



## IU Health/IU Master Data Sharing Agreement FAQ

### **Can I share de-identified data outside of IU without a data agreement?**

- If the data was originally collected from IU Health and/or medical records, a data sharing agreement is required for sharing, even if the data has been de-identified. Although de-identified data is not subject to HIPAA, the Master Data Sharing agreement states that a data agreement will need to be executed through the Office for Research Administration (ORA) between IU and the outside party.

### **What if I am sharing deidentified data from IU Health EMR to a commercial entity and have obtained informed consent and authorization? Do I need a data sharing agreement?**

- The master sharing agreement covers data collected under a waiver of authorization for recruitment or participation, so it is not applicable to data for which consent and authorization to share has been obtained. If a contract or subaward for the study was executed, please review its terms to determine if data sharing was already addressed within the agreement. If not, a separate data agreement may be necessary. If you have questions, you should contact the office who negotiated the original study agreement.

### **If I have a waiver of authorization for recruitment and am requesting a list of potential patients from the IU Health Clinical Research Systems team, will I be asked to execute a data agreement with IU Health?**

- No, the master sharing agreement negates the need for an individual data agreement between IU and IU Health for recruitment purposes.

### **When am I required to have an IU Health external data sharing subcommittee (EDSS) review?**

- IU Health EDSS review is required when IU is sharing data with a commercial for-profit entity (i.e., Pharma or Device manufacturer) OR if data will be shared outside of US or Canada
- Sharing identifiable information outside of IU or providing an external party (e.g., Purdue collaborator, coordinating center, etc.) access to the data even when the data remains on IU servers or systems.
- Email [DataSharingRequests@IUHealth.org](mailto:DataSharingRequests@IUHealth.org) to begin the process.

### **When is an IU Health IT Risk Assessment required?**

- When sharing identifiable data, an IT Risk Assessment (ITRA) for the location/system to which the identifiable data will be shared may be required prior to EDSS approval.
- Email [ITRA@iuhealth.org](mailto:ITRA@iuhealth.org) to begin the ITRA process.

### **How can I avoid the extra step of going through IU Health external data sharing subcommittee (EDSS) review?**

- Non-profit entities (Academic collaborators, non-profit foundations, etc.) in US or Canada
  - Only share de-identified information OR
  - Only share a limited data set OR
  - Obtain informed consent and authorization.
- Commercial entities
  - Obtain informed consent and authorization.



**Do we need a DUA when collaborating with Purdue personnel?**

- In most cases, any collaboration with a faculty member of another academic institution will require a DUA. This includes sharing with Purdue faculty.

The exception is Purdue Pharmacy Practice faculty who have adjunct IUSM appointments. These individuals are considered to be covered by the Master Agreement IF all data is maintained on IU systems, servers, or computers. If any data will be provided to other Purdue faculty or staff or stored on Purdue systems, a DUA will be required.

**Can I avoid the need for a data sharing agreement if I request an affiliate account for the person, I want to share data with?**

- No, a data agreement is needed for all sharing of identifiable data with anyone who is not a paid faculty or staff member of IU, with the exception of Purdue Pharmacy Practice faculty as described above. Individuals who are granted affiliate accounts are not covered by the Master Agreement. A separate agreement in addition to the Affiliate Account MOU is needed to share identifiable data with these individuals (unless consent and authorization for the sharing of data is obtained from the subject).

**With the Master Data Sharing Agreement in place, will all data agreements go through IU Office for Research Administration?**

- Yes.

**Do we need to go back and request new data agreements for ongoing projects, or will this be for new projects only?**

- This agreement applies to sharing of data from December 1, 2024, forward.

**What if a faculty member just wants to obtain data from Cerner for a chart review and a waiver of authorization is obtained. There is no plan to share with an external collaborator. Is a data agreement required?**

- No, the master data sharing agreement covers the sharing of IU Health data with IU research teams. A data agreement is not required.

**Would there ever be a scenario where a data agreement is needed with both IU and IU Health as parties?**

- It is possible, but the intent of the master data sharing agreement is to allow IU to negotiate the data agreements without IU Health as a party.

**If you have a collaborative research agreement with other institutions which will be sharing identifiable data under waiver of authorization, is the IUH external data sharing subcommittee (EDSS) review required?**

If you wish to share identifiable data, EDSS review and approval is required. If approved, a data use/sharing agreement will be negotiated by the Office for Research Administration (ORA).



**What is required if I want to give an external collaborator access to an IU REDCap project which contains identifiable data?**

- For purposes of determining whether agreements are required, REDCap access is no different than sharing data directly with a collaborator, e.g., via SecureShare. If the collaborator will have access to identifiable data in REDCap and consent and authorization was not obtained from the subject for the collaborator to have access to the data, a data agreement will be required. Additionally, EDSS review will be required.
- If the collaborator will have access only to a limited data set or de-identified data, a data agreement will still be required. However, EDSS review will only be required if the individual is an employee of a for-profit company.

**Where can I find definitions of de-identified, limited, and identifiable data set?**

- Indiana University: [Use of Protected Health Information \(PHI\) in Research Policy](#)
- IU Health: [Access to Health Data and Information for Research Purposes Policy](#) (also available on the OCR Website in the [IU Health Policy Section](#))
- IU Health: [De-Identification of Protected Health Information](#)
- HHS: [HIPAA Privacy Rule](#)