

Consolidated Roadmap for the new Industry Clinical Research Agreement process

1. Process scope and operating model

The new process applies specifically to **industry-funded clinical research projects**, including industry-funded clinical trials. It does **not** apply to foundation-funded studies or other sponsored projects. The standardized agreement classification will be **Industry Clinical Research Agreement (ICRA)**, covering all industry clinical research agreements, including clinical trials.

IMPORTANT: ICRA Agreement creation is pending. Until ICRA is created, Departments should use the **CTA** Agreement type.

Use CTA for now:

5. * Agreement type:

And make clear within the agreement description that this is an **Industry Clinical Research Agreement**.

6. Description:

Under the new model:

- The **IBIS Agreement record** becomes the primary administrative record.
- A separate **Funding Proposal, or FP, will not be required**.
- ORA will manage agreement negotiation, contractual terms, execution, award setup coordination, and related communications.
- CTAT will manage the Medicare Coverage Analysis, budget development and negotiation, applicable payment terms, by completion of the CTAT ancillary review.
- ORA and CTAT work concurrently rather than waiting for one another to finish.
- The IRB record must be created (MSOM submitted to IRB as well) and related to the Agreement record (under “Related Projects”) and submitted before CTAT begins MCA and budget work.

2. End-to-end workflow

Phase 1: Intake and eligibility confirmation

Step 1: Confirm that the project qualifies for this process.

Responsible party: Department and study team

Before using this ICRA workflow, the department should determine whether the project is:

- A clinical research project; and
- Funded by an industry sponsor.

Projects funded by foundations, nonprofit organizations, or other non-industry sources should continue through the appropriate existing sponsored-project process and should not enter this workflow.

Phase 2: Agreement and IRB record creation

Step 2: Create the Agreement record in IBIS

Responsible party: Department and study team

The department creates the appropriate Agreement record in IBIS, currently using **CTA** (using **ICRA** once agreement type is created) for an industry-funded clinical research agreement.

Step 3: Complete departmental approval

Responsible party: Department

Departmental approval must be captured through an Ancillary Review before submission to ORA and CTAT Ancillary Review. Please select your responsible Department from the Organization box in question #1.

(This control replaces the departmental approval previously associated with the FP.)

See below IBIS Screenshots for guidance:

Next Steps

- Edit Agreement
- Printer Version
- View All Correspondence
- Manage Relationships**
- Submit
- Manage Ancillary Reviews
- Manage Access
- Send Email
- Log Correspondence

Add Ancillary Review

- * Select either an organization or a person as reviewer:**
Organization:
Person:
- Review type:**
Department Chair/Center Director
- * Is a response required?**
☒ Yes ☐ No [Clear](#)
- Send notification now?**
☒ Yes ☐ No [Clear](#)
- Comments:**
- Supporting documents:**
[+ Add](#)
Name
There are no items to display

* Required

OK OK and Add Another Cancel

*If you need to add or remove anyone from the Departmental Reviewer Group, please have your department submit a request to the OVPRS Help Desk.

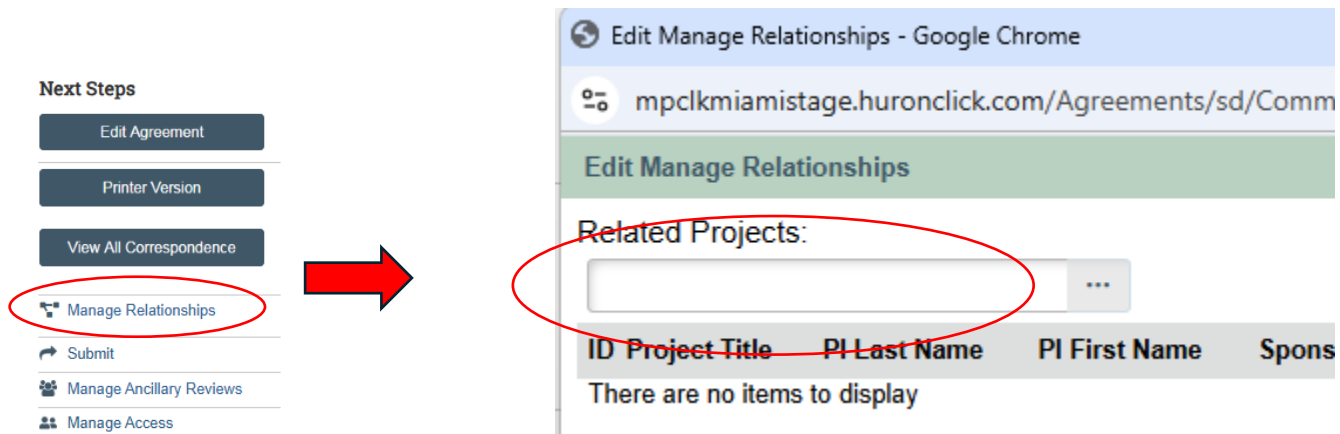
Step 4: Create and link the IRB record

Responsible party: Department and/or study team

The department should create the IRB record concurrently, upload the documents ordinarily provided to the IRB, and link the IRB record to the IBIS Agreement record.

“Simultaneous” submission is required, however, the IRB submission may occur to some extent later (since IRB completes initial review promptly), but it must occur before the CTAT Analyst begins MCA or budget work.

See below IBIS Screenshots for guidance:



IMPORTANT: If IRB submission is not linked as a “**Related Project**” to the IBIS Agreement submission when CTAT Analyst begins review, the agreement will be returned to Dept/Study team and possibly discarded. Dept/Study team can resubmit when ready.

Step 5: Submit the Ancillary Review to CTAT/Budget Review Group.

See below IBIS Screenshots for guidance:

Add Ancillary Review

- * Select either an organization or a person as reviewer:**
Organization: CTAT/Budget Review Group
Person: [empty]
- Review type:** [dropdown]
- * Is a response required?**
☐ Yes ☒ No [Clear](#)
- Send notification now?**
☒ Yes ☐ No [Clear](#)
- Comments:**
Please review and negotiate this budget.
[Please make note here if Project involves JHS]
- Supporting documents:**
[+ Add](#)
Name
There are no items to display

Required OK OK and

The IBIS Agreement record should include:

- Sponsor agreement;
- Sponsor budget;
- Internal Budget Template, when used;
- Any additional assignment information, if needed; and
- Any documents necessary for ORA's contractual review or CTAT's budget and MCA work. *

* Any documents uploaded to the IRB submission (i.e. Protocol, ICF, Etc.) do not need to be included in the IBIS Agreement submission.

IMPORTANT: For SCCC, if study is not submitted to the IRB, all relevant documentation will need to be included within IBIS Agreement submission.

Step 6: Submit the Agreement with the CTAT Ancillary Review open

Responsible party: Department or study team

The department submits the IBIS Agreement while the CTAT ancillary review remains open. This allows the contractual and budgetary workstreams to begin and proceed concurrently.

Phase 3: Assignment and coordinated startup

Step 7: Assign the CTAT analyst

Responsible party: CTAT leadership

CTAT leadership assigns a CTAT analyst using its internal procedures. The assignment will be documented in the IBIS Agreement record.

Step 8: Establish the ORA-CTAT working team

Responsible parties: CTAT analyst and ORA Contracts Officer

The CTAT analyst confirms assignment to the ORA Contracts Officer using the “**Contact Owner**” feature in the IBIS Agreement. The Contracts Officer then sends the sponsor introduction communication and copies the CTAT analyst. If the CTAT analyst changes, the replacement analyst repeats the introduction step.

- The Contracts Officer copies the CTAT analyst on relevant agreement communications.
- The CTAT analyst copies the Contracts Officer on relevant budget and payment-term communications.

Phase 4: Parallel agreement, budget, and MCA work

At this point, two connected workstreams proceed concurrently.

Workstream A: ORA agreement track

Responsible party: ORA Contracts Officer

ORA:

1. Reviews the agreement;
2. Negotiates legal and contractual terms;
3. Manages contract-related sponsor communications;
4. Coordinates final agreement approval and signature;
5. Routes the agreement for budgetary approval and PI signature when appropriate; and
6. Coordinates award setup after execution.
7. If JHS is involved, Contract Officer will create JHS WO in IBIS Agreements to track routing of JHS Work Order.

Workstream B: CTAT budget and MCA track

Responsible party: CTAT analyst

CTAT:

1. Develops the Medicare Coverage Analysis;
2. Develops the internal budget;
3. Negotiates the sponsor budget;
4. Negotiates applicable payment terms;
5. Coordinates JHS budget documentation when applicable;
6. Maintains budget-related communications and supporting records;
7. Completes the CTAT ancillary review when budget negotiations (including payment terms) are completed;
8. Approves final budgetary elements in final agreement routed by Contract Officer; and
9. Make MCA available in Velos.

Although the future state anticipates managing budget and MCA activities in Velos, the current process initiates and tracks the work through the CTAT ancillary review in the IBIS Agreement record.

...END...
