UNIVERSITY OF MIAMI

RESEARCH ADMINISTRATION

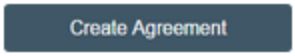
Clinical Trial Agreement (CTA) IBIS Submission Guidance

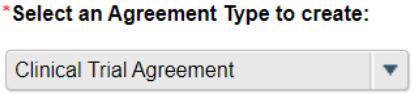
Prerequisite Checklist:

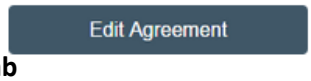
- ☐ Review Scope of Project and confirm it falls under NIH definition of a Clinical Trial https://grants.nih.gov/ct-decision/index.htm
- ☐ Funding Proposal (FP) related to this CTA is submitted to ORA in IBIS.
- ☐ A WORD version of the Clinical Trial Agreement is needed.
- ☐ Please reference Departmental Clinical Trial Checklist for further details on needed documents.

Clinical Trial Agreement IBIS Submission Instructions:

1. **Navigate to the associated FP and click Create Agreement:** 

2. **Click Create Agreement:** 

3. **Select Clinical Trial Agreement from the dropdown:** 

4. Navigate to Related Projects tab in the FP, where the new CTA should now be listed. Select the new CTA ID.
5. Click Edit Agreement: 

6. **Agreement Upload Tab**

1. **Agreement manager/Principal investigator:**	The Agreement manager/Principal Investigator should be the PI overseeing the overall project
2. * **Primary contact:** Holly Kasem-Beg	Primary contact automatically populated with the name of the individual submitting the request but can be changed.
3. * **Upload agreement draft:** (or check the box below) [None] Upload **First draft to be generated internally?** ☑	Upload the WORD version of the CTA here. If the Sponsor specifically asks for UM to generate the CTA: mark box as "First draft to be generated internally".
4. **Title or internal reference number:**	Title should already be included based off the study title of the FP.
5. * **Agreement type:** Clinical Trial Agreement	Agreement type should already be populated at Clinical Trial Agreement.
6. **Description:**	Describe Study here.

7. **Supporting documents:** + Add Name There are no items to display	The Final Protocol, Draft Informed Consent and Draft Budget and (if applicable) MSOM Feasibility Approval should have been included in the FP. If not, insert here. Also, include Letter of Indemnification (LOI) if provided by Sponsor/CRO.

7. Click Continue: 

8. General Information Tab

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

9. CTA Agreement Information Tab

1. **Phase of study:**	Insert Phase of Study here (or N/A).
2. **Sponsor protocol number:**	Insert Protocol Number
3. **Protocol title:**	Insert Protocol Title

4. * Type of trial:	Insert Type of Trial (Drug, Device or Other). If Drug or Device, an additional question regarding IND or IDE number will display which needs to be answered.
5. * Will this study use a contract research organization (CRO)? ○ Yes ○ No Clear	If CRO involved, marked Yes. There will be contact information questions then displayed that need to be filled out.

10. CTA Additional Information Tab

1. * Who developed the protocol?	Insert who developed the Protocol here.
2. * Principal Investigator National Provider Identification Number:	Insert PI NPI Number here.
3. Indicate the maximum time you will allow the sponsor to review your publication: ○ 90 Days ○ 120 Days ○ No Preference ○ No Intent to Publish Clear	Insert sponsor review time of publication.
4. * How many language translations are needed of the Informed Consent Form? ○ 1 ○ 2 ○ 3 or more ○ None Clear	Insert how many languages the ICF needs translation.
5. * What is the estimated enrollment at UM/JHS?	Insert estimated enrollment.
6. * What is the expected ratio of screen failures to enrolled patients?	Insert expected screen failure ratio.
7. * Does your per patient cost estimate differ from the Sponsor's? ○ Yes ○ No Clear	If "Yes" marked, an additional question for you to enter your estimated per patient cost is displayed where needs to be answered.

11. Intellectual Property Information Tab

1. * Is this agreement related to a submitted Funding Proposal? ○ Yes ○ No Clear	This should be marked Yes as a Funding Proposal is required if you are submitting a CTA.

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

13. The Clinical Trial Agreement should now be in Pre-Submission status. Click Submit on the leftmost menu:

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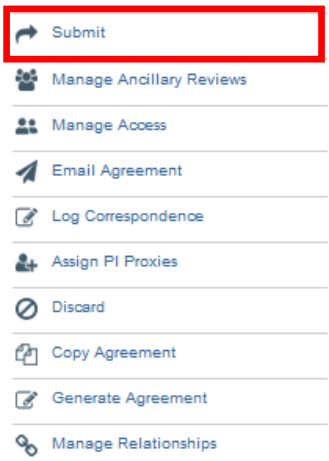

Notes: 1) Submission of a Clinical Trial Agreement request in IBIS constitutes department and PI approval for Research Administration to review and negotiate the agreement according to UM guidelines, policies and procedures.

2) Failure to include a Funding Proposal submission in parallel with this Clinical Trial Agreement Submission will result in the CTA being returned to the Department under Clarification Requested.

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