Before you start

In order to enter the agreement, the Provider (for Incoming MTAs) or the Recipient (for Outgoing MTAs) 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 MTA Website

In a web browser, go to https://your.yale.edu/research-support/office-sponsored-projects/contracts/material-transfer-agreements-mtas. Then choose the appropriate link depending on whether you are receiving or sending materials.

On the Incoming or Outgoing MTA web page, click the link to open the intake form (incoming shown).

Due to increased volume and a current backlog, expect a turnaround time of approximately 2-3 weeks to execute standard MTAs. Complex MTAs (industry, foreign, etc.) that require negotiation may require 4-8 weeks to execute. We are diligently working on process improvements to minimize the turnaround time. For MTAs that have exceeded this expected turnaround time, please contact Jeff McGuinness, jeffrey.mcguinness@yale.edu.

NOTE: If you are requesting data, such as clinical data for research purposes, this should be done under a Data Use Agreement (DUA). Visit the DUA webpage.

1. Complete and submit the Request for Incoming MTA form which will provide the initial background information the MTA team needs to review and evaluate the terms of the MTA.

The appropriate Material Transfer Agreement intake form will open.

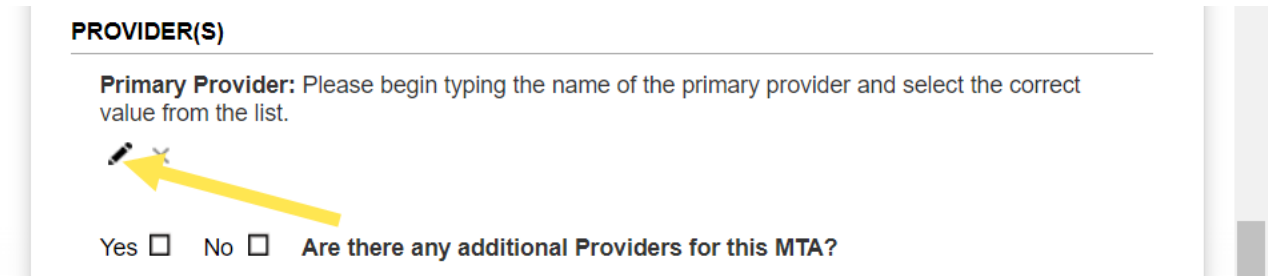
2. Complete the Material Transfer Agreement Intake Form

Enter Agreement Information

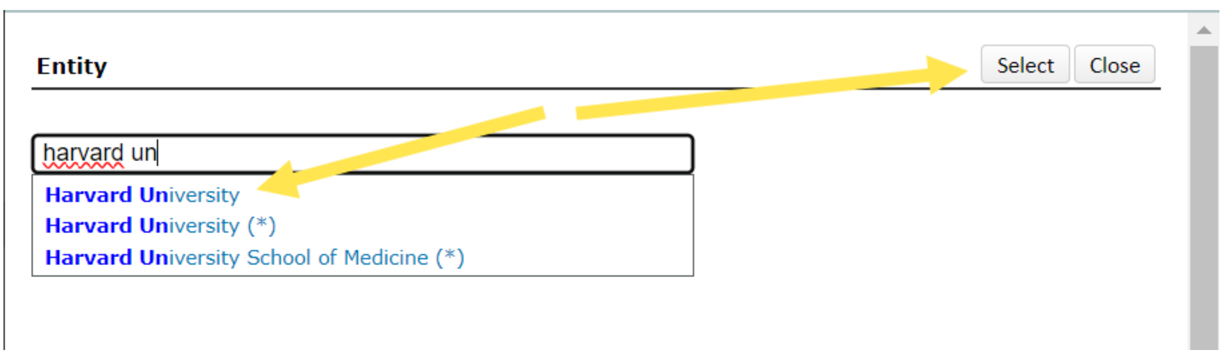
The Material Transfer Agreement intake form collects necessary administrative and regulatory information about the agreement and transmits this information along with a draft copy of the contract to the appropriate OSP Contract Manager for action. All fields on this form are required, unless "Optional"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

Add Provider/Recipient Institution and Contacts

To add the Provider or Recipient institution, click the pencil icon (Provider shown).

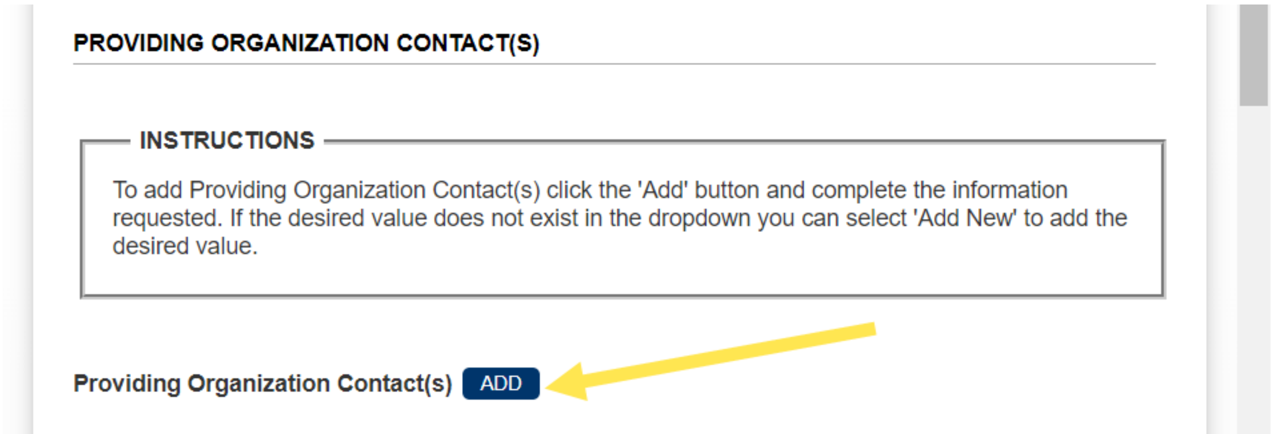


In the popup box, start typing the name of the provider or recipient. A list will generate and will narrow as you type more of the provider or recipient institution name. When the provider or recipient you need appears, select it from the list. Then click Select.



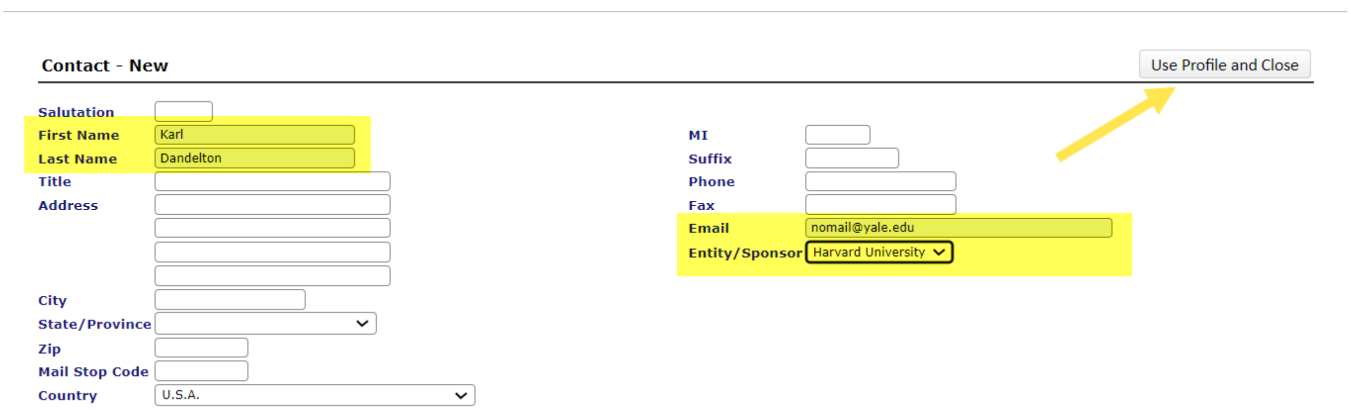
Contacts are used in IRES to communicate with the sponsor using the system. Specifically, OSP will need contacts in IRES in order to communicate using the system. At least one contact is required on the setup form for this reason. These contacts should be administrative in nature – the contracting office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

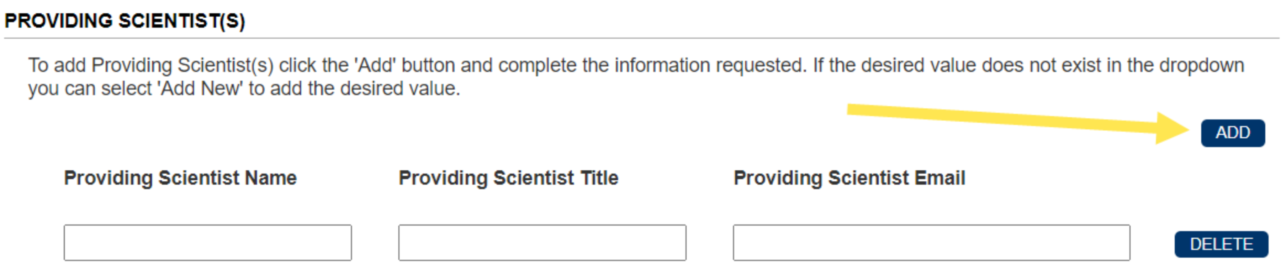
If you Add New, a first name, last name, and email address is required. You must also select the provider or recipient institution from the Entity/Sponsor dropdown. When you have entered the information, click Use Profile and Close.



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

Add Providing or Recipient Scientist Information

To add the contact information for provider or recipient scientists, click the Add button, then fill in the requested information. If there is more than one scientist, you may click Add again to add more rows. If you make a mistake, you can use the Delete button to remove a row.



Answer Questions About the Agreement

Some of the questions provide input for the negotiation process; others assess the regulatory oversight needed for the use of the material.

Context for Selected Intake Questions

Incoming MTA Question	Outgoing MTA Question	Why Is This Being Asked?
	Will the biological material be used in collaboration between your lab and the recipient investigator?	The Scope Of Work associated with the MTA should reflect the respective contributions under a collaborative project. The Yale PI may wishes to obtain rights to the results of the research for which the material or information is to be used, or ensure that correct and appropriate acknowledgement is included in any publication regarding the use of the material.
Do you anticipate receiving and/or exchanging confidential information?	Will any confidential information be included with the material or otherwise provided to the recipient investigator?	In contrast to material-only transfers, if you need to also provide sensitive information then such protections will need to be included in the MTA. Recipient PI will need to ensure that any such confidential information not be required for the publication of research results.
	Will the recipient pay for shipping?	This is generally a yes/no question in the MTA
	Will the recipient pay for the preparation of the material? Note: your department business office	If known, the amount should be specified in the MTA.

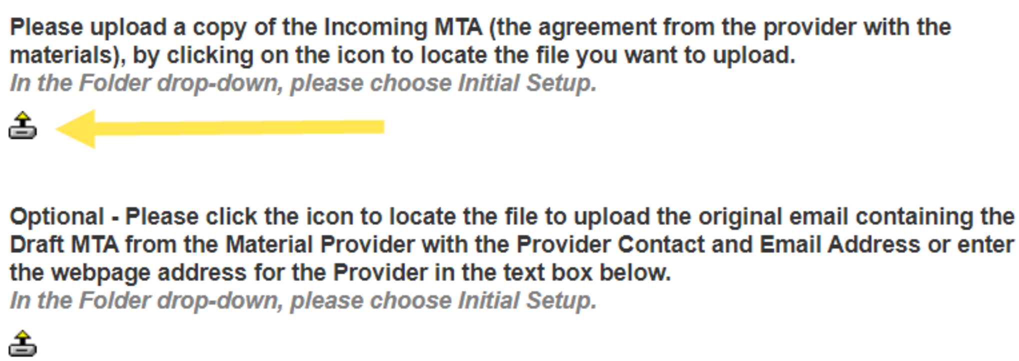
	will need to invoice the recipient, if required.	
	Does the proposed MTO refer to or require any of the following?	These restrictions require the additional review of other Yale administrators or offices (ex: the material is infectious, hazardous or subject to special regulations). This is why we ask below: • Is the material hazardous or a select agent?
Is the material(s) published or otherwise publicly known?	Is there a publication that describes this biological material(s) or have the biological material(s) otherwise been publicly disclosed?	As a matter of risk management, it is helpful to know the extent to which laws concerning, for example, privacy or intellectual property apply to this project. Additionally, any such "prior art" (e.g. information known publicly before the effective filing date of a U.S. patent application) impacts the patentability of an invention.
	Was the biological material entirely developed by you at Yale?	If the material was developed with third party contributions, then the terms of any associated agreements with such parties must allow for this outgoing transfer and may also specify specific provisions which apply to such use.
If the Research Plan is already detailed in the MTA then please select 'See MTA', if not please select 'Provide Research Plan Here' and include details in the text box provide.		How will the material be used in the research? Examples include: • The material is provided for the purpose of product testing and evaluation for the providing organization. • The material is a tool, kit or instrument that will be used in the conduct of research. • The material is a reagent. • The material will be used to make progeny, unmodified derivatives or descendant copies of the material(s). • The material will be modified or used to produce modifications. • The material will make derivatives of, modify or create a substance that contains or incorporates the material or is a cross-breed. • The material will be reverse-engineered (Reverse-engineering includes determining the structure or other physical property of the material).
What funding sponsor(s) and/or source(s) will support the research in	What funding source(s) supported development of the material?	If the material was developed using sponsored funds, then the terms of the funding agreement must allow for this outgoing transfer and this MTA may not

which this biological material will be used?		conflict with such terms. This is why we ask below: • Is the material derived from other materials obtained or purchased from a third-party? • Is the biological material subject to any third-party agreement(s) or restriction(s)?
Do you anticipate any commercially viable inventions or discoveries related to this research?	Does the material have a potential commercial value?	In such cases, the MTA should expressly claim, reserve or otherwise address ownership rights to results of the research and any developed intellectual property.
Are you working with Yale Ventures regarding this research? Visit the Yale Ventures website for information regarding invention disclosures and to discuss your idea. Has a disclosure been submitted to Yale Ventures on this area of research?	Have you submitted a disclosure to the Office of Cooperative Research (OCR) for the material? Visit the Yale Ventures website for information regarding invention disclosures.	For faculty with active licenses and IP portfolios, this MTA may need to be reviewed and approved by Yale's tech transfer office.
	Is the material derived from a human subject(s) either under standard treatment, under a clinical trial agreement or otherwise requires Yale HRPP approval?	If yes, then Yale's HRPP or IRB office will need to be consulted as part of this MTA preparation.
	Will any Protected Health Information (PHI) or other de-identified clinical information be provided with the human derived material?	If yes, then Yale's Chief Privacy Officer will need to be consulted as part of this MTA preparation.
	Please provide any additional comments, questions, or information.	This includes any specific restrictions on how the material is to be used by the recipient, any particular liability concerns that should be addressed, etc.
Outside of the PI, are there any other Yale collaborators or external collaborators who will have or require access to the material(s)?		Some MTAs require that such person(s) be expressly designated in the agreement and avoids the need for an amendment.
In addition to providing for the transfer of materials, will this MTA		Because MTAs ordinarily do not provide funding for the research utilizing the

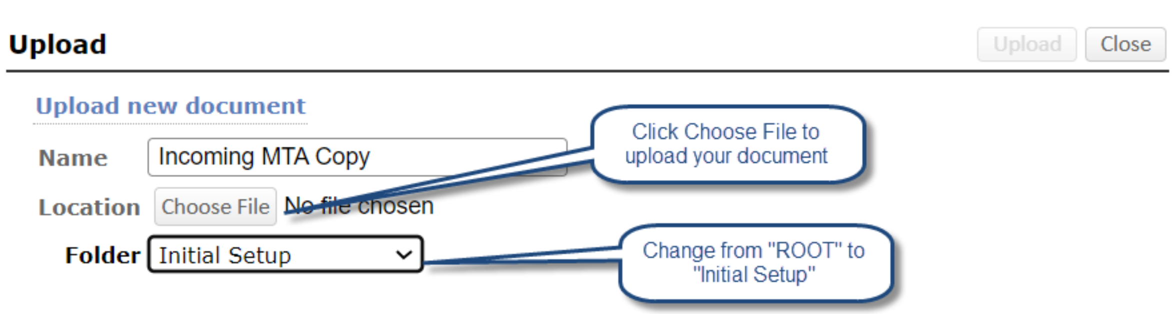
obligate Yale and / or the provider institution to carry out additional research activities?		transferred materials, the MTA often needs to be reviewed jointly with any pre-existing funding agreements to ensure that the terms of these agreements do not conflict with one another.
Has the Yale University Patent Policy Acknowledgement & Agreement (PPAA) been signed by the PI and all those with access to the material? The PPAA must be completed. Review and submit the PPAA acknowledgement online form.		In addition to being required under Yale policy, most incoming MTAs expressly require that any recipient personnel who will use the material have assigned their IP rights to the University before starting work with the material.
Will you modify the biological material, create derivatives or modifications, or in any way need to reverse engineer the material to determine the material's structure or physical properties?		Some MTAs expressly prohibit such activities, in which case the terms will need to be negotiated.

Add Attachments

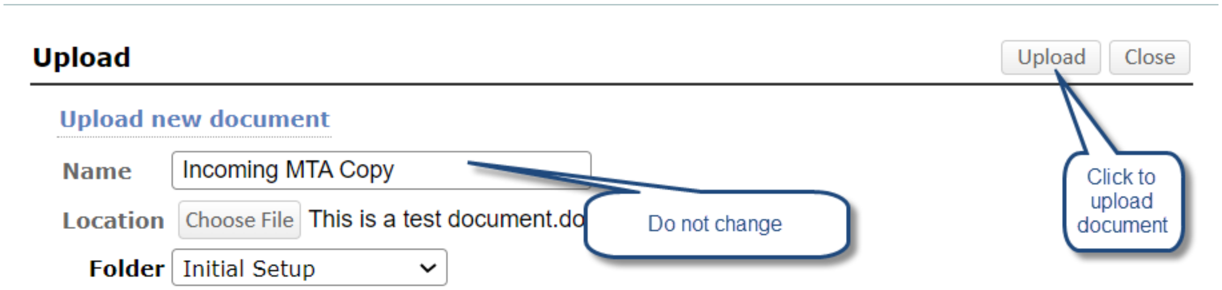
For each attachment, use the icon to upload a copy of the draft agreement and the correspondence that has been conducted with the sponsor.



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 MTA'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

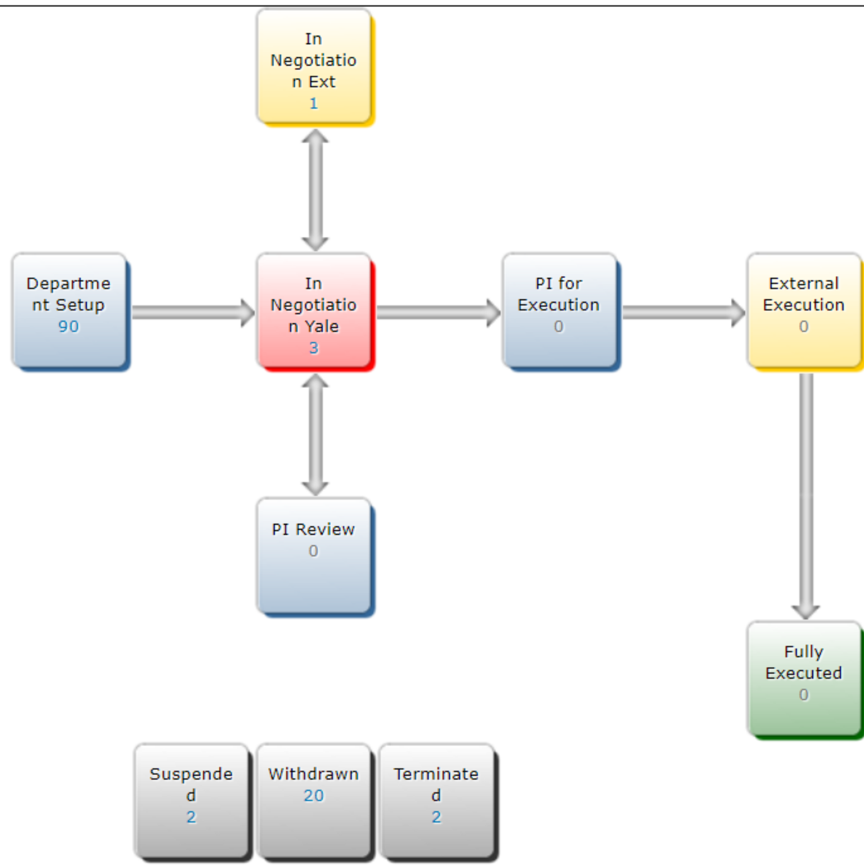
IRES Agreements are used to manage and document the process and outcomes of Material Transfer Agreements. Institutionally, this module provides:

- 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

All of which are based on data recorded in the agreements module.

How Metrics are Calculated

Process metrics are generally based on turnaround times in each status. The process is represented, at a high level, on the Workflow Maps (Incoming shown):



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.

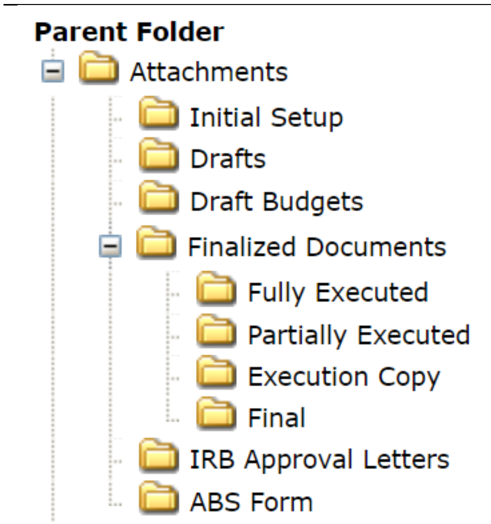
Statuses and What they Mean

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 MTAs)*	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	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.

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	MTA 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	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.

Agreement Summary

The Agreement Summary captures reportable characteristics of an agreement. Some of the characteristics are known up front and should be recorded as soon as they are known to facilitate reporting. Minimally, this form needs to be completed when the agreement is Fully Executed.

Record Summary vs. Submission

Each time an MTA is created or an amendment is submitted, a submission record is created under the master record in order to represent that specific piece of the overall agreement (i.e., original MTA or modification). Some parts of submissions flow up to the summary level (master record level).

Summary vs. Submission Statuses

If there is only one submission, the original MTA, the overall record/summary status is the same as the submission status.

Amendments only update the summary status when they've been submitted to OSP. That way, if PI or designee is working on an amendment but hasn't completed it, the amendment doesn't change the summary status until it's been more or less "finished" on their end. If there are multiple amendments, the summary status is updated by the submission that was most recently submitted to OSP.

In other words, once an amendment has been submitted to OSP, the overall record status equals the amendment status. If one or more additional amendments are submitted (or beyond that point), the overall record status equals the amendment most recently submitted, even if the status of a prior amendment or the original MTA gets changed.

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).

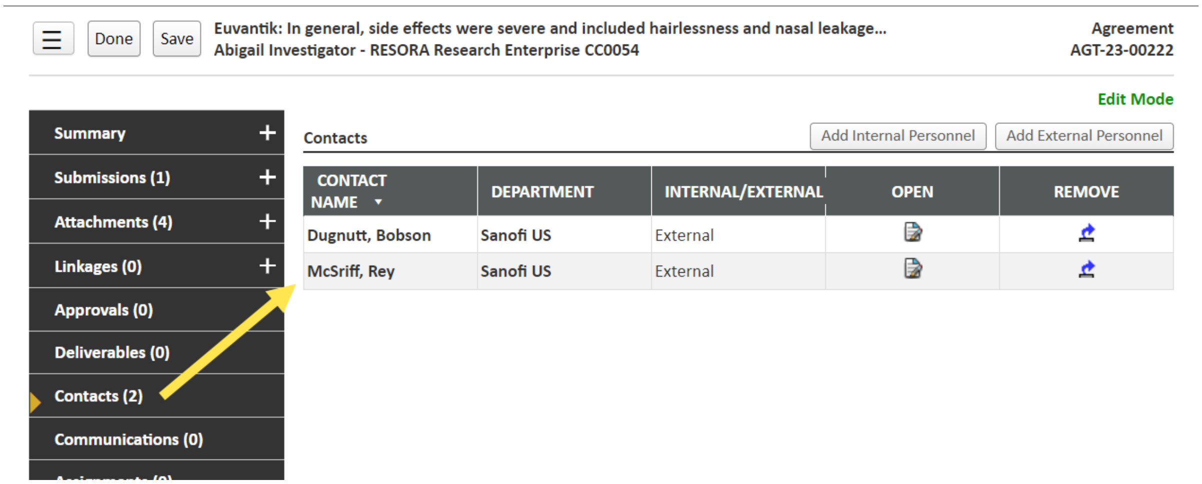
Initial metrics will be calculated based on status changes. Since many of the communications above happen with or because of a status change, there is a drop down on the communication window that makes it easy to change the status while a communication is being composed.

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.



If an agreement does not have contacts, and the contact exists in IRES, the contact can be added to the record. New contacts can be entered into IRES and added to the record simultaneously by un-completing the department setup form, entering them into the form, and re-completing the form; or by contacting ires@yale.edu to request the contacts be added.