

## All About Data Transfer and Use Agreements (DUAs)

### What is a Data Use Agreement?

A Data Use Agreement (DUA) (also referred to as a “Data Transfer and Use Agreement”) is a contractual agreement used to transfer non-public or otherwise restricted data from one party to another. DUAs memorialize the terms and conditions upon which the data will be transferred, including the ways in which the data may be used and how it must be protected.

### Why are DUAs Important?

DUAs are used to identify and contractually impose upon the data recipient any limitations on the use or disclosure of the protected or confidential information being transferred. This may include limitations on the permitted use of the data, data security requirements, obligations to safeguard the data, liability for inappropriate use or disclosure, publication restrictions, any privacy rights associated with the transfer, and any requirements regarding the return or destruction of the data upon completion of the project.

JHURA has a DUA template which includes these elements, along with other standard contractual provisions. However, the applicability of certain provisions may change depending on the project. In order to avoid confusion, please do NOT to share the DUA template with potential partners before there is a JAWS record or without JHURA's knowledge.

Please note that individual JHU PIs/employees are not authorized to sign DUAs and all DUAs must be signed by JHURA.

### When is a DUA required?

Under the Health Insurance Portability and Accountability Act (HIPAA), unless each data subject has signed a HIPAA authorization or there is an IRB HIPAA waiver otherwise permitting the transfer, a DUA is required for a “covered entity” to transfer a “limited data set” (LDS) to another party. HIPAA defines these terms as follows:

- A “Covered Entity” is an entity that is “covered” by the HIPAA regulations. HIPAA regulations apply to health plans, health care providers that bill electronically for services, health care clearinghouses, Medicare Part D Pharmaceutical Providers, and Business Associates. The JHU Schools of Medicine (SOM) and Nursing (SON) are part of the Johns Hopkins Medicine (JHM) Covered Entity, while APL, SPH, and the Homewood Schools (e.g. Whiting School of Engineering) are not.
- A LDS is “protected health information” (PHI) that excludes each of 16 categories of direct or “facial” identifiers. It is important to note that this information is still

PHI under HIPAA. It is not de-identified information and is still subject to the requirements of the HIPAA Privacy Regulations. For more information on LDSs, please visit [this site](#).

The School of Medicine Office of Research Administration (ORA) negotiates and executes DUAs and other research agreements with data use terms for Johns Hopkins Medicine (JHM) PIs when research involves JHM patients or their data.

For more information on access to JHM data for research, please visit [this site](#).

### **When is a DUA recommended?**

Even if not required under HIPAA, JHU requires some form of a DUA whenever JHU is sharing data with a third party in order to obtain certain assurances from the data recipient that they will use and disclose the data appropriately. This can be in the form of a Data Transfer and Use Agreement used by JHU ([JHU DUA Template](#)), or terms may be included in a research agreement between the parties.

If your project includes more than data transfer, and includes co-authorship or collaborative activities by both parties towards a goal or deliverable, then a DUA may not be the best agreement. Please consult your ORA/JHURA to discuss using a Collaboration Agreement that includes data terms instead. This agreement type chosen should be appropriate so that it better meets the expectations of both parties. If you have any questions about whether a DUA is a fit for your project, please reach out to ORA/JHURA.