Harvard T.H Chan School of Public Health
Research Administration

Process: Data Use Agreement (DUA) – Incoming Data

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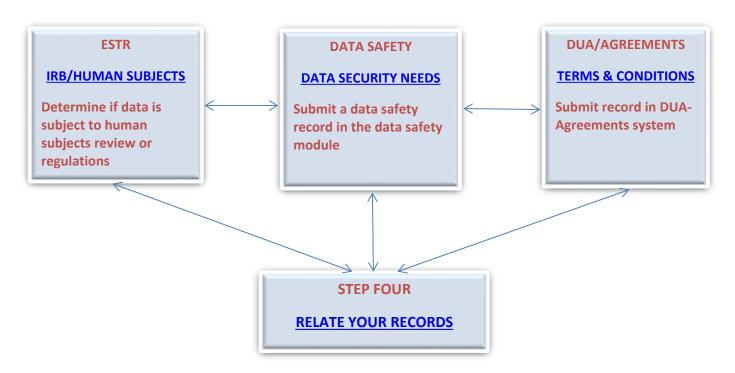Last revised: 04/04/2022

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Background

Harvard has expanded its Huron **IRB-ESTR** system to include two new modules: **DUA-Agreements** and **Data Safety**. The new modules are in response to the recent rise in data security requirements and regulations.

This updated process for data use agreements (DUA) is for when a Harvard Chan researcher requests access to another party's data - referred to as **INCOMING DATA**. There is a separate process similar to this one dealing with Harvard Chan researchers sending data out to another party.

Purpose of Process

The past few years have seen a sharp increase of specific data security regulatory requirements throughout the world for research data. Due to the evolving landscape of data safety laws and standards (e.g., GDPR[1], FISMA[2], NIST, CMMC, PIPL[3] etc.), the need for Harvard to be able to track more closely its research data commitments has become a necessity. This document updates Harvard Chan School's DUA process to align with the new DUA and Data Safety modules to the ESTR/Huron system.

Process Snapshot

ESTR	DATA SAFETY	DUA/AGREEMENTS
IRB/HUMAN SUBJECTS	**DATA SECURITY NEEDS**	**TERMS & CONDITIONS**
Determine if data is subject to human subjects review or regulations	Submit a data safety record in the data safety module	Submit record in DUA-Agreements system

STEP FOUR

RELATE YOUR RECORDS

Key Points of Process

1. A DUA cannot be signed/finalized until there is IRB approval (or a not human subjects determination) and Data Safety approval as well as the terms and conditions having been reviewed and, where necessary, negotiated.
2. The "Owner" in the DUA module is merely a system distinction. This person is only responsible for reviewing and, where necessary, negotiating the terms of the DUA. The researcher is responsible for making sure IRB/no-human-subjects and data safety are

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[1] General Data Protection Regulation; Harvard resource https://gdpr.fad.harvard.edu/

[2] FISMA – Federal Information Security and Modernization Act; NIST – National Institute of Standards and Technology; CUI – Controlled unclassified information (see also NIST 800-171 found at the NIST link above); FERPA – Family educational Rights and Privacy Act

[3] **PIPL:** *China's Personal Information Protection Law*

completed and related to the DUA record.

3. You can start the data review in any of the three modules and navigate between the modules from any other. MAKE SURE TO RELATE the records from each module

Process Steps

1. **Human Subjects**

   a. Data you are asking to use may be subject to IRB approval given the nature of the data.

      i. You can either connect with an IRB specialist in the [Office of Regulatory Affairs and Research Compliance](#) (ORARC)

         • **OR**

      ii. If you believe the data to not be human subjects you can follow the [IRB's not human subjects guidance](#) (the not human subjects form is also located in the DUA record you create).

2. **Data Safety**

   a. Most datasets require some type of security measure to keep it safe from those not authorized to use it. Penalties for breaches can be steep either financially, administratively, or likely both. These penalties would affect not only you, but the Harvard Chan School and Harvard University.

   b. The Harvard Chan School has a dedicated [Research Computing resource](#).

      i. [Andy Ross](#) is Harvard Chan's Information Security Officer who can assist with any research data security question you may have, whether related to a data use agreement or not.

      ii. Read the [Data Safety Submission Guide](#) for assistance

3. **DUA Terms and Conditions**

   a. This is the actual content of a DUA that outlines your responsibilities as well as Harvard's, as requested by the data provider (or by law), in storing, using, and disposing of the data.

   b. Access the [DUA module](#)

   c. Often the terms are not unlike those you may find in a research grant/agreement, such as:

      i. Intellectual property

  ii. Publishing

  iii. Indemnification

  iv. Data Security

d. The DUA is reviewed and, if needed, negotiated pursuant to Harvard's policies and practices by the Harvard Chan School's [Office of Research Administration](#) (ORA).

  v. ORA manages the DUA-Agreements module only. The IRB manages ESTR and Data Safety manages the Data Safety module

e. **PLEASE NOTE: A DUA CANNOT** be signed by Harvard until the IRB and Data Safety approvals are satisfied.

  vi. If you are certifying to not-human-subjects, you need to upload the completed IRB questionnaire referenced in section 1.ii above to the "Supporting Documents" area of the DUA record.

  vii. You can also access the not-human-subjects determination questionnaire in the DUA system

f. Read the [DUA-Agreements Submission Guide](#)

4. **Important: Relate Your Entries**

a. The system that ESTR, Data Safety, and DUAs are modules of allows you to "relate" records between the modules.

b. This is a key function that allows the three offices (ORARC, IT Security, and ORA) having a roll in finalizing a DUA to see the status of each record. An ORA reviewer can easily see if IRB and/or Data Safety has been approved, making finalizing a DUA quicker and efficient.

Resources

- [Office of the Vice Provost's Research Data Management](#)
- [Harvard Chan School's Research Computing](#)
- [HUIT Research Administration and Compliance Systems](#)

Revision History

4/4/22	DUA process updated to align with the new DUA and Data Safety modules to the ESTR/Huron system
5/24/13	DUA process created

Appendices: Harvard Global Top Funders and Keywords

Top Funders that would likely go through Harvard Global (not exhaustive – contact SPA if you have any questions):

Please Note: *Harvard Global cannot submit proposals or receive sponsored awards related to US federal funding*

- Foreign Commonwealth and Development Office (FCDO)
  - This is a United Kingdom governmental organization
  - Formerly known as Department for International Development (DFID)

- European Commission (EC or the European Union – EU)
  - An example of an initiative funded by the EC is Horizons 2020

In addition to Top Funders**,** if you see the following **keywords, reach out to Harvard Global immediately**

For FCDO proposals:
- [Supplier] Code of Conduct
- UN Global Compact
- International Aid Transparency
  - Initiative (IATI) Reporting
- Selection questionnaire (SQ)
- Principles for Digital Development
- Value for money
- Risk register or risk mapping

For European Commission proposals:
- Horizon Europe
- Work packages
- PIC Number (Participant Identification Code)
- Beneficiary International
- Partner Description of Action Consortium agreement Model Grant Agreement Linked third party