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:	ALICE
-MTA for materials to be used in humans in a clinical trial or for which PHI is being exchanged	

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

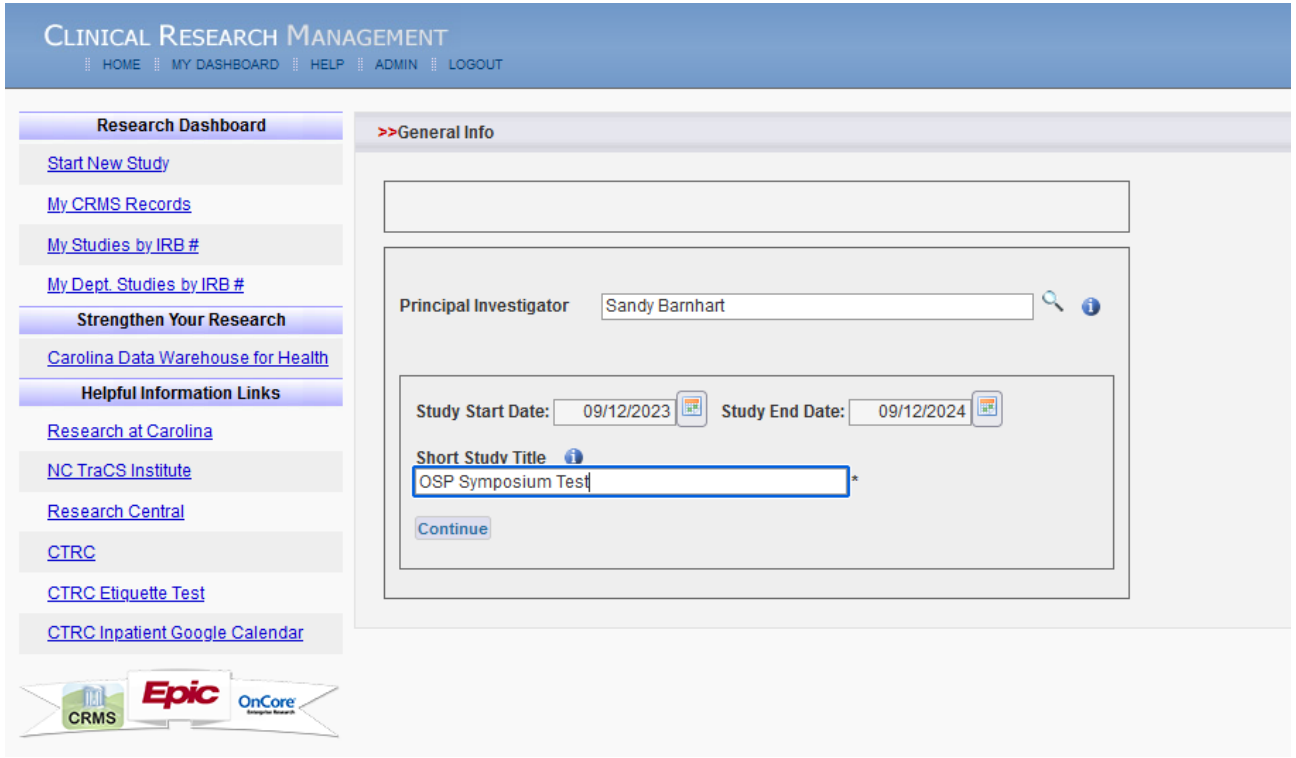
Clinical Trial Agreement (CTA)

CRMS & ALICE Submissions

- Start by creating a new study record in CRMs.

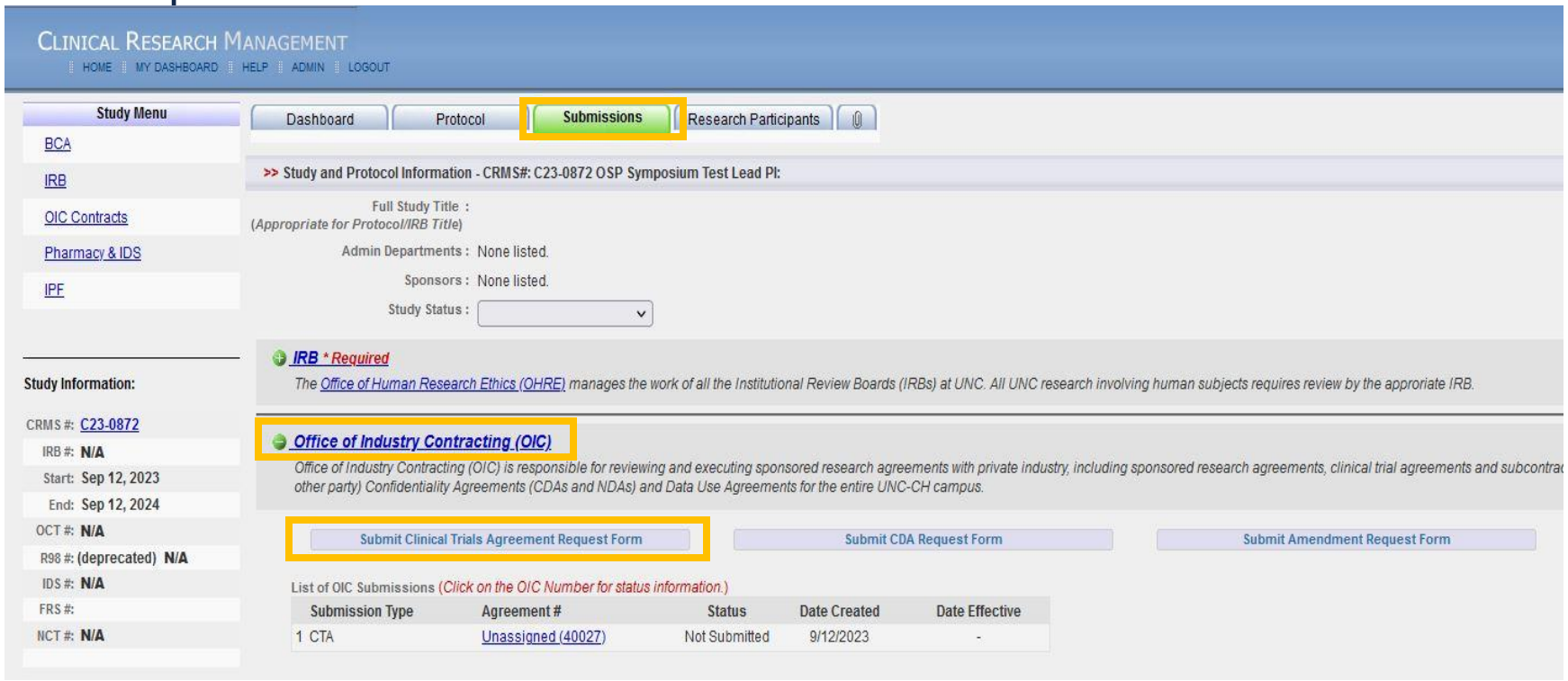
CRMS & ALICE Submissions

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



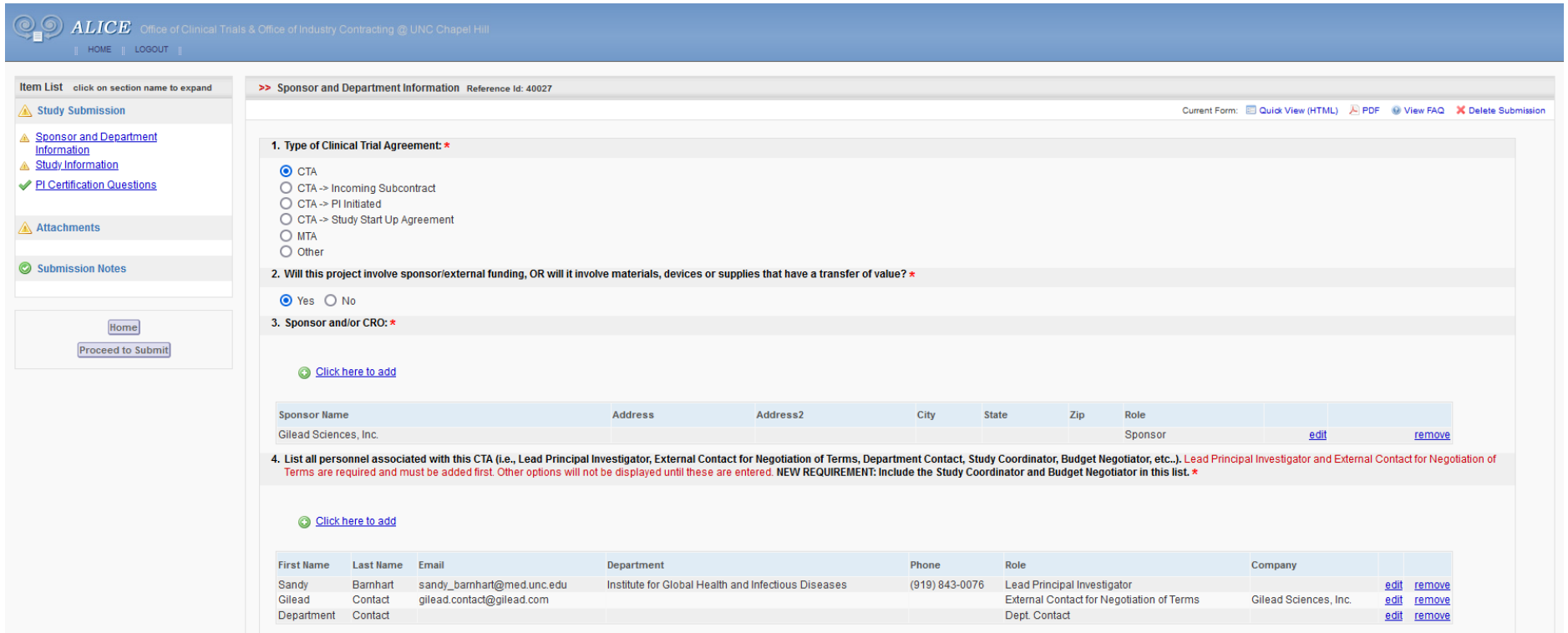
CRMS & ALICE Submissions

- 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”



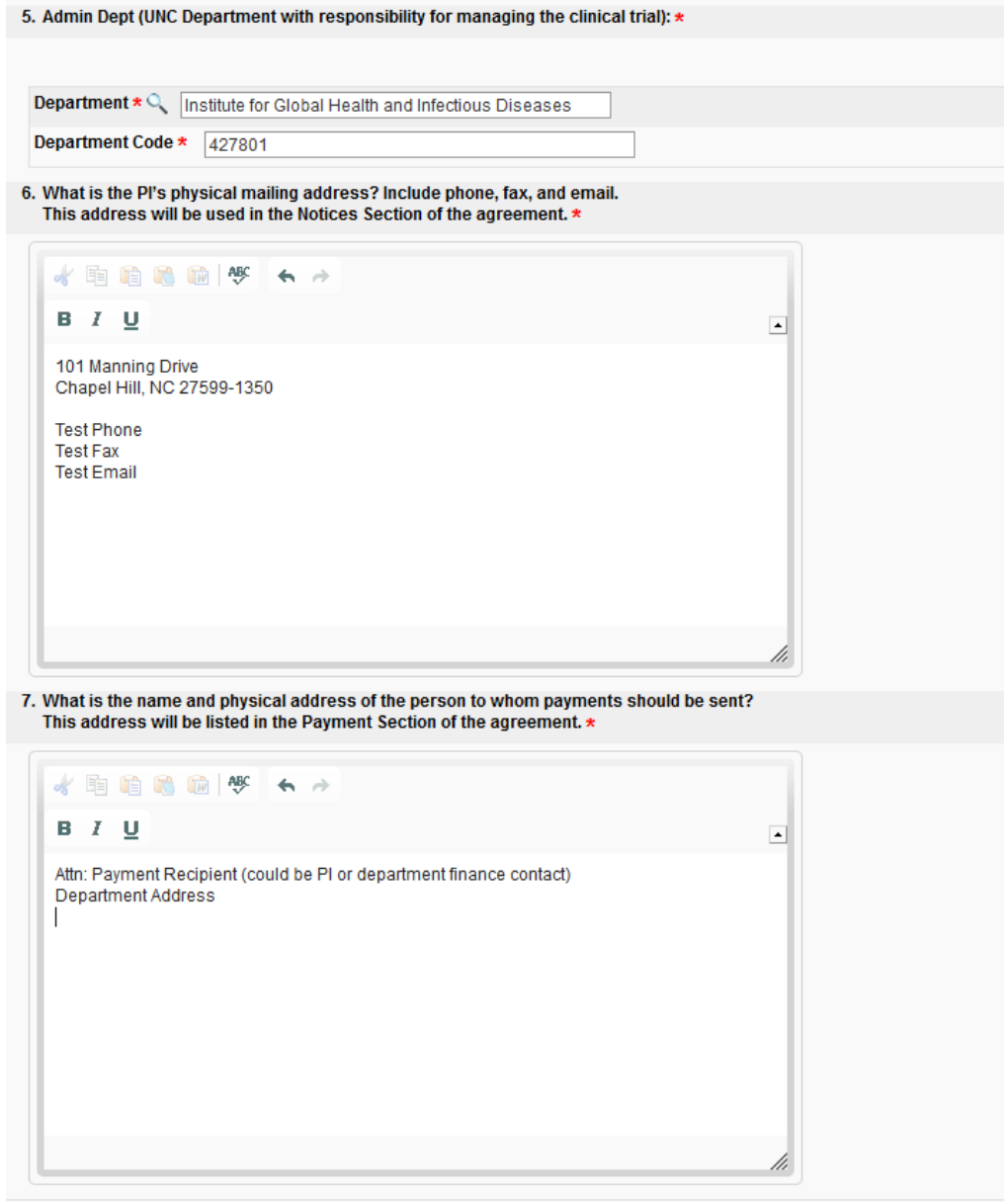
CRMS & ALICE Submissions

- 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.).



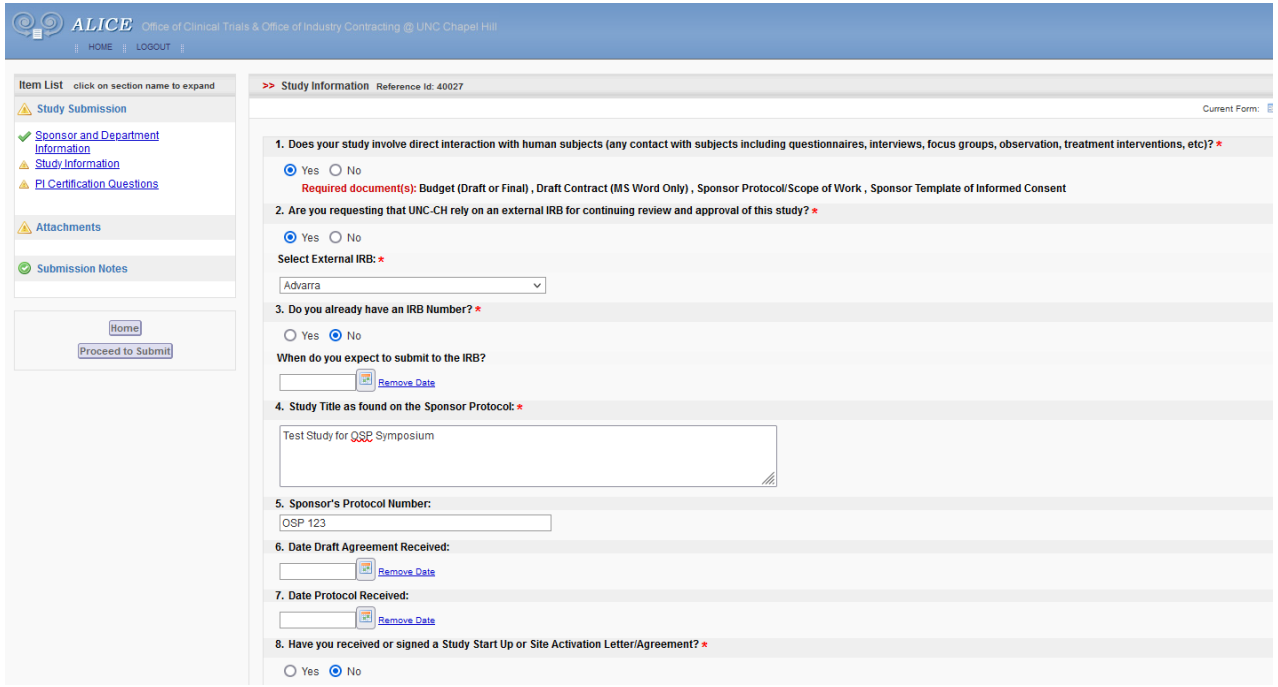
CRMS & ALICE Submissions

- 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)



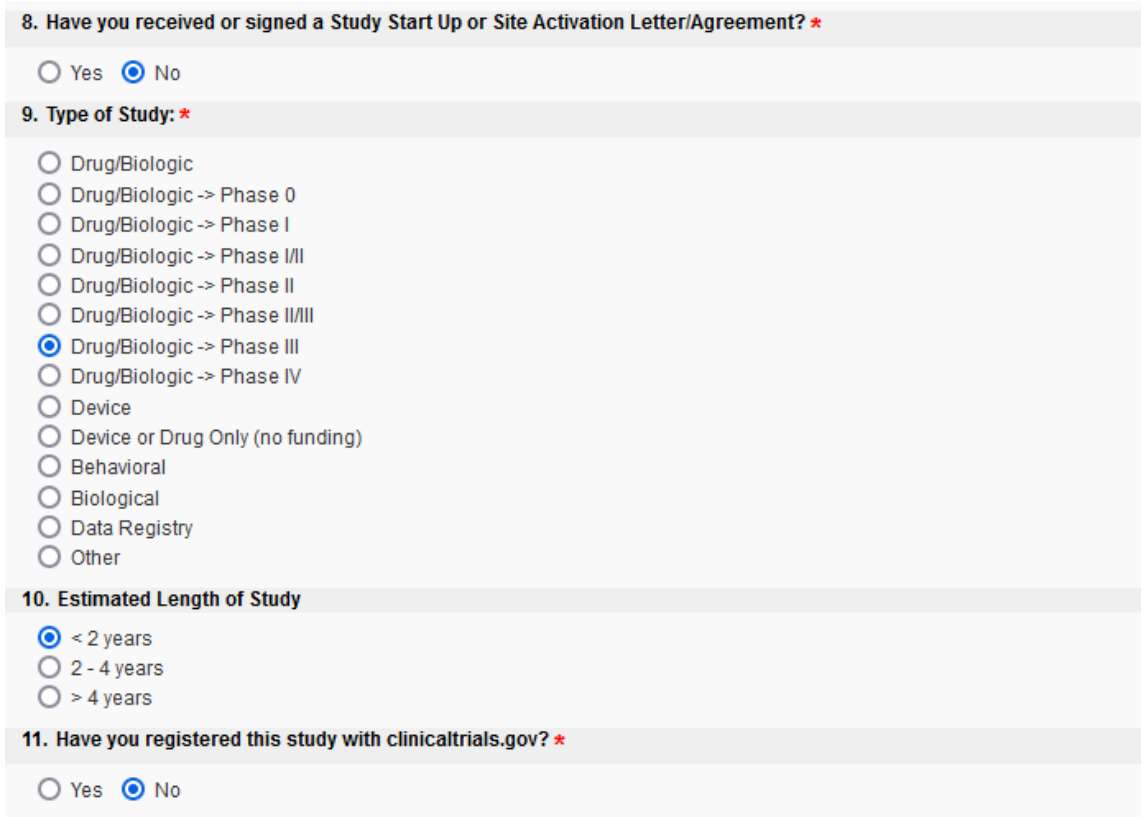
CRMS & ALICE Submissions

- 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



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

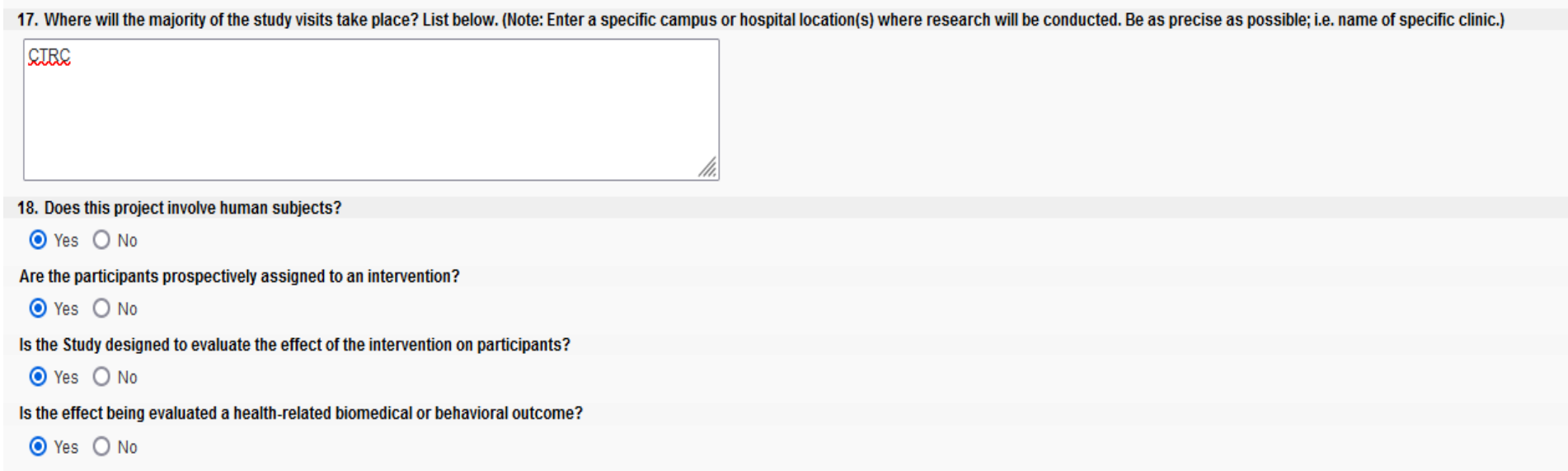


CRMS & ALICE Submissions

- 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

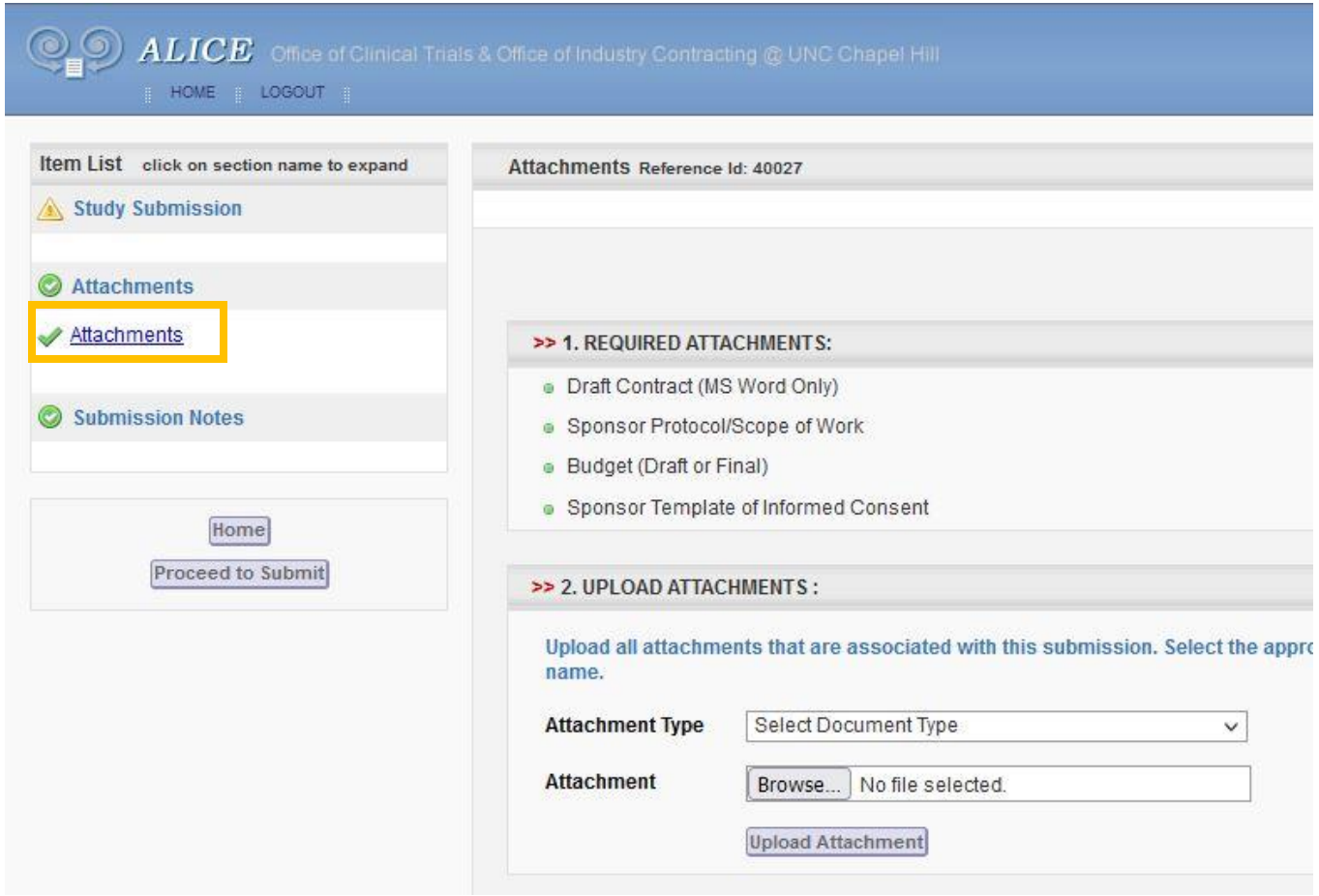
CRMS & ALICE Submissions

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



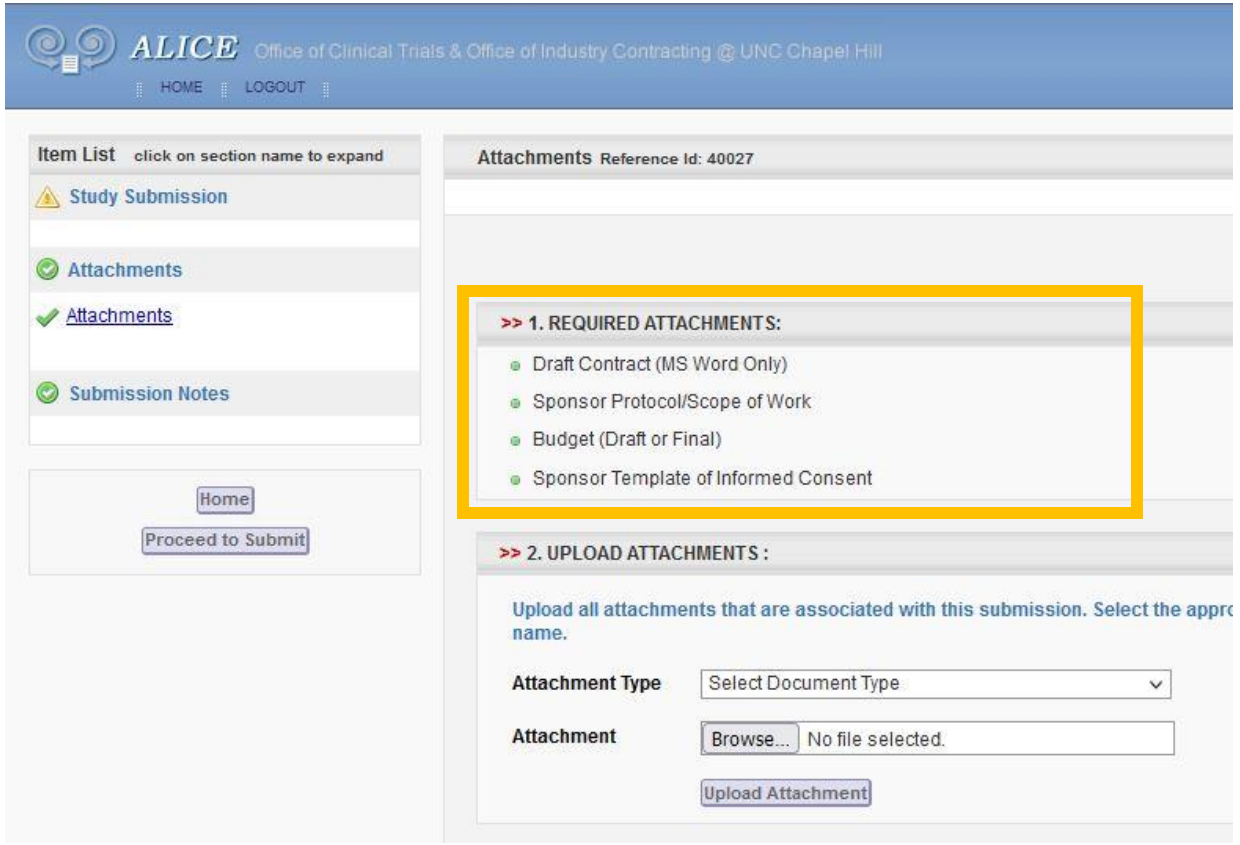
CRMS & ALICE Submissions

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



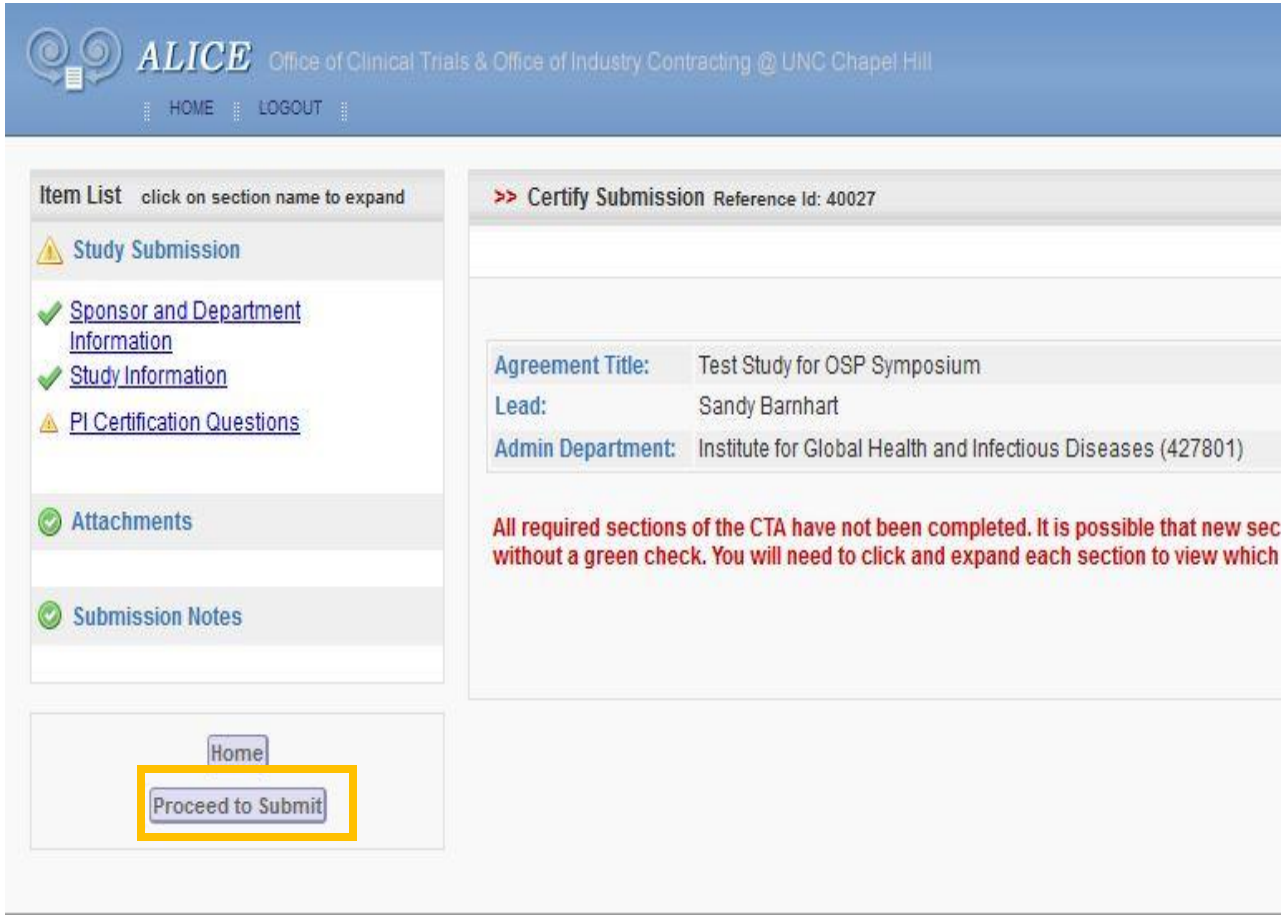
CRMS & ALICE Submissions

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



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.



What else?

Closing Thoughts

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?

THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL