

The IACUC Life Cycle: When Animals and Award Process Collide

Rebecca Dye, OACU Grants Manager

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September 15, 2021



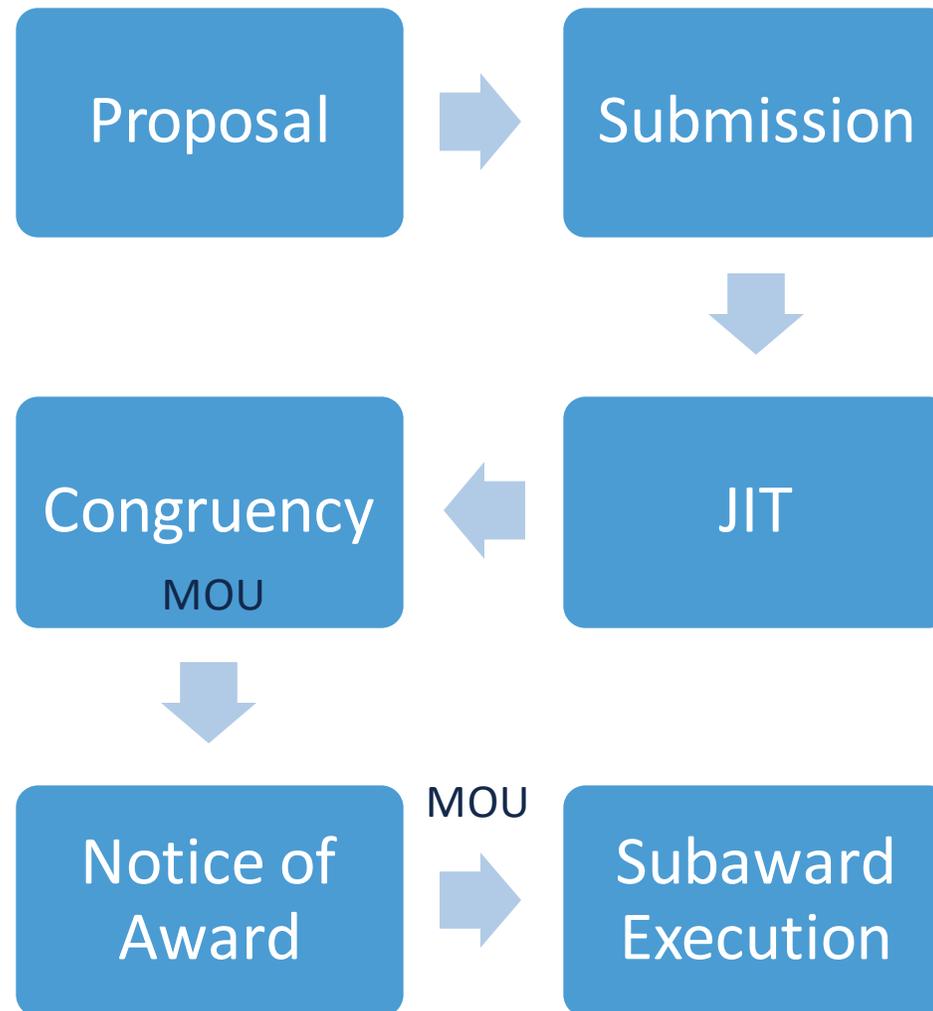
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The Cycle



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**Institutional Animal Care and Use Committee
(IACUC)**

vs.

**Office of Animal Care and Use
(OACU)**

vs.

**Division of Comparative Medicine
(DCM)**

Rebecca Dye



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IACUC

Institutional Animal Care and Use Committee

- Consists of UNC PI's, veterinarian(s), non-affiliated community member(s), and non-scientist(s).
- Responsible for ensuring that compliance regarding the use of live vertebrate animals in research is upheld;
 - Review all animal use protocols, amendments, and programs for approval; conduct inspections on all facilities; review animal concerns; have the authority to suspend activity.
- Exists because the use of live vertebrate animals in research is strictly regulated and must be done in accordance with the *Public Health Service (PHS) policy on the Humane Care and Use of Laboratory Animals*, the *Amended Animal Welfare Act of 1985*, and the regulations of the USDA.



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Office of Animal Care and Use

The administrative support team for the IACUC

- *Education and Oversight:* Conduct lab and facility inspections
- *Business Administration:* Oversee the processing of all protocol submissions and amendments, from submission to approval
- *Grant congruency and sub-awards:* Conduct grant to IACUC protocol comparisons, and process sub-awards and inter-institutional agreements



DCM

Division of Comparative Medicine

- Responsible for the care of all vertebrate animals on the UNC-CH campus: veterinarians, veterinary technicians and laboratory/room technicians
- Their program is reviewed semi-annually by the Institutional Animal Care and Use Committee
- Is accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC)



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Want to
know
more?

Helpful links for new PI's, transferring PI's, or anyone with questions about the process or services that fall under the IACUC OACU or DCM

IACUC link

<https://research.unc.edu/iacuc/>

Getting Started with your Animal Research link

<https://research.unc.edu/iacuc/getting-started/#oacu>

DCM link

<https://research.unc.edu/comparative-medicine/>



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Proposal Submissions

Kaylie Orlan



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RAMSeS Research Subjects Tab

>> Research Subjects

* Indicates Required Fields

Human Subjects [Help](#)

* Does this research involve **HUMAN SUBJECTS**?

Yes No

Animal Subjects [Help](#)

* Does this research involve **ANIMAL SUBJECTS**?

Yes No

* Is animal research being conducted at UNC-CH?

Yes No

* If yes, has your research team submitted an application for IACUC approval?

Yes No

* If yes, please provide animal subject information below:

[Click Here](#) to select from the list of Animal Use Applications we have on file for your research team.

List the Species involved with this project:

* Is animal research being conducted by subcontractor(s)?

Yes No



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RAMSeS Research Subjects Tab

>> **Research Subjects**

* Indicates Required Fields

Human Subjects [Help](#)

* Does this research involve **HUMAN SUBJECTS**?
 Yes No

Animal Subjects [Help](#)

* Does this research involve **ANIMAL SUBJECTS**?
 Yes No

* Is animal research being conducted at UNC-CH?
 Yes No

* If yes, has your research team submitted an application for IACUC approval?
 Yes No

* If you have not submitted an application for IACUC approval, please check reasons below:

JIT
 Not Yet Submitted

* Is animal research being conducted by subcontractor(s)?
 Yes No



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RAMSeS Research Subjects Tab

>> Research Subjects

* Indicates Required Fields

Human Subjects [Help](#)

* Does this research involve HUMAN SUBJECTS?
 Yes No

Animal Subjects

* Does this research involve ANIMAL SUBJECTS?
 Yes No

* Is animal research being conducted at UNC-CH?
 Yes No

* Is animal research being conducted by subcontractor(s)?
 Yes No

 ramses.research.unc.edu

IMPORTANT: It is required to enter information via the Subcontractors IPF screen about animal work being conducted by subcontractors as part of this research.

[OK](#)

>> Subcontractors

If this proposal involves Subcontractors, please add them below, and provide the following information to OSR:

1. Statement of Work
2. Budget
3. Budget Justification
4. Letter of Intent from subcontractor signed by an authorized official of the proposed subcontractor
[Click Here for a sample document providing the above information](#)

[Add Subcontractor](#) [Help](#)

Subcontractor:

IMPORTANT: Based on the Research Subjects screen response, it is required to enter information about human and/or animal research being conducted by subcontractor(s).

* The proposed subcontractor's scope of work includes the use of human subjects.
 Yes No Unknown

* The proposed subcontractor's scope of work includes the use of animal subjects.
 Yes No Unknown

* List the institutions and species below:

Institution: Domestic Foreign

[Click here for definitions](#)

Subcontract
 Fee-for-service
 Collaborating Site

Please list all animal species to be used in the project:

* Note: If animal work will be performed at institutions other than UNC-CH, for each institution please attach via the IPF Attachments screen (1) evidence of IACUC approval, (2) evidence of PHS Assurance, and (3) evidence of USDA Registration if the work involves USDA-covered species.

* Note: If the proposal is not subject to "JIT," it is required to attach all documents at the time of the IPF submission.



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Final Proposal Thoughts

- Always attach your required documents – scope of work, budget, budget justification, and a copy of the submitted application
- Federal grants should be listed as pending at the proposal stage
- Ensure the information provided is consistent throughout the proposal to prevent unnecessary delays.
- “The backbone of success is hard work, determination, good planning, and perseverance.”
-Mia Hamm



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Just-in-Time

Kaylie Orlan and Rebecca Dye



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What is it?

- After initial peer review, applications that have overall impact scores of ≤ 30 are sent an automatic email requesting further information through the eRA Commons
- Request to send listed information if the application scores within or near our published paylines
- Applicants must submit their information at least 60 days before the proposed project period start date.

https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.5.1_just-in-time_procedures.htm



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Required at JIT

... for proposals that involve animal research

- **Animal Welfare Assurance number: D16-00256 (A3410-01)**
<https://olaw.nih.gov/resources/documents/assur.htm>
- **Date of institutional animal care and use committee (IACUC) approval of the Research Plan**
 - Requires grant congruency review to confirm work proposed is covered in the approved IACUC protocol
 - The verification of the date must include any IACUC-imposed changes are submitted
 - Pending or out-of-date approvals are not allowed
 - NIH understands that obtaining IACUC approval can take time if not already in place, and therefore it may initially be submitted as "IACUC pending"



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Congruency Review

Rebecca Dye



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What

... does congruency review mean?

- It is the direct comparison of the IACUC approved animal use protocol(s) to the animal work proposed in the grant
- The Aims, Research Strategy, and Vertebrate Animal Section are the main parts used for this review



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Why

... is it done?

NIH Grants Policy Statement 4.1.1.2

"It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC."

https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.1_animal_welfare_requirements.htm#Verification



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Who

... requires congruency reviews?

Currently, the UNC Congruency Review Policy applies to sponsors that follow NIH Policy by declaration in the sponsor's grants policy/requirements statements.

- National Institutes of Health (NIH) and all subdivisions
- National Science Foundation (NSF) and all subdivisions
- USDA National Institute of Food and Agriculture
- Department of Health and Human Services (DHHS)
- American Cancer Society (ACS)
- American Heart Association (AHA)
- Department of Veterans' Affairs (VA)
- Cystic Fibrosis Foundation (CFF)
- March of Dimes (MOD)

The Department of Defense (DoD) does not require Congruency Reviews



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... is congruency approval found?

RAMSeS UNC-CH Proposal and Award Development
HOME MY DASHBOARD HELP REPORTING ADMIN LOGOUT

Proposal Administration

[Back To Search Results](#)

Proposal No: [07-0084](#) (coversheet) 424 Sponsor: Bill and Melinda Gates Foundation
Lead Investigator: [Christy Hall](#) Prime Sponsor: Bill and Melinda Gates Foundation
Deadline: 5/01/2008 New Electronic: Yes - Grants.gov
Proposal Specialist: Sponsored Projects Specialist: [Cara Pettit \(26\)](#)
Primary Award Contact: [Ellen Quinn](#) PS Project ID Manager: [Lori Saddler](#)
Project Title: TESTING ONLY PLEASE DISREGARD !! 4/16/18 PDF TEST - UPDATE TITLE OF PROJECT

test note

General Routing Personnel **Compliance** Organization Awards Events Email Log

Compliance Note: zack test compliance note 2
[Add Compliance Note](#)

Human Research

This proposal does not involve Human Research.

Animal Research

IACUC Number: .0 99-999 [Add](#)

Animal subjects are used in this research at UNC-CH.
Below is a list of protocols:

Verified	IACUC Number	Title	Initial Approval	Submissions	View PDF	Congruency Status	Congruency Date	
<input type="checkbox"/>	12-999.0	Test Dog Study	12/31/2017	View		Congruent	8/3/2015	Remove
<input type="checkbox"/>	17-999.0	Testing Copies	9/01/2017	View		Under Review		Remove

Conflict of Interest

Entity	Person	Role	Added Post Approval	AIR ID	Disclosure Submitted	Review Process	Review Result	Review Complete	Training
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Type: parsererror
Response: 200 -- OK
Error: SyntaxError: Unexpected token < in JSON at position 0

Where



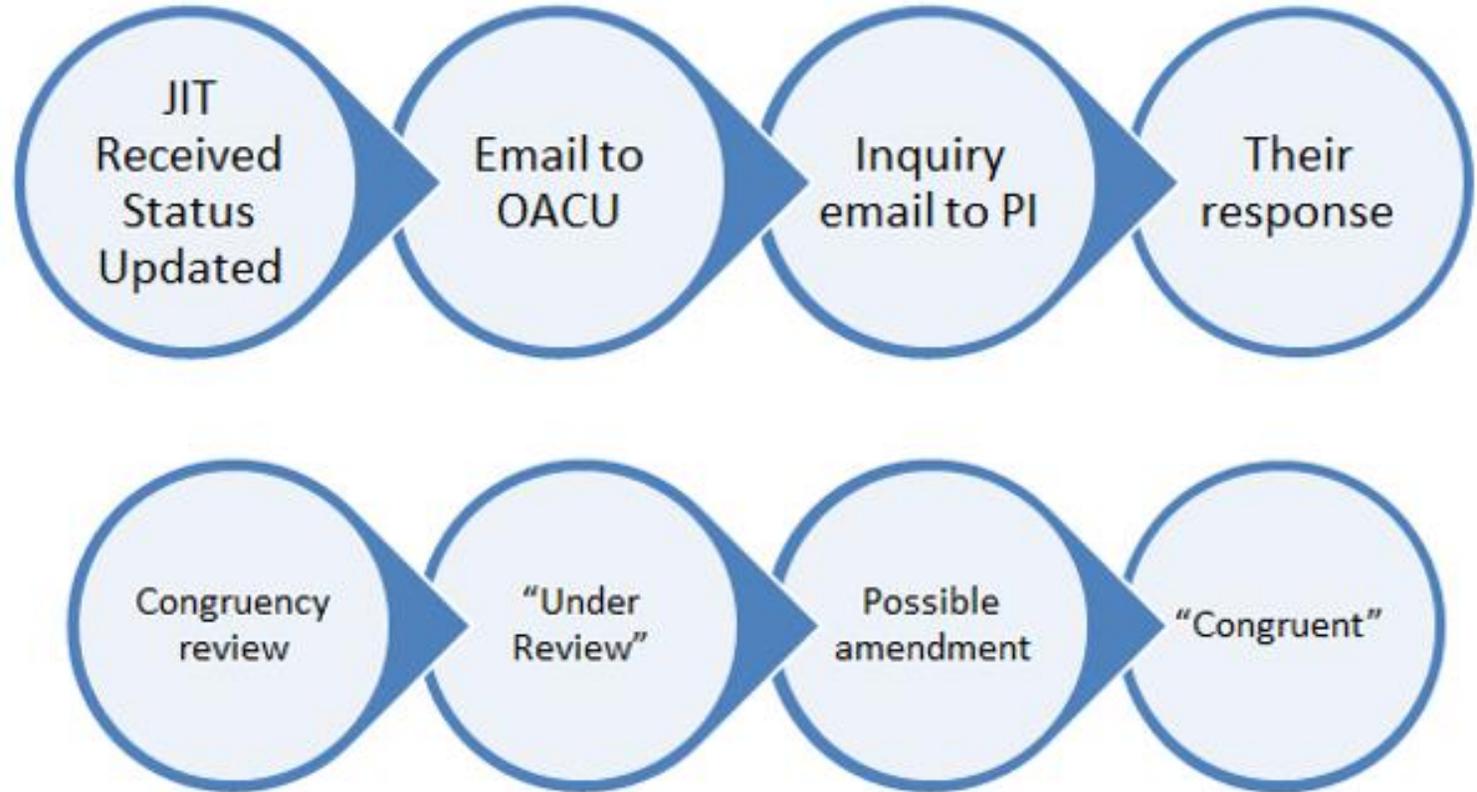
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Process



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Of Note

- The approval page \neq grant congruency. Completely separate process and approvals
- PI can access their protocol approval page in ACAP and they can provide it to funding agency who request it
- NIH has JIT = notification to OACU:
- Non-NIH = no JIT = no notice = must self request congruency review in ACAP
- Done for “New” or “Competitive Renewal” cycles



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Award Set Up

Kaylie Orlan, Sponsored Projects Specialist



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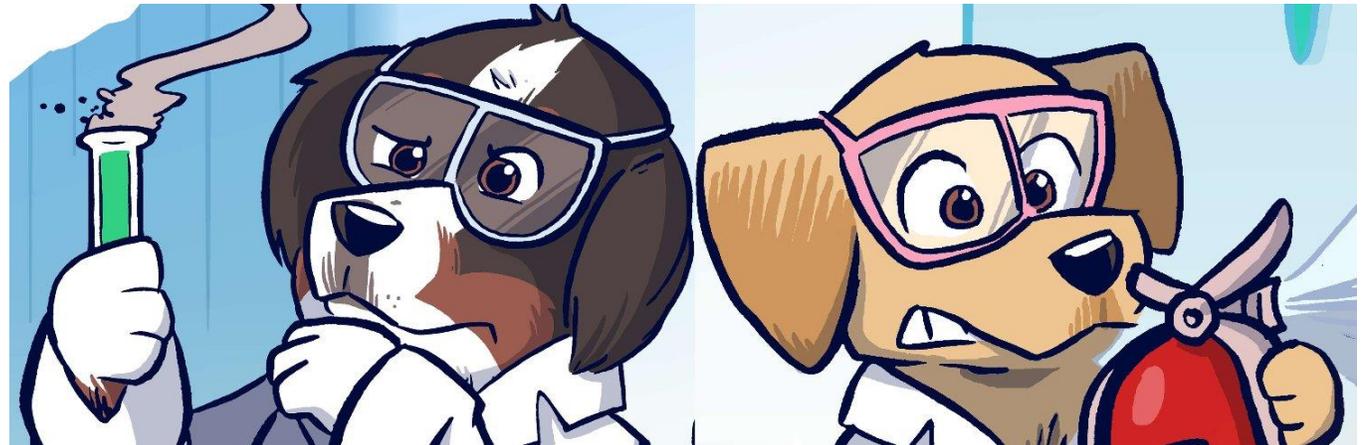
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Congratulations!

You've received an award notice!

Now what?



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Why

... do we need to be compliant?

- It's required by law as well as federal, state, and institutional policy.
- Maintaining compliance has many benefits, including enhanced animal well-being, improved quality of research, and greater advancement of scientific knowledge.
- Non-compliance can result in numerous issues, including but not limited to suspension of work, reimbursement of research funds, etc.



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Compliance

... during award set up

- The RAMSeS proposal/IPF
 - Research Subjects tab
 - Scope of work
 - Budget/budget justification
- The award
 - Does it indicate animal subjects will be involved in the project?
 - Do we need to provide the sponsor with a copy of the approved protocol now, or just as requested?
- The compliance
 - Has an IACUC protocol been approved? When is the expiration date?
 - If no, when will the animal subject research begin?



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IACUC Waiver

In special cases, a waiver (signed by the Principal Investigator and the Dean/Director) may be accepted to allow us to create the project ID prior to the approval of the IACUC protocol.

- This does NOT take the place of an approved protocol.
- No expenses may be incurred and expended for any research involving animal subjects until a valid certification of IACUC approval has been granted by the IACUC Committee and received in OSR
- Expenses must be clearly severable and independent from activities involving animal subjects
- Where you can find the draft template:
<https://research.unc.edu/files/2020/08/osr-IACUC-Waiver.pdf>



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Things To Keep In Mind

- Significant changes to previously approved protocols require IACUC review and approval; IACUC approval must be obtained before you make any significant changes to the research
- Adding animals after the fact – sponsor prior approval and IACUC approval
- Investigators, technicians, and other personnel working with animals are required to be appropriately trained and qualified
 - <https://research.unc.edu/iacuc/training/>
- Principal Investigators new to UNC or new to animal research should be directed to contact the Office of Animal Care and Use to establish the relationship between the PI and IACUC
 - <https://research.unc.edu/wp-content/uploads/sites/61/2019/10/Getting-Started-Checklist.pdf>



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Subaward IACUC Process

Amy Mabry and Rebecca Dye



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Document Review

Subaward Team Review of Documents

- If animal subjects are listed on SIP Request, the Subaward Team will also review subsite Scope of Work and budget expenditures, as well as Subrecipient Form and Letter of Intent to ensure that all documents are consistent for animal research
- We request campus departments to review these documents for accuracy as they prepare the subaward action; otherwise, there may be delays in verifying information and drafting subaward



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Modifications

Subaward Modifications

- Please include detailed notes in the SIP request should the UNC PI and/or subsite PI change Scope of Work over the project period and include or exclude animal subjects – we need email to document updates
- If animal subject research will not begin until after Yr 1 funding of Initial Subaward Agreement, indicate on SIP, as we can include notations in the subaward language
- If animal research terminates, but project will be ongoing, let our team know so change can be indicated on Subaward Amendment to subsite – provide email



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Requirements

Subaward Required Compliance Documents for IACUC Congruency

- UNC MOU (Memo of Understanding)
 - Subsite Scope of Work, Subrecipient Commitment Form, Budget justification reviewed by Rebecca Dye
- Subsite IACUC Letter indicating approval period for animal subjects research to be conducted at site
- **Without these two requirements, the Ram Tracker will be put on hold and is a hard stop for Subaward Team to fully execute subaward until compliance is met



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MOU

Memorandum of Understanding

- NIH requires it for all subawards
- UNC IACUC Requires for any animal work that is taking place outside UNC, regardless of category (subaward, contract, fee-for-service, no-cost collaboration)
- Establishes and shifts animal ownership and oversight to site conducting the work
- Subcontractor section in RAMSeS needs to be filled out



EMORY



THE OHIO STATE
UNIVERSITY



WASHINGTON STATE
UNIVERSITY



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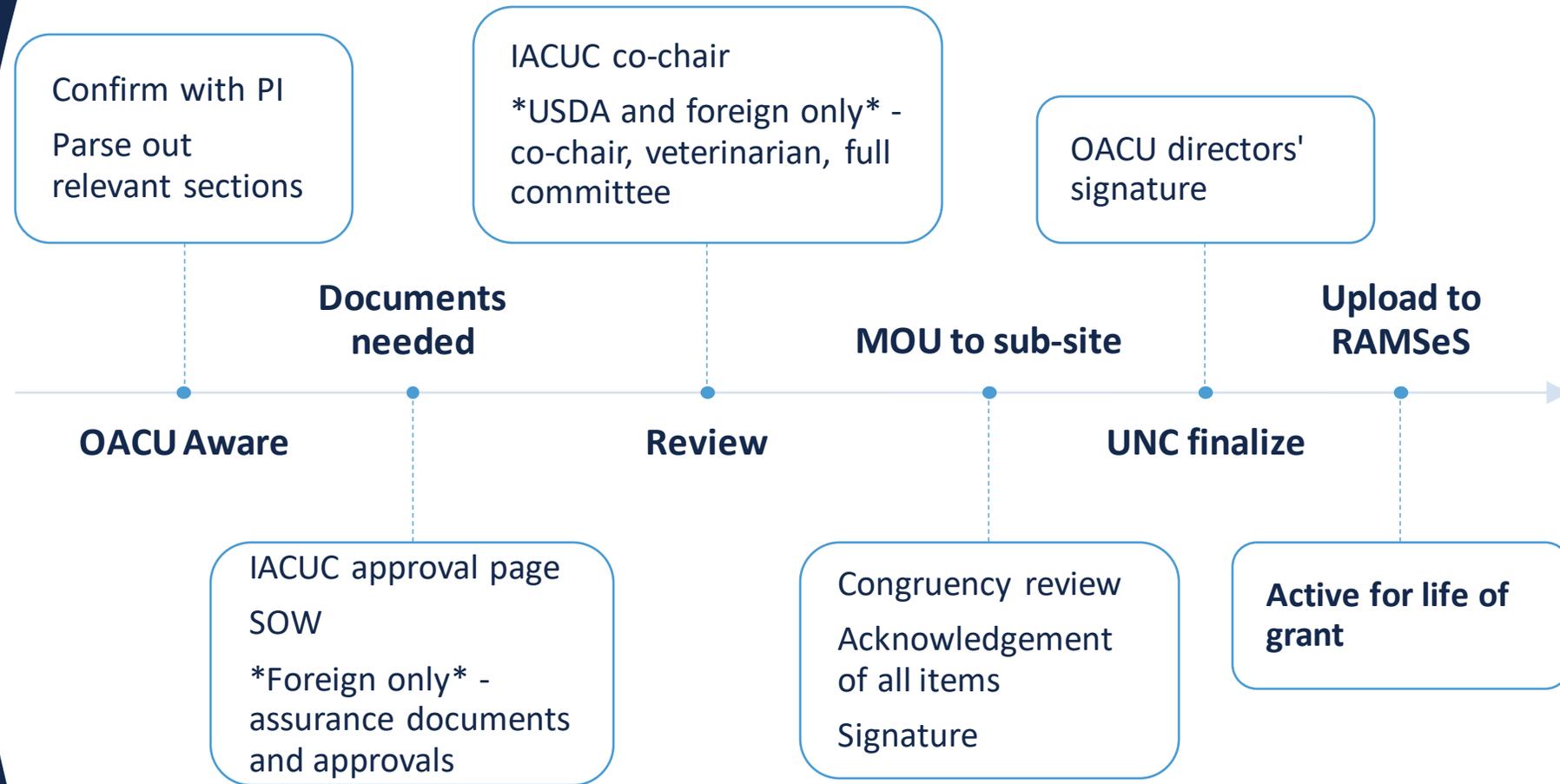
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Timeline

OACU MOU Process



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TIPS

Helpful Tips Throughout the Process

- At any point in award process, if IACUC questions arise, contact Rebecca Dye – we encourage department to be proactive in working on animal use protocol and approval before the subaward is in process to prevent delays
- Read Sponsor Notice of Award thoroughly to determine if special restrictions apply for animal research
- Ensure SIP attachments are complete and consistent, and all documentation indicates use of animal subjects, if applicable
- Reach out to SPS contact for your department and ask for assistance
- If subsite documentation is unclear, contact subaward PI or research team for clarification if animal use is not specified, but documents indicate otherwise
- As always, the Subaward Team is here to help and answer questions



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Questions?



- Is congruency approval required each time RPPRs are done?

When processing an RPPR please go to the IPF when the proposal was “new” and look under the compliance tab to confirm that the congruency review was conducted. If blank, please reach out to the Office of Animal Care and Use so that it can be investigated.

The 3 phases when congruency review is required;

- Prior to award when the proposal is “New”. It is to be done for JIT submission if a fundable score was received, or via self-request for those sponsors that do not have the JIT process.
- During a “Competitive Renewal”.
- When a “Supplement” is submitted that is proposing animal work that was not in the original grant.



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