

# Ask the Experts Panel

## Compliance in Research

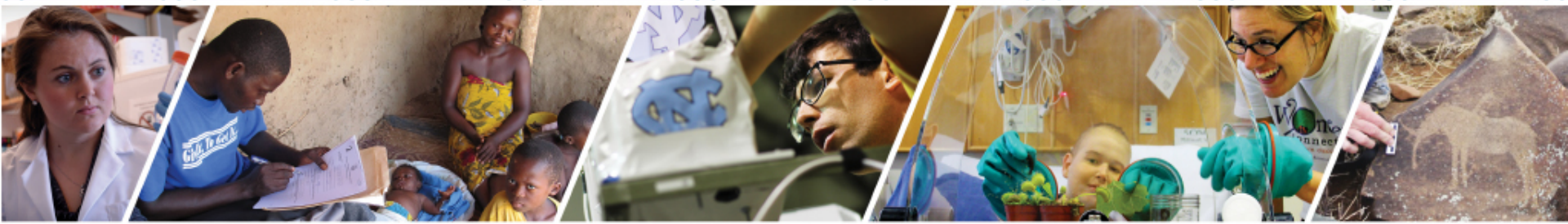
Colleen Fritsche, Assistant Director of Office of Animal Care and Use

Cassie Myers, Deputy Director of Office of Human Research Ethics

Chris Nelson, Director of Office of Clinical Trials

Emily Weston, Training & Compliance Manager of Office of Animal Care and Use

Rebecca Dye, Grants Manager in the Office of Animal Care and Use



August 10<sup>th</sup>, 2018

# IACUC

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*During the IACUC submission and review process what offices are involved?*

# Offices Involved in UNC Animal Care Application (ACAP) Submission/Review

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## Office of Animal Care and Use (OACU)

- Administrative Team – application intake, ensures submission are complete
- Training and Compliance – reviews techniques and certifications, conducts training classes and lectures
- Grants Manager – reviews details of non-UNC collaborators

## Environment, Health and Safety (EHS)

- Biosafety/Institutional Biosafety Committee (IBC) – biohazard and IBC forms
- Chemical Safety – chemical hazard forms and lab safety plans
- Radiological Safety – radiological hazard forms

## Division of Comparative Medicine (DCM)

- DCM Veterinarians – veterinary review of application, consults with PI

## Health Sciences Library

- Health Sciences Librarian – reviews literature searches

# IACUC

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*Please describe the difference between approval pages vs. title/funding changes vs. congruence review. When each are needed and what OSR needs for IACUC approval in each scenario.*

*When does the approval page need to reference the sponsor and Ramses title and when does it not?*

# UNC Animal Care Application Protocol Approval Page

The approval (or signature) page with the IACUC Chair's signature can be accessed in ACAP. It is required documentation for all funding agencies.

- The approval page can be downloaded and submitted to funding agencies by the PI to confirm approval of an active IACUC protocol.
- This page does not reflect the funding source/sponsor but can reflect a matching title to a grant.
- An email notification sent from ACAP to the PI and listed Official Contacts in the lab when the application is approved is not the approval page.

<b>Application to Use Live Vertebrate Animals</b>		PI: _____	Page: 1 of 1
		Dept: Office Of Research Information Systems	
		IACUC ID: 17- .0	Web ID: 253

Title: Copy of Super Old Example	IACUC Use Only	
Species: Mouse (All, Various) ( )	IACUC ID: 17- .0-A	
Application Type: New Application	Renewal Date: 08/2018	
Multiple Species: No	Expiration Date: 08/2020	
Total Animal Number: 5 (DCM)	Core Facility: No	

<b>IACUC Use Only</b>	
<input checked="" type="checkbox"/> Approved 4/03/2018	<b>This application has been reviewed and approved by the University of North Carolina - Chapel Hill Institutional Animal Care and Use Committee.</b>
<input type="checkbox"/> Require Modifications	
<input type="checkbox"/> Withhold Approval	
<input type="checkbox"/> Resubmitted	

<b>IACUC Signature</b>	
	04/03/2018
Signature of Authorizing IACUC Personnel	Date

# UNC Animal Care Application Title/Funding Changes


A Title/Funding Change can be used to link a specific funding source to the protocol after approval.

Title/Funding Changes are used when:

- A PI needs to add a funding source to an active IACUC protocol.
- A PI needs to have the title of a grant match the title of the protocol.

When should the titles of the grant and protocol match?

- Required by: DOD, VA
- Preferred by: AHA, CFF
- Not Necessary: NIH, NSF, ACS

Title And/Or Funding Agency Change Of An Approved Application to Use Animals		PI:	Page: 1 of 1
Principal Investigator		<b>IACUC Use Only</b>	
UNC PID :	7	IACUC ID:	17- _17 - B
Department:	Department	Annual Renewal Due Date:	02/2019
Phone:	(919) 966-		
Emergency Phone :			
Administrative Contact:			
Admin Phone:	(919) 966-		
<b>Title/Funding Agency</b>			
Protocol Title:	Maintenance of Animal Models		
New Title:	Gene Therapy		
Sponsor:			
Prime Sponsor:			
Grant Title:			
Funding Type:	Grant		
PI on Grant:			
IPF Number			
<input checked="" type="checkbox"/>	Approved	04/21/2017	This application has been reviewed and approved by the University of North Carolina at Chapel Hill Institutional Animal Care and Use Committee.
<input type="checkbox"/>	Denied Approval		
<b>IACUC Signature</b>			
		05/11/2018	
Signature of Authorizing IACUC Personnel		Original Application Approval Date	

# UNC Animal Care Application Grant Congruency Review

A side-by-side comparison of the details proposed in the grant submission to the IACUC protocol identified by the PI as covering the work.

Verified IACUC Number	Title	Initial Approval	Expiration Date	Submissions	View PDF	Congruency Status	Congruency Date	
<input type="checkbox"/> 18-02	Systems Immunogenetics	5/16/2018	4/30/2019	<a href="#">View</a>		Congruent	0/2/2016	<a href="#">Remove</a>

UNC Grant Congruency Review policy applies to sponsors that follow NIH Policy as declared in the sponsor's grants policy/requirements statements.

- NIH and all subdivisions
- NSF and all subdivisions
- USDA
- ACS
- VA
- CFF
- MOD
- AHA
- DHHS



# Office of Clinical Trials

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*What are compliance alerts departments should know?*

*Will a documented process for steps to initiate a clinical trial be created any time soon?*

*Who is required to take CITI training as far as the administrative staff within the department?*



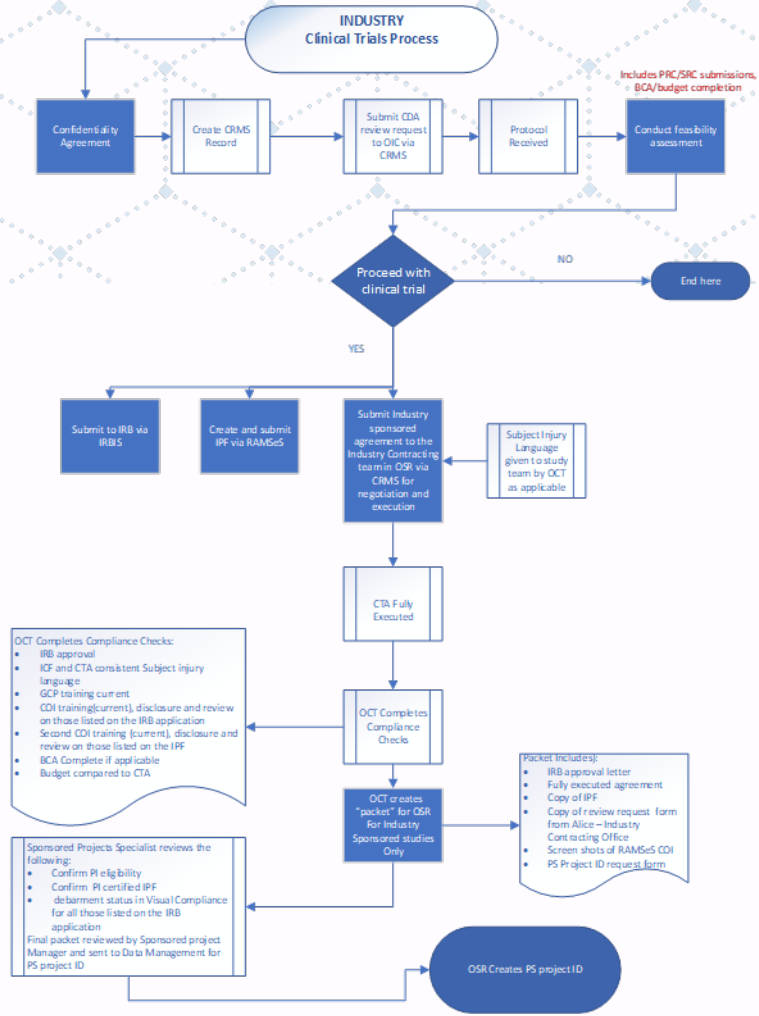


# Those pesky compliance checks

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## 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



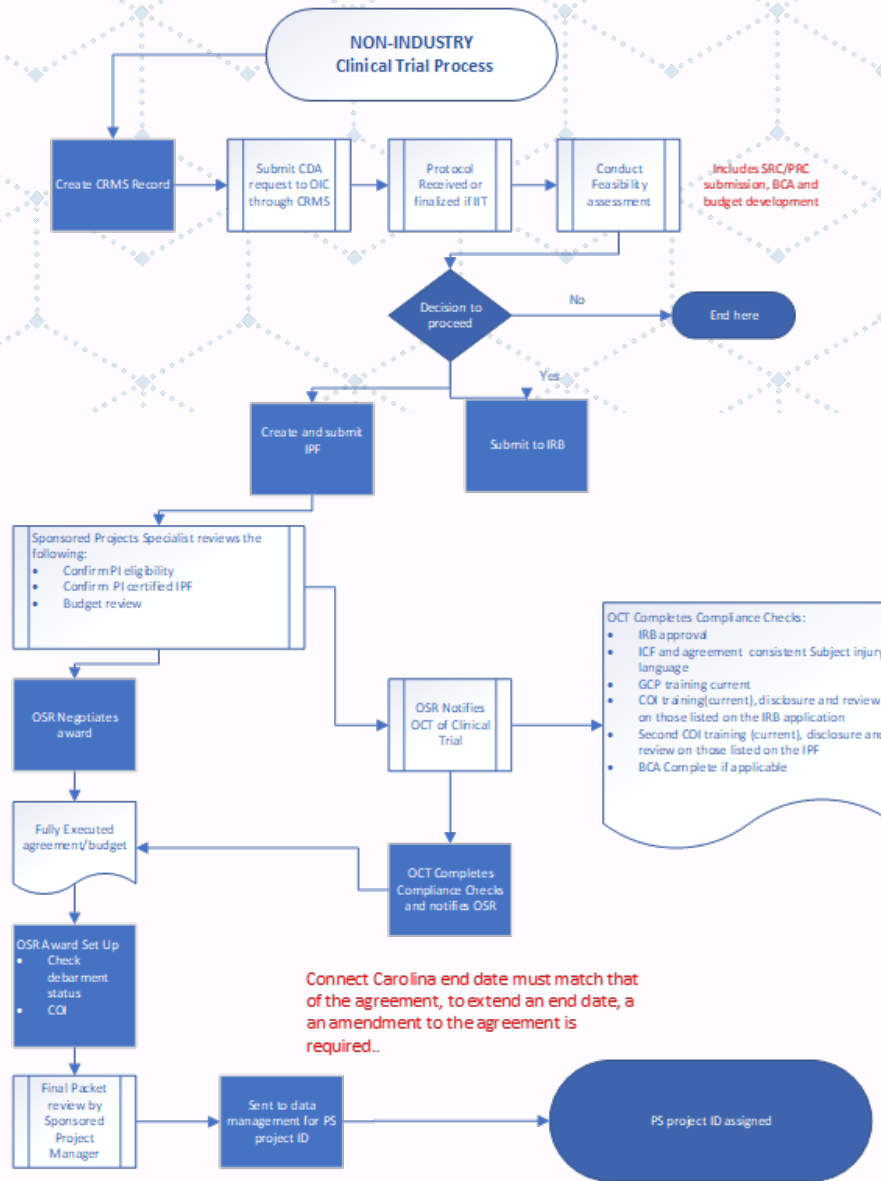


# Checklist for Industry Sponsored CTs

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## 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.





# Checklist for Non-Industry Sponsored CTs

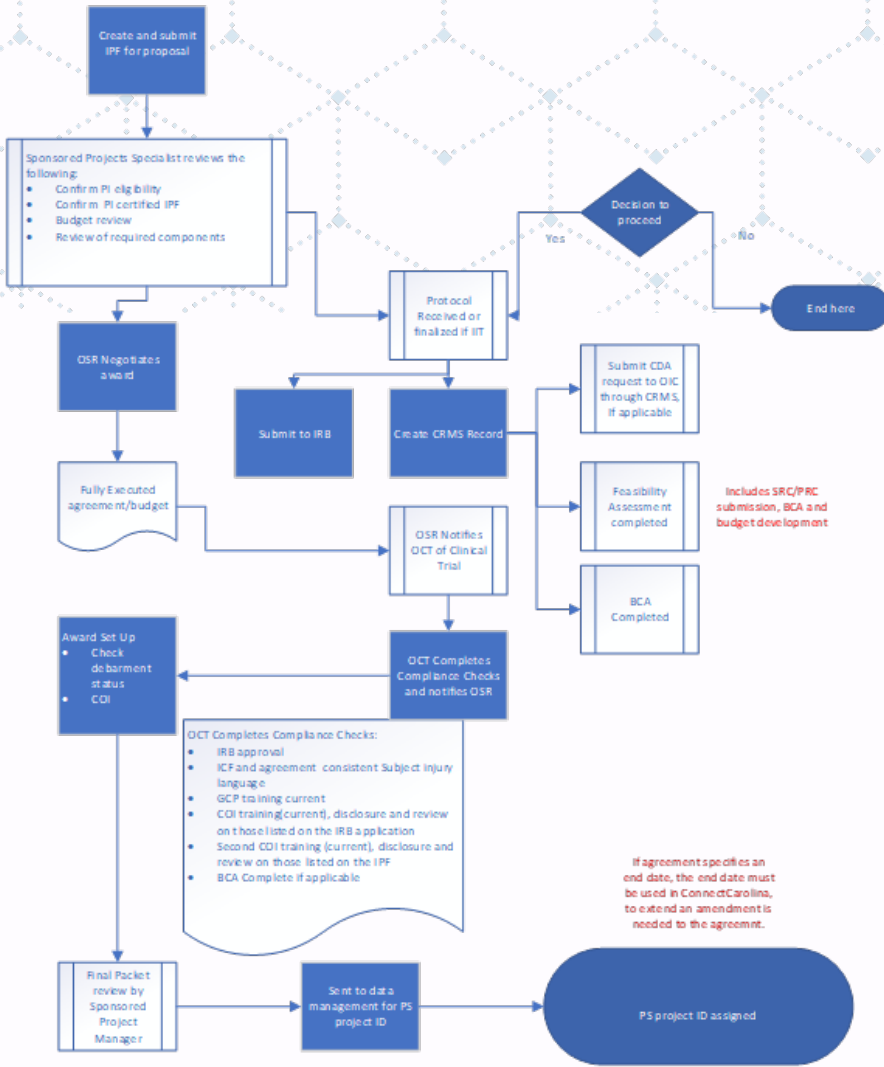
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## Non-Industry Sponsored Clinical Trial

- 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

# Solicited or Unsolicited Full Proposal

Formal proposal required by sponsor



# CITI Training

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Human Subjects Protection – HSP – requirement of OHRE

Good Clinical Practices – GCP

Effective October 1, 2014, all UNC-CH investigators and research staff who are involved in the design, conduct, or reporting of clinical trials involving human subjects **AND** a drug, device, or biologic are expected to document completion of GCP training.

NIH has also issued a [policy on Good Clinical Practice training](#) for NIH Awardees involved in NIH-funded clinical trials. This policy requires that PIs and clinical trial staff involved in **all new and ongoing [NIH-defined clinical trials](#)**<sup>1</sup> complete Good Clinical Practice (GCP) training by January 1, 2017.





# What is a Clinical Trial?

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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

# CITI Training - GCP

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The completion of the initial training is effective for **3 years**. At the end of a 3 year period, a GCP refresher course will be required. You will be notified, via email, prior to the expiration date to remind you to complete the refresher course.

**\*\*\*PLEASE NOTE – the GCP training is in ADDITION to the requisite Human Subjects Protection modules required by the Office of Human Research Ethics.**



# Full Proposal Checklist

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## 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

# Office of Human Research Ethics

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**What are the required HIPAA documents for agreements? Who negotiates HIPAA documents at UNC?**

The UNC IRB acts as the HIPAA research privacy board and therefore can grant partial (limited) or full waivers of HIPAA and also approves the language in the research HIPAA authorization.

# Office of Human Research Ethics.

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How do you differentiate between AEs related vs. unrelated to a research study in treatment trials that involve standard of care treatment procedures? For example, side-effects related to the treatment, but not the components modified by the study for investigative purposes, may be related to the SOC treatment itself but likely would have occurred outside the research study, as well.

Adverse events should be reported only if they meet the criteria of a UPIRTSO:

- Unexpected, and
- Related to participation in the research, and
- Serious or suggest that there are new or increased risks

# Office of Human Research Ethics.

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Why did the PRC submission process change for cooperative group studies? It used to be a part of the IRB submission process, now required to be done separately and approved prior to initial IRB submission.

When these processes were completed in parallel they created delays and often led to deferrals which delayed study start-up through:

- Re-review of changes
- Committee Limitations
- Limited Agenda Space

# Office of Human Research Ethics.

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Who is the best person to contact at the NCI-CIRB for regulatory issues with local IRB? Only helpdesk info available online and the UNC IRB director wants to speak directly with a member of the NCI regulatory team

The NCI now relies on Emmes IRB. They accept inquiries through e-mail at [NCICIRBContact@emmes.com](mailto:NCICIRBContact@emmes.com) or by calling 1-888-657-3711.

Issues may need escalation, and if not resolved satisfactorily or timely with Emmes/NCI, please contact either Elizabeth Kipp Campbell or Cassandra Myers for additional assistance.



# CITI Training-Human Subject Training

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The completion of training is required for any individual involved with human subject research activities.

This may include:

- Consent
- Intervention
- Access and utilization of identifiable data

# Office of Human Research Ethics

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*What is the best way to keep track of all the items (i.e. reg docs, CRFs, source documentation, tracking sheets, etc.) that need to be completed and submitted within a certain time frame for complex studies? Many trials have a mile-long table of events calendar with tons of different components to be completed by different people to meet all different deadlines and it can seem incredibly overwhelming trying to keep track of everything.*



*Questions?*