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# Outgoing Industry Subcontract Request Instructions

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## Starting from CRMS:

Go to the CRMS record for the prime agreement

Go to the “Submissions” tab

Select the Office of Industry Contracting (OIC) dropdown.

Select either “Submit CDA Request Form” or “Submit Amendment Request”

This will redirect to the [Organizational, Personnel, and Department Page](#) in ALICE ([below](#)).

The screenshot displays the 'Submissions' tab in the CRMS system. The navigation bar includes 'Dashboard', 'Protocol', 'Submissions' (highlighted), and 'Research Participants'. The main content area shows the following details:

- >> Study and Protocol Information - CRMS#: C18-0052 NO FEAR-BE Lead PI: Nicholas Shaheen - IRB#: 18-0388**
- Full Study Title (From IRB):** Nitrous Oxide For Endoscopic Ablation of Refractory Barrett's Esophagus (NO FEAR-BE)
- Admin Departments:** Center for Gastrointestinal Biology and Disease (429001)
- Sponsors:** C2 Therapeutics, University of North Carolina at Chapel Hill (UNC-CH), PENTAX of America, Inc.

Below the study information, there are two expandable sections:

- + IRB \* Required**  
The [Office of Human Research Ethics \(OHRE\)](#) manages the work of all the Institutional Review Boards (IRBs) at UNC. All UNC research involving human subjects requires review by the appropriate IRB.
- Office of Industry Contracting (OIC)**  
Office of Industry Contracting (OIC) is responsible for reviewing and executing sponsored research agreements with private industry, including sponsored research agreements, clinical trial agreements and subcontracts, among others. OIC also negotiates and executes all (industry, federal or other party) Confidentiality Agreements (CDAs and NDAs) and Data Use Agreements for the entire UNC-CH campus.

At the bottom of the interface, there are three buttons for submitting request forms:

- Submit Clinical Trials Agreement Request Form
- Submit CDA Request Form
- Submit Amendment Request Form



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## Starting from ALICE:

Go to the main ALICE page:

[https://apps.research.unc.edu/alice/index\\_auth.cfm](https://apps.research.unc.edu/alice/index_auth.cfm)

Click "Submit New Non-CTA Agreement Request" button

The screenshot shows the ALICE web application interface. At the top, there is a navigation bar with the ALICE logo and the text "Office of Clinical Trials & Office of Industry Contracting @ UNC Chapel Hill". Below the navigation bar, there are several sections:

- My Submissions:** A sidebar menu with links for "4 My Agreements" and "0 PI Certification Inbox".
- Office of Industry Contracting:** A section providing contact information for assistance with contracts, including the address (720 Martin Luther King, Jr. Blvd., Suite 101-E, Chapel Hill, NC 27599), phone (919.962.3630), fax (919.843.2399), and email (oic@unc.edu).
- Office of Clinical Trials:** A section providing contact information for assistance with clinical trial compliance and study subject billing, including the address (720 Martin Luther King, Jr. Blvd., Suite 100, CB# 1651, Chapel Hill, NC 27599-1651), phone (919.843.2698), fax (919.843.2399), and email (oct@unc.edu).
- Main Content Area:** A section titled ">> UNC - Chapel Hill" with a welcome message and a dashboard for managing agreements. It includes buttons for "View Agreements in Progress", "View Agreements on File", "Submit New CTA", "Submit New Non-CTA Agreement Request", "RAMSeS IPF", "BLUE MTA", and "EPAP".



## Subcontract Request Form - Steps

### A. Organizational, Personnel, and Department Page

The following form will open. A red asterisk denotes required information. Each step is explained below.

>> Organizational, Personnel, and Department

**1. Industry/Contracting Party \***

**2. All personnel associated with this agreement (i.e., Lead Principal Investigator, External Contact for Negotiation, Dept. Contact, etc.) \***

**3. Admin Dept (UNC Department with responsibility for managing the agreement/project): \***

Department \*

Department Code \*

**4. Agreement Type - All Clinical Trial Agreement request need to be submitted through CRMS \***

- CDA
- Collaboration Agmt
- DUA
- Inter-Institutional Agreement
- Letter of Intent
- Master Agreement
- MTA
- Other
- Sponsored Research Agmt (non-clinical)
- Amendment
- Subcontract



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1. "Industry/Contracting Party" – This is the subcontractor or site. Search for the "Sponsor Name" or "Entity" then select the appropriate "Role" from the dropdown menu ("Sub-site"). When finished, click "Save."

If the Sponsor (the contracting party/subcontractor) is not listed after searching, click "Sponsor Not Listed" and add in the information.



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2. "All personnel associated with this agreement" – Enter the UNC lead investigator, UNC department contact, subcontractor/site PI, external contact for contract negotiations.

When entering any other internal contact added besides the PI, their role needs to initially be listed as "External Contact for Negotiations." Once saved, click "Edit" next to the name to go back into the contact and edit the role (e.g. Dept. Contact). We are working to address this glitch.

When entering external contact information, search by "External Only", and then select "Person Not Listed" to enter the information manually.

2. All personnel associated with this agreement (i.e., Lead Principal Investigator, External Contact for Negotiation, Dept. Co

[close](#)

2. All personnel associated with this agreement (i.e., Lead Principal Investigator, External Contact for Negotiation, Dept. Contact, etc.)

3.

First Name

Last Name \*

PID

Title

4. Department

Email \*

Phone

Mobile Phone

Company There are no available answers for this question.

Role \*

Select Lead Principal Investigator above for Center Directors if applicable

Subcontract

5. Will any students (undergraduate, graduate, post-graduate, fellows, etc.) work on this project? \*

Personnel Search (choose the person by clicking their name)

[Gibbs, Robin](#)

[Gibbs, Ronnie](#)

[Gibbs, Shawn](#)

[Gibbsa, Carole](#)

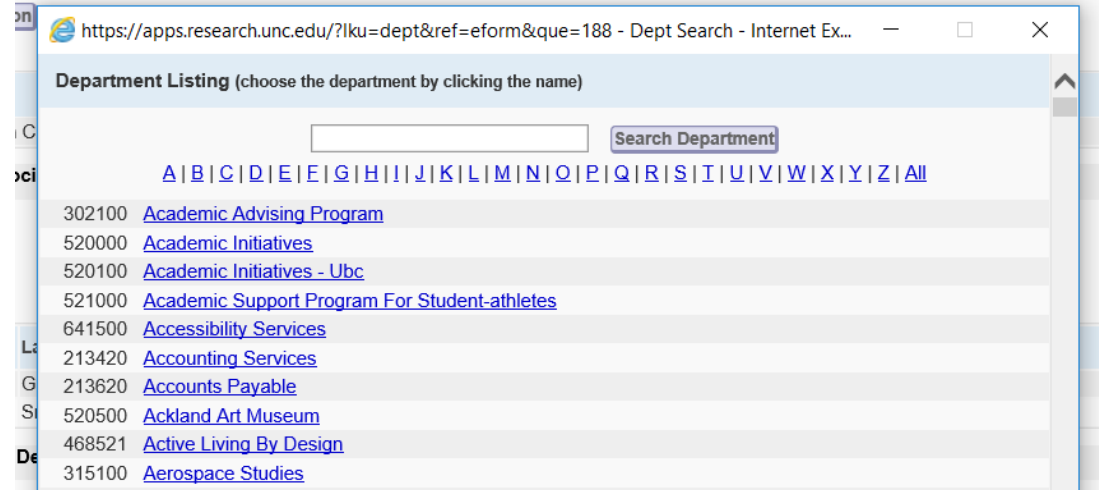
[Search Again](#) [Person Not Listed](#) [Close Window](#)



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3. “Admin Department” – This is the UNC department managing this project. Click the box next to “Department” to search for the appropriate department either by name or number. Click on the appropriate department name hyperlink to select and add the department.





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4. “Agreement Type” – select the appropriate agreement type (“Subcontract”). Questions 5-10 will then open.

4. **Agreement Type** - All Clinical Trial Agreement request need to be submitted through CRMS \*

- CDA
- Collaboration Agmt
- DUA
- Inter-Institutional Agreement
- Letter of Intent
- Master Agreement
- MTA
- Other
- Sponsored Research Agmt (non-clinical)
- Amendment
- Subcontract

5. **Will any students (undergraduate, graduate, post-graduate, fellows, etc.) work on this project? \***

Yes  No

6. **Have you worked with this entity before? \***

Yes  No

7. **Do you intend to engage with this entity again? \***

Yes  No

8. **Have you been in contact with anyone else at UNC-CH relating to this agreement or project? \***

Yes  No

9. **Are there any other agreements (including CDAs, Letters of Intent, etc.) associated with this project? \***

Yes  No

10. **Does the PI wish to be cc'd on correspondence and have prior review of contract? \***

Yes  No

\* Required.

To navigate the document, press continue or any link in the Item List to your left.

[Save and Stay](#) [Save and Continue](#) [Clear Responses](#)

5. “Will any students work on this project” – Select “Yes” or “No” as appropriate. If “Yes”, the following question will open, asking “Is there a likelihood that any such students may be exposed to any sponsor confidential information?” – Select “Yes” or “No” as appropriate.

5. **Will any students (undergraduate, graduate, post-graduate, fellows, etc.) work on this project? \***

Yes  No

**Is there a likelihood that any such students may be exposed to any sponsor confidential information? \***

Yes  No





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- 6. "Have you worked with this entity before?" - Select "Yes" or "No" as appropriate.
- 7. "Do you intend to engage with this entity again?" Select "Yes" or "No" as appropriate.

8. "Have you been in contact with anyone else at UNC-CH relating to this agreement or project?" - Select "Yes" or "No" as appropriate. If "Yes", the following box will open. Type in the name and associated office of each person that has been contacted about this agreement or project.

8. Have you been in contact with anyone else at UNC-CH relating to this agreement or project? \*

Yes  No

If yes, list the office(s) and name(s) of the person(s) you have contacted \*

9. "Are there any other agreements associated with this project?" - Select "Yes" or "No" as appropriate. If "Yes", these must be attached to the "Attachments" page later in the submission form. This could be the original agreement, template, subcontracts, or any other related agreements, such as a CDA.

9. Are there any other agreements (including CDAs, Letters of Intent, etc.) associated with this project? \*

Yes  No

**Required document(s): Additional Document**

**Please add any additional documents under Attachment tab**



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10. “Does the PI wish to be cc’d on correspondence and have prior review of contract?” – Does the UNC PI want to be copied on any email correspondence regarding this agreement and have a chance to review the agreement before it is sent to the sponsor (subcontractor/site) to review? Select “Yes” or “No” as appropriate.

When finished answering, select the appropriate button to save or clear responses. Click “Save and Continue” to proceed to the next page.

4. **Agreement Type** - All Clinical Trial Agreement request need to be submitted through CRMS \*

- CDA
- Collaboration Agmt
- DUA
- Inter-Institutional Agreement
- Letter of Intent
- Master Agreement
- MTA
- Other
- Sponsored Research Agmt (non-clinical)
- Amendment
- Subcontract

5. **Will any students (undergraduate, graduate, post-graduate, fellows, etc.) work on this project? \***

Yes  No

6. **Have you worked with this entity before? \***

Yes  No

7. **Do you intend to engage with this entity again? \***

Yes  No

8. **Have you been in contact with anyone else at UNC-CH relating to this agreement or project? \***

Yes  No

9. **Are there any other agreements (including CDAs, Letters of Intent, etc.) associated with this project? \***

Yes  No

10. **Does the PI wish to be cc'd on correspondence and have prior review of contract? \***

Yes  No

\* Required.

To navigate the document, press continue or any link in the Item List to your left.

[Save and Stay](#) [Save and Continue](#) [Clear Responses](#)



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## B. Agreement Information Page

1. “Please provide a short description of this agreement” - Enter a description of the agreement, e.g. subcontract with subcontractor name, or the study title.
2. “Protocol Number, if applicable” – If there is a protocol number enter it here. This could be the protocol number from the original CTA or prime study.
3. “Intent of the Agreement” - Include a brief description of the intent or purpose of this agreement. This could be the same as the title unless there is additional information. There is a separate [Additional Submission Notes](#) page to include relevant information as well.
4. “Do you have a draft agreement” – If you have a copy of the draft agreement, select “Yes.” If not, select “No” and the second question opens. Select “Yes” indicating that OIC needs to provide the draft agreement.

The screenshot shows a web form titled "Agreement Information" with a reference ID of 19551. At the top right, there are links for "Quick View (HTML)", "PDF", "View FAQ", and "Delete Submission". The form contains four numbered sections:

- 1. Please provide a short description of this agreement (i.e., study title, DUA with Company X, etc)**: A text box containing "SUBCONTRACT with Ashe County".
- 2. Protocol Number, if applicable**: A text box containing "N/A".
- 3. Intent of the Agreement**: A larger text box containing "SUBCONTRACT with Ashe County or other notes".
- 4. Do you have a draft agreement? \***: Radio buttons for "Yes" and "No", with "No" selected.

Below section 4, there is another question: **Does OIC need to provide a draft agreement? \*** with radio buttons for "Yes" and "No".

At the bottom of the form, there is a note: "\* Required." and a instruction: "To navigate the document, press continue or any link in the Item List to your left." Below this are three buttons: "Save and Stay", "Save and Continue", and "Clear Responses".

Click “Save and Continue” to proceed to the next page.



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## C. Attachments Page

If you selected “Yes” for any attachment questions above, they must be attached here. Suggested documents include the prime agreement, site budget, protocol, or any other relevant document.

Select the appropriate “Attachment Type” from the dropdown, then “Browse” for the document(s) to be attached.



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The document can be submitted after required documents have been attached by clicking the yellow submit button located left of the screen.

Attachments Reference Id: 19487

Current Form: [Quick View \(HTML\)](#) [PDF](#) [View FAQ](#) [Delete Submission](#)

### >> 1. REQUIRED ATTACHMENTS:

- Additional Document

### >> 2. UPLOAD ATTACHMENTS :

Upload all attachments that are associated with this submission. Select the appropriate Attachment Type for the document. Click Browse to locate the attachment on your computer and click Upload Attachment. Assign each document a unique file name.

Attachment Type

Attachment

### >> 3. UPLOADED ATTACHMENTS:

Download, replace, rename, delete, or view version history of the attached documents.

File Name	Document Type
-----------	---------------

To navigate the document, press continue or any link in the Item List to your left.

Click "Continue" to proceed to the next page.



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## D. Optional Submission Notes

Include any information that has not been covered above. It is preferable to include the ALICE number of the prime agreement, IRB, and CRMS numbers here.

Click “Save and Continue” to proceed to the next page.

The document can be submitted at this time by clicking the yellow submit button located on the bottom left of the screen.

Optional Submission Notes Reference Id: 19551

Current Form: [Quick View \(HTML\)](#) [PDF](#) [View FAQ](#) [Delete Submission](#)

Provide any additional information here that is not already addressed above.

**Submission Notes:**

ALICE 19-0001  
IRB 19-1010  
CRMS 19-2020]

To navigate the document, press any link in the Item List to your left.

[Save and Continue](#)



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## E. Certify Submission Page

This page is the final review before submitting the request to OIC for processing.

Click “Submit Agreement” to submit the request and proceed to the next page.

>> Certify Submission Reference Id: 19487

Current Form: [Quick View \(HTML\)](#) [PDF](#) [View FAQ](#) [Delete Submission](#)

**Agreement Title:** subcontract/site agreement with UNCG for Project X

**Lead:** LaToya Gibbs

**Admin Department:** Office of Industry Contracting (621800)

**Submit Agreement** **Cancel**



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## F. Status Page

This page shows a summary of the submission request, notes, status history, submitted documents, and personnel.

>> Status Reference Id: 19487

Current Form: [Quick View \(HTML\)](#) [PDF](#) [View FAQ](#)

<b>Status:</b>	Submitted for Review	<b>Created By:</b>	Liz Moore
<b>Lead Principal Investigator:</b>	LaToya Gibbs	<b>Submitted By:</b>	Liz Moore
<b>Submission Type:</b>	Subcontract	<b>Submitted On:</b>	10/05/2018
<b>Title:</b>	subcontract/site agreement with UNCG for Project X		

[Finalize](#)

Notes | **Status History** | Submitted Documents | Personnel

**Status History**

Status	Person	Date
Submitted for Review	<a href="#">Liz Moore</a>	10/05/2018 03:33 PM
Submitted	<a href="#">Liz Moore</a>	10/05/2018 03:33 PM
Created	<a href="#">Liz Moore</a>	10/05/2018 03:10 PM

**Routing Email History**

Email	Date
Admin Notification sent	10/05/2018 03:33 PM
Submission Notification sent to LaToya Gibbs	10/05/2018 03:33 PM

Once this has been submitted, an email notification will be sent to you. Once it has been assigned to a Contract Manager, another notification email will be sent to all internal contacts listed. An example of this email is shown below.

**From:** Office of Industry Contracting  
**Sent:** Friday, October 5, 2018 3:34 PM  
**To:** Gibbs, LaToya Nicole <[lgibbs@email.unc.edu](mailto:lgibbs@email.unc.edu)>; Moore, Liz Thornberry <[lizthorn@email.unc.edu](mailto:lizthorn@email.unc.edu)>  
**Subject:** [ALICE] New Agreement Submission

You have successfully submitted an agreement on behalf of LaToya Gibbs for review by the Office of Industry Contracting.

You will receive an email once the agreement has been assigned an Agreement Number letting you know who will be working on this agreement.

If you have any questions, you can contact [oiic@unc.edu](mailto:oiic@unc.edu) or by phone at 919-445-2929

Please email [oiic@unc.edu](mailto:oiic@unc.edu) if you have any questions that were not answered in this guidance.