



**Purpose:** Researchers at the School often obtain data from external sources for research purposes. Providers of these data typically require a Data Use Agreement (DUA) signed by an institutional officer of the School in order to have institutional verification that the University will protect the data. This process will ensure that the School/dept/researcher can agree and adhere to the terms and conditions required by the data provider and that all appropriate offices are consulted and provide sign off in order for data to be received in a timely manner.

**Considerations:**

Incoming Data:

1. Only the SPA office is authorized to sign DUAs. Researchers are NOT authorized to sign DUAs.
2. The Office of Research Administration and Regulatory Compliance (ORARC) provides a data security level for all DUAs regardless of whether or not human subjects are involved.
3. Harvard Chan School IT determines whether or not it is possible to comply with the security terms of the DUA and advises the PI on a plan to protect research information based on the data security level and based on existing Harvard security policies.
4. Agreements may contain complicated Intellectual Property (IP) or other legal terms. Therefore, SPA may engage the Office for Technology Development (OTD) as well as the Office of the General Counsel (OGC) to review agreements and advise SPA based on their findings. SPA shall be guided by these findings.

Outgoing Data:

1. Where no IP rights are transferred, SPA will draft/review/sign/assist dept.
2. Where IP rights are transferred, OTD will draft/review/sign/assist dept.

**Standards of Service:** The department is responsible for guiding the DUA process and will involve ORARC and IT as soon as the need for a DUA arises. ORARC and IT will provide the required information to the department. Departments will submit DUAs to SPA accompanied by the data security level and data information. SPA will review and negotiate once the security level and data security information is received. It should be noted that DUAs come in different forms and although some DUAs are relatively easy, others are complex and can take time to coordinate and negotiate.

**Process Steps - Incoming Data:**

Step	Role	Task/Activity
1	PI	Requests data from an organization for a project.
2	Data provider	Sends draft DUA to researcher.
3	PI	Fills out DUA questionnaire (see questionnaire below).
4	PI	Discusses DUA needs with GM/Dept.
5	Dept	Sends a copy of the scope of work to Department-assigned IRB Review Specialist in ORARC [ <a href="#">assignments found here</a> ] for the determination of the data security level. In the case of not human subjects (NHS), an NHS confirmation is still needed.
6	ORARC	Assigns the Harvard data security level and signs off.
7	ORARC	Sends IRB determination(s) and data security level to GM/Dept (cc. to AD).



8	Dept	Sends draft DUA, DUA Questionnaire, IRB determination(s) if applicable and data security level to Andy Ross, SPH IT.
9	Harvard Chan School IT	Andy Ross determines whether it's possible to comply with the data security terms and advises the PI on a plan to ensure compliance. Signs off and communicates with GM/Dept.
10	Dept	Sends draft DUA, DUA Questionnaire, IRB approval(s) if applicable, data security level and any information from IT to AD.
11	Assoc. Director, SPA	Negotiates terms of DUA with Data Provider (as necessary) and gathers additional internal signatures if needed.
12	Assoc. Director, SPA	Finalizes the DUA (investigator and ADF signature and written acceptance and acknowledgment of terms is required) and submits to EDRA for institutional signature.
13	Exec. Director, SPA	Signs Data Use Agreement & sends to AD.
14	Assoc. Director, SPA	Sends signed DUA to data provider and PI (with cc. to GM/Dept).
15	Data provider	Fully executes DUA and returns to SPA AD.
16	Data provider	Releases/sends data to PI.
17	Assoc. Director, SPA	Sends fully signed DUA to IT & GM/Dept.
18	Assoc. Director, SPA	Saves DUA on S drive in the following path: S:\OFS\RESEARCH ADMINISTRATION (SPA)\A6-AGREEMENTS & NEGOTIATIONS\DUAs and MTAs
19	Dept.	Follows up to ensure terms in DUA are adhered to (ex. disposal of data, etc.). Any data questions should go to Andy Ross in IT.

**Process Steps - Outgoing Data:**

Step	Role	Task/Activity
1	PI	Alerts AD of intentions to share data
2	Assoc. Director, SPA	Assesses if DUA: 1) Is appropriate mechanism for data sharing 2) Should stand alone or be associated with a subaward or service agreement
3	Assoc. Director, SPA	Determines if IP rights are involved. If so, involves OTD and OTD will draft/review/sign/and assist dept. If no IP, works with the Harvard Chan School investigator(s) to draft the DUA.
4	Assoc. Director, SPA	Sends DUA to collaborator
5	Collaborator	Contacts AD and negotiates terms
6	Exec Director	Signs final DUA



DUA Questionnaire: Describe the research issues that may affect the data use agreement.

1.	Where is the data coming from?	
2.	Who is the data coming to and who will be using it?	
3.	Is there a source of funding for this research? If so, what? Do you have industry support for the research?	
4.	Where will the data be stored?	
5.	What will you do with the data when you are done using it?	
6.	Does the data provider consider the data to be a limited data set under HIPAA?	
7.	Will you be accepting any confidential/proprietary information from the provider of the data that might affect the publication of the results of your data analysis?	
8.	Will the data set involve human subjects research?  If <i>yes</i> , provide the ORARC determination.  If <i>no</i> , provide the NHSR determination.  For all IRB determinations, specify the IRB protocol number(s) and notification date(s).  If IRB review is pending, please indicate the person listed as investigator on the application and the date of submission.	
9.	List all other agreements related to this DUA, i.e., sponsored research agreement, government or other grant, confidentiality agreement, license, MTA, other agreement and provide the Harvard Fund number if available for each.	

**To the best of my knowledge, the answers to the questions are true, complete and accurate. I have read the referenced DUA and agree to handle the data as outlined therein, adhering to applicable data security plans as well as Harvard policies and procedures. I am a Harvard faculty member authorized to oversee the transfer of the data named above.**

**Principal Investigator:** \_\_\_\_\_ **Date:** \_\_\_\_\_