



MEMORANDUM

From: Kathryn M. Mellouk, Associate Vice President, Research Compliance
Diane M. Lindquist, JD, Director Health Privacy and Compliance *Diane Lindquist*

To: Jean Morrison, University Provost
Karen H. Antman, Provost of the Medical Campus
Gloria Waters, Vice President and Associate Provost for Research
Christopher A. Moore, Dean, Sargent College
Jeffrey W. Hutter, Dean, Goldman School of Dental Medicine

Cc: Martin J. Howard, Sr. Vice President, Chief Financial Officer & Treasurer
Tracy Schroeder, Vice President for Information Services and Technology
Erika Geetter, Vice President and General Counsel

Re: Designation of Boston University's HIPAA Covered Components

Date: June 20, 2017

This Memorandum constitutes the formal record of Boston University's updated designation of its "HIPAA Covered Components" pursuant to 45 CFR Section 164.105(a)(2)(iii)(D). Since the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") went into effect in 2003, the University has elected to be a Hybrid Entity under HIPAA by designating its components that are subject to HIPAA. With this Memorandum, the University updates, effective June 20, 2017, its original designation dated March 19, 2003 and previously updated from time to time.

HIPAA Covered Components

BU designates the following organizational units as Covered Components:

1. Boston University Rehabilitation Services including the BU Physical Therapy Center and the BU Center for Neurorehabilitation
2. Sargent Choice Nutrition Center
3. Henry M. Goldman School of Dental Medicine Patient Treatment Centers
4. BU Dental Health Center
5. The Albert and Jessie Danielsen Institute

6. Boston University Student Health Services¹

Support Units

Each of the Covered Components receives services from a number of BU units that are not Covered Components (“Support Units”). BU employees who use, create or disclose PHI in the course of providing services to any Covered Component are considered members of the Workforce of that Covered Component.

BU has identified the following units as Support Units whose services to Covered Components commonly require the access, use, creation or disclosure of Covered Components’ PHI:

- Information Services & Technology, including Boston University Medical Campus Information Technology
- Financial Affairs, including Internal Audit and Advisory Services, Risk Management, and Accounts Payable
- Office of the General Counsel

Excluded from HIPAA Designation

Commitment to Protecting Sensitive Information

BU maintains many types of sensitive information not subject to HIPAA, such as student Education Records and Treatment Records whose confidentiality is governed by FERPA; patient records in units that do not conduct the types of electronic transactions that would make them subject to HIPAA, but whose records remain protected by state law; and human resources records governed by federal and state law. BU takes seriously its obligations under each of these laws and protects those records accordingly.

Individually Identifiable Health Information in Research

Individually identifiable health information created or obtained in the course of research at BU is covered by federal regulations protecting the well-being and privacy of human subjects of research and is not covered by HIPAA. BU’s Covered Components are designated as not including research functions, except to the extent the research involves a BU Covered Component’s provision of standard of care treatment services to its patients.

When a BU researcher creates or receives individually identifiable health information in connection with research activities where no standard of care treatment is involved, the individually identifiable health information is not PHI and is not subject to HIPAA. To the extent standard of care treatment is provided as part of a research protocol, such information—when it is part of a medical record—is PHI subject to HIPAA.

¹ While Student Health Services qualifies as a Covered Component because it engages in electronic transactions, its records are either Education Records or Treatment Records under the Family Educational Rights and Privacy Act, 20 U.S.C. Section 1232g. Student Health Services treats only “students” as that term is defined by FERPA. As a result, Student Health Services is not subject to either the HIPAA Privacy Rule or the HIPAA Security Rule, and is not subject to BU’s HIPAA Policy Manual.

Individually identifiable health information that is created as PHI at a BU Covered Component (or at another HIPAA Covered Entity) may be disclosed to a BU researcher (the same individual healthcare provider who is also a researcher may disclose PHI to him/herself in the research role) pursuant to the IRB-approved consent process, which includes proper research subject HIPAA authorization or IRB waiver of authorization. After the PHI is properly disclosed from the BU Covered Component (or another HIPAA Covered Entity) to BU researchers outside of that Covered Component or Covered Entity, the PHI transferred to the research setting becomes research information, which is no longer PHI subject to the requirements of HIPAA.

The University has designated all individually identifiable health information acquired and used in the course of research as Restricted Use data under University policy, requiring the most stringent safeguards. In addition, Researchers must follow the safeguards established in the written documentation under which their access to the data was permitted, including data protection requirements imposed by the Institutional Review Board. In certain cases, such as interventional clinical trials, it is expected there may be two copies of some individually identifiable health information: a copy kept in the patient's medical record which is PHI and subject to HIPAA, and a copy of the same data kept in the research record which is research information and not subject to HIPAA.

BU takes the confidentiality of all individually identifiable health information and other sensitive information used in the course of research very seriously. The confidentiality of such information is protected as Restricted Use Data under its University policies, under other federal and state laws and regulations, and, in the case of information obtained through human subject research, conditions imposed by the Institutional Review Board.