



Procedure Name: Contract Timelines	Number: BOU 2 v1.0
Subject: Clinical Research	Effective Date: October 31, 2024
Linked Policy: Business Operations Policy	Revised Date:

PURPOSE:

To establish the Office of Clinical Research (OCR) timelines and expectations regarding the negotiation of clinical agreements handled by the OCR.

SCOPE:

This SOP applies to all OCR Contracting Officers and Contracting Managers involved in the negotiation of clinical research agreements handled by the OCR.

RESPONSIBILITY:

This SOP sets forth the expected initial redline timelines for Contracting Officers and Contracting Managers involved in the negotiation of clinical agreements handled by the OCR.

PROCEDURES:

A clinical research agreement (“Agreement”) is first assigned to Contracting Officers by the Contracting Manager.

Agreements will remain under **Contracting Officer Review** during the Contracting Officer’s initial review and redline or drafting of the Agreement, until the Agreement is moved to **‘Internal Review,’ ‘Under Negotiation,’** or **‘Hold’** (see below).

The Contracting Officer will use the **Internal Review** status when their initial review and redline of the Agreement or initial draft of the Agreement is complete, but further information, review or input is needed from another GW/MFA department before they are able to send the finished initial redline or draft Agreement to the Sponsor. This status is used when the Agreement is still internal to GW/MFA but not in OCR:

1. IRB, IACUC information or approval
2. Budget review and/or updates needed from department and/or OSP
3. Waiting on other input from PI or department
4. IP Issues or review to GW’s TCO
5. OGC/other central office input required



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The Contracting Officer will use the Hold status primarily for delays due to external reasons or lengthy administrative processes, and will use the following guidance for specific Holds as applicable:

1. COI Review/PI management plan
2. Subcontracts that are pending prime execution
3. Contracting pending another Contract Manager’s contract negotiation
4. Sponsor or PI/study team is non-responsive
5. Sponsor or PI/study team indicates the project is on hold until a later date
6. Agreement was assigned without a completed Intake Form, Contract, COI disclosure, Budget, or ICF

The Contracting Officer will use the **Under Negotiation** status when the initial redline or draft Agreement is sent to the Sponsor or other entity to review.

TIMELINES:

From Assignment to Under Negotiation (If CO does not have to utilize the Internal Review or Hold status)

- CDAs – 3-5 business days
- Amendments – 5 business days
- DUAs – 5 business days
- MTAs – 10 business days
- Collaboration Agreements – 10 business days
- ACTA – 10 business days (if truly using ACTA with no changes)
- CTAs – 20 business days
- Master Agreements – 30 business days

TIMELINES FOR OSP ANCILLARY REVIEWS:

- Simple review of one section or a paragraph of a contract – 5 business days
- Full review – 20 business days



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Review and Revision

The SOP Review Committee shall review this SOP every 2 years. This SOP may be reviewed more frequently if it does not reflect current operations.