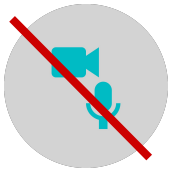
Welcome to

Working with ORSP to Process Data Use Agreements

The webinar will begin shortly.



Please mute your microphone and turn off your video.

Please use **Chat** to ask questions. Questions will be answered at the end of the presentation.

Today's Presenters

Michele Quick

Project Representative

Office of Research & Sponsored Projects

Gabrielle Hammoud

Project Representative

Office of Research & Sponsored Projects

*With special thanks to **Kirby Jewell** for consulting with us on the UFA process from the Research Administrator perspective.*

Agenda

- What is a Data Use Agreement (DUA)?
- What types of data does a DUA cover?
- Why and when is a DUA required?
- Helpful tips for creating an Unfunded Agreement (UFA) in eRPM for a DUA.
- Q&A

The webinar **recording and slides** will be available on the *Navigate Webinars: Past Sessions* webpage in a few days.

What Is a Data Use Agreement?

- A data use agreement is a contract that is used to define the terms and conditions upon which data is transferred or shared between organizations.
- Sometimes called a data transfer agreement (DTA) or data transfer and use agreement (DTUA) and is typically categorized as an Unfunded Agreement (UFA) at U-M.

Resource: Data Sharing and Use Agreements

What Types of Data Does a DUA Cover?

Data Type	Description
Human Subject Common Rule Regulated Data	Protect individuals who are the subject of research projects. Consideration is given to how various aspects of the research project, including privacy, confidentiality, data collection, data maintenance and data retention, impact physical, emotional, financial, and informational harms. • Personal Identifiable Information (PII)
Human Subject HIPAA Regulated Data	Protect individuals against information harm while allowing the necessary flow of health information with specific rules pertaining to the privacy and security of protected health information (PHI). • Protected Health Information (PHI) • Limited Data Set (LDS) • De-identified Data
Non-Human Subject Data	Data that does not meet the 45 CFR 46 definitions of human subjects research. • Program evaluations • Quality assurance • Quality improvement

For more detailed information see the 2019 *Navigate: Lunch & Learn* presentation: Demystifying Data Use Agreements.

Why Do You Need a DUA?

- Why is a DUA required when we are sharing data?
  - Health Insurance Portability and Accountability Act (HIPAA)
  - Family Educational Rights and Privacy Act (FERPA)
  - General Data Protection Regulation (GDPR) for contracting with European countries (EU Zone)
  - Some State Privacy laws
  - Institutional policies and practices

When Do You Need a DUA?

- When is a DUA typically required?
  - When data is leaving U-M.
  - When a contracting party is sending data to U-M and requires one.
  - Repository - data collected from multiple researchers, sometimes multiple sites, combined and stored for sharing with other researchers.
  - Consortium - data collected from multiple sites to be shared only with members of the consortium.
  - Multi-site (*Is U-M the Control Center?*) - Similar to a consortium, however, this is when there are multiple sites collecting similar data points for a shared purpose.

When Do You Use an UFA vs. PAF?

It Depends on the Purpose

- An UFA is utilized when the data is NOT being shared with an external entity for a fee.
    - **Resource**: eResearch Quick Reference Card: Unfunded Agreements (UFAs) - PI/Project Team
- An UFA will also be used when we are purchasing data from an external entity.

What Does “UFA Type” Tell Us?

UFA Type lets us know the direction in which data is being transferred. There are two “Types”:

Incoming DUA

- When an external entity is sharing data with us and we are the receiving party

UFA Category: Data Use Agreement
UFA Type: Incoming DUA

Outgoing DUA

- When U-M data is being shared with an external entity
- When there is a reciprocal transfer between U-M and the external entity

UFA Category: Data Use Agreement
UFA Type: Outgoing DUA

What Information Does ORSP Need?

- **Project Title**
  - Create a title we can use in the agreement. Example: *Understanding risk factors for poor outcomes in mild asthma*
- **Target Agreement Execution Date Reason**
- **External PI and External Entity Contact person for negotiations**
  - The PI is most likely not the person who is authorized to enter into an agreement on behalf of their institution.
- **Routing and Processing Instructions**
  - Any additional information not covered in the UFA that ORSP should be aware of.

Data and Project Descriptions

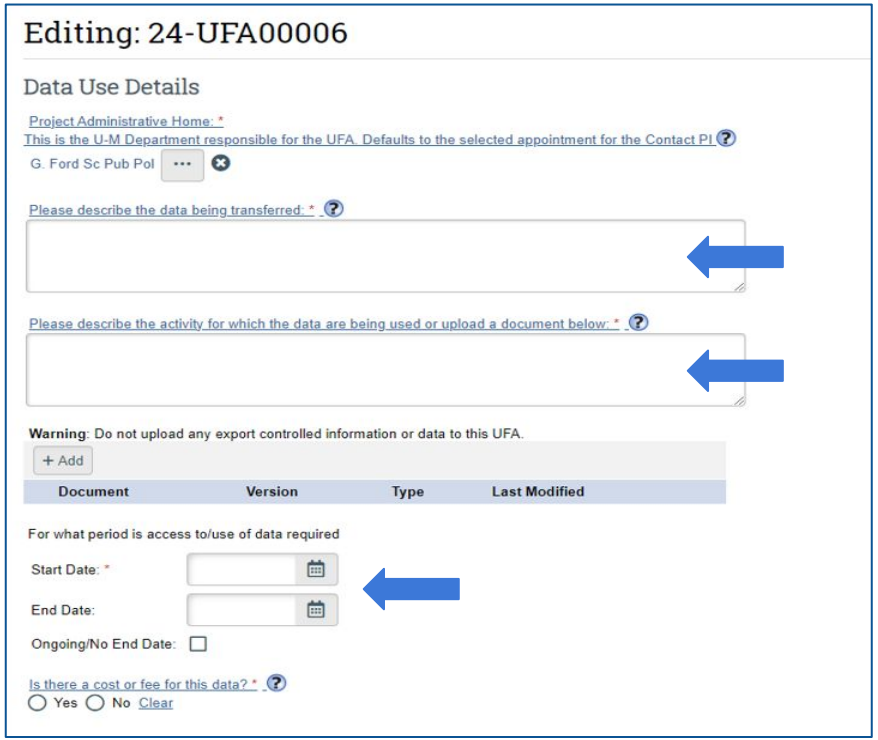
Data Description

- Include source for data
- Type of data (de-identified; limited data set; etc.)
- Was data collected for a research study?
- Data variables

Project Description - How will the data be used?

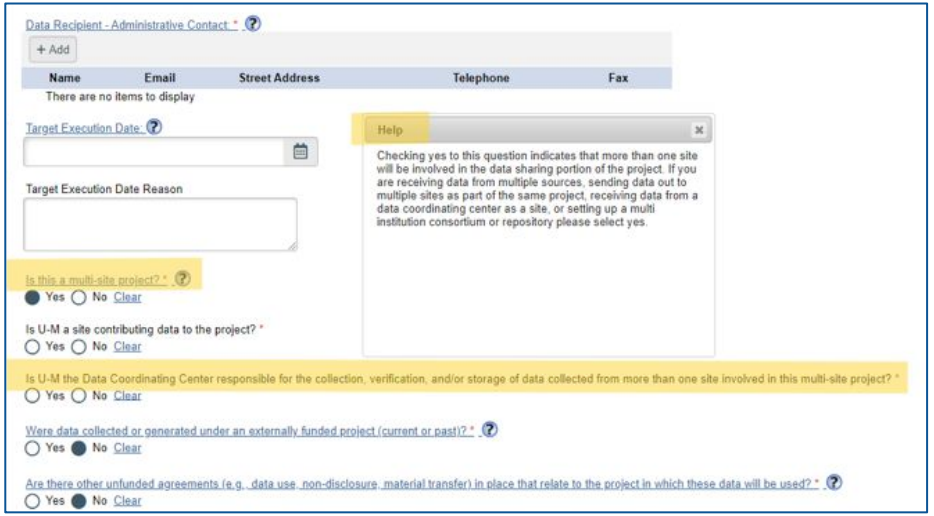
- Analysis
- The purpose of the study
- Will it be combined with other data
- Publications
- Multi-site project
- Longitudinal study
- Secondary research

Start and End Dates - The start date is required when creating the UFA, however this is subject to change.



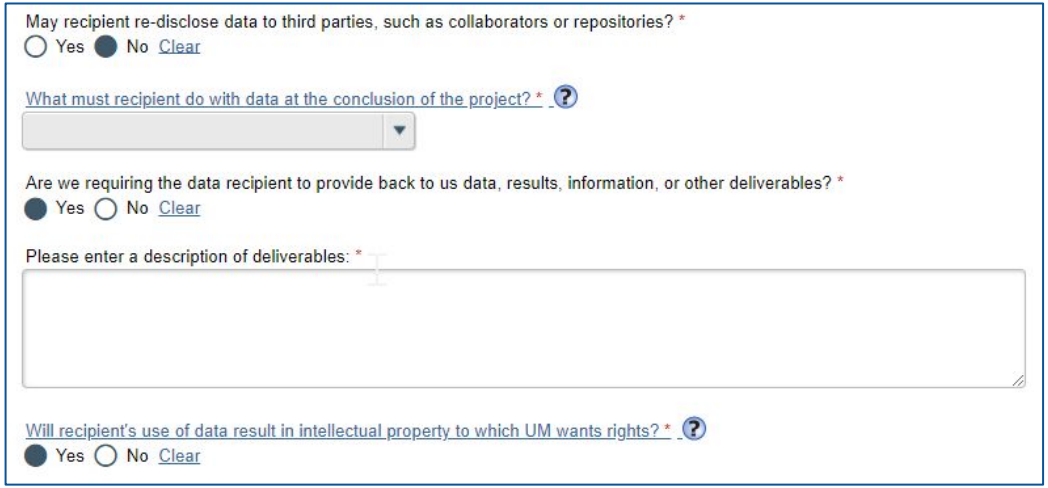
Multi-sites and Consortiums

- **Is this a Multi-site Project?**
  - Research study in which multiple sites are engaged in the same research project.
  - There is often a lead institution that is the prime recipient of the funding for the overall study and that may be responsible for administrative oversight of the overall study.
- **Is U-M contributing data to the project?**
  - Storage
  - Recruitment
  - Analysis
- **Is U-M the Data Coordinating Center?**
  - If “Yes” U-M will provide the data use agreement to contributing sites.
  - If “No” please upload the data use agreement that the Data Coordinating Center is sharing with all performance sites.



Some Info That Can Require Special Terms

- Sharing with third parties.
- Disposition of data at the conclusion of the project.
- Are there deliverables required?
- Will this work generate intellectual property?



Some Special Circumstances

When extended review and/or processing time might be needed

Are we sharing data with a for-profit company or foundation?	Requires review by the U-M Medical School Human Data & Biospecimen Release Committee. • Link to Process Information: Data & Biospecimen Sharing
Does the data being shared contain Human Subject Identifiers?	If we are sharing PHI, any patient identifiers, or electronic medical record (EMR) data, the UFA will need to be reviewed by UMHS Compliance.
Are any data, results, information or other Deliverables required?	We need to know this in order to add these terms to the agreement. If deliverables contain any U-M data that will be shared with the external entity, this may be a reciprocal agreement. Will data be aggregated, combined with other data, etc.

Some Special Circumstances (continued)

When extended review and/or processing time might be needed

Is there a fee for the data?	If the external entity is charging a fee, we need to know the source of the funds that will be used for payment. If U-M will be collecting a fee for the data, then this needs to be routed as a PAF.
Will recipient's use of this data generate intellectual property?	This indicates that we will need to consult Innovation Partnerships or the Office of the General Counsel (OGC).
Does Export Control apply?	This may need to be reviewed by OGC, Risk Management etc.

What Can Hold Up the Process?

- UFA does not contain complete information.
- Need clearance from the Medical School Human Data & Biospecimen Release Committee.
- The agreement contains terms and conditions about intellectual property.
- The HUM is not in an approved state.
- The agreement contains General Data Protection Regulation (GDPR) terms.
- There are terms and conditions in the agreement that U-M cannot accept.
    - Agreement Acceptance Request (AAR)

Always feel free to email ORSP or Post a Comment in the UFA record for a status update!

What Does “UFA Status” Tell Us?

Where is my DUA in this process?

Status	Description
Project Representative Review	When it is NOT actionable for the DUA team? ● If the UFA is not signed by the PI. ● If the HUM is not reviewed and approved/exempt it is NOT actionable. ● If we are sharing data with External Entity that is a for-profit company the DUA needs to be cleared by the Medical School Human Data & Biospecimen Release Committee. ● If the U-M PI is the same as the external entity PI. ● The DUA needs to be canceled and resubmitted as another type of agreement.
ORSP Review - Project Team Making Changes	ORSP has requested PI/Project Team make change(s) to the DUA.
HIPAA Review	ORSP sent DUA to UMMS Data Office for Clinical & Translational Research for review.
UMHS Processing	UMHS Compliance is processing the DUA.
Negotiation in Progress	Contract is being negotiated with the external entity.
Awaiting Outside Signature	Contract has been signed by U-M and is waiting for External Entity signature.

What Are the Ways to Communicate with the DUA Team?

- **Post a Comment for the Entire Project** (PI, Project Team, and Central Offices)
  - When posting comments in eRPM, be sure to add email addresses for those you want to see your comment and have to take action.
- **Email** - to get emails automatically entered into the UFA:
  - Send the email to erpmadmin-prod@umich.edu, and
  - Put the UFA ID in brackets in the Subject line: [23-UFA00444]
- **Scheduled Phone Call / Zoom Meeting:**
  - Email your ORSP Project Representative in advance to schedule a phone call or Zoom meeting.

Time for Q & A

Closing

Thank you!

Your Feedback is Important!
Please complete the webinar evaluation survey.

Contact the Navigate Team with questions
navigate-research@umich.edu