**GUIDANCE NUMBER 15**

**HIPAA GUIDANCE AND PHI**

15.1 HIPAA (Health Insurance Portability and Accountability Act)

On April 14, 2003, HIPAA rules came into effect. Under this rule, researchers working at RowanSOM are permitted to use and disclose PHI (Protected Health Information) for research with individual authorization, or waiver of authorization as set forth in the HIPAA Privacy Rule.

In clinical research, physician-investigators often stand in dual roles to the subject as a treating physician and as a researcher. For the treating physician, duties of confidentiality have long been established under well-known legal and ethical standards. The Privacy Rule adds to these existing obligations. Where a covered entity conducts clinical research involving protected health information (PHI), physician-investigators need to understand the Privacy Rule's restrictions on the use and disclosure of PHI for research purposes. As the Federal privacy standards are implemented throughout the country, one benefit is that many clinical researchers and hospitals may adhere to a common set of national standards for protecting the privacy of patients and clinical research subjects.

The fact sheet published by the NIH (http://privacyruleandresearch.nih.gov/clin\_research.asp.) discusses the Privacy Rule and its impact on covered entities that conduct clinical research. It places specific emphasis on the Authorization that is generally required for research use and disclosures of PHI by covered entities.

15.2 HIPAA Training

Every employee and students at Rowan SOM must complete HIPAA Compliance training (OCCl103). This training is available in the following link: https://www.rowan.edu/compliance/.

Investigators conducting medical research at all campuses who use protected health information must complete HIPAA Privacy and Security Medical Research Compliance Training OCCl1103 and OCCl109.

For additional information on HIPAA training, contact Rowan SOM at 856-566-6229 or 856-566-6136.

15.3 List of HIPAA Identifiers

The following identifiers of the individual or of relatives, employers, or household members of the individual, are considered PHI identifiers under HIPAA:

1. Names

2. Postal address

All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

(1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people are changed to 000.

3. Dates

All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, 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;

4. Telephone numbers

5. Fax numbers

6. Electronic mail address

7. Social security numbers

8. Medical record numbers

9. Account numbers

10. Health plan beneficiary number

11. Certification/license numbers

12. Vehicle identifiers and serial numbers, including license plate numbers

13. Device identifiers and serial numbers

14. Name of relative

15. Web Universal Resource Locator (URL)

16. Internet Protocol (IP) address number

17. Biometric identifiers, including fingers and voice prints

18. Full face photographic images and any comparable images

Any other unique identifying number, characteristic, or code

15.4 Honest Broker

The Privacy Rule (HIPAA) permits protected health information (PHI) to be used without patient authorization in a number of limited circumstances such as the use of de-identified PHI. PHI can either be de-identified by an honest broker, who is a member of the covered entity (RowanSOM) or by an honest broker that is a business associate of the covered entity.

An honest broker is an individual, organization or system acting for, or on behalf of, the covered entity to collect and provide health information to research investigators in such a manner whereby it would not be reasonably possible for the investigators or others to identify the corresponding patients/participants directly or indirectly. The honest broker cannot be one of the investigators. The information provided to the investigators by the honest broker may incorporate linkage codes to permit information collation and/or subsequent inquiries (i.e., a “re-identification code”), however the information linking this re-identification code to the patient’s identity must be retained by the honest broker and subsequent inquiries are conducted through the honest broker.

15.5 Preparatory to Research

Preparatory to research representation provision permits covered entities to use or disclose protected health information for the purpose of developing a research protocol, formulating a research hypothesis, or screen for study eligibility. See guidance for preparatory to research in the following link: https://sites.rowan.edu/officeofresearch/compliance/irb/policiesguidance/guidancelisting/preptoresearch.html#p7EPMc1\_27. However, the provision at 45 CFR 164.512(i)(1)(ii) does not permit the researcher to remove protected health information from the covered entity's site. As such, a researcher who is an employee or a member of the covered entity's workforce could use protected health information to contact prospective research subjects. The preparatory to research provision would allow such a researcher to identify prospective research participants for purposes of seeking their authorization to use or disclose protected health information for a research study. Preparatory to research activities are defined as:

A. The development of research questions;

B. The determination of study feasibility (in terms of the available number and eligibility of potential study participants);

C. The development of eligibility (inclusion and exclusion) criteria; and

D. The determination of eligibility for study participation of individual potential subjects and

E. The PHI used to identify prospective research participants could include contact information, diagnosis or condition, and other information necessary to determine study eligibility.

Although HIPAA considers the use and disclosure of PHI to determine study eligibility a preparatory to research activity, the actual process used to recruit subjects remains a research activity and requires IRB approval.

In order to receive approval for preparatory to research please complete the “Preparatory to Research Form” posted on the website <https://sites.rowan.edu/officeofresearch/compliance/irb/policiesguidance/guidancelisting/preptoresearch.html#p7EPMc1_27>.

15.6 Limited Data Set Agreement

Limited data set (LDS) is an exemption to the Privacy Rule requirement for an authorization from the subject for research use of protected health information (PHI). LDS lacks 16 of the 18 identifiers listed above (Section 15.2). LDS may contain dates of birth, date of death, dates of service, town or city, state or zip code. If you are using the dates and zip codes, you must obtain a limited data set agreement. For further information of obtaining LDS agreement, please contact the Office of Compliance, RowanSOM at 856-566-6136 or email at braeunrc@rowan.edu.

15.7 Data Use Agreement

A Data Use Agreement (DUA) is a contractual document used for the transfer of data that has been developed by nonprofit, government or private industry, where the data is nonpublic or is otherwise subject to some restrictions of its use. Often this data is a necessary component of a research project and it may or may not be human subject data from a clinical trial, or limited data set information as defined in HIPAA. The Institution wants to ensure that DUA terms protect confidentiality when necessary, but permit appropriate publication and sharing of research results in accordance with institution policies, applicable laws and regulations, and federal requirements. DUAs are similar to confidentiality agreements, and, in some cases, a CDA (confidentiality disclosure agreement) format may be used to transfer data. If data transfer is part of a larger agreement between institutions where in PHI is NOT part of the data that will be transferred, but they are part of a funding agreement (grant, contract, sub-award, contracted services agreement, etc.) in those cases, a separate DUA is not necessary.

All DUAs are reviewed by the general counsel’s office. DUAs should not be signed by Institution’s faculty or staff members and it is signed by the individual authorized to sign on behalf of the Institution.

15.8 Decedent Health Information

Use of decedent health information requires (1) the researcher seeking access to decedent’s PHI must obtain permission from the IRB indicating in a memo that the use and disclosure is sought solely for research on the PHI of decedents; (2) the memo indicating that the PHI for which use or disclosure is sought is necessary for the research purposes, and (3) documentation, at the request of the covered entity, of the death of the individuals whose PHI is sought by the researchers. For further information of obtaining LDS agreement, please contact the Office of Research Compliance, RowanSOM.