/#what) for information about the law and its effects on research at UA.

1.6 **Protected Health Information (PHI)** is any information, including demographic information, transmitted or maintained in any medium (electronic, paper, or spoken word) created or received by a health care provider, health plan, or health care clearinghouse that relates to or describes 1) past, present, or future physical or mental health or condition of an individual, 2) the provision of health care to an individual or 3) future payment for the provision of healthcare to the individual.

1.7 Responsibility for HIPAA compliance is not limited to physician and nurse investigators. Social-behavioral scientists, other health professionals (dieticians, pharmacists, social workers, etc.), and investigators of health care costs or other health policy may all need access to protected health information and must comply with University and IRB HIPAA requirements.

1.8 It is understood that specific federal, state, and local laws may mandate disclosure of otherwise private information.

1.9 Policy Statement.
1.9.1 It is the policy of the University of Alabama that:

1.9.1.1 Participants in human subjects research shall retain their right to privacy and confidentiality;

1.9.1.1.1 “Participants” may also include the identities of participating or facilitating organizations or agencies.

1.9.1.2 Participants’ cognitive impairment/diminished capacity shall not diminish their right to privacy and confidentiality;

1.9.1.3 Investigators shall understand the difference between privacy and confidentiality;

1.9.1.4 Investigators seeking IRB approval for studies involving participant Protected Health Information (PHI) shall complete the IRB-required PHI training;

1.9.1.5 Investigators seeking use of PHI for screening and recruitment will describe their needs and procedures in their IRB applications.

1.9.1.6 The process of informed consent shall include a clear communication between the investigator and the participant about what private information will be sought and how it will be used, including a description of those conditions under which such information may be withheld, and those under which it may be disclosed. This communication shall include a description of the potential risks associated with a breach of privacy or loss of confidentiality, specific plans to protect against such breaches and losses, and identification of possible mandated disclosure of private information.

1.9.1.7 The IRBs shall include an explicit assessment of the adequacy of privacy and confidentiality protections in its review of applications.

Objective

1.9.2 Compliance with this policy will ensure that research compromises the participant’s rights to privacy and confidentiality only to the extent necessary to accomplish valid research aims, that adequate efforts are made to protect those rights and inform the prospective participant or a Legally Authorized Representative, and that the University of Alabama is compliant with regulations and accreditation requirements.

1.10 Responsibility

1.10.1 The Vice President for Research is ultimately responsible for this policy. Enabling parties include the Office for Research Compliance, the IRBs, investigators, Associate Deans and Directors of Research, and UA faculty supervising student research.

2.0 PROCEDURE
2.1 Research protocols submitted to the IRB will describe measures to protect privacy and confidentiality. This requires that Investigators appraise their projects carefully from the perspective of prospective participants (both individuals and institutions) to identify potential threats to privacy and confidentiality.

2.1.1 Describe and document the training of investigators regarding Human Subjects Research Protections and HIPAA by having each investigator or staff member on the project with access to private information submit training documentation as evidence of completion of HIPAA training.

2.1.2 Describe sample characteristics and the potential of those characteristics to be linked to concerns about privacy or confidentiality. For example, employees may be concerned about whether their supervisors will know of their participation or responses in the study. Another instance might be that members of a particular vulnerable population or ethnic group maybe concerned about the use of genetic information to stereotype them.

2.1.3 Describe subject recruitment and subject participation so that risks to privacy can be clearly discerned. This description shall include the privacy characteristics of the setting(s) for recruitment, consent, and participation.

2.1.3.1 Note that loss of privacy may involve risk of bodily harm to participants. For example, participants who are victims of domestic abuse may require special privacy measures to ensure their physical safety.

2.14 Protocols will describe the kinds of information to be sought from participants. This description should state whether the information includes any of the identifiers described in the HIPAA Privacy Regulations:

2.1.4.1 Names;

2.1.4.2 Social Security numbers;

2.1.4.3 All geographic subdivisions smaller than a state (including street address, city, county, precinct, ZIP code, and equivalent geocodes);

2.1.4.4 All elements of dates (except year) for dates directly related to an individual (birth date, admission and discharge dates, date of death, and all ages over 89) and all elements of dates (including year) indicative of such age except that such ages and elements may be aggregated into a single category of age 90 or older;

2.1.4.5 Voice and fax telephone numbers;

2.1.4.6 Electronic mail addresses; Internet Protocol (IP) address numbers and Universal Resource Locators (URLs);

2.1.4.7 Medical record numbers, health plan beneficiary numbers, or other health plan account numbers;
2.1.4.8 Certificate/license numbers;

2.1.4.9 Vehicle identifiers and serial numbers, including license plate numbers;

2.1.5.0 Device identifiers and serial numbers;

2.1.5.1 Biometric identifiers, including finger and voice prints;

2.1.5.2 Full face photographic images and any comparable images;

2.1.5.4 Any other unique identifying number, characteristic, or code.

2.1.5 Applicants seeking use of PHI only for screening or recruitment will complete and append FORM: Request for Partial Waiver of Patient Authorization to use PHI for Recruitment or Screening.

2.1.6 Applicants seeking use of PHI within research studies (i.e., after/other than recruitment and screening), will require participants to complete FORM: Research Authorization for Release of Personal Health Information and Personally Unidentified Study Data. (NOTE: This form is the form used by the University Medical Center; it may be used as a template and adapted for settings other than UMC.)

2.1.7 Projects addressing sensitive, stigmatizing, or illegal activities will explicitly outline steps taken to ensure confidentiality of information provided by participants. This includes but is not limited to projects which gather information on:

2.1.7.1 Private Health Information (PHI)

2.1.7.2 Sexual attitudes, practices, history, and diagnoses

2.1.7.3 Illegal activities

2.1.7.4 History of arrest/incarceration

2.2 Protocols will describe:

2.2.1 The investigator’s efforts to oversee management of participant records, including training of research staff;

2.2.2 The range of individuals who will have access to participant records;

2.2.3 The method for substituting codes for identifiers in participant records;

2.2.4 The facilities where the records will be kept, including location, lockable doors, and locked file cabinets;

2.2.5 The nature and security of electronic forms of the data, including the use of passwords and encryption;
2.2.5.1 If participants select their own passwords, the investigator must provide instruction about the need to avoid using common identifiers or readily available information such as a spouse’s first name.

2.3 Protocols will describe how and when participant data will be de-identified or destroyed.

2.4 Protocols will describe any agreements about the identification or non-identification of participating institutions or agencies. For example, the investigator might assure agencies they will be identified only as “women’s health counseling agencies from a southeastern state”.

2.5 Consent documents will:

2.5.1 Provide clear information concerning what participants will be asked to do, including the kinds of information they will be asked to provide;

2.5.2 Describe any proposed use of HIPAA authorizations;

2.5.3 Describe threats to privacy and confidentiality which may arise before, during, and after the study and how the investigator plans to minimize such threats.

2.5.4 Inform participants about situations in which the researcher and participant may be unable to control privacy issues. For instance, although focus group participants can be asked not to discuss the meeting, participant privacy cannot be guaranteed. Or, the investigator may be legally and professionally required to report such activities as spouse, child, or elder abuse.

2.5.5 Inform participants if the investigator is required to share de-identified data with sponsors or data sets or if the investigator plans to release data to other investigators. If the latter is true, the consent document should describe potential uses of the data and whether the data will be de-identified or for restricted use.

2.6 In studies where the consent document is the only written record linking participants to the project and a breach of confidentiality presents the principal risk of harm anticipated, the requirement of signed consent may be waived by the IRB. See FORM: Waiver of Written Consent.

2.7 In studies where prospective participants may be of diminished capacity, the protocol will describe the procedure for informing and obtaining consent from a participant’s Legally Authorized Representative.

2.7.1.1 All reasonably expected threats to privacy are described.

2.7.1.2 The plans for managing threats to privacy cover all identified threats and in the judgment of the board appear capable of controlling them;

2.7.1.3 The description of situations in which release or disclosure of identifiable data covers the possibilities.
2.7.1 Protection of confidentiality will be considered adequate when:

2.7.1.1 The investigator has identified and managed all the threats to privacy that the IRB considers likely.

3.0 REFERENCES

3.1 45 CFR §46.111 (a) (7), 21 CFR §56.111 (a) (7)


3.3 UA website on HIPAA: http://hipaa.ua.edu/#what

3.4 The Belmont Report

4.0 RELATED SECTIONS

4.1 FORM: IRB Checklist for Reviewers and Investigators

4.2 GUIDANCE: IRB Application Guidance

4.3 GUIDANCE: Template for Informed Consent

4.4 FORM: Request for Partial Waiver of Patient Authorization to use PHI for Recruitment or Screening.

4.4 FORM: Research Authorization for Release of Personal Health Information and Personally Unidentified Study