

## Working with ORSP to Process Data Use Agreements Webinar October 19, 2023

*The information in this document is current as of November 2023.*

### Questions & Answers

***If we need to help a partnering organization draft a DUA, are there templates that can help guide the research team?***

We definitely can help with templates! Unfortunately, we do not have these templates available on our website at this time, but you can contact the DUA team member assigned to your unit and they can provide the appropriate template.

To find the DUA team member assigned to a specific unit, visit the ORSP Staff website. If your unit is not listed, please contact Lisa Kiel at [lkiel@umich.edu](mailto:lkiel@umich.edu) for assistance.

***Will Process be implementing a dynamic form to assist ORSP with the information needed? Can we expect to see an UFA Status Map in our queue at some time in the future?***

There are plans to make changes to the eRPM system to make it more efficient. It is a work in progress and as our department goes through re-alignment, this will be addressed.

***If we are creating an incoming DUA and the organization where we are getting the data doesn't have a legal contact identified, but they use a general submission system for requesting data, how should we fill out the DUA application?***

In this situation, you could provide a comment in the routing instructions to let us know that there isn't an external contact. Include a link to the site for submission. You can also put an organizational email address in the contact box if you have that.

It is best to include as much information as possible in the UFA. Once triaged, the UFA will be assigned to a member of the DUA team and then this Project Representative will communicate with both the Primary Investigator and Research Administrator regarding any questions or clarifications needed. Sometimes these external systems require the PI to submit the agreement and it can be challenging to get the authorized signature on it. The PR assigned to this will review the terms and conditions and will work with you for these unique situations.

***If the U-M site is collecting data via surveys from participants and doing analysis and we share the results but not participant level data ... is this a data coordinating center or considered that we are sharing data with the partnering site (health center or health dept)?***

A true Data Coordinating Center (DCC) is established at the onset of a specific project. Most often it is a funded project and the DCC was determined before proposal submission. The DCC provides leadership for the research project, data management, and study administration for a common research purpose with multiple sites participating in this research. This is not the same as being a site that houses data that can be shared with multiple sites/researchers for their research projects.

If any U-M data is being shared by itself or combined with other data that has been received from multiple sites, a DUA is required. If the data being shared does not contain any U-M data, a DUA is not required. E.g. Data collected from multiple external sites and combined and then shared.

A DUA is not required when data has been received at U-M and analysis is being returned to the external entity as a deliverable. In this case, there may have been a DUA between U-M and the external entity to receive the data, but that is determined by the external entity.

A DUA is needed any time there will be a transfer of data, a dataset or software that is non-public or is otherwise subject to restrictions on its use, a DUA may or may not consist of human subject data.

***Is there a group email for just the DUA team we can use?***

At this time there is no group email for the DUA team. To find the DUA team member assigned to a specific unit, visit the [ORSP Staff website](#). If your unit is not listed, please contact Lisa Kiel at [lkiel@umich.edu](mailto:lkiel@umich.edu) for assistance.

***If there are multiple project representatives listed for our department on [the ORSP website](#), who should we put on our UFA?***

There are multiple ORSP teams and these teams serve your departments in different ways. The ORSP team member who will be assigned to assist with your agreement depends on the type of agreement.

If you are routing a UFA for a DUA, choose the PR that is assigned to your department for DUA's or contact Lisa Kiel ([lkiel@umich.edu](mailto:lkiel@umich.edu)) for assistance.

***When receiving money for data - is there a monetary limit, or is it everything beyond zero? I have seen that sometimes another institution is offering a small (few hundred dollars) gift card. Does that count as "paying for" data?***

If the university will be receiving funds directly related to processing and sharing data with an external entity, the request for a DUA will need to be submitted as a PAF in eRPM. In this case, it does not seem like a gift card could be used to reimburse the department for the costs of storing and processing the data. There are always unique situations that occur, and in this case, it is recommended that you contact the PR assigned to your department for DUAs to determine the correct way to move forward.

***Are multi-site UFA's only for those projects with two sites or more? Is it correct that a project with only one other site does not qualify as a multi-site?***

A true "multi-site project" describes a subset of cooperative non-exempt human research where the same research procedures (i.e., the "same protocol") are conducted at **two or more research sites** under the control of a participating investigator at each site.

A multi-site project typically involves a lead site (lead PI) that manages the administrative functions of the project in addition to conducting the same research procedures as the participating sites. A multi-site project could be a clinical trial, an observational study, or a basic clinical research study.

***What about data stewardship transfers, when a faculty transfers to another institution? What are the retention requirements for data if we enter into a data stewardship agreement:? Are we required to retain for any length of period? Or does this depend upon the data?***

The [Data Sharing & Resources and Policies](#) website provides detailed information regarding data stewardship.

Data Use agreements are not used for transferring data to a faculty member who has transferred to another organization for indefinite use. Data Use Agreements can be used for U-M to share data with a faculty member who has transferred to another institution to use that data for a specific purpose such as analysis, project completion, or publication.

***Are there any exceptions to the data retention? Does it depend on the type of data?***

The general rule is that research data must be retained for a minimum of seven years after the initial closeout of a project unless an applicable agreement, contract, or grant is in place. There is no standard maximum time frame for retention.

The retention of data that has been collected by U-M faculty for research purposes will depend on whether the data was collected for an externally funded project and what the award agreement states.

The retention of data that was received from an external entity with a data use agreement will need to be retained/returned/destroyed per the disposition terms in the agreement.

***Is a data use agreement required if, for example, the U-M main campus is sharing data with the U-M Medical campus?***

If you are contracting with any University of Michigan affiliate, whether it's Dearborn, Flint, or the medical campus versus the main campus, a data use agreement is not used. However, if your faculty member is collaborating with the University of Michigan Health-West, a data use agreement is required.

***What is the preferred process to get status updates when the agreement is under review by a non-ORSP committee? Post a comment in eRPM or email the PR?***

Project Teams should follow up with the entity/person that is listed in the UFA as the Project Representative. For example, when the record has been forwarded to Compliance for review and processing, the PR will be listed as UMHS Compliance Office and they should be contacted.

***When there are data and materials being sent, should an MTA or DUA be routed? Is it dependent on what type of data is being sent?***

If materials and data are being transferred an MTA should be requested. The DUA team will consult on the terms related to the data if needed. A DUA should be requested if there is only data being shared.

Here are some helpful websites that offer more information:

- [Material Transfer Agreement - Incoming](#)
- [Material Transfer Agreement - Outgoing](#)