Before you start

In order to enter the agreement, the sponsor need to be available in IRES to add them to the record. If your Provider or Recipient is not in IRES, use the IRES New Sponsor Request Form to have them set up in the system. The Principal Investigator (PI) must meet Yale's PI Eligibility Requirements.

1. Navigate to the CDA website

In a web browser, go to https://your.yale.edu/research-support/office-sponsored-projects/contracts/confidentiality-agreements-cdas. Then click on the CDA url.


CONTRACTS

Contract FAQs

> Sponsored Research Agreements

> Federal Contracts

Confidential Disclosure Agreements (CDAs)

Data Use Agreements (DUAs)

> Material Transfer Agreements (MTAs)

Visiting Scientist Agreements

Other Agreements

Confidential Disclosure Agreements (CDAs)

A Confidential Disclosure Agreement, also sometimes referred to as a Non-Disclosure Agreement (CDA or NDA), is designed to protect the confidential information that may be released between a potential sponsor and the faculty and staff of Yale University so that they can determine whether or not to enter into a subsequent agreement for research. CDAs may be unilateral (where only one party is sharing confidential information) or mutual/bilateral (where each party expects to share confidential information with the other) and are generally requested by sponsors prior to disclosing a study protocol or other information which the sponsor considers proprietary. Not all sponsors require a CDA prior to disclosure of confidential information.

The Office of Sponsored Projects (OSP) negotiates and processes all of the CDAs for Yale University pertaining to disclosures for prospective research that involves Yale University resources.

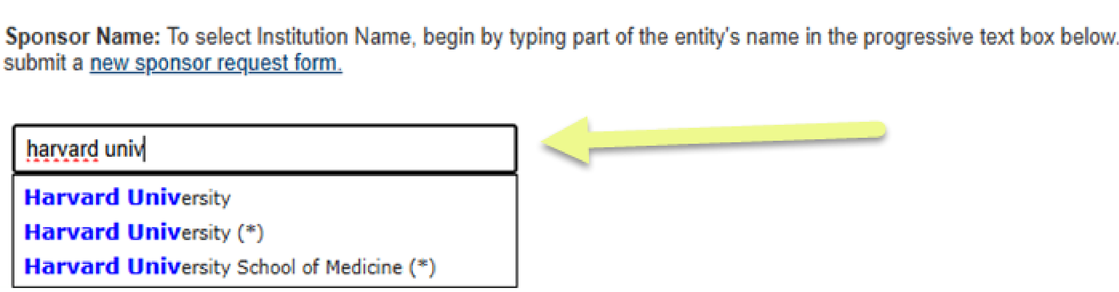
2. Complete the Confidential Disclosure Agreement Intake Form

Enter Agreement Information

The Confidential Disclosure Agreement intake form collects necessary administrative and regulatory information about the agreement and transmits this information along with a draft copy of the contract to the appropriate OSP Contract Manager for action. All fields on this form are required, unless
"Optional" is indicated.

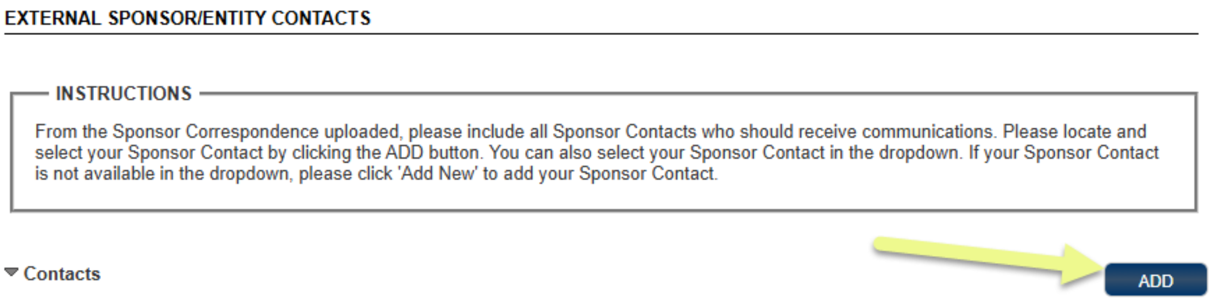
Add Sponsor Institution and Contacts

Start typing the name and select the Sponsor from the list (Provider shown).



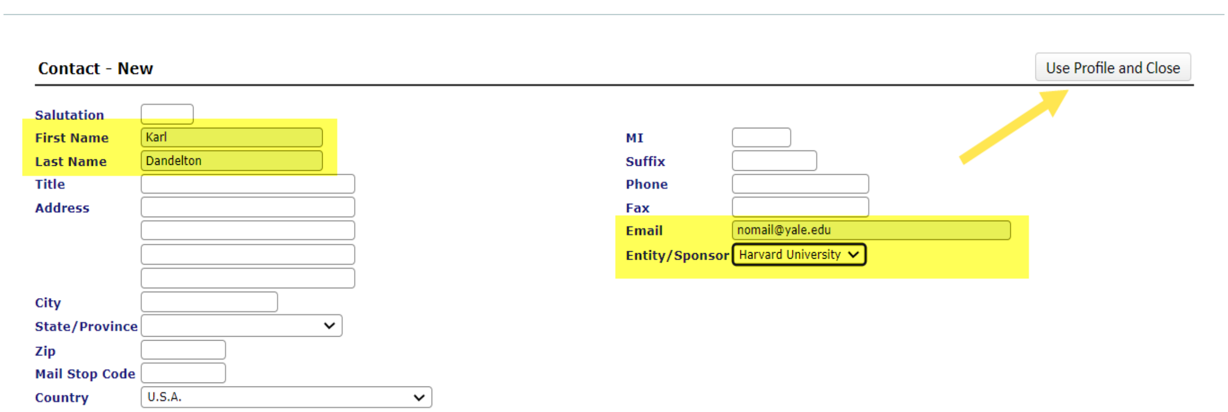
Contacts are used in IRES to communicate with the sponsor using the system. Specifically, OSP will need contacts in IRES in order to communicate using the system. At least one contact is required on the setup form for this reason. These contacts should be administrative in nature – the contracting office for the provider or recipient.

To add a contact to the Agreement record, click the ADD button.



If contacts exist for the provider or recipient, they will be shown in the dropdown on the left. If the contact that you have does not exist, or the dropdown is blank, click Add New to add a contact.

If you Add New, a first name, last name, and email address is required. You must also select the provider or recipient institution from the Entity/Sponsor dropdown. When you have entered the information, click Use Profile and Close.

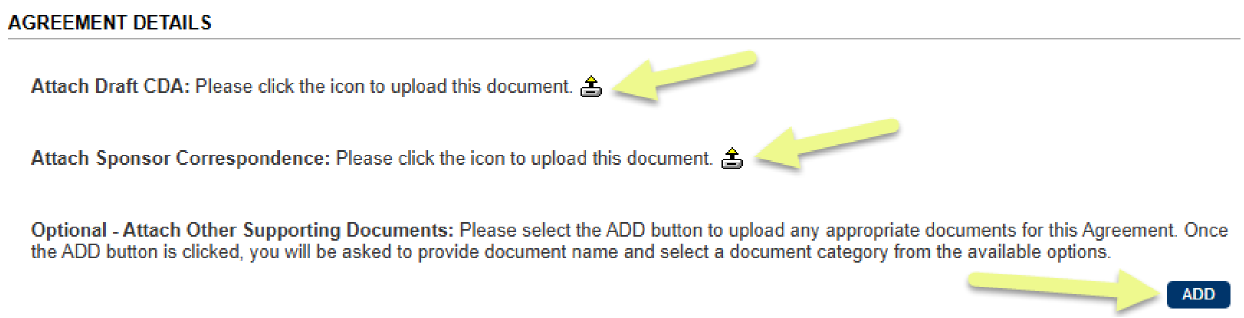


In the Contacts popup, select the contact you would like to associate with the record from the dropdown and click Select.

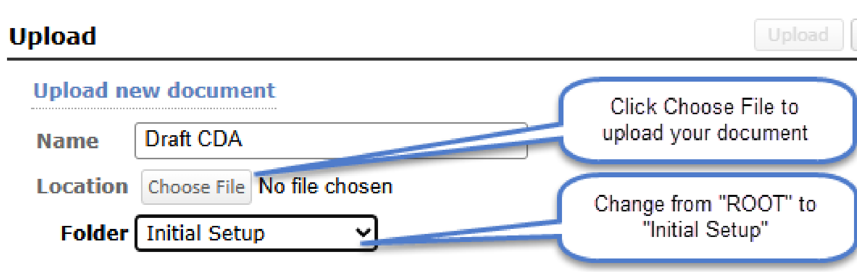
Add Attachments

For each attachment, use the icon to upload a copy of the draft agreement and the correspondence that has been conducted with the sponsor.
Depending on the selection of the proposed purpose for sharing receiving information associated with the CDA, the draft CDA and sponsor correspondence are required.

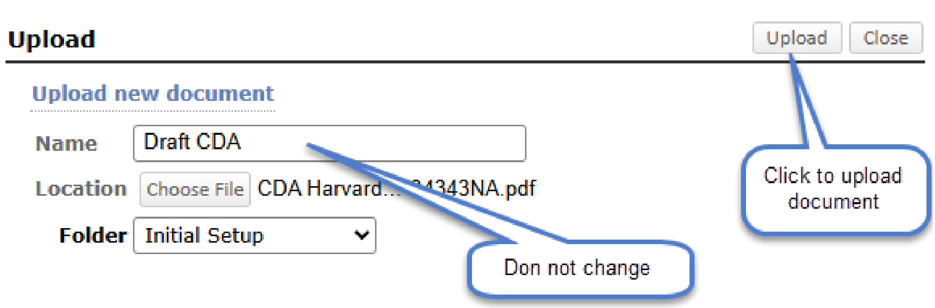
For a CDA purpose of future industry supported clinical trial.



In the popup, use the Choose File button to find your document on your computer. Change the folder to Initial Setup so that all of the documents that were submitted initially are easy to find later in the CDA's lifecycle.



The system will default a document name for you; you do not have to rename your file. Once a file has been selected, the Upload button will become active. Click Upload to complete the attachment process.



Submit the Agreement to OSP

Submit the form to OSP using the Submit button located at the top or bottom of the page. If any required information is missing, a popup will appear; you may Dock or close this popup. Any missing required fields will appear in a red box. Once the field is completed, the box will disappear, and you may attempt to Submit the agreement again.

3. Record and Manage the Negotiation (OSP

Background

IRES Agreements are used to manage and document the process and outcomes of Confidential Disclosure Agreements. Institutionally, this module provides:

- Metrics about the overall process
  - Locally, about how a specific agreement's negotiation and execution unfolded and where it was delayed
  - Broadly, about how agreements in the aggregate move through the process
- A simple, common file structure so that anyone who accesses the record can tell where to look for specific documents
- A record of communications that were sent and replies that were received, with any attachments automatically appearing on the agreement record
- Additional attributes useful for reporting; for example, whether the agreement is or is related to a master agreement, or whether the trial is investigator-initiated

Workflow, Statuses and What they Mean

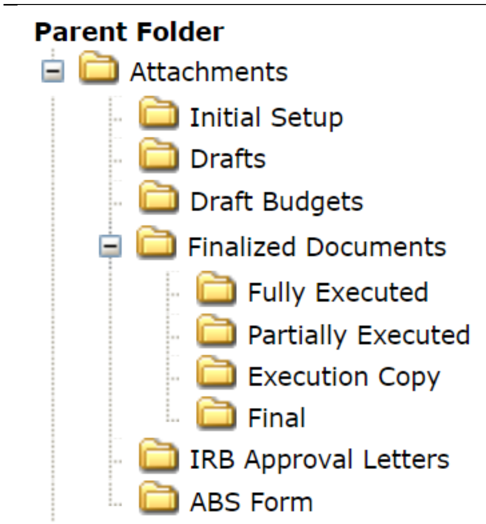
The Department Setup status occurs when the agreement is first initiated; when complete, the Contract Manager is automatically assigned to the record, and the In Negotiation Yale status is invoked. From this point, status changes are recorded manually in the record by the Contract Manager; some internal communications will inform calculations showing the time spent working with other Yale departments

Status	**Use**
Department Setup	The agreement record has been started by the department, but the initial setup form is not yet complete.
In Negotiation Yale	The PI or designee has submitted the initial setup, and the record is now with OSP for review and negotiation. The contract manager is the best contact for details about this.
In Negotiation External	There is a question or issue pending with the sponsor; the contract manager is the best contact for details about this.
PI Review	There is a question or issue pending with the PI; the contract manager is the best contact for details about this.
Awaiting Budget or Other Docs *(not used for CDAs)*	OSP has completed negotiations and finalized the contract language. Execution of the agreement is pending receipt of the finalized budget or other documentation. *Note: Invoking this step automatically sends a communication to the department, prompting them to attach the ABS form.*
To PI for Execution	The finalized budget has been received, and OSP has contacted the PI for signature on the contract.
To External for Execution	The PI and OSP have signed the contract, and OSP has sent it to the sponsor for their signature.
Fully Executed no COI	The contract has been signed by all parties, and is in effect. The agreement has been turned over to ISCU for compliance review and financial setup, if applicable.
Suspended	The negotiation is on hold, either because OSP has been asked to pause moving the agreement forward or because the sponsor has become unresponsive.
Withdrawn	One or both parties are ending participation in the study or negotiation.
Terminated	The agreement has been formally ended by the sponsor.
Inactive	The agreement has been created in error, for example a duplicate.

Folder Structure

A standard folder structure has been put in place to make the record easy to understand, particularly for people who need to access the information less frequently and/or after negotiations have concluded. The structure is simple:

Folder	**Purpose**
Initial Setup	CDA submitters are instructed to use this folder when submitting attachments when initiating the record.
Drafts	All contract working documents are stored here.
Draft Budgets	Any unfinalized budgets received during the negotiation, after the record has been created, are stored here.
Fully Executed no COI	The final contract, signed by all parties, is stored here.
Partially Executed	The final contract, signed by some parties, is stored here.
Execution Copy	The unsigned final contract in PDF format, including any budget and other attachments, is stored here.
Final	The final contract language in Word format, including payment terms, is stored here.



IRB Approval Letters	All approval letters from the Institutional Review Board are stored here.
ABS Form	When the ABS form is received, move it here for easy identification.

Record Summary vs. Submission

Each time an CDA is created, a submission record is created under the master record in order to represent that specific piece of the overall agreement. Some parts of submissions flow up to the summary level (master record level).

Communications Tab

The Agreements Module includes a Communications tab which facilitates, among other things, connecting email correspondence and attachments within the Agreement record. When irescontracts@yale.edu is included in the To or CC field of an email and the record number is in either the subject or body of the email, that email will automatically become part of the referenced agreement(s).

Initial metrics will be calculated based on status changes. Since many of the communications above happen with or because of a status change, there is a drop down on the communication window that makes it easy to change the status while a communication is being composed.

Templates

Several email templates are configured to include irescontracts@yale.edu in the CC field, and the Contract Manager in the From field. This way, when the recipient uses reply all, the Contract Manager can monitor incoming communications via Outlook and the communication automatically attaches to the record. Where the recipient is known and can be identified through an IRES role (i.e., PI), those values are also pre-configured. Some templates may be used to calculate metrics; that development is ongoing.

Verify Contacts

IRES can send email to Yale employees and to anyone who is listed as an Entity Contact. PIs and their designees are instructed to add Contacts when they are completing the intake form. To view the Contacts available to the Agreement record, click Contacts on the spine, and a list will appear.