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MCA Agreement IBIS Submission Guidance (**externally funded studies**)

1. Navigate to the associated Funding Proposal (FP) in Grants (*For certain cooperative groups, it may be an M or FP-REV instead of an FP - Please make sure it is linked to the correct source*).

2. To create new MCA Agreement, click



Create Agreement

3. Select MCA Agreement from the dropdown: ***Select an Agreement Type to create:**

MCA Agreement ▼

4. Navigate to **Related Projects tab** in the FP, where the new MCA Agreement should now be listed. Select the new MCA Agreement ID.

5. Click Edit Agreement:

Edit Agreement

6. **Agreement Upload Tab**

<p>1. Agreement manager/Principal investigator:</p> <input type="text"/>	<p>The Agreement manager/Principal Investigator should automatically populate based off the FP, i.e. be the PI listed in funding document under which the funds for the study are provided. If PI listed with IRB is different, change Manager/PI to match IRB record.</p>
<p>2. * Primary contact:</p> <p>Holly Kasem-Beg <input type="text"/> <input type="button" value="x"/></p>	<p>Primary contact automatically populated 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 type="button" value="help"/></p> <p>[None] <input type="button" value="Upload"/></p> <p>First draft to be generated internally? <input checked="" type="checkbox"/></p>	<p>Mark box as "First draft to be generated internally". <u>Do not upload any documents here.</u></p>



<p>4. Title or internal reference number: </p> <input type="text"/>	<p>Title should already be included based off the study title of the FP. Edit it by adding IRB number to the title and “MCA” or “MCA Amendment” as applicable.</p>		
<p>5. * Agreement type:</p> <input type="text" value="MCA Agreement"/>	<p>Agreement type should already be populated at MCA Agreement.</p>		
<p>6. Description:</p>	<p>Not required for new MCA Agreements. <i>Enter “Protocol amendment” OR “PI Change” if amendment.</i></p>		
<p>7. Supporting documents:</p> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> <input type="button" value="+ Add"/> </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Name</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">There are no items to display</td> </tr> </tbody> </table>	Name	There are no items to display	<p>Include the following documents here:</p> <ul style="list-style-type: none"> Study Protocol (final) ICF (draft is acceptable) Draft Study Protocol with tracked changes (if available), for amendments only Routine care (RC) Worksheet (for some cooperative groups and similar sponsors, if available) Intramural budget (if study is partially supported internally)
Name			
There are no items to display			

7. Click Continue:

✕ Exit

💾 Save

Continue

8. General Information Tab

<p>1. * Contracting party:</p> <input type="text"/> <p style="font-size: 0.8em; margin-top: 5px;">If you cannot find the organization in the list above, enter its information here: Contracting party name:</p> <input type="text"/>	<p>Insert the name of the funding source as shown in FP and pick from available options.</p>						
<p>2. Contracting party contact name:</p> <input type="text"/>	<p>Not required.</p>						
<p>3. Contracting party contact e-mail:</p> <input type="text"/>	<p>Not required.</p>						
<p>4. Contracting party contact phone:</p> <input type="text"/>	<p>Not required.</p>						
<p>5. * Responsible department/division/institute: </p> <input type="text" value="ORA Administration"/>	<p>Ensure accuracy (this should be the relevant Department/division/institute that is conducting the project).</p>						
<p>6. Agreements collaborators: (institutional staff given read/edit permissions for this Agreement)</p> <input type="text"/> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <thead> <tr> <th style="text-align: left;">Name</th> <th style="text-align: left;">E-mail</th> <th style="text-align: left;">Phone</th> </tr> </thead> <tbody> <tr> <td colspan="3" style="text-align: center;">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 MCA Agreement are added.</p>
Name	E-mail	Phone					
There are no items to display							



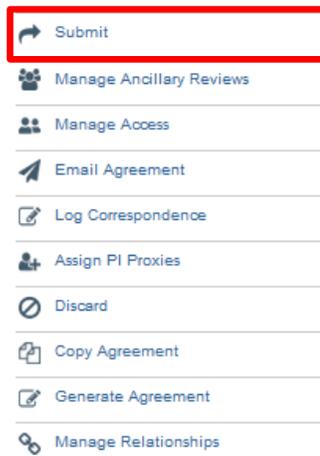
9. Click Continue:



10. Completion Instructions Tab: confirm all information inputted accurately and Click Finish



11. The MCA Agreement/Amendment should now be in Pre-Submission status. Click Submit on the leftmost menu:



Notes: Failure to comply with this guidance document may result in rejection/discarding of the MCA Agreement or a formal Request for Clarification in IBIS.



MCA Agreement Amendment IBIS Submission Guidance (externally funded studies)

1. Navigate to the associated Funding Proposal (FP) in Grants (For certain cooperative groups, it may be an M or FP-REV instead of an FP - Please make sure it is linked to the correct source).

2. To create an Amendment to MCA Agreement, first, click 

a. If you cannot see related MCA Agreement, go to Item 2 on pg. 1 and follow the process for New MCA Agreement, paying attention to some differences for amendments as outlined.

b. If you can see related MCA Agreement, navigate to this original MCA requiring an amendment, open it, click “Create Amendment” on the leftmost toolbar  and follow the process below.

3. Amendment Information Tab:

<p>1. Upload draft amendment file: (or check the box below)</p> <p>[None] </p> <p>Amendment file draft to be generated internally? <input type="checkbox"/></p>	<p>Mark box as “Amendment file draft to be generated internally”. <u>Do not upload any documents here.</u></p>
<p>2. Supporting documents:</p> <p></p> <p>Name</p> <p>There are no items to display</p>	<p>Include the following documents here:</p> <ul style="list-style-type: none"> • Study Protocol (final) matching the amendment. • Draft Study Protocol with tracked changes (if available) • ICF (draft is acceptable)
<p>3. * Amendment Description:</p>	<p>PI change OR Protocol Amendment</p>

4. Click Continue: 

5. Agreement Upload Tab:

<p>1. Agreement manager/Principal investigator:</p> <p><input type="text"/></p>	<p>Automatically populates. The Agreement manager/Principal Investigator should be the PI reflected in UM IRB record.</p>
<p>2. Title or internal reference number: </p> <p><input type="text"/></p>	<p>Title should be the title for the original agreement, which automatically populates based on the original submission, preceded by amendment number.</p>
<p>3. * Agreement type:</p> <p>MCA Agreement </p>	<p>Agreement type should always be MCA Agreement.</p>
<p>4. Description:</p> <p><input type="text"/></p>	<p>DO NOT CHANGE.</p>

6. Click Continue: 



7. General Information Tab

<p>1. * Contracting party:</p> <input type="text"/> ...	<p>Ensure the Contracting Party is consistent with sponsor identified in the amendment. Note: this field automatically populates based on the original submission but can be updated.</p>
<p>If you cannot find the organization in the list above, enter its information here: Contracting party name:</p> <input type="text"/>	<p>Not required.</p>
<p>2. Contracting party contact name:</p> <input type="text"/>	<p>Not required.</p>
<p>3. Contracting party contact e-mail:</p> <input type="text"/>	<p>Not required.</p>
<p>4. Contracting party contact phone:</p> <input type="text"/>	<p>Not required.</p>
<p>5. * Responsible department/division/institute: ?</p> <p>ORA Administration ... ✕</p>	<p>Automatically populates based on the original submission but can be updated – change only as needed to ensure accuracy.</p>

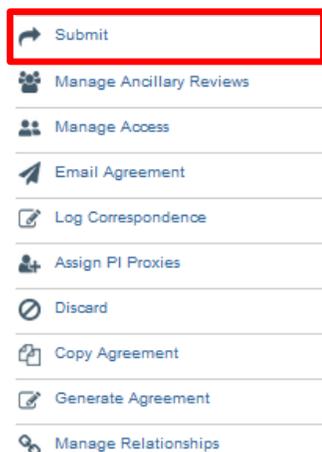
8. Click Continue:



9. Completion Instructions Tab: confirm all information inputted accurately and Click Finish



10. The MCA Amendment should now be in Pre-Submission status. Click Submit on the leftmost menu:



Notes: Failure to comply with this guidance document may result in rejection/discarding of the MCA Agreement or a formal Request for Clarification in IBIS.



MCA Agreement IBIS Submission Guidance (internally funded studies)

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>Enter the Agreement manager/Principal Investigator as listed with IRB.</p>		
<p>2. * Primary contact:</p> <p>Holly Kasem-Beg <input type="text"/> <input type="button" value="x"/></p>	<p>Primary contact automatically populated 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 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>Mark box as "First draft to be generated internally". <u>Do not upload any documents here.</u></p>		
<p>4. Title or internal reference number: <input type="button" value="?"/></p> <input type="text"/>	<p>Enter: MCA_PI name_IRB#_Short study title_Amendment (if applicable)</p>		
<p>5. * Agreement type:</p> <input type="text" value="MCA Agreement"/>	<p>Agreement type should already be populated at MCA Agreement.</p>		
<p>6. Description:</p>	<p>Not required for new MCA Agreements. Enter "Protocol amendment" OR "PI Change" if amendment.</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>Include the following documents here:</p> <ul style="list-style-type: none"> • Study Protocol (final) • ICF (draft is acceptable) • Draft Study Protocol with tracked changes (if available), for amendments only • Routine care (RC) Worksheet (for some cooperative groups and similar sponsors, if available) • Intramural budget (if study is partially supported internally)
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>Insert: Intramurals</p>						
<p>2. Contracting party contact name:</p> <input type="text"/>	<p>Not required</p>						
<p>3. Contracting party contact e-mail:</p> <input type="text"/>	<p>Not required.</p>						
<p>4. Contracting party contact phone:</p> <input type="text"/>	<p>Not required.</p>						
<p>5. * Responsible department/division/institute: ?</p> <p>ORA Administration <input type="text"/> <input type="text"/></p>	<p>Ensure accuracy (this should be the relevant Department/division/institute that is conducting the project).</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 MCA Agreement are added.</p>
Name	E-mail	Phone					
There are no items to display							

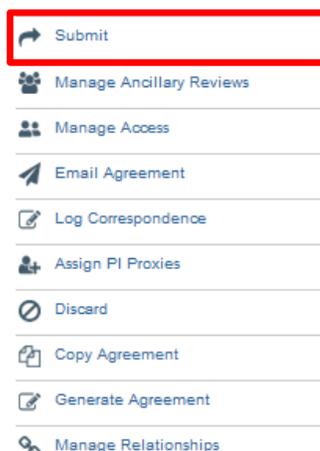
6. Click Continue:



7. Completion Instructions Tab: confirm all information inputted accurately and Click Finish



8. The MCA Agreement/Amendment should now be in Pre-Submission status. Click Submit on the leftmost menu:



Notes: Failure to comply with this guidance document may result in rejection/discarding of the MCA Agreement or a formal Request for Clarification in IBIS.



MCA Agreement Amendment IBIS Submission Guidance (internally funded studies)

1. To create an **Amendment to MCA Agreement**, first review if the information on the original MCA Agreement was provided in IRB ancillary review (original agreement number MCAXXXXXXXX)
 - a. If information **was not** provided, **go to Item 1 on pg. 6** and follow the process for **New MCA Agreement**, paying attention to some differences for amendments as outlined.
 - b. If information (original agreement number MCAXXXXXXXX) **was provided**, locate original MCA Agreement record requiring an amendment, open it, click “Create Amendment” on the leftmost toolbar  **Create Amendment** and follow the process below.

2. Amendment Information Tab:

<p>1. Upload draft amendment file: (or check the box below)</p> <p>[None]  Upload</p> <p>Amendment file draft to be generated internally? <input type="checkbox"/></p>	<p>Mark box as “Amendment file draft to be generated internally”. <u>Do not upload any documents here.</u></p>
<p>2. Supporting documents:</p> <p></p> <p>Name</p> <p>There are no items to display</p>	<p>Include the following documents here:</p> <ul style="list-style-type: none"> • Study Protocol (final) matching the amendment. • Draft Study Protocol with tracked changes (if available) • ICF (draft is acceptable)
<p>3. * Amendment Description:</p>	<p>PI change OR Protocol Amendment</p>

3. Click Continue:   **Continue** 

4. Agreement Upload Tab:

<p>1. Agreement manager/Principal investigator:</p> <p><input type="text"/></p>	<p>Automatically populates. The Agreement manager/Principal Investigator should be the PI reflected in UM IRB record.</p>
<p>2. Title or internal reference number: </p> <p><input type="text"/></p>	<p>Title should be the title for the original agreement, which automatically populates based on the original submission, preceded by amendment number.</p>
<p>3. * Agreement type:</p> <p>MCA Agreement </p>	<p>Agreement type should always be MCA Agreement.</p>
<p>4. Description:</p> <p><input type="text"/></p>	<p>DO NOT CHANGE.</p>

5. Click Continue:   **Continue** 



6. General Information Tab

<p>1. * Contracting party:</p> <input type="text"/> ...	<p>Ensure the Contracting Party is consistent with sponsor identified in the amendment. Note: this field automatically populates based on the original submission but can be updated.</p>
<p>If you cannot find the organization in the list above, enter its information here: Contracting party name:</p> <input type="text"/>	
<p>2. Contracting party contact name:</p> <input type="text"/>	<p>Not required.</p>
<p>3. Contracting party contact e-mail:</p> <input type="text"/>	<p>Not required.</p>
<p>4. Contracting party contact phone:</p> <input type="text"/>	<p>Not required.</p>
<p>5. * Responsible department/division/institute: ?</p> <p>ORA Administration ... *</p>	<p>Automatically populates based on the original submission but can be updated – change only as needed to ensure accuracy.</p>

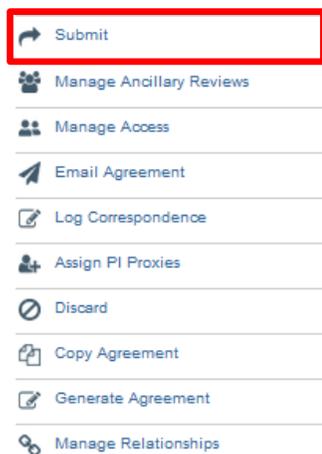
7. Click Continue:



8. Completion Instructions Tab: confirm all information inputted accurately and Click Finish



9. The MCA Amendment should now be in Pre-Submission status. Click Submit on the leftmost menu:



Notes: Failure to comply with this guidance document may result in rejection/discarding of the MCA Agreement or a formal Request for Clarification in IBIS.