

Data Use Agreement Guidance

Introduction

Data Use Agreements (DUAs) are contractual documents used for the transfer of non-public data that is subject to some restriction on its use. DUAs serve to outline the terms and conditions of the transfer. Specifically, DUAs address important issues such as limitations on use of the data, obligations to safeguard the data, liability for harm arising from the use of the data, publication, and privacy rights that are associated with transfers of confidential or protected data. The understanding established by a DUA can help avoid later issues by clearly setting forth the expectations of the parties (provider and recipient). Having a signed DUA in place may be a required precondition to transfers of certain data, or it may simply be a good idea. Determining whether a DUA is required is necessarily context dependent. When a DUA is required, it must be purpose specific – i.e., data cannot be transferred pursuant to “master” or blanket sharing agreements without a unique implementing letter identifying the specific data set and uses.

DUAs shall be signed by a University of Iowa (UI) official who has the appropriate delegated signature authority. DUAs to receive or share data for research or economic development purposes shall be signed by the Vice President for Research and Economic Development or the Executive Director of the Division of Sponsored Programs. DUAs for UI Health Care data stored in the hospital's electronic medical record shall be signed by the Chief Executive Officer of University of Iowa Hospitals and Clinics. DUAs for UI Health Care data that has not been accumulated through an approved research grant and is not stored in the hospital's electronic medical record shall be signed by the Vice President of Medical Affairs. All other DUAs shall be signed by the appropriate authorized UI official depending on the type of data involved, such as the UI's Business Manager, in accordance with the UI's [Operations Manual, Part V, Section 6.1](#).

The purpose of this guidance is to assist its users in assessing whether a proposed outgoing transfer of data that is in the possession of UI and/or a UI investigator (developed in his or her work for UI) to a third party (i) is permissible; and (ii) if so, whether a DUA is necessary or recommended to effect the transfer. This guidance contemplates the **outgoing** transfer of data to third parties who have a bona fide research use or practical application for the data (e.g., collaborating research institutions, academicians, public policy makers, community service providers, etc.). Note: this guidance does not address incoming data to be accepted by UI, or a UI investigator, from a third party, nor does it address providing data to a web hosting service, which comes with a different set of considerations such as accessibility. Where incoming transfer of data is proposed, the data provider, subject to similar principles described herein, will ultimately determine whether a DUA is necessary.

Is the Proposed Data Sharing Permitted? (See Exhibit A for Flow Chart)

1. If the data is derived from human subjects research:
 - a. Does the associated informed consent form that subjects signed upon entering the study, or the relevant IRB waiver of consent, permit disclosure for the contemplated DUA purpose?
 - b. Has the IRB or Privacy Board reviewed and approved the data sharing proposal underlying the potential DUA?
2. If the data was collected pursuant to a sponsored research project, has the sponsor placed restrictions on the subsequent transfer of the data?
3. If the data was initially received from, or derived from data received from a third party pursuant to a contract, does that contract place restrictions on the subsequent transfer of the data?
4. Does any policy, law or regulation prohibit the proposed data sharing? (See also #3 in the following “When is a DUA Necessary” section).

When is a DUA Necessary? (See Exhibit B for Flow Chart)

1. Is the data to be transferred derived from human subjects research?
 - a. No → If the data does not involve human subjects (either directly, or indirectly via animal or bench research), privacy concerns may no longer drive the need for a DUA, but the data may still be subject to contractual

restrictions (see #4 & 5 below) or constitute proprietary data (see #6 below).

b. Yes → Proceed to #2.

2. Is the data personally identifiable or HIPAA-protected (i.e., clinical data belonging to a Covered Entity or to the clinical component of a Hybrid Entity)?

a. No – if it is completely de-identified with no remaining personally identifiable information within the meaning of HIPAA, and is not disclosed with a code or other means to re-identify the data. Proceed to #3. Note: in order to qualify as completely de-identified, there must be no actual knowledge that the information to be shared could be used alone or in combination with other information to identify an individual, and the data must be stripped of the following elements:

- Names
- Geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, etc.
- Telephone numbers
- Fax numbers
- Email addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers
- Device identifiers and serial numbers
- Web URLs
- IP addresses
- Biometric identifiers, including finger and voice prints
- Photographic images
- Any other unique identifying number, characteristic or code

b. Yes – if the data contains identifiers (see above) or constitutes a Limited Data Set (LDS) within the meaning of HIPAA. Proceed to #2(b)(i) and (ii) below. Note: an LDS is Protected Health Information that excludes all of the above identifiers except for dates and geographical information at the zip code, town or city level.

- i. If the data is being transferred pursuant to authorizations contained in a Business Associate Agreement (BAA) and in accordance with a signed underlying agreement stating what data will be transferred between the parties and how the receiving party will use the data to assist the sending party in a healthcare function, then **a data use agreement is not required**; but
- ii. If the data transfer is not part of a larger existing relationship between the parties and being transferred pursuant to authorizations contained in a BAA, then **a data use agreement is required**.

3. Does the data contain: (i) “Identification Information” as defined by Iowa Code §715A.8—Iowa’s identity theft statute; (ii) “Education Records” as defined by the Family Educational Rights and Privacy Act (FERPA); (iii) “Customer Record Information” (CRI) as defined by the Gramm Leach Bliley Act; (iv) “Card Holder Data” as defined by the Payment Card Industry (PCI) Data Security Standard; (v) employee personnel file information of the type mentioned in Iowa Code §91B.1—an Iowa statute protecting such information; (vi) information deemed confidential in accordance with Iowa Code Chapter 22—the Iowa Public Records Law, including trade secrets; (vii) any other information that is protected by UI policy or federal or state law from unauthorized access, such as Level II Moderate Sensitivity or Level III High Sensitivity data as defined in the UI’s IT Security & Policy Office’s Policy on Institutional Data Access available [here](#); or (viii) any proprietary data?

a. No → Proceed to #4.

b. Yes → Then **a data use agreement is required**, unless a policy, law or regulation prohibits the proposed data sharing in which case a data use agreement is not appropriate or adequate. (See also #4 in the “Is the Proposed Data Sharing Permitted” section above). Note, with respect to determinations about whether the data to be shared contains any “proprietary data” per #3(viii) above, UI’s default position is that the work

product of faculty is not proprietary to UI. So unless the data was collected under a sponsored research agreement that allocates ownership of the data and/or imposes restrictions on use (see #4 below), UI is willing to share, and the question of “proprietary” becomes one for the principal investigator (see #6 below).

4. Was the data collected pursuant to a sponsored research project?
 - a. No → Proceed to #5.
 - b. Yes → Does the sponsor claim ownership of or licensing rights to the data and/or restrict disclosure and use of the data? Check the terms and conditions of the grants, contracts, agreements, etc. governing the sponsored research project. **Sponsor may require a data use agreement. Even if not, a data use agreement may be recommended** to flow through the limitations and restrictions placed on UI’s use and disclosure of the data.
5. Are there other contractual restrictions on the contemplated data transfer?
 - a. Do rules governing access to publicly available databases apply? (e.g., publicly available federal data repository click-through agreements). No → Proceed to #5(b).
 - b. Was the data initially received from, or derived from data received from a third party pursuant to a contract? Does that contract restrict use or disclosure? No → Proceed to #5(c).
 - c. Yes to either (a) or (b) → **Data use agreement may be recommended** to flow through the limitations and restrictions placed on UI’s use and disclosure of the data.
6. Even if not required, is a data use agreement a good idea?
 - a. Does the principal investigator (PI) consider the data to be “proprietary?” (i.e., internally generated, not publicly available, and containing technical or other types of information that the PI would like to safeguard to protect his/her/UI’s competitive edge).
 - b. Does the PI wish to restrict use of the data, secure publication review and acknowledgement rights, or otherwise direct and control use of the data post-transfer?
 - c. Yes to either (a) or (b) → **Data use agreement may be recommended** to clarify the expectations, rights and responsibilities of the data recipient.

For more information regarding:

- Data use agreements related to research or economic development please contact the Division of Sponsored Programs, dsp-contracts@uiowa.edu or 335-2123.
- Data use agreements related to UI Health Care data please contact the UI Health Care Legal, 356-4760.
- Other data use agreements, please contact the Office of the General Counsel, general-counsel@uiowa.edu or 335-3696.