Clinical Trial Process

Steps to obtaining your Project ID

Or why does it take so long to get my project started?

It's Complicated...

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  Associate Director of Clinical Research Billing Compliance
  Office of Clinical Trials

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  Office of Industry Contracting/Office of Sponsored Research

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  Coordinator, UNC Scientific Review Committee
  Office of Clinical Trials
Where do I start?

Start by answering a few questions:

- Is this a clinical trial?
- Who is funding the clinical trial?
  - Full proposal
  - Non-industry (federal, non-profit)
  - Industry
What is a Clinical Trial?

NIH: **Definition** of a Clinical Trial. A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
What is a Clinical Trial?

FDA: Clinical investigation means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of part 58, regarding nonclinical laboratory studies. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of this part. 21 CFR 56.102(c)
What is a Clinical Trial?

ICH E6 Good Clinical Practice: Clinical trial/study:
Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous."

What is a Clinical Trial?

Clinical Trial is defined in the final rule as a clinical investigation or a clinical study in which human subject(s) are prospectively assigned, according to a protocol, to one or more interventions (or no intervention) to evaluate the effect(s) of the intervention(s) on biomedical or health-related outcomes. [Source: 42 CFR 11.10(a); 81 FR 65139]
NON-INDUSTRY Clinical Trial Process

Create ORMS Record
Submit CDA request to ORS through ORMS
Protocol Rated for Feedback UFT
Conduct Feasibility assessment
Decision to proceed

Yes

Create and submit IIE
Submit to IRB

Sponsored Projects Specialist reviews the following:
- Confirm eligibility
- Confirm Protocols IIE
- Budget review

OSR Registries award
Fully executed agreement/budget

OSR Award Set Up:
- Check agreement status
- Check

Final Packet review by Sponsored Project Manager

DCT Completes Compliance Checks:
- IIE approval
- IRB and agreement consistent; Subject injury language
- SOP training current
- CCR training (current); disclosure and review on those listed on the IRB application
- Second (IRB training) current; disclosure and review on those listed on the IRB application
- RSA Complete (if applicable)

DCT Completes Compliance Checks and notifies OSR

OSR Notifies OCT of Clinical Trial

PS project ID assigned

Connect Carolina end date must match that of the agreement, to extend an end date, an amendment to the agreement is required.
NON-INDUSTRY Clinical Trial Process

Create ORMS Record → Submit CDA request to OIC through ORMS → Protocol Review for Feasibility IIRT → Conduct Feasibility assessment

Decision to proceed:
- Yes → Create and submit IHE
- No → End here

- Submit to ORI

Sponsored Projects Specialist reviews the following:
- Confirm eligibility
- Confirm Protocol IHE
- Budget review

OSR Registries award

Fully Executed agreement/budget

OSR Award Set Up:
- Check agreement status
- CCO

Final Packet review by Sponsored Project Manager

Send to data management for PS project ID

PS project ID assigned

DCT Completes Compliance Checks:
- IRB approval
- IF and agreement consistent. Subject injury language
- SOP training current
- CCO training current. Documentation and review on those based on the IRB application
- Second (BIR) training current. Disclosure and review on those listed on the BIR
- BIR Complete (if applicable)

DCT Completes Completion Check and notifies ORS

DCT Notifies OIC of clinical Trial

Connect Carolina and date must match that of the agreement, to extend an end date an amendment to the agreement is required...
CRMS Record

Start with CRMS
CRMS to Alice for Industry Contracting

May need a confidentiality agreement (CDA)
Submit CDA

1. Industry/Contracting Party

Add Organization

- Sponsor Name: Chiltern International, Inc
  - Role: CRO

2. All personnel associated with this agreement (i.e., Lead Principal Investigator, External Contact for Negotiation, Dept. Contact, etc.)

Add Personnel

- Lindsey Howard, Office of Clinical Trials, Other
- Christine Nelson, Office of Clinical Trials, Lead Principal Investigator

3. Admin Dept (UNC Department with responsibility for managing the agreement/project)

- Department: Office of Clinical Trials
- Department Code: 821200

4. Agreement Type - All Clinical Trial Agreement request need to be submitted through CRM5

- CDA
- Collaboration Agmt
- DUA
- Inter-Institutional Agreement
- Letter of Intent
- Master Agreement
- MTA
- Other
- Sponsored Research Agmt (non-clinical)
Protocol Received or finalized if IIT

Decision to proceed

Conduct Feasibility assessment

Includes SRC/PAC submission, BCA and budget development

No

End here
# Feasibility Assessment

Includes SRC/PRC submission, BCA and budget development

## New Clinical Trial
Feasibility Review Checklist

<table>
<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>Protocol Number</td>
<td></td>
</tr>
<tr>
<td>Study Title</td>
<td></td>
</tr>
<tr>
<td>Final version of protocol</td>
<td>Yes ☐ No ☐</td>
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<tr>
<td>Principal Investigator</td>
<td></td>
</tr>
<tr>
<td>Sub-investigators</td>
<td></td>
</tr>
<tr>
<td>Other Facilities where research will be conducted</td>
<td>Rex ☐ Chatham ☐ Highpoint ☐</td>
</tr>
<tr>
<td>Phase</td>
<td>I ☐ II ☐ III ☐ IV ☐ Other ☐</td>
</tr>
<tr>
<td>IND/IDE Number</td>
<td></td>
</tr>
<tr>
<td>Potential Enrollment</td>
<td>Overall ☐</td>
</tr>
<tr>
<td></td>
<td>Arrival ☐</td>
</tr>
<tr>
<td></td>
<td>Adequate targeted patient population? Yes ☐ No ☐</td>
</tr>
<tr>
<td></td>
<td>Age requirement for potential patients ☐</td>
</tr>
<tr>
<td></td>
<td>Comments ☐</td>
</tr>
<tr>
<td>Study Schedule (Reasonable Practical)</td>
<td></td>
</tr>
<tr>
<td>Study duration</td>
<td></td>
</tr>
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</table>

Available on the OCT website: [https://research.unc.edu/clinical-trials/forms/](https://research.unc.edu/clinical-trials/forms/)
Connect Carolina and date must match that of the agreement, to extend an end date, an amendment to the agreement is required.
Decision to proceed

- Yes: Create and submit IPF
- No: Submit to IRB

Sponsored Projects Specialist reviews the following:
- Confirm PI eligibility
- Confirm PI certified IPF
- Budget review
**RAMSeS IPF**

### Start New Proposal

To begin a new proposal, please fill in the information below:

* Indicates Required Fields

<table>
<thead>
<tr>
<th>Funding Agency(ies)</th>
<th>Help</th>
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<td>Funding Agency:</td>
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<tr>
<td>Funding Opportunity/Sponsor Application No:</td>
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</tr>
<tr>
<td>Sponsor Program Name:</td>
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<tr>
<td>Proposal Guideline URL:</td>
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<table>
<thead>
<tr>
<th>Prime Funding Agency:</th>
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<tbody>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td>Contact Phone:</td>
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### General Proposal Information

<table>
<thead>
<tr>
<th>Short Project Name:</th>
<th>(not project title, used for tracking purposes)</th>
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<tbody>
<tr>
<td>Project Start Date:</td>
<td></td>
</tr>
<tr>
<td>Project End Date:</td>
<td></td>
</tr>
<tr>
<td>Activity Type/Chess Code:</td>
<td>[Click Here to Add/Remove CHESS Code](click here for descriptions)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Proposal Type:</th>
<th>New</th>
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<tbody>
<tr>
<td>Award Type:</td>
<td>Select One</td>
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**UNC Research**
Non-Industry Sponsored Clinical Trial Process

1. Create CRMS Record
2. Submit CDA request to OIC through CRMS
3. Protocol Received or finalized if IIT
4. Feasibility Assessment completed

Decision to proceed

Yes

No

End here

Create and submit IPF

Sponsored Projects Specialist reviews the following:
- Confirm PI eligibility
- Confirm PI certified IPF
- Budget review

OSR Negotiates award

Fully Executed agreement/budget

Award Set Up
- Check debarment status
- COI

Final Packet review by Sponsored Project Manager

Sent to data management for PS project ID

Includes SRC/PRC submission, BCA and budget development

OSR Notifies OCT of Clinical Trial

OCT Completes Compliance Checks:
- IRB approval
- ICF and agreement consistent Subject injury language
- GCP training current
- COI training (current), disclosure and review on those listed on the IRB application
- Second COI training (current), disclosure and review on those listed on the IPF
- BCA Complete if applicable

If agreement specifies an end date, the end date must be used in ConnectCarolina, to extend an amendment is needed to the agreement.

PS project ID assigned

Non-Industry Sponsored Clinical Trial Process

Includes SRC/PRC submission, BCA and budget development
OSR Notifies OCT of Clinical Trial

OCT Completes Compliance Checks:
- IRB approval
- ICF and agreement consistent Subject Injury language
- GCP training current
- COI training (current), disclosure and review on those listed on the IRB application
- Second COI training (current), disclosure and review on those listed on the IPR
- BCA Complete if applicable

OCT Completes Compliance Checks and notifies OSR
Checklist for Non-Industry Sponsored CTs

Non-Industry Sponsored Clinical Trial

☐ Create CRMS record.

☐ Submit CDA to in the Industry Contracting Office through CRMS. (note: CRMS still has the OCT listed and not the Industry Contracting).

☐ Industry Office notifies of fully executed CDA.

☐ Conduct feasibility assessment.

☐ Submit to the Scientific Review Committee or Protocol Review committee as applicable.

☐ Submit to IRB.

☐ Create IPF.

☐ PI certifies IPF.

☐ OSR will confirm PI Eligibility and review budget, and notify OCT for Compliance checks.

☐ Once all compliance checks completed and agreement executed, PS project ID assigned.
Create and submit IPF for proposal

Sponsored Projects Specialist reviews the following:
- Confirm PI eligibility
- Confirm PI certified IPF
- Budget review
- Review of required components
Formal Proposal Required

Treat this like any other grant proposal...

- Create a Proposal record in Ramses
- Attach the call for proposal (if applicable)
- Attach internal budget
- Attach full application or note where it is found (Cayuse, Workspace)
- Attach all subaward commitment documents (if applicable)

Include on the personnel list everyone at UNC who will be paid from the grant

School of Medicine proposals will route either to SPO or OSR based on sponsor.
Full Proposal Checklist

Solicited or Unsolicited Full Proposals

☐ Create and submit IPF.
☐ PI certifies.
☐ OSR review.
☐ Create CRMS record.
☐ Conduct feasibility assessment.
☐ Submit to the Scientific Review Committee or Protocol Review committee as applicable.
☐ Submit to IRB.
☐ OSR will confirm PI Eligibility and review budget, and notify OCT for Compliance checks.
☐ Once all compliance checks completed and agreement executed, PS project ID assigned.
Submit to IRB via IRBIS

Create and submit IPF via RAMSeS

Submit Industry sponsored agreement to the Industry Contracting team in OSR via CRMS for negotiation and execution

Subject Injury Language given to study team by OCT as applicable
Subject Injury Language

Start with UNC template language

- Send draft to sponsor for approval
- If sponsor makes no changes, you can proceed with submission to the UNC IRB
- If submitting to an external IRB you will need an “official” email from OCT (we are working with OHRE to update their SOP)
- If sponsor makes changes to template, please send to Christine_nelson@unc.edu or OCT@unc.edu
OCT Completes Compliance Checks:
- IRB approval
- ICF and CTA consistent Subject injury language
- GCP training current
- COI training (current), disclosure and review on those listed on the IRB application
- Second COI training (current), disclosure and review on those listed on the IPF
- BCA Complete if applicable
- Budget compared to CTA

OCT creates "packet" for OSR for Inivity
Checklist for Industry Sponsored CTs

Industry Sponsored Clinical Trial

☐ Create CRMS record.
☐ Submit CDA to in the Industry Contracting Office through CRMS. (note: CRMS still has the OCT listed and not the Industry Contracting).
☐ Industry Office notifies of fully executed CDA.
☐ Regulatory packet received from sponsor.
☐ Conduct feasibility assessment.
☐ Submit CTA to the Industry Contracting Office for negotiation, PI certifies submission.
☐ Create BCA.
☐ Submit to the Scientific Review Committee or Protocol Review committee as applicable.
☐ Submit to IRB.
☐ Create IPF.
☐ PI certifies IPF.
☐ OSR will confirm PI Eligibility.
☐ Once all compliance checks completed and agreement executed, PS project ID assigned.
OCT creates "packet" for OSR
For Industry
Sponsored studies
Only

Packet includes:
- IRB approval letter
- Fully executed agreement
- Copy of IFP
- Copy of review request form from Alice – Industry
- Contracting Office
- Screen shots of RAMSeS COI
- PS Project ID request form
Those pesky compliance checks

OCT Completes Compliance Checks:
• IRB approval
• ICF and CTA consistent Subject injury language
• GCP training current
• COI training (current), disclosure and review on those listed on the IRB application
• Second COI training (current), disclosure and review on those listed on the IPF
• BCA Complete if applicable
• Budget compared to CTA
What can you do to help?

• Work with the study staff to ensure their COI and GCP training are current.
• Read the approved ICF and check for errors as soon as it’s received.
• Check it against the subject injury language you were given, if the IRB made a clerical error, notify ASAP to get it corrected.
• Check the approved ICF against the fully executed CTA and budget.
• If using an external IRB upload load your approval documents to IRBIS ASAP.
• If you have questions call OCT 919-843-2698.
QUESTIONS