JOHNS HOPKINS
SCHOOL of MEDICINE

JHU School of Medicine
Data Use Agreement Request Form

A Data Use Agreement (DUA) is required if you will be sending data to or receiving data from an entity outside of JHU. Please use this form to submit data transfer requests that do not include funding. **DUA requests that include nominal costs associated with the transfer of data are eligible to use this form.**

*Do not use this form if your data transfer includes funding **(other than nominal costs for the data transfer)**. Requests for agreements that include the transfer of funding (incoming or outgoing) must be submitted to ORA via Fibi. Please contact your department administrator for Fibi assistance if you have a funded DUA. Please consult the ORA website for additional information.*

Requests for non-School of Medicine DUA's should be submitted to JHURA via the JAWS Intake Form.

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* **QA Will incoming or outgoing funds be included with this data transfer request?**

- ◯ Yes
- ◯ No

If YES, do not submit this form.
Please work with your department Grants & Contracts Analyst (GCA) to submit a Fibi PD for a funded agreement.

* **Q1 Will JHU be providing data, receiving data, or both?**

- ◯ Providing data to another entity (Outgoing)
- ◯ Receiving data from another entity (Incoming)
- ◯ Both providing and receiving data (Both)

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* Indicates required fields in Qualtrics. *Please answer all questions relevant to your project.*

Bilateral (Incoming & Outgoing) Data Use Agreements

*** Q2 JHU PI Information**

- ○ JHU PI's Full Name _____
- ○ PI's email address _____
- ○ Department _____
- ○ Department Cost Center (if known) _____
- ○ Project Title _____
- ○ Anticipated agreement term/duration (in years) _____
- ○ Department contact name _____
- ○ Department contact email _____
- ○ Additional department contact(s) _____

*** Q3 Please select the type of Recipient/Provider Organization:**

- ○ University or Non-Profit/Foundation
- ○ Federal/Government
- ○ Commercial/For-Profit

*** Q4 Will the data be sent to a Recipient/Provider Organization in a foreign country?**

- ○ Yes
- ○ No

If YES, please answer Q5 on the next page.

Q5 Please list the foreign country and describe the type of activity that you expect to occur in this country.

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*** Q6 Please provide contact information for the Recipient/Provider Organization:**

- ○ Organization Name (no abbreviations) _____
- ○ Contact Name _____
- ○ Contact Email Address _____
- ○ Address _____
- ○ Address 2 _____
- ○ City _____
- ○ State _____
- ○ Postal code _____
- ○ Country/Region _____
- ○ Recipient PI Full Name _____
- ○ Recipient PI Email _____

OUTGOING DATA USE PORTION – *The following questions are related to the data that JHU will be sending to the Recipient Organization.*

* **Q7 Were the data generated under a project funded by a JHU School of Medicine sponsored award/contract?**

◯ Yes

◯ No

If YES, please complete Q8 below:

Q8 If yes, please provide the specific JHU award information, including SAP grant number, if available:

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Data Use Questions

* **Q9 Will the Recipient use the data for non-commercial research purposes only?**

◯ Yes

◯ No

* **Q10 Please provide a detailed description of the data that JHU will be sending to the Recipient.**

Examples of information that should be provided include:

- Whether the data is obtained from human subjects and, if so, a description of the population included in the data.
- If the data is from animal subjects, the species of animal the data was obtained using.
- If not from human or animal subjects, a description of the focus of the data.
- The number of subjects and/or experiments included
- Name of the study that the data was obtained under
- If there is a particular study that needs to be acknowledged/cited as the source of the data, this information should be included here

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* **Q11 Please provide a detailed description of how the Recipient will use the data.**
Content of this section will be very similar to the Statement of Work used in other types of Agreements. Examples of information that should be provided include:

- Objective or purpose of the Recipient's work
- A general description of the actions to be performed by the Recipient using the Data and possibly the anticipated results
- Include whether or not the Recipient is permitted to link the Data with other data sets (If yes, be sure to include any special disposition requirements related to the linked data sets in Section 5 of this attachment).

For modifications, please include identification number(s) from the original agreement (e.g sponsor agreement number, Coeus PD, or MyRap number).

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* **Q12 Are there any additional restrictions that should be added on the Recipient's use of the data?**

◯ Yes

◯ No

If YES, please answer Q13 below:

Q13 Please describe any additional restrictions that should be added on the Recipient's use of the data.

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Conflict of Interest

* **Q14 Do you hold a paid or unpaid appointment, position, or affiliation at the Recipient entity?** This includes unpaid positions such as guest, adjunct, honorary, or visitor titles at other institutions.

- ◯ Yes
- ◯ No

If NO, please skip to Q16.

If YES, please answer Q15 below:

Q15 Has the appointment been disclosed to and approved by your divisional dean's office? *All outside appointments require prior approval by your divisional dean's office. Please ensure that all appointments are included in your* eDisclose *record.*

- ◯ Yes
- ◯ No

Special Review Information

* **Q16 What type of data will be transferred to the Recipient?**

- ◯ Human Subjects data
- ◯ Animal Research data
- ◯ Other non-human derived data

If ANIMAL RESEARCH Data please skip to Q20 on page ???

If OTHER NON-HUMAN DERIVED Data, please skip to Skip To: Q21 on page ???

If HUMAN SUBJECTS Data, please answer questions Q17 and Q18 on the next page.

* **Q17 If you are sending human-derived data to the Recipient, are the data HIPAA de-identified, a limited data set, or full Protected Health Information (PHI)?**
Please note that limited data sets are not de-identified data - they still contain a limited set of identifiers. A list of identifiers that must be removed to make health information de-identified can be found here.

- ◯ Yes, sending de-identified data
- ◯ Yes, sending limited data set(s)
- ◯ Yes, sending full PHI

* **Q18 Has the JHM IRB reviewed and approved the transfer of this human-derived data to this specific entity either as part of a new application or a Change in Research (CIR)?**
Please be advised that your DUA cannot be fully executed until IRB approvals are in place.

- ◯ Yes
- ◯ No

If YES, please answer Q19 below.
If NO, please answer Q59 further down on this page.

* **Q19 Please provide the relevant IRB and/or Change in Research (CIR) protocol number(s) that approves the data transfer to this entity.**

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Q59 Please submit a Change in Research (CIR) to the IRB or provide an explanation of why IRB approval is not needed.

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If you answered Animal Research Data on Q9, please answer Q20 below.

* **Q20 Please provide the IACUC protocol number under which the data were collected.**

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* **Q21 Will the data be returned or destroyed after research use by the Recipient Organization/Recipient PI?**

- ◯ Returned to JHU
- ◯ Destroyed by Recipient
- ◯ Other

If OTHER, please answer Q22 below:

Q22 If other, please describe the disposition of the data.

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* **Q23 Please describe any data or research deliverables that the Recipient will be providing to JHU.**

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INCOMING DATA USE PORTION – *The following questions are related to the data that JHU will be receiving from the Provider Organization.*

* **Q24 Will you be using the Provider's data on a JHU sponsored project?**

- ◯ Yes
- ◯ No

If YES, please answer Q25 on the next page.

Q25 If yes, please list the project, including SAP grant number, if available:

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Special Review Information

* **Q26 What type of data will be transferred from the Provider to JHU?**

- ◯ Human Subjects data
- ◯ Animal Research data
- ◯ Other non-human derived data

If ANIMAL RESEARCH or OTHER NON-HUMAN DERIVED Data, please skip to Q28 on the next page.

If HUMAN SUBJECTS Data, please answer questions Q27 and Q60 below.

* **Q27 If you are receiving human-derived data from the Provider, are the data HIPAA de-identified, a limited data set, or full Protected Health Information (PHI)?** *Please note that limited data sets are not de-identified data - they still contain a limited set of identifiers. A list of identifiers that must be removed to make health information de-identified can be found* here.

- ◯ Yes, receiving de-identified data
- ◯ Yes, receiving limited data set(s)
- ◯ Yes, receiving full PHI

* **Q60 Please provide the IRB protocol number for the study for which the data is being collected.**

Please be advised that your DUA cannot be fully executed until IRB approvals are in place.

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Data Use Questions

* **Q28 Will JHU use the data for non-commercial research purposes only?**

- ◯ Yes
- ◯ No

* **Q29 Please provide a detailed description of the data that the Provider will be sending to JHU.**

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* **Q30 Please provide a detailed description of how JHU will use the data.**

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* **Q31 Please describe any data or research deliverables that JHU will be sending to the Provider related to the incoming data.**

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Q32 If the other institution has a Data Use Agreement template that they would like JHU to use, please upload an editable version here:

[*Upload DUA template in Qualtrics form*]

Q33 If necessary, please provide any additional information, special circumstances, or concerns that ORA should be aware of prior to negotiating this DUA request.

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Q34 Ready to submit? Please click the "next" button to send your request to ORA. If you do not click "next" your request will not be submitted and will remain in draft form.

End of Bilateral DUA Questionnaire