

Responsible Office: Office of the Vice Provost for Research  
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## Data Use Agreement (DUA) Guidance

### Purpose

The purpose of this guidance is to set forth the administrative review procedures for the approval and execution of Data Use Agreements at Harvard when Harvard is either the Provider or Recipient.

The transfer of data between organizations is common in the research community. When the data is confidential, proprietary, or otherwise considered sensitive, the organization providing the data (“Provider”) will often require that the organization receiving the data (“Recipient”) enter into a written contract to outline the terms and conditions of the data transfer. For the purpose of this guidance, such a contract is referred to as a Data Use Agreement (DUA). However, this type of contract may also be referred to as a License Agreement, Confidentiality Agreement, Non-Disclosure Agreement, Memorandum of Understanding, Memorandum of Agreement, or other names if these agreements include data sharing or data transfer requirements. Any agreement for confidential or proprietary data should be legally structured as a contract between the President and Fellows of Harvard College (“Harvard”) and the Provider or Recipient and be reviewed and signed by an authorized Harvard signatory in either the Office for Sponsored Programs (“OSP”) for University area schools, the Sponsored Programs Administration (“SPA”) office at the Harvard T.H. Chan School of Public Health, or the Office of Research Administration (“ORA”) at the Harvard Medical School (collectively, the “Negotiating Office(s)"). DUAs may not be signed by University faculty or staff members in the absence of institutional approval from the appropriate Negotiating Office.

### Roles and Responsibilities

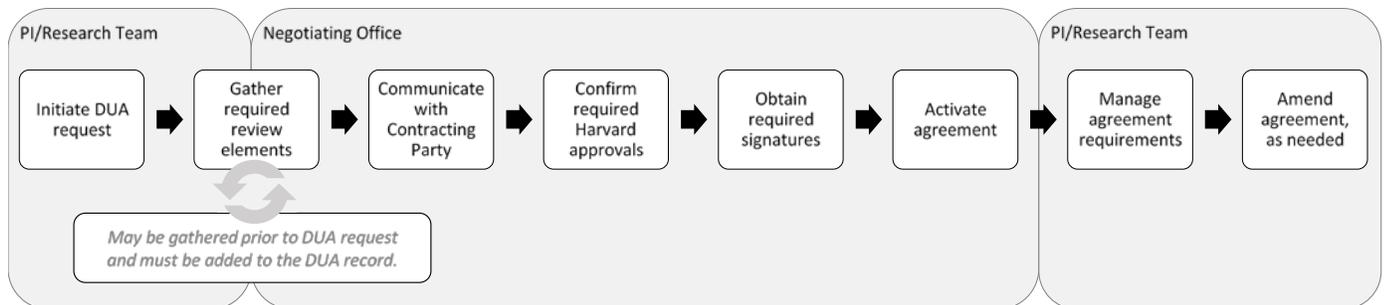
The following describes the roles and responsibilities related to the DUA process for various individuals and offices at Harvard.

1. *Harvard Data Requestor*: Initiates the DUA review in the Agreements System and corresponds with the appropriate Negotiating Office to provide additional information, as needed, to facilitate review and negotiation of the DUA. Confirms the appropriate Data Security Level determination per the processes articulated in the Harvard Enterprise Information Security Policy and verifies ability to meet the protection requirements with the relevant IT Support team.
2. *Responsible Faculty Member or Individual with Principal Investigator status (if different from Harvard Data Requestor)*:
  - Responsible for overall compliance with information protection and use requirements, including Data Security Level determination, if not provided by the IRB, and making sure that all individuals who have access to the information have received appropriate training

- on the DUA requirements and relevant policies and procedures related to data security and access.
- Approves final language and agrees to the responsibility as indicated by the DUA, including, if required by the DUA, by way of signature.
  - Ensures that all study team members are aware of their responsibilities under the DUA.
  - Ensures that the protection requirements can be met and that all individuals who have access to the information have received appropriate training on the DUA requirements and relevant policies and procedures related to data security and access.
  - Promptly notifies appropriate technical support service who manages access to the data in the event of any changes in composition of the study team, so that any new team members may be appropriately briefed, trained, and authorized (as defined by the DUA and Harvard policy) before they are granted access to the data, and so any departing team members' authorization may be promptly discontinued.
  - When the DUA lists team members with access to the data, promptly notifies the appropriate Negotiating Office of any changes to the team.
  - Once storage and security needs are determined and before data arrives works with the [appropriate technical representative](#) (for example; Information Technology or local School Security Officer, or Research Computing), as needed, to identify and adhere to: (a) needs of the data in compliance with University Data Security Policy and the DUA, and (b) appropriate storage space is available to receive and house the data described in the DUA.
3. *Research Team*: Each research team member is responsible for meeting and complying with the specific Harvard Policy and DUA security and access requirements, including any required training. Team members shall promptly notify the appropriate parties, per Harvard Enterprise Information Security Policy, if they become aware of any breaches of security or unauthorized access.
4. *The Negotiating Offices*:
- Responsible for negotiation of the DUA and is the Institutional Signatory for all DUAs for schools within their purview.
  - Generates a summary outlining key points of each DUA for the PI.
  - Negotiates and signs modifications to previously executed DUAs (amendments).
  - Reports any confirmed breaches of security or unauthorized access as reported by the research team to the Provider promptly, and in accordance with the terms of the DUA and the Harvard Enterprise Information Security Policy.
  - Confirms that the PI has completed appropriate reviews or obtained necessary approvals, including provisioning and any needed Institutional Review Board (IRB) review, and manages timing of DUA execution accordingly.
5. *Institutional Review Board (IRB)*: Responsible for review and approval of research protocols involving the participation of human subjects, and Not Human Subjects Research determinations as needed. The IRB identifies the data security classification level as part of their review.
6. *Office of General Counsel (OGC)*: The Negotiating Offices may consult with OGC, if necessary, to negotiate a particularly problematic term of the DUA, including if the other party is a foreign government.

7. *Office of Technology Development (OTD)*: The Negotiating Offices may consult with OTD if the other party requests non-standard rights in Harvard’s project intellectual property.
8. *Provisioning Resource*: Ensures that the data storage location and method are compliant with the assigned Data Security Level and the terms set forth in the DUA. Notifies the research team, the appropriate Negotiating Office and appropriate parties if they become aware of any breaches of security or unauthorized access promptly, per the Harvard Enterprise Information Security Policy.
9. *Harvard University Information Technology Security (HUIT Security) or School Security Officer*: Harvard Data Requestor (or PI or Responsible Faculty Member) and/or the IRB may consult with their local School Security Officer or HUIT Security Office if they are unable to determine the appropriate data classification level for research data. Works with other responsible parties to resolve any uncertainties pertaining to security controls set forth in the DUA relevant to the computers or systems that will be used to access and house the data.
10. *Office of the Vice Provost for Research (OVPR)*: Responsible for all regulatory and policy compliance related to research activities. OVPR ensures that the Harvard Research Data Security Policy is implemented for research projects.

## Procedures



### 1. Types of Data Requiring a Data Use Agreement

Whether or not a DUA is required depends on applicable laws and regulations governing the particular data type, the policies and/or requirements of the Provider and/or Requester, and Harvard’s Data Ownership Policy.

**When Harvard is the Provider**, a DUA is required to transfer the following data types:

- a. Individual identifiable health information or protected health information (“PHI”) as defined by the Health Insurance Portability and Accountability Act (“HIPAA”) privacy requirements, even if the data is not identifiable
- b. Student information derived from education records that are subject to Family Educational Rights and Privacy Act (“FERPA”)
- c. Data that is controlled by laws or regulations other than or in addition to those listed above

- d. Data obtained from another individual or organization under obligations of confidentiality
- e. Data whose storage, use, and transfer must be controlled for other reasons (e.g. HRDSP Level 3 data that will be shared with anyone outside of Harvard, or proprietary concerns)

***When Harvard is the Recipient***, a DUA may be required for any of the reasons listed above or as otherwise required by the Provider.

If it is unclear whether a DUA is needed, please contact the appropriate Negotiating Office for assistance in making a determination.

## **2. Data Request, Transfer, and Disposition**

***When Harvard is the Provider (in cases other than submission of research data to a repository)***, the following steps are generally involved:

- a. An external researcher (the “Recipient Data Requestor”) submits a data request to the Harvard Principal Investigator (“Harvard PI”) of the study under which the data was generated.
- b. The Harvard PI reviews the request and determines whether it should be approved.
- c. If approved, the Harvard PI reviews the criteria set forth in Section 1 above and/or consults with the appropriate Negotiating Office to determine whether a DUA is needed in order to transfer the data outside of Harvard.
- d. If a DUA is needed, the Harvard PI submits the request through the Agreements System for an outgoing DUA to the appropriate Negotiating Office.
- e. In consultation with other offices and individuals as needed, the Negotiating Office prepares a DUA to send to the Recipient Data Requester, negotiates the DUA as needed, and signs when complete.
  - i. If human subjects data, the Negotiating Office consults with the IRB to ensure that the proposed use of the data is consistent with any consent form(s) signed by the subjects and conforms to the Data Security Level assigned to the data.
  - ii. If the data is not human subject data, the Negotiating Office may consult with OGC, OVPR or OTD on any regulatory, intellectual property or other legal requirements that may need to be included in the DUA.
  - iii. It is important to note that if it is determined that a DUA is appropriate by the Negotiating Office, documentation of IRB approval and IT Support attestation of a plan for sufficient security controls for data transfer and storage may be required from the Recipient prior to DUA signature.
- f. The Negotiating Office notifies the Harvard PI that the DUA is complete and provides a copy of the signed agreement.
- g. Data is transmitted to the Recipient Data Requestor in accordance with the DUA terms and conditions.
- h. When the DUA expires or is terminated, the Recipient Data Requestor destroys or returns the data in accordance with the DUA terms and conditions, which may involve consultation with the Harvard PI and/or the Negotiating Office.

***When Harvard is the Recipient***, the following steps are generally involved:

- a. A Harvard Data Requestor submits a data request to the Provider which describes the purpose of the study, identifies the data set being requested, and includes any other information and/or documentation required by the Provider.
- b. The Provider reviews the request and, if approved, will either send the Harvard Data

- Requestor a draft DUA for review and signature by Harvard, ask that Harvard provide a draft DUA, or enter into a conversation with the appropriate Negotiating Office to determine whether a DUA is needed.
- c. Once the Provider and/or the Negotiating Office have confirmed that a DUA is needed, the Harvard Data Requestor submits the DUA request through the Agreements System.
  - d. The Negotiating Office: Reviews information and documentation submitted by the Harvard Data Requestor, including any draft DUA received from Provider, and requests additional information as necessary to complete the review or drafting of the DUA, including confirmation of the following:
    - i. Unless the Harvard Data Requestor is able to self-determine and certify that the project is not human subject research, IRB will provide the appropriate documented determination. For the avoidance of doubt, if IRB approval is required, documentation of such approval may be obtained at any point during the DUA review process (including prior to DUA review) and must be provided by the Harvard Data Requestor to the Negotiating Office prior to DUA execution.
    - ii. Storage requirements and access controls for the data will be at least as stringent as those set forth under the Harvard Enterprise Information Security Policy for the determined data classification level.
    - iii. If the DUA includes explicit data security requirements, the Harvard Data Requestor must verify with their IT Support group that the minimum protections can be met, prior to execution of the DUA.
  - e. The DUA is negotiated in compliance with all applicable Harvard policies and in consultation from other offices and individuals as needed. If, after negotiation with the Provider, the Negotiating Office determines that the DUA cannot be brought into compliance with an applicable policy, the Negotiating Office will consult with the Harvard Data Requestor's School Dean, OVPR, and other offices as required. When the negotiation and all applicable compliance reviews are complete, the DUA is executed by the Negotiating Office on behalf of Harvard.
  - f. The Negotiating Office notifies the Harvard Data Requestor that the DUA is complete and makes available within the system a fully executed copy along with a summary which outlines key points of the DUA. Note that any special requirements for individual users must be completed *before* access is granted or, in some cases, before the DUA may be signed. It is the Harvard Data Requestor's responsibility to understand and comply with the terms of the DUA and to ensure data is only used as specified in the DUA. Therefore, prior to accepting the data from the Provider, the Harvard Data Requestor should read the DUA and accompanying correspondence from the Negotiating Office and seek clarification on any requirements that remain unclear.
  - g. Data is transmitted to the Harvard Data Requestor in accordance with the DUA terms and conditions.
  - h. The DUA may contain specific conditions on publication review and/or the final disposition of the data such as destruction, limited time archiving, etc. The Harvard Data Requestor is responsible for following any such requirements for prior review of publications and/or for the disposition of the data once the DUA has expired or been terminated. Any requested updates to the DUA are to be submitted by the Harvard Data Requestor in the Agreements System. The Agreements System will notify the Harvard Data Requestor when the expiration date of the DUA is approaching, and the Harvard Data Requestor is responsible for requesting an extension of the expiration date if additional time is needed to complete his or her research.

## Definitions

- **Agreements System:** University-wide system of record used by the Harvard faculty, students, and staff to prepare, submit, review, and manage DUAs and DUA updates.
- **Data Use Agreement (DUA):** A binding contract between organizations governing the transfer and use of data. DUA terms and conditions vary depending on the laws and regulations governing the particular type of data as well as the policies and/or requirements of the Provider. A DUA must be signed by an Institutional Signatory.
- **Data Security Level (DSL):** A qualification applied to a data set considering the content and use. The determined DSL corresponds with required security controls (including data storage and management).
- **Harvard Enterprise Information Security Policy (HEISP):** Policy which addresses the need to protect confidential and sensitive information. When indicated in this document, it is inclusive of the Harvard Research Data Security Policy.
- **Provider:** Individual or organization providing data to a recipient individual or organization.
- **Receiver/Recipient:** Individual or organization receiving data from a provider individual or organization.
- **Related Offices:**
  - Institutional Signatories
    - Harvard T.H. Chan School of Public Health: Sponsored Programs Administration (SPA)
    - Harvard Medical and Dental Schools: Office of Research Administration (ORA)
    - University Area, all other Harvard schools: Office for Sponsored Programs (OSP)
  - Institutional Review Boards (IRB)
    - Harvard T.H. Chan School of Public Health, and Harvard Medical and Dental Schools: Office of Human Research Administration (OHRA)
    - University Area, all other Harvard schools: Committee on the Use of Human Subjects (CUHS)
  - Information Security Policy and Consultation
    - Harvard Enterprise Information Security Policy: Harvard University Information Technology
    - Harvard Research Data Security Policy: Office of the Vice Provost for Research

## Related Resources

### University-Wide

Office of the Vice Provost for Research (OVPR)

<https://vpr.harvard.edu/pages/research-policies-guidance>

Harvard Enterprise Information Security Policy (HEISP)

<https://policy.security.harvard.edu/>

Harvard Research Data Security Policy

<https://vpr.harvard.edu/pages/harvard-research-data-security-policy>

Harvard Data Ownership Policy

<https://vpr.harvard.edu/pages/research-data-security-and-management>

HEISP Reporting Possible Breach, Loss or Theft of Confidential Information

<https://security.harvard.edu/pages/reporting-incident>

Policy and Procedures for Data Submission to NIH Designated Data Repositories

[http://files.vpr.harvard.edu/files/vpr-documents/files/harvard\\_gds\\_policy\\_and\\_procedures\\_revised\\_9\\_2015.pdf?m=1445960751](http://files.vpr.harvard.edu/files/vpr-documents/files/harvard_gds_policy_and_procedures_revised_9_2015.pdf?m=1445960751)

**Harvard Medical and Dental Schools**

Office of Research Administration (ORA)

<https://hlcra.harvard.edu/>

Harvard Biomedical Research Data Management

<https://datamanagement.hms.harvard.edu/>

**Harvard T.H. Chan School of Public Health**

Sponsored Programs Office (SPA)

<https://www.hsph.harvard.edu/financial-services/sponsored-programs-administration/>

**All other Harvard Schools (Harvard University Area)**

Office of Sponsored Programs (OSP)

<https://osp.finance.harvard.edu>

**Revision History**

TBD - New guidelines released