

Navigating Contract Submission Using CRMS and ALICE

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2023 SYMPOSIUM
FOR RESEARCH ADMINISTRATORS

ALICE vs. CRMS

Which system do I use?



CRMS/ ALICE

Confidential Disclosure/Nondisclosure Agreements (CDA/NDA)	
- CDA for Clinical Purpose	CRMS
- CDA for Non-clinical Purpose	ALICE
Clinical Trial Agreements (CTA), including:	
- Investigator Initiated Trials (IIT) and any applicable Outgoing Subcontracts	CRMS/ALICE
- Task/Work Order under a Master CTA	CRMS
- Incoming Clinical Subcontract	CRMS
- CTA Amendments	CRMS/ALICE

ALICE

Collaboration Agreement & Other Agreements without Funding	ALICE
Data Use/Transfer Agreements (DUA), including Amendments, that do not fall into the following:	ALICE
- DUA with Centers for Medicare & Medicaid Services (CMS)	N/A
- DUA with NIH dbGaP	N/A
- DUA for Carolina Data Warehouse (CDW/TraCS)	N/A
Material Transfer Agreements (MTA), specifically:	
-MTA for materials to be used in humans in a clinical trial or for which PHI is being exchanged	ALICE

Agreement Types

Broad overview of the agreements that are submitted in CRMS/ALICE



Confidential Disclosure Agreement (CDA)

- A contractual agreement which outlines the terms under which such confidential information will be exchanged.
- Required if confidential information will be disclosed in order for the University and an external partner to evaluate a potential collaboration (clinical trial, sponsored research agreement, etc).

Clinical Trial Agreement (CTA)

- A legally binding contract between an external sponsor and the University which outlines each party's responsibilities and obligations for the clinical trial.
- Required for sponsor-initiated protocols and investigator-initiated protocols.

Collaboration Agreement

- A contractual agreement used to outline the research obligations of each party in pursuit of a common research objective.
- Each party to the Agreement funds its own costs.

Data Use Agreement (DUA)

- A contractual agreement used to define how access to and/or exchanged data may be used.
- Required when transferring (incoming or outgoing) human subject data that includes at least one of the 18 HIPAA identifiers and no other agreement governs the transfer and use.

Material Transfer Agreement (MTA)

- A contractual agreement which governs the transfer of tangible materials between two entities when the recipient intends to use it for their own research purposes.
- Required when the University desires to send or receive tangible material such as reagents, cell lines, plasmids, vectors, chemical compounds, mouse models, and software for research purposes.
- Most often there is no funding associated.

CRMS/ALICE Walkthrough

Clinical Trial Agreement (CTA)



CRMS & ALICE Submissions

- Start by creating a new study record in CRMs.

CLINICAL RESEARCH MANAGEMENT
HOME MY DASHBOARD HELP ADMIN LOGOUT

Research Dashboard

[Start New Study](#)

[My CRMS Records](#)

[My Studies by IRB #](#)

[My Dept. Studies by IRB #](#)

Strengthen Your Research

[Carolina Data Warehouse for Health](#)

Helpful Information Links

[Research at Carolina](#)

[NC TraCS Institute](#)

[Research Central](#)

[CTRC](#)

[CTRC Etiquette Test](#)

[CTRC Inpatient Google Calendar](#)

Your CRMS Studies

CRMS #	IRB #
C11-0139	12-1660
C12-0062	11-1785
C12-0450	12-1274
C12-0525	12-1319
C12-0728	12-0482
C12-0743	02-1470
C12-0806	12-1377
C12-0891	10-2262
C12-1182	12-1550
C12-1195	
C12-1229	
C12-1232	
C12-1288	12-1993
C13-0051	12-0108
C13-0228	13-2083
C13-0233	13-2243
C13-0300	13-2782
C13-0381	13-3242
C13-0433	13-3613

CRMS & ALICE Submissions

- Enter PI name, estimated time frame for entire study, and a short study name

The screenshot displays the 'CLINICAL RESEARCH MANAGEMENT' web application. The top navigation bar includes links for HOME, MY DASHBOARD, HELP, ADMIN, and LOGOUT. The left sidebar contains a 'Research Dashboard' with links for 'Start New Study', 'My CRMS Records', 'My Studies by IRB #', and 'My Dept. Studies by IRB #'. Below this are sections for 'Strengthen Your Research' (Carolina Data Warehouse for Health) and 'Helpful Information Links' (Research at Carolina, NC TraCS Institute, Research Central, CTRC, CTRC Etiquette Test, and CTRC Inpatient Google Calendar). At the bottom of the sidebar are logos for CRMS, Epic, and OnCore. The main content area is titled '>>General Info' and contains a form with the following fields: 'Principal Investigator' (Sandy Barnhart), 'Study Start Date' (09/12/2023), 'Study End Date' (09/12/2024), and 'Short Study Title' (OSP Symposium Test). A 'Continue' button is located at the bottom of the form.

CRMS & ALICE Submissions

- Select Submissions > Office of Industry Contracting (OIC)
 - If sponsor has sent a CDA, select “Submit CDA Request Form”
 - If a CDA is already on file or not applicable, select “Submit Clinical Trials Agreement Request Form”

The screenshot displays the CLINICAL RESEARCH MANAGEMENT system interface. At the top, there is a navigation bar with links for HOME, MY DASHBOARD, HELP, ADMIN, and LOGOUT. Below this is a 'Study Menu' sidebar with links for BCA, IRB, OIC Contracts, Pharmacy & IDS, and IPF. The main content area shows the 'Submissions' tab selected, with a sub-tab for 'Office of Industry Contracting (OIC)'. The OIC section includes a description of its role and three buttons: 'Submit Clinical Trials Agreement Request Form', 'Submit CDA Request Form', and 'Submit Amendment Request Form'. Below these buttons is a table titled 'List of OIC Submissions' with columns for Submission Type, Agreement #, Status, Date Created, and Date Effective. The table contains one entry: a CTA with Agreement # Unassigned (40027), Status Not Submitted, Date Created 9/12/2023, and Date Effective -.

CLINICAL RESEARCH MANAGEMENT
HOME MY DASHBOARD HELP ADMIN LOGOUT

Study Menu
BCA
IRB
OIC Contracts
Pharmacy & IDS
IPF

Dashboard Protocol **Submissions** Research Participants

>> Study and Protocol Information - CRMS#: C23-0872 OSP Symposium Test Lead Pt:

Full Study Title :
(Appropriate for Protocol/IRB Title)

Admin Departments : None listed.

Sponsors : None listed.

Study Status :

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 subcontractor party Confidentiality Agreements (CDAs and NDAs) and Data Use Agreements for the entire UNC-CH campus.

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

List of OIC Submissions (Click on the OIC Number for status information.)

Submission Type	Agreement #	Status	Date Created	Date Effective
1 CTA	Unassigned (40027)	Not Submitted	9/12/2023	-

CRMS & ALICE Submissions

- Proceed to enter info in Alice
 - Question 1 - Agreement Type
 - Question 2 – Funding Info
 - Question 3 – Sponsor Name
 - Question 4 – list personnel in this order: Lead PI, Sponsor Contact, Department Contact, any applicable study staff (budget negotiator, coordinators, etc.).

ALICE Office of Clinical Trials & Office of Industry Contracting @ UNC Chapel Hill

HOME LOGOUT

Item List click on section name to expand

- Study Submission
- Sponsor and Department Information
- Study Information
- PI Certification Questions
- Attachments
- Submission Notes

Home

Proceed to Submit

>> Sponsor and Department Information Reference Id: 40027

Current Form: Quick View (HTML) PDF View FAQ Delete Submission

1. Type of Clinical Trial Agreement: *

CTA
 CTA -> Incoming Subcontract
 CTA -> PI Initiated
 CTA -> Study Start Up Agreement
 MTA
 Other

2. Will this project involve sponsor/external funding, OR will it involve materials, devices or supplies that have a transfer of value? *

Yes No

3. Sponsor and/or CRO: *

[Click here to add](#)

Sponsor Name	Address	Address2	City	State	Zip	Role		
Gilead Sciences, Inc.						Sponsor	edit	remove

4. List all personnel associated with this CTA (i.e., Lead Principal Investigator, External Contact for Negotiation of Terms, Department Contact, Study Coordinator, Budget Negotiator, etc.). Lead Principal Investigator and External Contact for Negotiation of Terms are required and must be added first. Other options will not be displayed until these are entered. NEW REQUIREMENT: Include the Study Coordinator and Budget Negotiator in this list. *

[Click here to add](#)

First Name	Last Name	Email	Department	Phone	Role	Company		
Sandy	Barnhart	sandy_barnhart@med.unc.edu	Institute for Global Health and Infectious Diseases	(919) 843-0076	Lead Principal Investigator		edit	remove
Gilead	Contact	gilead.contact@gilead.com			External Contact for Negotiation of Terms	Gilead Sciences, Inc.	edit	remove
Department	Contact				Dept. Contact		edit	remove

CRMS & ALICE Submissions

- Question 5 - Add study administering department.
- Question 6 – PI address and contact info
- Question 7 – Payment address and contact info (May be OSP, but we use our department)

5. Admin Dept (UNC Department with responsibility for managing the clinical trial): *

Department *

Department Code *


6. What is the PI's physical mailing address? Include phone, fax, and email.
This address will be used in the Notices Section of the agreement. *


B I U

101 Manning Drive
Chapel Hill, NC 27599-1350

Test Phone
Test Fax
Test Email

7. What is the name and physical address of the person to whom payments should be sent?
This address will be listed in the Payment Section of the agreement. *


B I U

Attn: Payment Recipient (could be PI or department finance contact)
Department Address
|

CRMS & ALICE Submissions

- Study Information
 - Question 1 – Does your study involve human subjects?
 - Question 2 – Are you using an outside IRB?
 - Question 3 – IRB number, if known; if not, anticipated IRB submission date
 - Question 4 - Full Study Title
 - Question 5 – Sponsor’s Protocol Number
 - Question 6 – Date Draft CTA received
 - Question 7 – Date Protocol received

The screenshot displays the ALICE web application interface. The header includes the ALICE logo and the text 'Office of Clinical Trials & Office of Industry Contracting @ UNC Chapel Hill'. Below the header, there are navigation links for 'HOME' and 'LOGOUT'. The main content area is titled 'Study Information' with a reference ID of 40027. On the left side, there is a sidebar with a list of sections: 'Study Submission', 'Sponsor and Department Information', 'Study Information', 'PI Certification Questions', 'Attachments', and 'Submission Notes'. The 'Study Information' section is currently active. The form contains the following questions and fields:

1. Does your study involve direct interaction with human subjects (any contact with subjects including questionnaires, interviews, focus groups, observation, treatment interventions, etc)? *
 Yes No
Required document(s): Budget (Draft or Final) , Draft Contract (MS Word Only) , Sponsor Protocol/Scope of Work , Sponsor Template of Informed Consent
2. Are you requesting that UNC-CH rely on an external IRB for continuing review and approval of this study? *
 Yes No
Select External IRB: *
Advarra
3. Do you already have an IRB Number? *
 Yes No
When do you expect to submit to the IRB?
 [Remove Date](#)
4. Study Title as found on the Sponsor Protocol: *
5. Sponsor's Protocol Number:
6. Date Draft Agreement Received:
 [Remove Date](#)
7. Date Protocol Received:
 [Remove Date](#)
8. Have you received or signed a Study Start Up or Site Activation Letter/Agreement? *
 Yes No

CRMS & ALICE Submissions

- Study Info cont.
 - Question 8 – Do you have a study start-up or site activation letter? Not all studies provide these this far in advance.
 - Question 9 – Which study type is this? FDA phase, if applicable.
 - Question 10 – estimated length of the entire study
 - Question 11 – ClinicalTrials.gov number, if sponsor has provided

8. Have you received or signed a Study Start Up or Site Activation Letter/Agreement? *

Yes No

9. Type of Study: *

Drug/Biologic
 Drug/Biologic -> Phase 0
 Drug/Biologic -> Phase I
 Drug/Biologic -> Phase I/II
 Drug/Biologic -> Phase II
 Drug/Biologic -> Phase II/III
 Drug/Biologic -> Phase III
 Drug/Biologic -> Phase IV
 Device
 Device or Drug Only (no funding)
 Behavioral
 Biological
 Data Registry
 Other

10. Estimated Length of Study

< 2 years
 2 - 4 years
 > 4 years

11. Have you registered this study with clinicaltrials.gov? *

Yes No

CRMS & ALICE Submissions

- Study Info cont.
 - Question 12 – This will determine if department funds are needed, and also indicates the budget negotiation status
 - Question 13 – Applicable if there are multiple industry sponsors
 - Question 14 – Applicable if there are any federal funds being received for the study
 - Question 15 – Applicable if another party besides the sponsor is providing IP or materials
 - Question 16 – Applicable if there will be any subsites reporting to UNC

12. Does the sponsor listed on Page 1 provide ALL the funding for this study? *

Yes No

Study Budget Status: *

Negotiations Not Started
 Under Negotiation
 Final

13. Are there any additional industry sponsors? *

Yes No

14. Will ANY federal funds be supporting this clinical trial? *

Yes No

15. Will any materials or equipment be provided by someone other than the Sponsor of this clinical trial? *

Yes No

16. Will outgoing subcontracts be required? *

Yes No

CRMS & ALICE Submissions

- Study Info cont.
 - Question 17 – Study location (hospital, CTRC, offsite clinic, etc.)
 - Question 18 – Human Subjects research and applicable clinical trials outcome questions

17. Where will the majority of the study visits take place? List below. (Note: Enter a specific campus or hospital location(s) where research will be conducted. Be as precise as possible; i.e. name of specific clinic.)

18. Does this project involve human subjects?

Yes No

Are the participants prospectively assigned to an intervention?

Yes No

Is the Study designed to evaluate the effect of the intervention on participants?

Yes No

Is the effect being evaluated a health-related biomedical or behavioral outcome?

Yes No

CRMS & ALICE Submissions

- Skip PI Certification Questions, but do not skip the attachments.

The screenshot displays the ALICE web application interface. The header includes the ALICE logo and the text "Office of Clinical Trials & Office of Industry Contracting @ UNC Chapel Hill", with navigation links for "HOME" and "LOGOUT".

The main content area is divided into two columns:

- Item List:** A sidebar menu with the following items:
 - Study Submission (with a warning icon)
 - Attachments (with a green checkmark icon)
 - Attachments (with a green checkmark icon, highlighted by a yellow box)
 - Submission Notes (with a green checkmark icon)
- Attachments:** The main content area for Reference Id: 40027. It contains two sections:
 - 1. REQUIRED ATTACHMENTS:** A list of required documents:
 - Draft Contract (MS Word Only)
 - Sponsor Protocol/Scope of Work
 - Budget (Draft or Final)
 - Sponsor Template of Informed Consent
 - 2. UPLOAD ATTACHMENTS :** A section for uploading files, including a dropdown menu for "Attachment Type" (set to "Select Document Type"), a "Browse..." button, and an "Upload Attachment" button.

At the bottom of the Item List sidebar, there are two buttons: "Home" and "Proceed to Submit".

CRMS & ALICE Submissions

- Required Attachments (these are needed for the billing coverage analysis (BCA) and for Sandi Florence to get this assigned to a contract manager).

The screenshot displays the ALICE web application interface. At the top, the header includes the ALICE logo and the text "Office of Clinical Trials & Office of Industry Contracting @ UNC Chapel Hill", along with navigation links for "HOME" and "LOGOUT".

The main content area is divided into two columns. The left column, titled "Item List", contains a list of sections: "Study Submission" (with a warning icon), "Attachments" (with a checkmark), "Attachments" (with a checkmark), and "Submission Notes" (with a checkmark). Below this list are buttons for "Home" and "Proceed to Submit".

The right column, titled "Attachments Reference Id: 40027", contains two main sections:

- >> 1. REQUIRED ATTACHMENTS:** This section is highlighted with a yellow border and lists four required attachments:
 - Draft Contract (MS Word Only)
 - Sponsor Protocol/Scope of Work
 - Budget (Draft or Final)
 - Sponsor Template of Informed Consent
- >> 2. UPLOAD ATTACHMENTS :** This section includes instructions: "Upload all attachments that are associated with this submission. Select the appropriate name." It features a dropdown menu for "Attachment Type" (set to "Select Document Type"), a file upload field labeled "Attachment" with a "Browse..." button and the text "No file selected.", and an "Upload Attachment" button.

CRMS & ALICE Submissions

- Proceed to Submit after all attachments have been included and all yellow triangles except for PI certification have a green check (PI will get a separate email). **Please note, the study submission will be on hold until the PI has certified.**
- **Important to note** - Once the study has been submitted to OSP, it will be reviewed by a Contracting Coordinator before being "pulled in" for assignment to a Contracting Officer. This step can cause delays if any of the requirements are missing.

The screenshot displays the ALICE web application interface. At the top, the header includes the ALICE logo and the text "Office of Clinical Trials & Office of Industry Contracting @ UNC Chapel Hill". Below the header, there are navigation links for "HOME" and "LOGOUT".

The main content area is divided into two columns. The left column, titled "Item List", contains a list of sections with expandable options:

- Study Submission (indicated by a yellow triangle icon)
- Sponsor and Department Information (indicated by a green checkmark icon)
- Study Information (indicated by a green checkmark icon)
- PI Certification Questions (indicated by a yellow triangle icon)
- Attachments (indicated by a green checkmark icon)
- Submission Notes (indicated by a green checkmark icon)

The right column, titled ">> Certify Submission Reference Id: 40027", displays submission details:

- Agreement Title: Test Study for OSP Symposium
- Lead: Sandy Barnhart
- Admin Department: Institute for Global Health and Infectious Diseases (427801)

Below the details, a red warning message states: "All required sections of the CTA have not been completed. It is possible that new sec without a green check. You will need to click and expand each section to view which".

At the bottom of the interface, there are two buttons: "Home" and "Proceed to Submit". The "Proceed to Submit" button is highlighted with a yellow border.

What else?

Closing Thoughts



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Common Errors/Delays

- ALL required attachments have not been uploaded:
 1. Draft contract
 2. Sponsor Protocol/Scope of Work
 3. Budget (Draft or Final)
 4. Sponsor Informed Consent template
 - Missing or incorrect information (Protocol number, Sponsor name, etc.)
 - PI Certification missing
- **Any of the above errors will result in a delay of contract assignment****

Resources and Links

Industry Contracting: <https://research.unc.edu/sponsored-programs/resources/industry-contracting/>

CRMS: <https://apps1.research.unc.edu/crms/>

ALICE: <https://apps2.research.unc.edu/alice/index.cfm>

Thank you for your attendance!

Questions?

Office of Sponsored Programs – Industry Contracting
OSPContracting@unc.edu

Can you provide a quick tip sheet re: the ways records may be duplicated in CRMS (until the problem get fixed), so that we may share those tips with team our study members who may not have attended this session?





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of NORTH CAROLINA
at CHAPEL HILL