



## Data Use Agreement (DUA) Agreement IBIS Submission Guidance

### Prerequisite Checklist:

- A DUA or DTA governs the transfer or use of specific data between UM and another organization but does not involve the transfer of funds.
- Standalone DUAs are only needed in the event that no other contract with the same parties will be executed in support of the project (inbound sponsored agreement or outbound subagreement). If such other agreement will be executed, that agreement should incorporate appropriate data transfer terms.

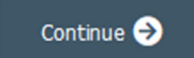
### Collaboration Agreement IBIS Submission Instructions:

1. Navigate to the Agreements Tab: 

2. Click Create Agreement: 

3. Agreement Upload Tab

<p>1. Agreement manager/Principal investigator:</p> <input type="text"/>	<p>The Agreement manager/Principal Investigator should be the PI overseeing the overall project.</p>		
<p>2. * Primary contact:</p> <p>Holly Kasem-Beg <input type="text"/> <input type="button" value="x"/></p>	<p>Primary contact automatically populates with the name of the individual submitting the request but can be changed.</p>		
<p>3. * Upload agreement draft: (or check the box below) <input data-bbox="808 1100 833 1131" type="button" value="?"/></p> <p>[None] <input type="button" value="Upload"/></p> <p>First draft to be generated internally? <input checked="" type="checkbox"/></p>	<p>Upload the WORD version of the Agreement here.</p> <p>If the counterparty specifically asks for UM to generate the agreement: mark box as "First draft to be generated internally".</p>		
<p>4. Title or internal reference number: <input data-bbox="678 1251 703 1283" type="button" value="?"/></p> <input type="text"/>	<p>Title should be a short unique identifier.</p>		
<p>5. * Agreement type:</p> <p>Data Use Agreement <input type="button" value="v"/></p>	<p>Agreement type should always be Data Use Agreement.</p>		
<p>6. Description:</p>	<p>Provide a brief description of the data being transferred/exchanged (this information is REQUIRED for many DUA agreements).</p>		
<p>7. Supporting documents:</p> <p><input type="button" value="+ Add"/></p> <table border="1"> <thead> <tr> <th>Name</th> </tr> </thead> <tbody> <tr> <td>There are no items to display</td> </tr> </tbody> </table>	Name	There are no items to display	<p>Provide the scope or work of the collaboration here.</p> <p>UM and the collaborator may have differing scopes of work, if that is the case, please include both.</p>
Name			
There are no items to display			

4. Click Continue:   



5. General Information Tab

<p>1. * Contracting party:</p> <input type="text"/> <p>If you cannot find the organization in the list above, enter its information here: Contracting party name:</p> <input type="text"/>	<p>This is the other party that the Agreement is with.</p>						
<p>2. Contracting party contact name:</p> <input type="text"/>	<p>This Contact should be an individual employed by the Contracting Party responsible for the negotiation of agreements.</p>						
<p>3. Contracting party contact e-mail:</p> <input type="text"/>	<p>Email address is <b>required</b>.</p>						
<p>4. Contracting party contact phone:</p> <input type="text"/>	<p>Optional.</p>						
<p>5. * Responsible department/division/institute: ?</p> <p>ORA Administration <input type="text"/> <input checked="" type="button" value="x"/></p>	<p>Ensure accuracy.</p>						
<p>6. Agreements collaborators: (institutional staff given read/edit permissions for this Agreement)</p> <input type="text"/> <table border="1"> <thead> <tr> <th>Name</th> <th>E-mail</th> <th>Phone</th> </tr> </thead> <tbody> <tr> <td colspan="3">There are no items to display</td> </tr> </tbody> </table>	Name	E-mail	Phone	There are no items to display			<p>Ensure all individuals who must have read/edit access to the request are added.</p>
Name	E-mail	Phone					
There are no items to display							

6. Data Use Agreement Information Tab

<p>1. * Is the data being received or provided?</p> <p><input type="radio"/> Received (Inbound)</p> <p><input type="radio"/> Provided (Outbound)</p> <p><input type="radio"/> Both</p> <p><a href="#">Clear</a></p>	<p>Select the direction of the data transfer.</p>
<p>2. * Is the data human subject data?</p> <p><input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a></p> <p>If yes, the following additional questions will appear:</p> <p>3. * Is the Data:</p> <p><input type="checkbox"/> Protected Health Information (PHI)</p> <p><input type="checkbox"/> Limited Data Set</p> <p><input type="checkbox"/> Personally Identifiable Information (PII)</p> <p><input type="checkbox"/> De-Identified</p> <p><input type="checkbox"/> Only coded data will be shared with the sponsor</p>	<p>Confirm whether the data being transferred constitutes human subjects data.</p> <p>If yes, select the appropriate data classification—see <a href="#">end of this document for data classification definitions</a>.</p>



<p>4. * Please briefly describe the purpose or use of the data being transferred:</p> <div style="border: 1px solid black; height: 80px; width: 100%;"></div>	<p>Please include the applicable information.</p>
<p>5. * Is any data originating in the EU?  <input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a></p>	<p>Please respond to this required question.</p>
<p>6. * Will any of the data be sent to or received in the EU?  <input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a></p>	<p>Please respond to this required question.</p>

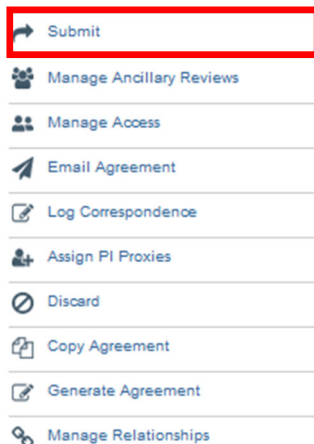
**7. Intellectual Property Information Tab**

<p>1. * Is this agreement related to a submitted Funding Proposal?  <input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a></p> <p>If no, the following additional questions will appear:</p> <p>2. * Does this project/activity involve any of the following (check all that apply):</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Existing invention disclosure on file with the Office of Technology Transfer?</li> <li><input type="checkbox"/> Any unique Innovations that are not publicly available?</li> <li><input type="checkbox"/> Anticipate any NEW Innovations to be developed by UM under this project?</li> <li><input type="checkbox"/> Not applicable.</li> </ul> <p>3. * In relation to this project/activity (check all that apply):</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Do any investigators play a role and/or have a vested interest in external companies related to this project?</li> <li><input type="checkbox"/> Do you anticipate the involvement of a UM PI Start-up or a Start-up that is affiliated with a UM employee?</li> <li><input type="checkbox"/> Do you, or any one on the research team have any relationship, including any type of agreement, or funding in place with any of the entities involved in the project?</li> <li><input type="checkbox"/> Do you have any other relationships, including financial, with the company/entity?</li> <li><input type="checkbox"/> Not applicable.</li> </ul>	<p>If yes, the DUA may not be needed, as there is likely an associated agreement with the same party in process or anticipated.</p> <p>If no, respond to these additional required questions.</p>
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**8. Completion Instructions Tab: confirm all information inputted accurately and Click Finish**



**9. The Data Use Agreement should now be in Pre-Submission status. Click Submit on the leftmost menu:**





**Notes:** 1) Submission of a Data Use Agreement request in IBIS constitutes department and PI approval for Research Administration to review and negotiate the agreement according to UM guidelines, policies and procedures.

2) Failure to comply with this guidance document may result in rejection/discarding of the Data Use Agreement request or a formal Request for Clarification in IBIS.

### **Data Classification Definitions:**

Government or legal classifications for certain types of data and information. Government may elect through legislation or practice to codify certain groups of data by classifying them to facilitate consistent data management in accordance with government expectations and needs.

### **Data Classification, HIPAA**

HIPAA (defined under H) requires entities performing a covered function to identify and classify data based on these identifiers:

1. names (including initials),
2. geographic location smaller than a state (i.e. address),
3. any dates specific to an individual except year (i.e. date of birth, hospital admission and discharge dates, date of death, et cetera) and for those over 89 must aggregate into a single category of age 90 or older any year that might be indicative of age;
4. telephone numbers;
5. fax numbers;
6. e-mail addresses;
7. social security number;
8. medical record number;
9. health plan number;
10. account numbers of any kind;
11. certificate or license number(s);
12. Vehicle identifiers and serial numbers, including license plates;
13. device identifiers and/or serial numbers;
14. web URLs;
15. IP addresses,
16. biometric identifiers,
17. photographic images; and
18. any other unique identifier.

### **De-Identified Data**

Data are considered de identified if the covered entity removes 18 specified personal identifiers from the data.

### **Limited Dataset (LDS)**

Protected Health Information that excludes the following direct identifiers of the patient or of relatives, employers, or household members of the patient: Names; Postal address information, other than town or city, State, and zip code; Telephone numbers; Fax numbers; Electronic mail addresses; Social security numbers; Medical record numbers; Health plan beneficiary numbers; Account numbers; Certificate/license numbers; Vehicle identifiers and serial numbers, including license plate numbers; Device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; Biometric identifiers, including finger and voice prints; Full



face photographic images and any comparable images; and Any other unique identifying number, characteristic, or code except as specifically permitted by HIPAA.

**Full Personal Health Information (PHI)**

Contains identifiers that could be linked to a specific individual, such as initials or address. See list above.

**Coded Data**

Data that has: 1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertains has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and 2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens. Coded data may constitute a limited data set, as further defined above. Office of Health Policy Research (OHPR) considers private information or specimens not to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.