CLINICAL TRIALS QUICK REFERENCE

Old Dominion University | ODU Research Foundation, Sponsored Programs Administration

Full Clinical Trial Information & Guidance: www.odu.edu/odu-research-foundation/clinical-research

THE 5-PHASE PROCESS – CLINICAL STUDIES

Contract, budget/coverage analysis, and IRB run in **parallel** — not one after another. This integrated approach helps expedite trial launch and ensures alignment across administrative, financial, and ethical reviews.

Phase 1 **Feasibility & Intake**	Completion of intake questionnaire, formal site go/no-go assessment, and receipt of sponsor site-selection letter.
Phase 2 **Intake & Parallel Initiation**	Submission of intake form; CDA/NDA execution; CTA negotiation prep, IRB preparation, and vendor setup begin.
Phase 3 **Budget & Coverage Analysis**	Statement of Work (SOW) drafting, thorough coverage analysis, and finalization of sponsor clinical trial budget.
Phase 4 **Review, Submission & Alignment**	Securing IRB approval, coordinating and routing the billing grid to Sentara, and submitting the SOW for MAC review.
Phase 5 **MAC Review & Execution**	Formal SOW execution via Adobe Sign, final administrative alignment, and official clearance to open the clinical study.

SUBMIT ALL REQUESTS HERE (ODU RESEARCH FOUNDATION JIRA SUPPORT DESK)

All official requests must be submitted directly to the ODU Research Foundation Clinical Trials Office (CTO). Requests submitted via email are NOT accepted under any circumstances. Log into the portal below and select Clinical Trial Administration:

Clinical Trials Office Portal: https://odurf.atlassian.net/servicedesk/customer/portals
Note: All fields are required. Upon submission, you will receive an email confirmation with a ticket number and tracking link. You can add comments and upload documents to that ticket at any time.

WHICH FORM DO I NEED?

Need	Use This Pathway / Intake Form
New industry-sponsored clinical trial	**Clinical Trial Agreement Intake Form**
Protocol, CTA, budget, or other project amendment	**CTA Amendment Intake Form**
New or revised SOW for purchased services/facility use	**Clinical Statement of Work (SOW) Intake Form**
Non-funded clinical agreement (e.g., NDA/CDA, DUA, MTA)	**Clinical Non-Funded Agreements Intake Form**
Task order under an existing master agreement	**Clinical Task Order Intake Form**
Sponsored clinical activity outside a standard CTA	**Other Sponsored Activities Intake Form**

Direct link to all intake forms listed above: https://odurf.atlassian.net/servicedesk/customer/portal/60/group/-1

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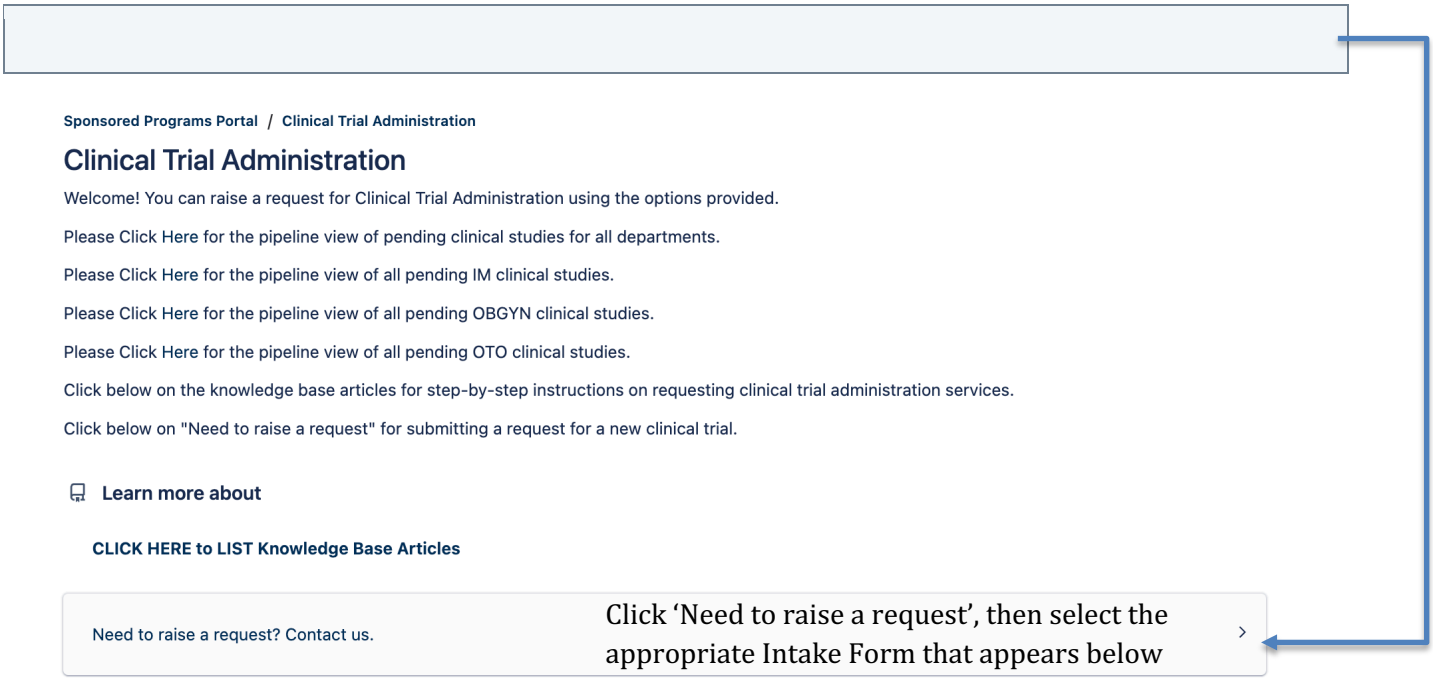

Sponsored Programs Portal / Clinical Trial Administration
Clinical Trial Administration
Welcome! You can raise a request for Clinical Trial Administration using the options provided.
Please Click Here for the pipeline view of pending clinical studies for all departments.
Please Click Here for the pipeline view of all pending IM clinical studies.
Please Click Here for the pipeline view of all pending OBGYN clinical studies.
Please Click Here for the pipeline view of all pending OTO clinical studies.
Click below on the knowledge base articles for step-by-step instructions on requesting clinical trial administration services.
Click below on "Need to raise a request" for submitting a request for a new clinical trial.
Learn more about
CLICK HERE to LIST Knowledge Base Articles
Need to raise a request? Contact us.
Click 'Need to raise a request', then select the appropriate Intake Form that appears below


What can we help you with?
Clinical Trial Agreement Intake Form
CTA Amendment Intake Form
Clinical Task Order Intake Form
Clinical Non-Funded Agreements Intake Form
Non-funded agreements are those that do not include any payment terms. These may include: Non-disclosure, Data Use, Material Transfer, Teaming Agreements, Memoranda of Understanding (MOU), Master Agreements, IP Transfer Agreements, Collaboration agreements, or other agreements that have no external funding source.
Clinical Statement of Work (SOW) Intake Form
This intake form is for SOWs that accompany purchased services or facility use agreements with a third-party hospital or clinic, as part of ODU's performance of a clinical trial study.
Other Sponsored Activities Intake Form
This Intake Form is for other types of sponsored (funded) activities requiring an agreement (e.g. funding agreement for CAB activities).

CONTRACT SPEED-UP, SECURITY & COMPLIANCE

Guidelines for Clinical Research Agreements and Regulatory Protocols

SPEED UP YOUR CLINICAL TRIAL AGREEMENT (CTA)

Contract negotiations are often the longest part of study startup. You can drastically speed up the execution of your Clinical Trial Agreement by adhering to these best practices:

- Use Standard Templates: Strongly encourage the sponsor or Contract Research Organization (CRO) to utilize unmodified industry-standard templates such as the Standard ACTA (Accelerated Clinical Trial Agreement), CRO-ACTA (provided on the ODU Research Foundation Clinical Research website).
- Expedited Review Disqualification: Be aware that any revision or amendment to the ACTA or CRO-ACTA template disqualifies the study from expedited legal and administrative review.
- Provide the Open Letter: Share ODU's official Open Letter with CROs early. This letter details the institution's expectations and preferred negotiation practices for CTAs, preemptively resolving common negotiation sticking points.

⚠ **WARNING: Never sign a CDA, CTA, or SOW yourself.** Faculty members, Principal Investigators, and study teams do not have the legal authority to sign clinical research agreements, confidential disclosure agreements, or statements of work on behalf of Old Dominion University or the ODU Research Foundation. Doing so can result in personal legal liability. All sponsored contracts must be routed through the ODU Research Foundation for authorized institutional signature.

CONFIDENTIAL & PROPRIETARY INFORMATION OBLIGATIONS

Sponsor or partner confidential and proprietary information is strictly regulated. All research personnel must handle sensitive data with extreme care. Keep the following obligations in mind:

- Legitimate Need & Authorization: Confidential info may only be accessed by personnel with a verified, legitimate need and proper institutional authorization.
- Authorized Purpose Only: Any accessed proprietary or confidential data must be used strictly for the designated, authorized research purposes of the study and nothing else.
- Safeguards: Active measures must be taken to safeguard information against unauthorized access, theft, or disclosure.
- PI Responsibility: Principal Investigators (PIs) are strictly responsible for making all project personnel aware of these confidentiality obligations before their access to any sensitive information begins.

Detailed guidance on handling confidential information can be found at: www.odu.edu/odu-research-foundation/getting-started#v-pills-12905162

EXPORT CONTROLS & RESEARCH SECURITY — FLAG EARLY

Federal regulations on research security and export controls carry heavy penalties for non-compliance. To avoid administrative bottlenecks, contact Research Security (exportcontrol@odu.edu) early if your study or any related activity involves:

- International shipments or international travel: Mailing equipment, biologics, or data overseas, or traveling for study-related business.
- Visiting scholars or researchers: Hosting or providing research access to visiting scholars, researchers, students, or other visitors, particularly foreign nationals, who may have access to laboratories, equipment, technical data, software, research systems, or other controlled or proprietary information.
- Foreign-national participation or foreign collaboration: Involving non-U.S. citizens in the research, or partnering with foreign academic/corporate entities.
- Publication or access restrictions: Sponsor-imposed restrictions on publishing results, or limits on who can access the research findings.
- Military, space, or controlled technical information, or encryption: Technical data subject to ITAR or EAR, or proprietary encryption software.
- Select agents/pathogens or other controlled technologies: Handling regulated biological materials, toxins, or advanced dual-use technologies.

UNDERSTANDING THE ODU RESEARCH FOUNDATION

For New Faculty & Study Teams | Sponsored Programs Administration

Partnering to advance research and clinical studies at ODU — across all campuses and the medical school.

WHO WE ARE	WHY WE EXIST
• **Independent but Connected:** We are a separate 501(c)(3) non-profit organization closely aligned with ODU's Division of Research & Economic Development (DivRED). • **Administrative & Fiscal Partner:** We handle the business side of sponsored research and clinical trials, budget development, proposal submission, fiscal and sponsor and federal, state, and local compliance administration of grants and contracts, project personnel HR/hiring, procurement, closeout, as well as Faculty and Departmental Research Support Account. • **100% Dedicated to Research:** Our team is fully focused on supporting faculty and enabling research and clinical activities.	• **Enabling Success:** To provide the robust infrastructure, administrative expertise, and regulatory compliance support that helps faculty succeed in securing external funding. • **Growing Capacity:** To expand ODU's institutional and clinical capacity for clinical trials and advanced research. • **Complex Navigation:** To serve as a dedicated partner in navigating and keeping current with complex sponsor, state, and federal regulatory requirements.

HOW IT'S ORGANIZED

- Division of Research & Economic Development (DivRED): Old Dominion University oversees institutional research strategy through DivRED.
- Board of Trustees: A 23-member Board of Trustees (including the ODU President, VP of Research, EVP VHS, Provost, and CFO) governs the ODU Research Foundation.
- Sponsored Programs Administration (SPA): This is the operational arm through which the Research Foundation carries out its pre-award, post-award, and clinical support work.
- Two Specialized Support Teams:
  - Medical Campus Team: Serves the EVMS School of Medicine and School of Health Professions, including the Clinical Contract/Administration Support Team.
  - Main Campus & Regional Centers Team: Serves the Norfolk main campus and regional centers (Peninsula, Tri-Cities, Virginia Beach).
- Funding Flow: New clinical studies funding typically flows through the University to the Research Foundation as a pass-through, ensuring institutional alignment while the Research Foundation manages day-to-day administrative and financial transactions.
- Point of Contact: All sponsored project activity flows through the Research Foundation, with the Research Portal (hera.odurf.odu.edu/RFPortal) as your primary tool. The Research Foundation is always your point of contact for all sponsored research and clinical studies.

WHAT THIS MEANS TO YOU

Enablement	Flexibility	Continuous Improvement
We provide hands-on assistance to help you successfully launch and manage sponsored research and complex clinical studies.	We align with ODU academic values while utilizing foundation-specific processes that streamline contracts, purchasing, and hiring.	Our administrative and technology systems are fine-tuned continuously to support our faculty and partners better.

Your Core Takeaway:
• You focus on discovery, innovation, and outstanding patient care.

- We focus on the behind-the-scenes business, compliance, and administration.
- Together, we advance research, clinical studies, and ODU's growing research enterprise.

YOUR FIRST STEP

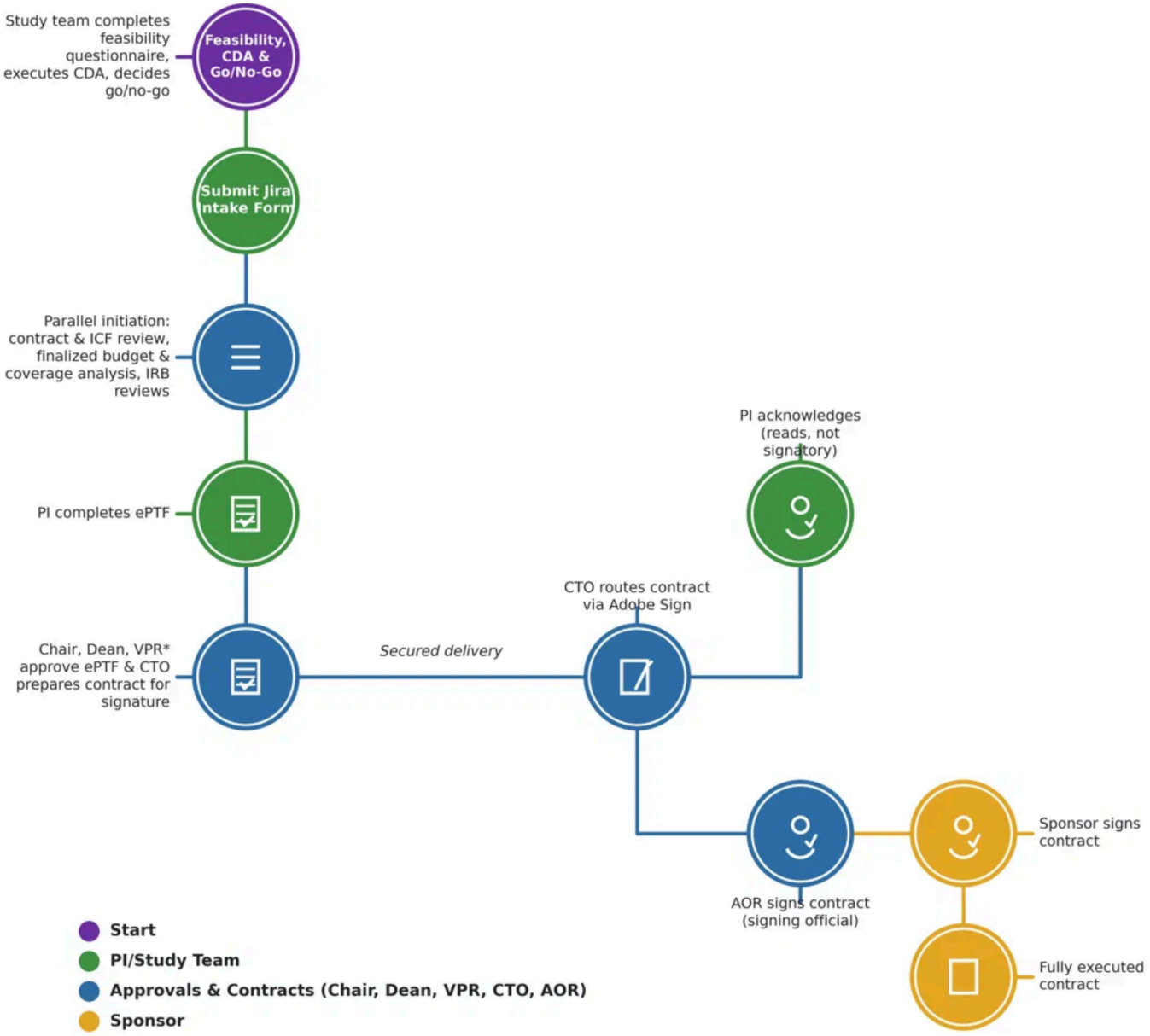
Reach out to Sponsored Programs early when planning a research proposal or clinical trial — we will guide you through every step.

- Research Proposals: Proposal Submission Preparation Guide: https://www.odu.edu/sites/default/files/2024/documents/Proposal-Submission-Preparation-06132024.pdf
- Clinical Research Information Page: www.odu.edu/odu-research-foundation/clinical-research
- Sponsored Programs Knowledgebase & Support Portal – Intake Forms and FAQs: odurf.atlassian.net/servicedesk/customer/portals

CLINICAL AGREEMENT ROUTING, KEY DATES & PAYROLL

Administrative Quick Reference for Deadlines, Hiring, and Agreement Pathways

How a clinical trial contract moves from Jira intake through ePTF approvals to a fully executed Adobe Sign agreement.



*VPR signature required only when the project includes cost share.
PI completes the ePTF; the Grants & Contracts Administrator (GCA) routes it for approval.
PI signs to acknowledge the contract; the Authorized Organizational Representative (AOR) is the official signatory.

Quick answers for payroll, hiring, and where to send an agreement.

KEY ADMINISTRATIVE DEADLINES	HIRING & PAYROLL ON SPONSORED PROJECTS
• **Annual COI Disclosure Window:** January 1 – February 28. All investigators must file disclosures. Contact: coiadmin@odu.edu • **Timesheets:** Normally due every other Monday by 10:00 AM. *Note: Coterminous employees must follow ODU deadlines. • **Grant Submission:** Full proposal materials must be submitted by 12:00 PM (EST) at least five (5) business days prior to the sponsor's deadline to guarantee review.	• **Hiring Personnel:** Is the position paid from a sponsored project? - Yes → Contact ODU Research Foundation HR (ODU RF HR). - No → Contact standard ODU Human Resources (ODU HR). • **Existing Employees:** Is the employee already paid on a sponsored project? Contact your assigned ODU RF Post-Award Team. • **Payroll Schedule:** Access the ODU RF Payroll Schedule online at: www.odu.edu/for-research-foundation-employees

AGREEMENT PROCESS — WHERE TO SEND

Different types of agreements must be routed to specific institutional offices. Use the table below to ensure your agreement is sent to the correct triage team:

Situation / Agreement Type	Send To
Medical Campus Clinical Trials Triage: NDA, CDA, MTA, DUA	**ODU Clinical Trials Office (CTO): rfhsc-clinical@odu.edu**
All other unfunded agreements (NDA, CDA, MTA, DUA, etc.) not associated with an active project or clinical trial	**DivRED: mdutta@odu.edu**
Unfunded agreement associated with an active project	**Your Post-Award Support Team***
Sponsored agreements	**Your Post-Award Support Team***

*POST-AWARD SUPPORT TEAMS DIRECTORY

- Main Campus & Regional (Silver Team): preaward@odu.edu / rfawards@odu.edu
- Medical Campus (Blue Team): RFHSCPreaward@odu.edu / RFHSCAwards@odu.edu
- Medical Campus Clinical (Sky Blue Team): RFHSC-Clinical@odu.edu

Stay Informed:
Keep up with the latest ODU Research Foundation developments, deadlines, and events by visiting the News & Announcements portal at: www.odu.edu/odu-research-foundation/news-announcements