POLICY REGARDING USE AND DISCLOSURE OF INDIVIDUAL HEALTH INFORMATION FOR RESEARCH PURPOSES

**Purpose:**
To set forth the policy and procedures of WVU Physicians of Charleston (WVUPC) regarding uses and disclosures of individual health information for research purposes.

**Standard:**
WVUPC will strive to comply at all times with rules governing the use or disclosure of individually identifiable health information for research purposes. These rules include the federal regulations under HIPAA, and applicable state law to the extent that state law provisions are more protective of individuals’ privacy rights in research settings.

**Policy:**

1. **As a general rule, a health care provider may not release PHI to a researcher unless the subject whose PHI is requested has signed a HIPAA compliant authorization permitting the release of such health information. A health care provider who is also the researcher still must obtain an authorization from the subject before the provider can use the PHI for research purposes.**

2. **Exceptions:** The following are exceptions whereby it is not necessary to obtain an authorization from subjects to use or release their protected health information: (a) **IRB Waiver** (The IRB has approved a waiver of the need to obtain a HIPAA authorization); (b) **De-identification** (the health information has been de-identified); (c) **Limited Data Set** (the health information is used or disclosed in a limited data set); (d) **Disclosure to the FDA** (disclosures may be made to a person who is subject to the jurisdiction of the Food and Drug Administration with respect to an FDA regulated product or activity for which that person has responsibility); (e) **Preparatory to Research** (PHI may be used/disclosed to a researcher as necessary to prepare a research protocol or for similar purposes preparatory to research to the covered entity that holds the PHI if all of the following apply: i) the use/disclosure is sought solely for purposes preparatory to research; ii) no PHI will be removed from the entity’s premises in the course of the review; and iii) the PHI for which use/access is sought is necessary for the research purposes; and (f) **Decedents’ Research** (PHI may be used/disclosed to a researcher for research on decedents, provided the researcher represents to the covered entity that holds the PHI that the use/disclosure is sought solely for research on the PHI of...
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decedents, provides documentation of the death of the research subject and represents that the PHI is necessary for the research.

A. Researchers/persons with access rights and responsibilities:

1. Certain members of the WVUPC workforce require access to individual health information in the course of carrying out research. Persons with access have a responsibility to understand their obligation to protect the privacy of individual health information that has been entrusted to them, and are responsibility for complying with all relevant IRB procedures, WVUPC policies and procedures as well as applicable state and/or federal law.

2. Researchers/Persons with access are responsible for the following:

- Compliance with all WVUPC policies and procedures and applicable laws relating to the privacy of individual health information in research;
- Every faculty member, employee, trainee, student, vendor and volunteer at WVUPC who conducts human subjects research will maintain the privacy of all individual health information entrusted to them;
- Complete all required training on policies, procedures, and state/federal laws related to the privacy of individual health information in research;
- Use/disclose individual health information only as permitted or required by WVUPC or health care component policies/procedures and state/federal law;
- Request access to or access information only as necessary to perform their research related function;
- Exercise reasonable diligence and common sense in any discussion or use of individual health information in research;
- Researchers who hold PHI and are in a covered health care component must keep an accounting of certain disclosures made for purposes other than the original research purpose for which the information was obtained;
- Researchers who find violations in their own research must notify the IRB for advice/direction on how to mitigate the breach and any resulting harm to research subjects;

Consequences of violations—alleged policy violations will be referred to the appropriate WVUPC investigative or disciplinary
3. **IRB Rights and Responsibilities**

WVUPC utilizes an outside IRB, namely, the CAMC Health, Education and Research Institute (CHERI). IRB functions include, but may not be limited to, all of the following:

- Reviewing and acting on all research proposals involving PHI to determine that PHI is used in a manner permitted by HIPAA
- Reviewing and acting on all requests for waiver or alteration of the individual authorization requirements for research purposes. The review will be conducted under a full convened review or expedited review procedure as governed by federal regulations at 45 CFR 46.108(b) and 46.110.
- Developing internal policies and procedures for review and granting of waiver or alteration of individual authorizations in accordance with 164.512(i).
- Maintaining ongoing communication with the Privacy Officers for the affiliated institutions as necessary.
- Maintain ongoing communication with the Security Officers of the affiliated institutions as necessary.
- Providing documentation to persons requesting waiver of authorization and maintaining said documentation for at least 6 years after completion of the study
- Responding to requests for further information regarding practices related to privacy of individual health information in research, or referring such requests to the Privacy or Security Officers as appropriate.
- Processing or referring, as appropriate, complaints received regarding the privacy of individual health information in research.

4. **WVUPC Rights and Responsibilities**

WVUPC shall take measures to ensure that the privacy of individual health information used or disclosed in the course of performing research is protected in accordance with applicable state and federal laws. When WVUPC becomes aware of prohibited uses or disclosures of individual health information,
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either through routine administrative activities or from a complaint, WVUPC shall investigate as needed and take necessary actions to end, mitigate and/or to prevent the violation.

REFERENCES:
45 C.F.R. § 164.512