EFFECTIVE DATE: May 2023

This Standard Operating Procedure supports the USA HIPAA Privacy and Security Compliance For Research and other USA privacy policies, as well as the fully executed Clinical Trial Agreement. This SOP provides a mechanism by which a sponsor's proprietary information, data, and a subject's personal information are protected from disclosure to anyone other than authorized individuals.

This procedure pertains to any confidential information that is a part of a research study operated through the USA Clinical Trial Office. Confidential information includes but is not limited to protocols, investigator brochures, case report forms, research data, and identifiable personal health information. It is meant to supplement, not replace, other University of South Alabama's policies and procedures involving Protected Health Information (PHI) and/or protecting confidential information.

Establishes a legally-binding relationship between HIPAA-covered entities and business associates to ensure complete protection of PHI.

A legal contract through which the parties involved in executing the agreement are obligated not to disclose any proprietary information covered under the CDA. A CDA outlines the scope of the confidential information the parties wish to share with each other for specified purposes. A CDA is also known as a nondisclosure agreement (NDA), confidentiality agreement or secrecy agreement.

Any and all protected health information and proprietary information.

A clinical trial agreement (CTA) or clinical study agreement (CSA) is a legally binding agreement that governs the conduct of a particular study and sets forth the obligations of each party to the agreement.

Any health care plan, provider, or service that transmits health care information in an electronic form and is thereby governed by laws and regulations in the handling of such data.

Material and information relating to or associated with a company's products, business, or activities, including but not limited to financial information, data or statements, trade secrets, product research and development, existing and future product designs and performance specifications. Examples in

6. To use PHI without authorization by the research subject one of the following criteria must be met:

   6.1. The PI must obtain an alteration or waiver of Authorization by the Institutional Review Board (IRB). IRB may determine a Waiver of Authorization is appropriate when direct permission from the research participant is either not necessary or not possible, and, as documented by an investigator on a Waiver of Authorization document, the use or disclosure of PHI involves no more than a minimal risk to the research participant's privacy. Clinical research will generally not qualify for a waiver if the research participant will be asked to sign an informed consent form.

   6.2. PHI may be reviewed preparatory to research when use of the PHI is solely to prepare a research protocol or similar activities preparatory to research such as determining the feasibility of a study. No PHI can be recorded or removed from the Covered Entity.

   6.3. An Authorization is not required for research that involves only the PHI of decedents. Records/specimens of deceased individuals that contain PHI will be examined and will adhere to all the following: The research requires the review of PHI solely for research on deceased individuals; The access sought to PHI is necessary for research purposes; If requested, documentation of the death of the individual(s) whose protected health information that will be accessed will be provided.

7. All PHI must be redacted when being electronically transmitted to a sponsor or a sponsor designee.

8. Any equipment/device used for clinical trials that store electronic PHI must be approved by the USA HIPAA compliance office prior to use.

   8.1. All equipment that electronically stores PHI must include an approved safeguard, such as encryption software.

   8.2. A Manufacturer Disclosure Statement for Medical Device Security form must be completed for such equipment.

9. PHI may be sent without redaction to appropriate people using an encryption program. Communication of PHI by text is strictly prohibited by hospital policy.

10. The HIPAA Privacy Rule gives subjects the right to receive an account of any or all disclosures of their PHI made by the Covered Entity.

    10.1. Covered Entities and Business Associates that are listed in the research ICF are exempt from the above requirement.

11. Data that is collected for the sole purpose of the sponsored research is property of the sponsor unless otherwise stated in the Clinical Trial Agreement. This data is subject to confidentiality measures outlined in this SOP.

12. All confidential information must stay on a University of South Alabama property. Transporting or storing of confidential information at an unapproved site or on an unapproved device is a breach of confidentiality.