

**HIPAA GUIDANCE:
RESEARCH AND BUSINESS ASSOCIATE CONTRACTS (BACs)
aka BUSINESS ASSOCIATE AGREEMENTS (BAAs)**

Revised: September 16, 2004

This guidance addresses:

1. Why Business Associate Contracts are not appropriate for research conducted by UB Researchers
2. Situations where Business Associate Contracts between a HIPAA covered entity and UB may be appropriate for the performance of covered entity duties in support of research

NB: Parts of this guidance are specific to the SUNY-UB HIPAA hybrid entity environment where the SUNY-UB research function, and consequently any SUNY-UB researcher, has been specifically defined as being separate from, and not part of, any HIPAA covered function/entity. It is specifically applicable to all SUNY-UB researchers in any setting dealing with a HIPAA covered function/entity and, separately, all SUNY-UB covered functions.

1) Why Business Associate Contracts are not appropriate for research conducted by UB Researchers

45 CFR §160.103 introduces the concept of a Business Associate (BA) of a HIPAA Covered Entity (CE), and 45 CFR §164.504(e)(1) contains the requirements for a Business Associate Contract (BAC). Separately, HIPAA defines seven mechanisms¹ by which Protected Health Information (PHI) may be accessed by a researcher (independent of their CE status) and used for research purposes. None of these seven mechanisms incorporate a BAC into their requirements.

In general, a BAC is a mechanism by which a CE binds a 3rd party entity to maintain confidentiality of PHI when the 3rd party performs services *for* the CE. Since research is an activity a UB faculty member performs in fulfillment of their professional obligation to the State University of New York, that research is not an activity performed for a CE and, consequently, the BAC concept does not apply to that activity.

Specifically with respect to research, the University does not arrange, perform or assist in the performance of a function, service or activity for or on behalf of the CE involving the use or disclosure of individually identifiable information, such as those described in 45 CFR §160.103(1)(i). Similarly the University does not provide any functions on behalf of the CE, such as those defined in 45 CFR §160.103(1)(ii). Further guidance in this area has been provided by the Department of Health and Human Services²:

Question
Is a business associate contract required for a covered CE entity to disclose protected health information to a researcher?
Answer
No. Disclosures from a covered entity to a researcher for research purposes do not require a business associate contract, even in those instances where the covered entity has hired the researcher to perform research on the covered entity's own behalf. A business associate agreement is required only where a person or entity is conducting a function or activity regulated by the Administrative Simplification Rules on behalf of a covered entity, such as payment or health care operations, or providing one of the services listed in the definition of "business associate" at 45 CFR 160.103. However, the HIPAA Privacy Rule does not prohibit a covered entity from entering into a business associate contract with a researcher if the covered entity wishes to do so. Notwithstanding the above, a covered entity is only permitted to disclose protected health information to a researcher as permitted by Rule, that is, with an individual's authorization pursuant to 45 CFR 164.508, without an individual's authorization as permitted by 45 CFR 164.512(i), or as a limited data set provided that a data use agreement is in place as permitted by 45 CFR 164.514(e).

¹ Authorization (45 CFR §164.508), Waiver or Alteration of Authorization (45 CFR §164.512(i)(1)(i) & 45 CFR §164.512(i)(2)), Reviews Preparatory to Research (45 CFR §164.512(i)(1)(ii)), Research on Decedents (45 CFR §164.512(i)(1)(iii)), Transition Provisions (45 CFR §164.532(c)), De-identified Data (45 CFR §164.514(a-c)), Limited Data Set (45 CFR §164.514(e))

² Available on HHS WEB FAQ (http://answers.hhs.gov/cgi-bin/hhs.cfg/php/enduser/std_alp.php;) Answer ID=239, dated 07/18/2003 11:13 AM

2) Situations where Business Associate Contracts between a HIPAA Covered Entity and UB may be appropriate for the performance of Covered Entity duties in support of research

There are some circumstances where a BAC may be appropriate in support of CE activities associated with research. Creation of a dataset for research purposes comprised of PHI *held by the CE* is a *CE* activity (not a research activity) under HIPAA.

The CE's creation of the PHI data set required by the researcher can be approached in basically one of two ways:

- a) The data set is generated by the CE through activities of its workforce.
- b) The data set is generated by a business associate of the CE, with an appropriately executed business associate contract (BAC) in place governing the service of creating this data set.

In both cases, creation of the data set is an activity of the CE that falls within the "Operations" component of its HIPAA "Treatment, Payment and Operations" activities. Consequently, all access to and use of PHI for this activity constitutes a "use" of PHI by the CE.

In instances where the researcher, in a *separate and distinct* capacity from their research (non-covered function) duties, is also a member of a covered function's workforce, they may create the required data set via mechanism (i) provided that activity is formally part of their separate and distinct job duties within the covered function.

Note that per 45 CFR §160.103 *Definitions: Workforce*, volunteers are defined to be members of the covered function's workforce. An external researcher who is also a formal volunteer of the covered function could create the required data set by way of this mechanism *provided* that the covered function has an formally and appropriately established mechanism for appointing volunteers, that this activity is formally defined by the covered function as part of the volunteer's duties, and that volunteers in the covered function are required to fully comply with all aspects of the covered function's HIPAA implementation pertaining to its workforce.

If the researcher is not part of the covered function which possesses the required PHI, and the covered function does not have a mechanism for providing the researcher with only the PHI identified in the waiver, then the researcher may perform the dataset creation only via mechanism 2)(b).³

³ HHS WEB FAQ (see footnote 2); Answer ID=249; Category: Privacy of Health Information/HIPAA, Business Associates, Limited Data Set; Date updated: 03/03/2003 06:16 PM; generalized from example where BAA is identified as the proper mechanism to be used by a researcher to create limited data required to conduct their research when the covered entity cannot provide this service.



Director of HIPAA Compliance

Mechanism 2)(b) is not recommend for use by SUNY-UB researchers wishing to access PHI within a SUNY-UB covered function.

It is important to note that any Business Associate Contract binding a UB researcher must be between the appropriate SUNY entity and the external covered entity, and that this contract is for an activity *separate* from the research activity. Individual researchers may not enter into such agreements with an external covered entity on behalf of SUNY. If a SUNY-UB researcher wishes to enter into a BAC with a non-SUNY-UB covered entity, an appropriate SUNY-UB signatory agent needs to be identified by the UB Director of HIPAA Compliance and the BAC must be vetted by legal counsel associated with the signatory agent.