

HIPAA GUIDANCE: RESEARCH AND LIMITED DATA SETS / DATA USE AGREEMENTS (LDS/DUAs)

Revised: September 16, 2004

This guidance addresses:

1. The Limited Data Set (LDS) / Data Use Agreement (DUA) mechanism
2. When should a UB researcher utilize a LDS/DUA to acquire Protected Health Information from a HIPAA Covered Entity (CE)
3. 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 associated with creating a LDS

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) The Limited Data Set (LDS) / Data Use Agreement (DUA) mechanism

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.

45 CFR §164.514(e)(2) defines the contents of a Limited Data Set (LDS) as a data set of PHI that excludes the following identifiers:

- (i) Names;
- (ii) Postal address information, other than town or city, State, and zip code;
- (iii) Telephone numbers;
- (iv) Fax numbers;
- (v) Electronic mail addresses;
- (vi) Social security numbers;
- (vii) Medical record numbers;
- (viii) Health plan beneficiary numbers;
- (ix) Account numbers;
- (x) Certificate/license numbers;
- (xi) Vehicle identifiers and serial numbers, including license plate numbers;
- (xii) Device identifiers and serial numbers;
- (xiii) Web Universal Resource Locators (URLs);
- (xiv) Internet Protocol (IP) address numbers;
- (xv) Biometric identifiers, including finger and voice prints; and
- (xvi) Full face photographic images and any comparable images.

A covered entity may use or disclose a LDS to a researcher for research purposes if the covered entity enters into a Data Use Agreement (DUA) with the limited data set recipient.

It is important to note that any Data Use Agreement binding a UB researcher must be between the appropriate SUNY entity (SUNY, Research Foundation, etc.) and the external CE. Individual researchers may not enter into such agreements with an external CE on behalf of SUNY. If a SUNY-UB researcher wishes to enter into a DUA 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 DUA must be vetted by legal counsel associated with the signatory agent.

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) When should a UB researcher utilize a LDS/DUA to acquire Protected Health Information from a HIPAA Covered Entity (CE)

Because HIPAA does not prescribe which of the seven mechanisms a researcher should use to obtain PHI from a covered entity, and because of the potential time delay and extra resources required to implement a DUA, UB recommends that its researchers *not* pursue this course of action unless none of the other HIPAA mechanisms for acquiring PHI from a CE for research purposes are applicable. In particular, if PHI is being sought, researchers should seek to acquire individual authorization from the research subjects. If obtaining such authorization is not practicable, then researchers should rule out the feasibility of obtaining a waiver or alteration of the authorization requirement from the UB IRB before proceeding with the Limited Data Set approach.

3) 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 associated with creating a LDS

There are some circumstances where a Business Associate Contract (BAC) may be appropriate in support of CE activities associated with research. Creation of a LDS 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 LDS 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 LDS 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

Director of HIPAA Compliance

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 required for the LDS, then the researcher may create the LDS only via mechanism 3)(b) per guidance provided by the Department of Health and Human Services.²

Question
Under the HIPAA Privacy Rule, may a covered entity contract with a business associate to create a limited data set the same way it can use a business associate to create de-identified data?
Answer
Yes. See 45 CFR 164.514(e)(3)(ii). For example, if a researcher needs county data, but the covered entity's data contains only the postal address of the individual, a business associate may be used to convert the covered entity's geographical information into that needed by the researcher. In addition, the covered entity may hire the intended recipient of the limited data set as the business associate for this purpose in accordance with the business associate requirements. That is, the covered entity may provide protected health information, including direct identifiers, to a business associate who is also the intended data recipient, to create a limited data set of the information responsive to the recipient's request. However, the data recipient, as a business associate, must agree to return or destroy the information that includes the direct identifiers once it has completed the conversion for the covered entity.

Mechanism 3)(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.

² HHS WEB FAQ (http://answers.hhs.gov/cgi-bin/hhs.cfg/php/enduser/std_alp.php); Answer ID=249; Category: Privacy of Health Information/HIPAA, Business Associates, Limited Data Set; Date updated: 03/03/2003 06:16 PM.
173 Biomedical Education Building; 3435 Main Street Bldg. 22; Buffalo, NY 14214-3013
Tel: (716) 829-3172 Fax: (716) 829-3456