

**UNC Charlotte Contract Review Guidance on
Business Associate Agreements
under the Health Insurance Portability and Accountability Act (HIPAA)**

This document is intended for guidance purposes only. If you have specific questions about the parameters of Business Associate Agreements or the situations in which they might be appropriate, contact the Office of Legal Affairs at (704) 687-5732.

- Clinical Affiliation Agreements

A business associate agreement (BAA) is never appropriate when the University enters into an affiliation agreement with a HIPAA-covered entity for University students to obtain clinical experience (e.g. practicum, field experience, internship, etc.) at a facility of that covered entity.

In accordance with the principles of HIPAA, the facility, as a “covered entity,” retains responsibility for the HIPAA compliance of its workforce. “Workforce” includes “employees, volunteers, *trainees*, and other persons whose conduct, in the performance of work for a covered entity, is under the direct control of such entity, whether or not they are paid by the covered entity.” 45 CFR § 160.103. Furthermore, a covered entity’s health care operations include “conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers.” 45 CFR § 164.501. Therefore, because University students are participating in a clinical education program at a HIPAA-covered entity, the students are considered part of the facility’s workforce for HIPAA compliance purposes (even though they are not considered employees for workers’ compensation or any other purposes).

A business associate relationship is not created between the covered entity and the University because the covered entity will neither look to the University for business associate support services nor exchange protected health information (PHI) with the University, and the students are not University employees. Therefore, UNC Charlotte will not enter into business associate agreements with covered entities with which we have Clinical Affiliation Agreements.

- Research Activities

It will almost never be appropriate for a University researcher to enter a business associate agreement (BAA) with a HIPAA covered entity. In many cases, a data use agreement, rather than a BAA, will be appropriate.

A BAA is typically used when the recipient of protected health information (PHI) will be performing a task or a business support service involving the PHI that is for the covered entity’s own purposes. When a covered entity serves as a research or clinical trial site, the investigator/sponsor/researcher that receives research data pursuant to an authorization is not a business associate of the covered entity. A covered entity must seek authorization to use or disclose an individual’s PHI—if it includes identifiable information—for specific research purposes.

The process of de-identification, by which identifiers are removed from the health information, mitigates privacy risks to individuals. A covered entity may use or disclose facially de-identified PHI for research purposes provided that it executes a data use agreement with the recipient of the data.

A data use agreement is not like a BAA under HIPAA. Although HIPAA does not specify the form of a data use agreement, it requires that the agreement:

1. Establish the permitted uses and disclosures of such information by the limited data set recipient, which can be only for the purpose of research, public health, or health care operations; and
2. Provide that the limited data set recipient will protect the information according to certain requirements.