Disclose/Disclosure: The release or transfer of information to, or the provision of access to information by, a person or entity outside of the entity holding the information.

Informed consent: The process by which individuals are given information necessary to decide whether or not to participate in a research study and provided the opportunity to voluntarily agree to such participation without coercion or undue influence.

Limited Data Set: Protected health information from which direct identifiers have been removed that may be used and disclosed for research purposes pursuant to a data use agreement.

Privacy Rule: Standards for Privacy of Individually Identifiable Health Information, promulgated by the U.S. Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and codified at part 160 and part 164, subpart E, of Title 45 of the U.S. CFR (as amended from time to time).

Protected Health Information (PHI): Information transmitted or maintained in any form (i.e., by electronic means, on paper, or through oral communication) that: (1) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for health care; and (2) identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Security Rule: Adopted to implement provisions of the Health .c005 Tw6 (in)6 (e)3 ( )10 (pC-7e)(n)-3.9 (s)2i)4

Procedures

The IRB Office conducts a preliminary review of all new research, continuing review, or modification submissions to determine that those studies involving the collection of PHI or electronic PHI include the appropriate HIPAA documentation.

1.0 The IRB Office or the convened IRB reviews the collection, use, and/or disclosure of PHI for each submission to determine if an Authorization, waiver, Data Use Agreement, or other HIPAA privacy form is needed.

2.0 The IRB Office correspondences with the research team to request an alternate or

2.0 HIPAA Authorization and Informed Consent

The authorization document must include all elements defined in the HIPAA regulations as described in the USA HIPAA in Research Compliance Plan. The full compliance plan is available on the Office of Research Compliance and Assurance website at: http://www.southalabama.edu/com/research/hipaa.shtml Researchers must generally obtain authorization for the use of PHI from the human subjects whose PHI will be included in the study. The HIPAA authorization is incorporated into the informed consent within the confidentiality section. The USA IRB provides an authorization template that complies with HIPAA requirements. The researcher must customize the authorization template for the specific study he/she intends to perform. The USA IRB approved HIPAA Authorization template located in IRBNet, Forms/Templates.

The following differences in procedures for signing an authorization are outlined below:

Adults: A competent individual 18 years of age and older, should always sign the authorization to use or disclose his/her PHI. (the general ability to understand the concept of releasing his/her medical information).

Minors: Any parent or legal guardian may sign an authorization for a minor child in his/her legal custody. HIPAA does not require that an assent document specifically for research participation include any version of a HIPAA authorization.

3.0 HIPAA Security/ Use of ePHI

The IRB application collects information on the maintenance of electronic identifiable health information (ePHI) for each individual study. If ePHI is maintained, a separate application for registering research utilizing and storing ePHI must be submitted by the study site for review and approval. This form provides minimum standards and instructions for utilization and storage of ePHI and located in IRBNet forms and templates. There are several key components that are evaluated during the review process to include the following, 1) workstation use for sending, receiving, storing, or accessing e-PHI information; 2) workstation security; 3) transmission security and implementing measures to protect the security of ePHI when transmitted electronically from one point to another; 4) data disposition; 5) information system(s) the data will be obtained; and 6) applications(s) used for the storage of data. .1.4b/;4 (c)8 (a)4 (e)Tj0act k3 (bta)4IBD0a-204 (c)4 (ti)14e

Assurance. If a determination of non-compliance is made, the IRB may sanction suspension of project approval.

4.0 HIPAA-related Noncompliance or Breaches

The Office of Research Compliance and the IRB follows the procedures described in the USA HIPAA Privacy and Security Compliance Plan when information is received that