IU and IU Health Data Sharing Workflow

NOTE: **Navy Box:** IU Health Office/Process
Red Box: IU Office/Process

Is transfer of IU Health Data only to **IU Faculty and/or Staff?** (via Cohort Pull or Direct Access to the EMR)

YES → Data used under a waiver of authorization will be described in IRB approval letter when identifiable data will be shared → No additional agreement required. Data provided or accessed.

NO → Data Sharing Agreement required → Data used under a waiver of authorization will be described in IRB approval letter when identifiable data will be shared

When do I need a Waiver of authorization from the IRB?

- Waiver of Authorization for Recruitment is needed wen using IU Health data to identify and screen potential patients who you plan to approach for consent and authorization in a clinical study. Access to IU Health data can be shared via direct access to the EMR or a cohort list from IU Health CRS team. (Currently Regenstrief has a separate process for providing cohort list.)
- Waiver of Authorization for Participation is needed when IU Health data will be accessed and shared without patient consent or authorization as in a retrospective chart review of large scale registry without consent.

WHO is IU sharing data with? Either sending the data outside of IU or providing access to IU Data (i.e. via REDCap)

→ For-profit or Commercial Entity **OR** any entity outside US or Canada → Submit SBAR to IU Health External Data Sharing Subcommittee (EDSS)

Non-profit entity within US or Canada (ex. academic institution, foundation, etc.)

NO → Submit SBAR to IU Health External Data Sharing Subcommittee (EDSS)

YES → WHAT Type of Data?

- De-identified Data or Limited Data set → Submit to Office for Research Administration (ORA) through the Contract Request Form (CRF)
- Identifiable Data → Submit to Office for Research Administration (ORA) through the Contract Request Form (CRF)

The SBAR is a tool to describe your request to share data outside of IU Health and IU

- S-Situation, B-Background, A-Assessment, R-Recommendation
- Complete the SBAR and send to DataSharing Requests@iuhealth.org by the 2nd Monday of month

IT Risk assessment may be required when identifiable information will be housed outside of IU.

Submit SBAR to IU Health External Data Sharing Subcommittee (EDSS) → Attend EDSS monthly meeting → EDSS Approval → Submit to Office for Research Administration (ORA) through the Contract Request Form (CRF)

- EDSS members will review SBAR and may request revisions or additional information prior to EDSS meeting
- After review, an invitation will be sent for EDSS meeting (3rd Monday of Month)
- It is helpful to attend in case any questions arise during the meeting
- If approved, expect to receive approval documents within 1 week.

Provide all documents noted below or CRF will be rejected

- Provide EDSS approval when applicable
  - If sharing with commercial for-profit entity
  - If identifiable information will be shared
- Provide IRB approval noting
  - Waiver of authorization for participation
  - Brief description of PHI to be shared

Submit to Office for Research Administration (ORA) through the Contract Request Form (CRF) → ORA will negotiate the appropriate sharing agreement with external entity → Data shared or may be accessed upon execution of appropriate agreement

Indiana University Health

INDIANA UNIVERSITY

IU Health Data Sharing: For Recruitment Purposes

Is transfer of IU Health Data only to IU Faculty and/or Staff? (via Cohort Pull or Direct Access to the EMR)

YES → Identifiable data shared for recruitment purposes will be described in IRB approval letter ("brief description of PHI") → No additional agreement required. Data provided or accessed.

NO ↓

Identifiable data shared for recruitment purposes will be described in IRB approval letter ("brief description of PHI")

IRB Approval with Waiver of Authorization ↓

IRB Approval of a **Waiver of Authorization for Recruitment** (often called a partial waiver of authorization) is needed when using IU Health data to identify and screen potential patients who will be approached for consent and authorization in a clinical study. Access to IU Health data can be shared via direct access to the EMR or a cohort list from IU Health CRS team. (Currently Regenstrief has a separate process for providing cohort list.)

Submit SBAR to IU Health External Data Sharing Subcommittee (EDSS)

The SBAR is a tool to describe your request to share data outside of IU Health and IU

- S-Situation, B-Background, A-Assessment, R-Recommendation
- Complete the SBAR and sent to DataSharing Requests@iuhealth.org by the 2nd Monday of month

IT Risk assessment (ITRA) may be required when identifiable information will be shared and housed outside of IU (itra@iuhealth.org).

Attend EDSS monthly meeting

- EDSS members will review SBAR and may request revisions or additional information prior to EDSS meeting
- After review, an invitation will be sent for EDSS meeting (3rd Monday of Month)
- It is helpful to attend in case any questions arise during the meeting
- If approved, expect to receive approval documents within a week

EDSS Approval ↓

Submit to Office for Research Administration (ORA) through the Contract Request Form (CRF)

Provide all documents noted below or request will be rejected

- Provide EDSS approval
- Provide IRB approval notiing
  - Waiver of authorization for recruitment
  - Brief description of PHI to be shared

ORA will negotiate the appropriate sharing agreement with external entity

Data provided or may be accessed upon execution of appropriate agreement

NOTE: **Navy Box:** IU Health Office/Process
Red Box: IU Office/Process

IU Health Data Sharing Under a Waiver of Authorization for Participation

Is transfer of IU Health Data only to **IU Faculty and/or Staff?** (via Cohort Pull or Direct Acces to the EMR)

YES → Data used under a waiver of Authorization for participation will be described in IRB approval letter when identifiable data will be shared → No additional agreement required. Data provided.

IRB approval of a Waiver of Authorization for Participation is needed when IU Health data will be accessed and shared without patient consent or authorization as in a retrospective chart review of large scale registry without consent.

This process is NOT APPLICABLE if obtaining informed consent and authorization from subject

NO → Data Type

- Identifiable Data
- Limited Data Set
- De-identified Data

Will data be shared with commercial/for-profit entity **OR** any entity outside of US or Canada?

YES → Submit SBAR to IU Health External Data Sharing Subcommittee (EDSS) → Attend EDSS monthly meeting

NO → Data used under a waiver of Authorization for participation will be described in IRB approval letter when identifiable data will be shared

The SBAR is a tool to describe your request to share data outside of IU Health and IU

- S-Situation, B-Background, A-Assessment, R-Recommendation
- Complete the SBAR and sent to DataSharing Requests@iuhealth.org by the 2nd Monday of month

- EDSS members will review SBAR and may request revisions or additional information prior to EDSS meeting
- After review, an invitation will be sent for EDSS meeting (3rd Monday of Month)
- It is helpful to attend in case any questions arise during the meeting
- If approved, expect to receive approval documents within 1 week.

EDSS Approval → Submit to Office for Research Administration (ORA) through the Contract Request Form (CRF)

- Provide all documents noted below or CRF will be rejected
- Provide EDSS approval when applicable
- If sharing with commercial for profit entity
- If identifiable information will be shared
- Provide IRB approvalnoting
- Waiver of authorization for participation
- Brief description of PHI to be shared

ORA will negotiate the appropriate sharing agreement with external entity

Data provided or may be accessed upon execution of appropriate agreement

NOTE:
Navy Box: IU Health Office/Process
Red Box: IU Office/Process