Operational **Excellence**

Federal Research Playbook

GUIDANCE ON PRE-AWARD AND AWARD SETUP PROCESS FOR FEDERAL GRANTS & COOPERATIVE AGREEMENTS

Version 1.1
Last updated on October 17, 2019

THE UNIVERSITY *of* NORTH CAROLINA *at* CHAPEL HILL

How to use this playbook

The following pages will provide the right tools and information to complete each step of the pre-award and award setup process. By following the sample checklists (not all-inclusive) and process maps, you will take advantage of the best practices designed by research leaders across campus units and central offices, be informed on when it is necessary to engage various compliance units, and enhance the quality and completeness of the initial submission which directly impacts response time.

Disclaimer

While this playbook is meant to capture the **standard** process for federal grants and cooperative agreements, it is not all inclusive. **By thoroughly reading the RFA first,** you can likely become aware of variances in processing requirements to unique or one off situations. It is always suggested to create a checklist as a base document and add any additional special requirements listed within the RFA. Please always consult with your OSR/ SPO representative if you have questions not addressed in this playbook or if you think your situation is unique or differs from what is stated here.

Useful Acronyms To Get Started

A more comprehensive list of acronyms and definitions can be found HERE

Acronym	Term
AIR	Activities, Interests, and Relationships Management System
COI	Conflict of Interest
EHS	Environmental, Health, and Safety
EPAP	External Professional Activities for Pay
eSNAP	Electronic Streamlined Non-Competing Award Process
F&A	Facilities and Administrative
FISMA	Federal Information Security Management Act
HIPAA	Health Insurance Portability and Accountability Act
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IPF	Internal Processing Form
IRB	Institutional Review Board
JIT	Just-In-Time
LOI	Letter of Intent
NOA	Notice of Award
OACU	Office of Animal Care and Use
OCI	Organizational Conflict of Interest

Acronym	Term
OCT	Office of Clinical Trials
OHRE	Office of Human Research Ethics
OIC	Office of Industry Contracting
ORD	Office of Research Development
OSR	Office of Sponsored Research
PD / PI	Program Director / Principal Investigator
RAM Tracker	Research Award Management Tracker System
RAMSeS	Research Administration Management System & eSubmission
RFA	Request for Applications
RFP	Request for Proposals
RPPR	Research Performance Progress Report
SBIR	Small Business Innovation Research
SF424	Standard Form 424
SOW	Statement / Scope of Work
SPO	Medical School Sponsored Programs Office
SPS	Sponsored Projects Specialist
STTR	Small Business Technology Transfer

Welcome!

Research Playbooks are a new resource to help you be a successful research administrator at UNC. Playbooks will focus on specific topic areas on sponsored research and are designed to provide an experience that is informative, intuitive, and efficient.

In this playbook, you will find guidance on roles and responsibilities, process, tips and tricks, and several resources to aid in your task of working **with Federal grant or cooperative agreements**.

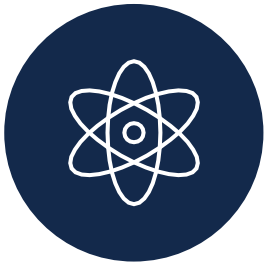
When to use this playbook

AWARD LIFECYCLE OVERVIEW

This playbook is applicable when you are dealing with a Federal grant or cooperative agreement and are at any phase from proposal conception to award setup (highlighted in light blue above).

NOTE: For projects initiated without funding for which you are now seeking funding or have received a notice with intent to fund, the sequence and timing of steps may differ from those provided in this playbook.

Table of contents



OVERVIEW

PROPOSAL CREATION

PROPOSAL SUBMISSION

COMPLIANCE SUBMISSIONS

AWARD SETUP READINESS

RESEARCH 101

ADDITIONAL RESOURCES

- OSR Information Sheet
- OSR Resources
- OSR Award Lifecycle
- OSR Forms and Tools

FREQUENTLY ASKED QUESTIONS WHEN GETTING STARTED

- **What is an IPF and why is it required?**
- A: The RAMSeS Internal Processing Form (IPF) is required for each research proposal of a grant, contract, or cooperative agreement. It is used to collect financial, scientific, and compliance information and documentation necessary for internal review and approval by OSR and/or SPO. The IPF must be certified by the PI that the questions have been answered correctly and the proposal is compliant since the IPF serves as the internal proposal of record. It is recommended that when answering the questions within the IPF form that the PI is consulted if the answer is unclear in any of the sections.

- **Q: What are the primary research systems I should learn to use?**
- A: The main research systems used for research administration purposes include RAMSeS (all research types), RAMTracker (viewing award transactions), AIR (COI disclosures), ACAP (animal care research), IRBIS (human subjects research), ALICE (industry contracts/clinical trials) and CRMS (clinical research). A list of research systems and their use may be found HERE. Agency submission systems are further elaborated on p.27-28.

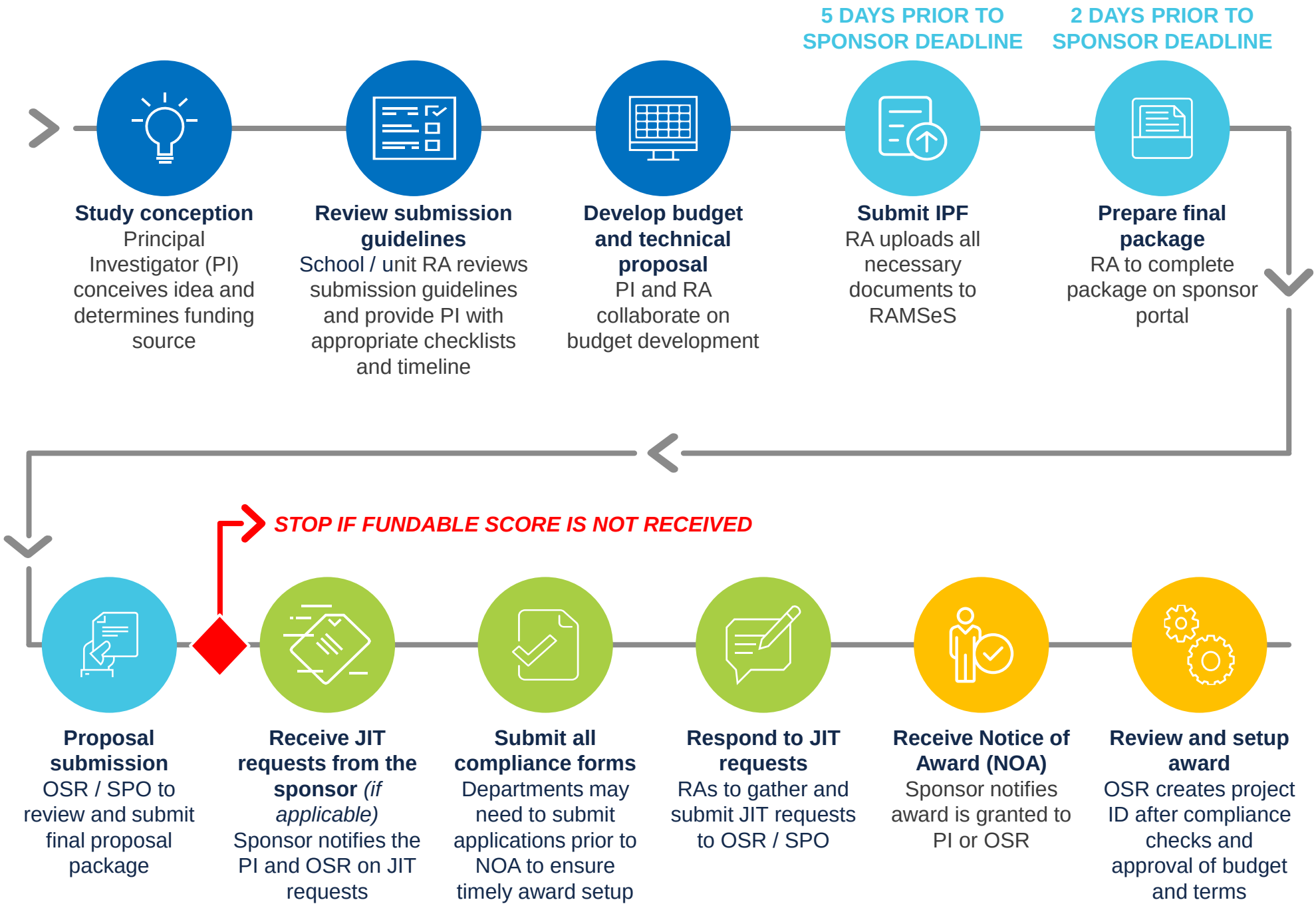
- **Q: Why does OSR require an internal budget, especially if the sponsor doesn't?**
- A: OSR requires a budget in order to appropriately load the awarded fund amounts into ConnectCarolina. The budget pool account code may be used when a sponsor does not require a detailed budget. Upon award, OSR may request assistance when a budget category is not clearly defined in the budget or budget justification to allow the department to expense to the correct account codes.

- **Q: Why does OSR require the unit to re-do a budget when faced with a temporary cut upon award?**
- A: OSR may only load the amount of funding that has been awarded. If additional funds are awarded, then they will be added to the project via a budget revision request.

OVERVIEW OF THE PRE-AWARD PROCESS

An overview of the pre-award and award setup journey for federal grants

STANDARD PROCESS FOR FEDERAL GRANTS FROM PROPOSAL CONCEPTION TO PROJECT ID CREATION



Roles and responsibilities in the pre-award process

PRINCIPAL INVESTIGATOR (PI)

- Initiates intent to submit proposal and identifies funding mechanism
- Develops the technical proposal
- Partners with the unit research administration (RA) to develop / obtain the budget, budget justification, F&A waivers, and administrative documents per sponsor guidelines
- Identify subrecipients
- Responsible for accurate compliance disclosures
- Responsible for meeting the milestones laid out in the RFA dependent upon sponsor
- Review IP, commercialization, and export control submissions prior to certification
- Certify that the questions and information submitted within the IPF and application is true, complete, and accurate to the best of their knowledge

CAMPUS UNIT RESEARCH ADMINISTRATION (RA)

- Provides PI with proposal submission guidance document customized based on sponsor RFA
- Coordinates with the PI and central / compliance offices to ensure timely pre-award submissions
- Initiates requests to central / compliance offices if assistance is required on submissions
- Prepares final proposal submission package (note: submission to sponsors is performed by OSR / SPO)
- Complete and route IPF in RAMSeS and submit other administrative components at least five business days prior to the sponsor deadline
- Partners with the PI to develop / obtain the budget, budget justification, F&A waivers, and administrative documents per sponsor guideline
- Obtain statement of work, budget, letter of intent, and other required documents for subagreements as soon as possible to not delay submission of other administrative components

Note: If your department does not have a research administrator, the above responsibilities would fall on the PI

SCHOOL DEAN / DEPARTMENT CHAIR

- Determine if proposed project is an appropriate activity for the department and supports the mission of the University
- Evaluate requests for F&A waivers
- Responsible for providing resources identified in the application, including cost sharing and reimbursement in the event the sponsor is unable to pay the University even if not in the administering department
- Approve an individual's eligibility to serve the role of PI despite part-time employment status where applicable

OSR - SPONSORED PROJECTS SPECIALIST / SPONSORED PROGRAMS OFFICE (SPO) – GRANTS ANALYST

- Provides institutional review and approval of the proposal
- Checks that all compliance requirements have been obtained prior to award setup
- Assists on questions related to eligibility, allowable costs and other administrative elements in the proposal
- Approves F&A waivers

Note: Once an award is received, all responsibilities are transferred to OSR; to find your unit's representative, click HERE

OFFICE OF RESEARCH DEVELOPMENT (ORD)

- Responsible for conducting selection process for limited submissions
- Provides consultations to faculty and researchers at the idea development, proposal planning, and proposal preparation stages

The OSR roles and responsibilities matrix from proposal preparation to project closeout as well as supporting activities can be found HERE.

Roles and responsibilities in the award acceptance and setup process

PRINCIPAL INVESTIGATOR (PI)

- Receive sponsor notification of award (NOA) and forward to department research administration (RA) and OSR
- Review sponsor agreement and provide input where necessary
- Provide approved compliance acknowledgement waiver to OSR, if applicable
- Approve any budget modifications following agreement terms and conditions, if necessary

CAMPUS UNIT RESEARCH ADMINISTRATION (RA)

- Review sponsor agreement and provide input where necessary
- Review and make budget modifications in partnership with OSR Research Administration (OSR-RA) following agreement terms and conditions, if necessary

OSR

- Review and negotiate contract terms, confidentiality agreements, and data use agreements with the sponsor
- Confirm all regulatory compliance requirements have been met by the department
- Review and make budget modifications in partnership with department RA following agreement terms and conditions, if necessary
- Accept award terms and conditions
- Complete award, project, budgets, contract, and bill plan setup in ConnectCarolina
- Notify PI and department RA of award setup via RAMSeS email; provide chartfield and Project ID(s)
- Activate the ConnectCarolina contract

The OSR roles and responsibilities matrix from proposal preparation to project closeout as well as supporting activities can be found HERE.

Roles and responsibilities in compliance submissions for funded projects

OFFICE OF HUMAN RESEARCH ETHICS (OHRE)

- Responsible for ensuring ethical and equitable treatment of all human subjects in research conducted under its auspices
- Responsible for ensuring compliance with federal regulations, state law and organizational policies
- Completes JIT/118 review and provide certification of IRB approval in principal as part of the Just-in-Time federal funding process
- *The investigator must re-submit and obtain 45 CFR 46.111 IRB approval before conducting human subjects research
- Completes initial or modification submission reviews, as activities should not begin until the reviews is completed
- Respond to questions regarding the protection of human subjects and OHRE/IRB processes and procedures

OFFICE OF CLINICAL TRIALS (OCT)

- Responsible for the Clinical Trial Quality Assurance Program, conducts routine and directed audits of clinical trials
- Responsible for Clinical Research Billing Compliance, oversees the Billing Coverage Analysis process and conducts audits of clinical trials with subject billing through the UNC Health Care System
- Ensures compliance with ClinicalTrials.gov registration and results reporting requirements
- Completes compliance checks on all clinical trials before OSR creates PS project ID

OFFICE OF ANIMAL CARE AND USE (OACU)

Also called the IACUC Office

- Provide IACUC review and approval of the animal care protocol
- Checks that all compliance, veterinary pre-review, hands-on training and lectures, Environmental, Health and Safety (EHS) requirements, Institutional Biosafety Committee (IBC) approvals have been obtained prior to animal use protocol approval
- Conducts a comparison of the grant application with the approved animal care protocol to ensure congruency
- Ensures that the animal care protocol has been amended to address incongruencies between the grant and the protocol

ITS - DATA SECURITY

- Provides: review of information security requirements of the proposal; guidance to researchers and IT support staff for completing risk assessment documentation required in proposal; templates and guidance for completing System Security Plans required in the proposal
- Provides expertise in information security to assist researchers with designing a safe environment for their data

CONFLICT OF INTEREST (COI) PROGRAM

- Provides University's COI training, project-specific disclosure, and review process in compliance with federal law, state regulations, and university policies
- Along with school-based committees, ensures individual project-specific COI review, management plan, and reporting to sponsor before award funding can begin (PS Project ID setup). With schools, implements monitoring oversight for investigators
- Conducts organizational COI and reports as required by sponsors either upon proposal or award, per project
- Supports Institutional COI Committee which reviews projects, with an emphasis on human studies, involving University-owned licensed Intellectual Property and/or a faculty start-up company

EXPORT CONTROL

The Export Control Officer will review and assist as necessary for proposals and awards that may include any of these transactions or activities:

- Shipping (including plans to hand-carry) equipment, items, samples, or controlled data to an international destination or foreign end-user
- Traveling internationally for actually or potentially controlled, restricted, or sensitive activities, programs, or efforts
- Receiving controlled data, materials, or research samples for use in sponsored research projects
- Agreements that include publication or foreign national restrictions
- Collaboration with a foreign institution, person or entity
- Providing foreign nationals with access to actual or potentially controlled items or information
- Participating in any transactions or activities involving sanctioned countries such as Cuba, Iran, North Korea, Sudan, and Syria

PRIVACY

- Responsible for the general oversight and compliance will all applicable laws, regulations and policies that govern privacy related activities
- Responsible for monitoring compliance with federal and state privacy regulations as well as general industry privacy standards for the use and/or retention of restricted or sensitive personal identifiable information by the university
- Responsible for investigating and reporting privacy violations to the appropriate authorities
- Responsible for providing the university response to complaints of privacy violations in the conduct of University research
- Assists the IRB in resolving human subjects research review or performance issues related HIPAA privacy regulations
- Provides assistance to Covered Entities in obtaining information required for their compliance with HIPAA regarding UNC-Chapel Hill research access and use of PHI in the Covered Entities' designated record sets
- Serves as the University's contact person for all patient requests for further information regarding research projects listed in an accounting of disclosures of the patient's PHI

Cheat sheet on submissions to the major federal sponsors (1/4)

The 9 federal sponsors listed below receive the greatest number of proposals from UNC in fiscal year 2018. For the latest and most comprehensive information on federal grant making agencies, please refer to Grants.gov

Major Sponsor	Distinct items the sponsor asks for in proposal submissions	Useful links / checklists
National Institutes of Health (NIH)	▪ Ensure eRA Commons ID (only one active ID) in the R&R Sr/Key Person profile matches the information listed in Commons. If there are multiple active IDs, delete additional IDs. ▪ Use legal names in the R&R Sr/Key Person profiles ▪ Biosketches should only have active link to publications ▪ NIH documents should not have headers or footers ▪ RPPRs should address the reduction in effort of key personnel listed on NIH Notice of Award. This applies to change of effort of 25% or more that was approved at the time of the initial competing year award ▪ For fellowships make sure current stipend level is being used ▪ Project Summary/Abstract attachment is limited to 30 lines of text. ▪ Project narrative attachment should describe the relevance of this research to public health in, at most, three sentences. ▪ There are two primary types of Budget Forms: detailed R&R and PHS 398 modular. Generally, you must use the R&R Budget Form if you are applying for more than $250,000 per budget period in direct costs, and you must use the Modular Budget Form if you are applying for less than $250,000. ▪ If you are requesting a budget with $500,000 or more in direct costs for any budget period, contact the awarding component to determine whether you must obtain prior approval before submitting ▪ NIH uses a salary cap so involved departments will need to cost-share the difference	▪ Tips on how to write your application ▪ Grants.gov alerts ▪ NIH quick links ▪ Roles and responsibilities at the NIH ▪ NIH Proposal Checklist ▪ RO1 Checklist ▪ RO1 RPPR Checklist

National Science Foundation (NSF)	▪ If you are submitting a Collaborative Proposal, state in the submission notes if UNC is the lead/non-lead
	▪ A broader impact statement is required
	▪ Make sure biosketches are NSF format:
	  ▪ 2 page limit
	  ▪ 10 citations (5 closely related, 5 other)
	  ▪ 5 Synergistic activities
	▪ Current and pending effort for all NSF projects should not exceed 2 calendar months
	▪ Give at least view access for OSR in Fastlane
	▪ References Cited must include the names of all authors (et al is not allowed)
	▪ Fill out the Collaborators & Other Affiliations (COA) template which is used during the merit review process
		▪ Proposal and award policies
		▪ COA template and information

Cheat sheet on submissions to the major federal sponsors (2/4)

The 9 federal sponsors listed below receive the greatest number of proposals from UNC in fiscal year 2018. For the latest and most comprehensive information on federal grant making agencies, please refer to Grants.gov

Major Sponsor	Distinct items the sponsor asks for in proposal submissions	Useful links / checklists
Department of Defense (DOD)	▪ Requires pre-proposal that is submitted via eBRAP ▪ If accepted to submit a full proposal, the PI will receive an email with a specific federal identifier number that goes on the SF424 application cover page under 4.a.Federal Identifier ▪ Attachments must be PDF file and named specifically per guidelines ▪ Credential log in on the Research & Related Senior/Key Person Profile should be the PI's eBRAP log in and not era commons ▪ Requires other support at time of proposal- very specific guidance on what should be included: previous (award performance ending within 5 years), current, pending research support ▪ DOD does have a specific biosketch form, but they allow the NIH biosketch form ▪ Other Supports are required at time of submission. Start working on these as soon as possible because they require more detail than a standard NIH Other Support (see attached template). Note that prior awards over the last 5 years need to be included. ▪ No salary cap, unless stated in the RFA ▪ Strict formatting requirements (typically Times New Roman, 12 point font, no headers/footers, no page numbers, no hyperlinks). Confirm with RFA. ▪ Review RFA to confirm submission system – some require the use of Workspace instead of Cayuse ▪ For individual or total materials and supplies costing $5,000 or more per year, an additional breakdown and vendor quotes are required to be included in the budget justification. Additionally, provide a detailed breakdown of travel costs (location, lodging, per diem, airfare, etc.). ▪ For Partnering PI proposals, if the Partnering PI is at another institution, a subagreement will not be needed. The other institution will receive an award directly from DOD. This also applies if a UNC faculty member is the Partnering PI and the Initiating PI is at another institution. We do not need to submit a subagreement package to the other institution, but RAMSeS and Cayuse/Workspace submissions will be required	▪ eBRAP (portal) ▪ DOD general applications instructions ▪ eBRAP program and user guide ▪ DOD information ▪ DOD Other Support Template
Department of Energy (DOE)	▪ Guidelines vary by Funding Opportunity Announcement (FOA) ▪ SF-LLL Disclosure of Lobbying Activities Form required when applicable	▪ Funding and Financing

Cheat sheet on submissions to the major federal sponsors (3/4)

The 9 federal sponsors listed below receive the greatest number of proposals from UNC in fiscal year 2018. For the latest and most comprehensive information on federal grant making agencies, please refer to Grants.gov

Major Sponsor	Distinct items the sponsor asks for in proposal submissions	Useful links
Agency for Healthcare Research and Quality (AHRQ)	▪ Project Summary/Abstract attachment is limited to 30 lines of text. ▪ Project narrative attachment should describe the relevance of this research to public health in, at most, three sentences. ▪ There are two primary types of Budget Forms: detailed R&R SF 424 and PHS 398 modular. Generally, you must use the R&R Budget Form if you are applying for more than $250,000 per budget period in direct costs, and you must use the Modular Budget Form if you are applying for less than $250,000. ▪ If you are requesting a budget with $500,000 or more in direct costs for any budget period, contact the awarding component to determine whether you must obtain prior approval before submitting ▪ AHRQ proposals require the use of the detailed R&R budget. ▪ Salary escalation is not allowed per policy found HERE	▪ AHRQ funding announcements ▪ HHS grants policy statement ▪ AHRQ homepage
DHHS Health Resources and Services Administration (HRSA)	▪ PI must grant access to the unit RA and OSR SPS's for each grant ▪ The award for a continuation year is usually awarding the money as a lump sum and awardees are required to submit a revised SF 424 A, Line Item Budget and Budget Justification (within 30 days of budget start date) ▪ If project works with Human Subjects – NOA will request awardees to submit documentation of IRB approval or exemption within 120 days of budget start date ▪ Reminders are sent to grantees when the annual performance report is available in EHB, and the campus unit can begin working on it	▪ HRSA funding opportunities ▪ Electronic handbook (EHB) knowledge base and FAQs ▪ Manage your grant ▪ How to manage your grant ▪ HHS grant policy statement
National Aeronautics and Space Administration (NASA)	▪ Guidelines vary by Program Solicitation	▪ NSPIRES - NASA solicitations

Cheat sheet on submissions to the major federal sponsors (4/4)

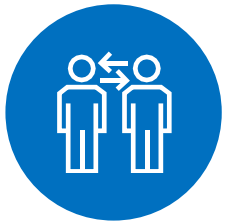
The 9 federal sponsors listed below receive the greatest number of proposals from UNC in fiscal year 2018. For the latest and most comprehensive information on federal grant making agencies, please refer to Grants.gov

Major Sponsor	Distinct items the sponsor asks for in proposal submissions	Useful links
Centers for Disease Control and Prevention (CDC)	▪ CDC proposal solicitations should be read very carefully to ensure they are submitted to the correct portal. Many of the solicitations now require submission through ASSIST. Some applications still require submission through Grants.gov so it's important to check this first. ▪ Any post award actions that need to go to CDC such as prior approval requests such as budget revisions, no cost extensions, or change in PI requests must be submitted through ASSIST. CDC will no longer accept any prior approval requests through email. ▪ When CDC has decided to award a project, they will often send an email to ResAdmin and the PI requesting a phone conference at a certain date and time to go over specific aspects of the award. This email usually gives specific information on what all parties should be prepared to discuss during this call. Most times the information is technical in nature. ▪ CDC often places restrictions on the Notice of Awards once they are issued. They will also often request a revised budget at the time of award. All of these things must be submitted via ASSIST as well. ▪ An example of a common restriction from CDC is withholding a certain amount of money until the IRB approval is received. In this case the IRB Approval must be submitted via ASSIST. The approval would be uploaded to the research strategy section in ASSIST.	▪ How to submit a prior approval request ▪ Application Resources
Department of Education (DOED)	▪ **Funding Mechanisms for** grants: 3 different types – Discretionary, Formula, and Block ▪ **Project ID Request Form Guidance:** ▪ Terms & Conditions: Uniform Guidance (2 CFR Part 200) - Note: Title 34, Code of Federal Regulations (CFR), Parts 75-79, 81 to 86 and 97-99 EDGAR is currently in transition. For awards made prior to 12/26/2014, EDGAR Parts 74 and 80 still apply. For awards made on or after 12/26/2014, 2 CFR Part 200, which includes the substance formerly in parts 74 and 80, applies. ▪ Budget Revision Allowability: 005 - The written authorization of the Project Officer is required for certain budget revisions described in 34 CFR 74.25 ▪ Budget/Project Period: Funding issued on an annual basis – project period can span for several years (typically 3-5 years) ▪ Interim Financial Reports: Annual Grant Performance Reports required (see section below) ▪ Final Financial/Technical Report: Due within 90 days after the expiration or termination of grant (see section below) ▪ Invoice Frequency: Letter of Credit – OSR Cash Management will draw down funds via the Payments module in the G5 system. ▪ Expanded Authority: Blank ▪ Automatic Carryover: New project IDs are not required each year.	▪ DOED grants information

6 ways to expedite submissions and the award setup process

Review the Request for Application (RFA) and specific agency guidelines

- Create a checklist that defines RA and PI responsibilities including a timeline for PIs on proposal creation based on RFA
- Review the RFA for unusual cost sharing requirements or compliance language (e.g., foreign travel language can imply export control limitations); for specific keywords to look for, see p.20

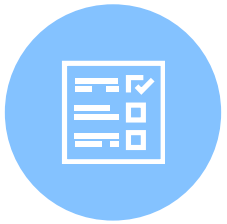


Collaborate with your PI often, especially during proposal creation

- A high quality proposal submission requires faculty input on the budget and proposal development
- Faculty input will likely be required in certain fields in the IPF, so ask these questions to your PI early

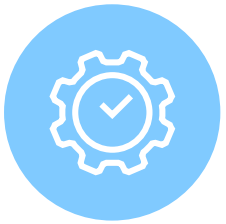
Contact your OSR / SPO representative early in the pre-award process

- Notify OSR / SPO as early as you can when you know the PI has the intent to submit, especially if certain keywords are identified in the RFA / proposal guidelines (see p.20)



Start gathering documents for JIT once requests are received

- Agencies often require a tight turnaround time for JIT requests (can be as little as 3-4 days)



Start compliance applications as soon as JITs are submitted

- IRB and IACUC applications can take >2 months to complete, especially if a full board review is required

Always read the terms and conditions in the NOA

- Agreement terms listed in the NOA can be different from the one stated in the RFA (e.g., budget reductions, added restrictions, etc). Make sure the PI is clear of these changes

STAGES IN THE PRE-AWARD PROCESS

PROPOSAL CREATION – Process deep dive

Responsible party

Timeline

PI

Study conception

Determine funding mechanism / source

Note: May include feasibility analysis

Notify Department RA on intent to submit

Please follow internal school / unit deadlines

Develop technical proposal

Department RA

Review RFA and provide guidelines to PI for proposal creation

- *Guidance on p.20*
- *Example guidelines for NIH proposals included on p.12*

Develop proposal alongside PI (Department RA to focus on administrative and budget requirements)

Checklist on p.21-22

OCI disclosure triggered by department RFA review

PROPOSAL CREATION

ADDITIONAL RESOURCES

- OSR resources on funding sources
- Grants.gov
- OSR proposal creation guidelines
- SPO Tools
- Guidance on Subrecipient vs. Vendor and Subrecipient vs. Contractor
- Budget development SOP
- Grant writing tips from the Writing Center
- OSR definitions
- Sample email to subrecipient

TIPS TO ACCELERATE THE PROCESS

- **As soon as possible, read and ensure understanding of RFA**
- **Create customized checklist for Proposal Creation based on RFA**
- **Identify circumstances that require additional attention earlier on in the proposal process** (e.g., subrecipients, export control and compliance, large procurements, F&A waivers, cost share) and incorporate into checklist
- **As needed, schedule a call / meeting with your OSR / SPO** to review and customize the checklist for the Proposal Package. This provides your PI with accurate and timely information. Send your checklist to OSR / SPO ahead of the call
- Check **PI eligibility** per UNC policy HERE
- **Create and share with PI a timeline of activity**, with internal deadlines, starting with **Proposal Creation** and running through **Proposal Submission**
- **Determine responsible parties for each element of the proposal** (e.g., for when multiple PIs work on one proposal simultaneously)
- Understand and adhere to **version control** and file storage processes in place for documents (e.g., budgets, budget justifications, research strategy, etc.)
- Confirm you are **using the most up to date rates for budgets** (e.g., Salary Cap, Fringe Rates, Tuition Fees, Faculty Salaries, etc.)
- If any **OCI language is identified in the RFA**, **contact your SPS and the COI office immediately**. (For specific keywords to look for, see p.20.) OCI approval is almost always required prior to proposal submission for federal agencies that seek OCI disclosure
- If subagreement(s) are involved**, connect with the business manager of the subrecipient(s) as early as possible**. A sample email can be found under the “ADDITIONAL RESOURCES” section on the left. **Cross-check the addition of subagreement budgets** to ensure they **match with the justification dollar amounts and the total dollar amount proposed** to the agency

FREQUENTLY ASKED QUESTIONS

- **Q: How do I determine if someone should be a subrecipient, vendor, or a consultant?**
- A: See OSR guidance on Subrecipient vs. Vendor and Subrecipient vs. Contractor under the “ADDITIONAL RESOURCES” section.
- **Q: What is the Research Administrators role in developing the technical proposal?**
- A: It depends on department and PI; could range from no responsibility to coordination of technical proposal

GUIDANCE ON KEYWORDS TO LOOK OUT FOR IN RFAs

Topics	Keywords in RFA	Guidance
Limited submission	▪ Limited submission	▪ Route your submission through the Office of Research Development; details HERE
Organizational Conflict of Interest (OCI)	▪ Unequal Access to Information ▪ Biased Ground Rules ▪ Impaired Objectivity	▪ Reach out to your OSR / SPO contact and UNC COI office (coi@unc.edu)
Individual COI	▪ Financial COI ▪ Personal COI	▪ Same as above but go straight to COI ▪ Review information on research.unc.edu/COI
PI eligibility	▪ PI eligibility	▪ Review policy HERE; for any related questions, contact your OSR / SPO contact
Budgeting *(For additional keywords, see p.22)*	▪ Direct Limitations / Indirect Rates ▪ Modified Total Direct Cost (MTDC) vs Total Direct Cost (TDC) vs Total Project Cost (TC) ▪ Patient Capitation or Patient Care Costs	▪ Reach out to your OSR / SPO contact
Research data	▪ Data management plan ▪ FISMA ▪ Controlled Unclassified Information (CUI) ▪ NIST 800-171 ▪ Covered Defense Information (CDI) ▪ Publication Restrictions	▪ Reach out to your OSR / SPO contact
Foreign influence / interference	▪ Foreign influence / interference	▪ Reach out to your OSR / SPO contact
Export control	▪ International Traffic in Arms Regulations (ITAR) ▪ Export Administration Regulations (EAR) ▪ NIST 800-171 / 800-53 / 800-173 ▪ ISO 27002 ▪ Data Security ▪ Data Share ▪ Data protection ▪ Safeguarding ▪ Information systems ▪ Privacy ▪ Access Control ▪ Risk vulnerabilities ▪ Security Assessment ▪ Controlled Unclassified Information ▪ Processes, stores, transmits information ▪ Cybersecurity	▪ Contact your OSR / SPO contact if you see any of the keywords on the left

SECTIONS REQUIRED FOR IPF SUBMISSIONS IN RAMSeS

Please review the comprehensive list of items to include in the IPF for submission in RAMSeS on this webpage. If you notice items that are unique about any of the components (e.g., per page X in guideline, no budget is required), please mention them in the IPF notes.

Tip: Some units use an intake form to gather the required information ahead of time when meeting with the PI. An example intake form for NIH grants can be found HERE

Major components in the IPF and tips for submission

General Information	▪ If you have questions about the dropdown options and option descriptions under activity type / chess code, reach out to your OSR / SPO representative for guidance. ▪ The research team must include individuals named on the budget, as well as administrative contacts and investigators whose research protocols (human and animal) may be used on the project (if applicable)
Personnel	▪ The first role that MUST BE entered is the Lead Principal Investigator ▪ Fellows, postdocs, or graduate students submitting grants must list the PI as the mentor in the IPF
Regulatory Compliance	▪ No funding may be used for human / animal subjects until the appropriate approved protocols are in place ▪ If human / animal subjects are involved and no submission to IRB / IACUC have been made, indicate one of the two options: – JIT: (Just in Time processing) Note that the JIT status will need to be selected once OSR is notified that funding/award is imminent – Not Submitted
Budget	▪ Cost share: All cost sharing must be documented in accordance with established criteria. The Lead PI and his/her Department Chair must concur with and commit to any cost shared resources ▪ Are you requesting the Vice Chancellor for Research provide funds to support this proposal? Please indicate whether this proposal commits the University (not the Department/Institute) or a subrecipient to provide cost sharing or cash matching in support of this project
F&A Sharing	▪ At this time, the “F&A Sharing” tab on the IPF is strictly for documentation of departmental F&A recovery. All departments are strongly encouraged to revisit and review their internal processes for routing and approving IPFs when the project involves a Lead PI and collaborating Co-PI(s) from different home departments.
Intellectual Property	▪ If your proposal is an SBIR of STTR, please see the Office of Technology Commercialization for more information
Other Categories	▪ Export control, subrecipients, community engagement, location of sponsored activities, application abstract, approving departments, and attachments (see p.26 in the PROPOSAL SUBMISSION chapter for details)

GUIDANCE ON COMMON BUDGET DEVELOPMENT TOPICS

For more information on how to create a budget and helpful calculations, see attached HERE and HERE

Topics	Guidance
Tuition & Fees	▪ Consult this webpage for guidance on student fees allowable
GShip	▪ Consult the Finance website to identify current and up to date Yearly Rate
Salary Caps	▪ Consult this webpage for latest information on salary caps for PHS funded agencies. Additional information can also be found HERE ▪ Refer back to RFA for sponsor specific Salary Caps
Fringe Rate	▪ Consult the UNC Research Information Sheet webpage for latest information on Fringe Benefits information
9 vs. 12 month appointments	▪ Consult this webpage to obtain latest operating standards around 9 vs. 12 month appointments
Equipment	▪ Equipment includes items with a useful life of two or more years and an acquisition cost of $5K or more per item or aggregate component parts ▪ For significant (expensive) equipment purchases, contact Asset Management to run an inventory search for current availability on campus. If it does not, ensure a robust budget justification. Budget should also consider ongoing (maintenance) and setup costs within the budget ▪ See HERE for additional information regarding equipment and Uniform Guidance. Also, see UNC Policy for more information
Travel	▪ Understand if project will have any restrictions around travel and notify Export Control ▪ If foreign travel is required, ensure it is well justified in the budget
Modular vs. detailed budget	▪ Whether a modular or detailed budget is requested by the sponsor, a detailed budget is required for OSR submission
Indirect rate	▪ Ensure use of proper indirect rates when building budgets – depends on factors like Location, Type of Award, Sponsor, etc. ▪ Additional information can be found HERE
Subrecipients vs. Consultants vs. Suppliers/Vendors	▪ See OSR guidance on Subrecipient vs. Vendor determination in “ADDITIONAL RESOURCES” section in PROPOSAL CREATION chapter
Effort	▪ Ensure PI has capacity to execute requirements of research outlined in the proposal and meets min. RFA reqs ▪ Translate effort into weekly hours to ensure effort estimated can be reasonably be accomplished (see UNC Policy for calculation information) ▪ There is a 1% minimum effort requirement for Lead PI’s (see HERE for more information)
Incentives/ Subject Payments	▪ Ensure they are reasonable, allowed and outlined in the budget justification for consideration ▪ Ensure any subject payments or incentives avoid undue inducement or coercion to participate in research ▪ Consult the following links for more information on: Payment to research subjects, Collection of SSN for payment purposes, and Recruitment incentives
Other special circumstances	▪ This includes things like buying food for focus groups, lodging, parking, etc. ensure they are reasonable, allowed and outlined in the budget justification for consideration; note that THESE EXPENSES ARE RARELY ALLOWED ON A GRANT OR CO-OPERATIVE AGREEMENT
Inpatient / Outpatient costs	▪ Federal grants typically cannot pay for anything that is standard of care
Participant support costs	▪ Participant: the recipient of a service or training associated with a workshop, conference, or other short-term instructional or information-sharing activity (e.g. may include students, scholars, scientists, private sector or state / local government individuals) ▪ Uniform Guidance states that participant support costs are typically exempt from F&A on federally sponsored projects
Services	▪ For services that exceed $5,000, a quote is required when non-UNC services are procured outside ▪ Effort for services in the core should not be included in the budget
Hospital Employees	▪ To learn more about hospital employees as research staff, consult the webpage HERE
Billing coverage analysis	▪ A Billing Coverage Analysis is required to be performed prior to the initiation of the clinical trial to ensure proper billing of services and financial feasibility, see link HERE

PROPOSAL SUBMISSION – Process deep dive

For more guidance on the requirements of compliance offices (e.g., IRB, OCT, IACUC, etc.), please see the "Compliance Submissions" chapter starting on p.29.

Responsible party

Timeline

5 business days prior to deadline

2 business days prior to deadline

Department RA

Proposal developed

Submit IPF in RAMSeS

Prepare final administrative package in sponsor portal

Submission system details on p.27-28

Approve IPF by administering department[1]

COI disclosure triggered

Prepare final proposal package in sponsor portal (add technical component)

Notify OSR / SPO that final package has been uploaded

OSR / SPO

Perform initial review on submitted content

Perform final review; approve and submit proposal to sponsor

Pause until sponsor responds

1 If multiple campus units are involved and other departments do not certify the IPF within 2 business days prior to the sponsor deadline, the IPF will be automatically routed to SPO / OSR; Proposals not submitted 5 business days prior to the sponsor deadline will be flagged for "Expedited review" where only the final review (and not the initial) will be performed at SPO / OSR

PROPOSAL SUBMISSION

ADDITIONAL RESOURCES

- Proposal submission deadlines
- Using RAMSeS for proposal submission
- Institutional information
- Pre-submission compliance requirements
- Guidance on Subrecipient vs. Vendor and Subrecipient vs. Contractor
- PI eligibility policy

TIPS TO ACCELERATE THE PROCESS

- Check ahead of time **which electronic system is used for proposal submission and ensure access** to the agency (see p.27-28 for details)
- F&A sharing is applicable for personnel with the following roles in the RAMSeS IPF: Lead Principal Investigator, Principal Investigator, and Investigator. If F&A sharing should not apply to a key personnel, denote this by assigning the role of Other Key Participant.
- OSR / SPO submits the final application to the sponsor in most cases; however, **always check the "submission note" tab in the IPF for who is the final submitter**
- **Attach the subaward package at the point of IPF submission**
- For PI eligibility, the University requires a minimum of 1% effort for 1 effort period either directly charged or provided as pre-approved cost share on most sponsored projects; however, the **1% effort does not apply to PIs who have strictly mentoring roles for training grants.** For more information on University policy, click here
- Gather the **name and email address of the consultant** for COI disclosures and submit letter of support prior to IPF submission
- If you **list someone as a consultant**, be prepared to **answer the following 4 questions at IPF submission**:
  1) Did this person substantially contribute to the design of the study?
  2) Is this person conducting any experiments or activities?
  3) Is this person directly involved in or have control over the collection of data?
  4) Is this person involved in the analysis of the data?
- If the **study involves human / animal subjects, radioactive / hazardous chemicals / biological materials, subagreements, or use of materials by the sponsor or any other party**, correspond with your PI ahead of time so you are prepared to **answer additional questions at IPF submission** in RAMSeS (see p.21 attached file for details)
- A **UNC employee cannot be a consultant** while employed or up until 1 year after ending employment. This policy is applicable to all UNC System institutions, however other state entities may have their own requirements.
- If your study **involves any activities that include Human Subjects** (e.g., interaction, intervention, data analysis of identifiers), check the **"Human Subjects" checkbox in the IPF.** If you study involves **human tissue work**, please contact OHRE to determine if the "Human Subjects" checkbox should be checked.
- If your study **involves animal tissue work**, **please contact IACUC office** to determine if you need to check the "Animal Subjects" checkbox in the IPF. If your study **involves any animal work that will take place outside of UNC**, subaward or otherwise, please contact the OACU.
- If your study involves **any animal work that will take place outside UNC**, subaward or otherwise, please contact the IACUC office
- If your unit is part of a **multi-site study** that involves **human subjects work** and **UNC is the sub awardee**, a **Letter of Support from the IRB at UNC may be required (check the RFA and with the Prime site for requirements)** at the proposal submission stage.

PROPOSAL SUBMISSION

ADDITIONAL RESOURCES

- Proposal submission deadlines
- Using RAMSeS for proposal submission
- Institutional information
- Pre-submission compliance requirements
- Guidance on Subrecipient vs. Vendor and Subrecipient vs. Contractor

FREQUENTLY ASKED QUESTIONS

- **Q: Why is the following question on international activity added to the IPF submission, and what are the implications for answering "Yes": "Will the proposed project involve activities primarily focused outside of the United States?"**
- A: Your answer to this question helps the University better support faculty and reduce institutional liability overseas. For all questions concerning this question, please contact globaloperations@unc.edu

- **Q: How do I get access to the electronic systems for proposal submission to the sponsor?**
- A: Please refer to p.27-28 that contains the list of major systems used for federal sponsors, user tips, and useful resources.

- **Q: What is the minimum on PI effort reporting, and are there exceptions?**
- A: For PIs, the University requires a minimum of 1% effort either directly charged or provided as pre-approved cost share on most sponsored projects. Typically, it will be more. PIs must commit and expend at least 1% effort during at least one effort reporting period of performance to accurately reflect their leadership of the project and meet this requirement. If there are multiple Principal Investigators, at least one listed PI assuming responsibility for the scientific and administrative direction of the project during a given effort reporting period of performance must fulfill the 1% commitment.

- **Q: What are the requirements for PI eligibility?**
- A: TBD until UNC policy is clarified.

- **Q: In what circumstances do PIs or department research administrators submit the proposal in the sponsor portal?**
- A: The submitter is typically specified in the RFA. If it is unclear, please consult your OSR / SPO representative. ALL proposals must be submitted to OSR / SPO regardless of whether the department ends up being the submitter.

PROPOSAL SUBMISSION GUIDANCE AND DEADLINES

5 business days prior to sponsor deadline

Proposal attachments

- ❑ Internal Budget
- ❑ Budget Justification
- ❑ Proposal application with all final sponsor portal attachments (listed on the right) and drafts of the technical components (listed below)
- ❑ Provide access to your proposal in one of two ways:
  - ❑ Upload application if you are using a grants.gov downloaded from their website; or your application is being submitted in hardcopy.
  - ❑ Allow access to Proposal application if using agency web portal to prepare and submit application. (e.g., Cayuse, NSF Fastlane, NASA NSpires)
- ❑ F&A waiver request (as applicable)
- ❑ PI waiver form (as applicable)
- ❑ Subagreement proposal documents (as applicable):
  - ❑ LOI signed by an authorized signing official of the sub's institution
  - ❑ SOW
  - ❑ Budget
  - ❑ Budget Justification
  - ❑ Note: If using PHS 398 forms - a checklist would be needed
- ❑ Agency guidelines for the submission

Sponsor portal attachments

- ❑ Biosketches (Training Grants: Mentor biosketches due 2 days before.)
- ❑ Sponsor's Budget
- ❑ Final Budget Justification
- ❑ Letters of Commitment for In-Kind/Cost-share or Matching Support (as applicable)
- ❑ Certs and Reps (as required)
- ❑ Current and Pending Support (as required)
- ❑ Data Management Plan (as required)
- ❑ Facilities, Equipment and Other Resources (as required)
- ❑ Letters of Reference (as required)
- ❑ Letters from Consultants (as required)
- ❑ Other supplemental docs - vendor price quotes, fee for service documentation (if using an external agency), management plans, etc. (as required)
- ❑ Other administrative/business or regulatory documents requested by the sponsor for this specific proposal per the guidelines for this submission (as required

2 business days prior to sponsor deadline - final

Technical components

- ❑ Abstract
- ❑ Project Description/Science
- ❑ References Cited
- ❑ Sections on Human and Animal Subjects (as applicable)
- ❑ Human Subjects – recruitment plans (as applicable)
- ❑ Other items regarding the technical/scientific aspects of this proposal per the guidelines for this submission (as required)
- ❑ NIH RPPR: Draft RPPR due at this time

Other items

- ❑ Final completed application package that is ready to submit
- ❑ Training grants: Mentor biosketches and tables due at this time

For more information, please consult the OSR Operating Standards and Procedures

GUIDELINES ON MAJOR SYSTEMS USED FOR FINAL PACKAGE SUBMISSION

Major submission systems	Applicable federal sponsors	User tips	Useful links
ASSIST *(most preferred[1])*	▪ **NIH** ▪ **AHRQ** ▪ **CDC** ▪ **FDA** ▪ **SAMHSA** ▪ **VA**	▪ Pre-populates data from investigator's eRA Commons profiles ▪ When copying an application, make sure you have the correct attachments uploaded into the new application ▪ Multiple users can edit the proposal at the same time, just not the same page ▪ Does not interface with CAYUSE or Workspace ▪ Do not necessarily rely on the validation system; manual review is always necessary	https://public.era.nih.gov/assist
CAYUSE *(most preferred[1])*	▪ **NIH** ▪ **AHRQ** ▪ **CDC** ▪ **HRSA** ▪ **All PHS agencies** ▪ **ONR (Navy)** ▪ **DOD** ▪ **And more**	▪ Provides autofill and data reuse capability ▪ Automatically tracks errors and warnings	https://unc.cayuse424.com
Workspace	▪ **NIH** ▪ **DOD** ▪ **NSF** ▪ **DOE** ▪ **Etc.**	▪ Caution: Can take hours to days for the application to reach the sponsor ▪ Do not rely on the validation system; manual review is always necessary ▪ Anyone working on the proposal (e.g., administrator, PI, or collaborator) is a "Participant" and need their profile setup in Grants.gov ▪ UNC participants need their profile affiliated with UNC or else OSR will not be able to view, edit, or submit the proposal ▪ Downloading forms to multiple people to complete leaves great room for error. Make sure correct and final version of the form is uploaded	https://research.unc.edu/files/2018/08/Workspace_Final.pdf
Grants.gov	▪ **USAID** ▪ **DOD** ▪ **DOE** ▪ **DOED** ▪ **DHS** ▪ **DOJ** ▪ **VA** ▪ **EPA** ▪ **NASA** ▪ **NSF**	▪ Provides list of proposal announcement for Federal sponsors in one location ▪ Feeds proposal information into applicable award management systems if funded ▪ Integrates with Cayuse	https://www.grants.gov
EHB	▪ **HRSA**	▪ P.I. must grant access to OSR's SPS for each grant	https://grants.hrsa.gov
Fastlane	▪ **NSF**	▪ Works with Research.gov to collect and store proposal information	https://www.fastlane.nsf.gov/

1 It is up to the submitter which system to use for final package submission as long as it meets sponsor requirements. Cayuse and ASSIST are most preferred as it is easier for central office review.

USEFUL LINKS TO ADDITIONAL SYSTEMS USED FOR FINAL PACKAGE SUBMISSION

Major submission systems	Applicable federal sponsors	Useful links
Grants Online	▪ DOC ▪ NOAA	https://grantsonline.rdc.noaa.gov
GMS	▪ DOJ ▪ NEH ▪ NEA	https://grants.ojp.usdoj.gov
FedBid	▪ Federal Contracts ▪ EPA	https://fedbid.com
FedConnect	▪ Federal Contracts	https://www.fedconnect.net
Grant Solutions	▪ COE ▪ CDC	https://home.grantsolutions.gov
NSPIRES	▪ NASA	https://nspires.nasaprs.com
Research.gov	▪ NSF	https://www.research.gov
CPARS	▪ DOD - Navy	https://www.cpars.gov

COMPLIANCE SUBMISSIONS – Process deep dive

The process below is relevant if the proposal receives a fundable score. If a score is not received or the score is not in the fundable range, the proposal is considered unfunded. The PI notifies the department RA the intent to create a resubmission proposal at a later time if desired.

Responsible party

Timeline

PI / Department RA

PI and central research offices: JIT request received from the agency

Both parties: Gather JIT documentation

Details on p.30

Both parties: Begin work on compliance submissions

Details on p.31-39

Department RA: Submit JIT to OSR / SPO for review

OSR / SPO

Change status to “JIT request received” in RAMSeS

Review, approve, and submit JIT to agency

Change status to “JIT request approved” when all documents are received in RAMSeS

Pause until sponsor responds with questions or notice of award (NOA)

IACUC notified to initiate congruency review

JIT SUBMISSION

ADDITIONAL RESOURCES

- JIT NIH checklist

TIPS TO ACCELERATE THE PROCESS

- A **partial JIT submission to the sponsor is allowed** if the IRB / IACUC applications are pending and there is a **short turnaround time** to respond to the JIT request
- The **UNC OHRE/IRB or the reviewing IRB can issue a 118[1]/JIT approval for certain types of applications** for grants, cooperative agreements, or contracts that are funded by federal departments (e.g., NIH, USDA, some DHHS agencies) **where plans have not been fully developed:**
  - The 118 approval may support certain aspects of development (e.g., study instruments, conduct of animal studies, or purification of compounds)
  - No human subjects may be involved in any project supported by these awards until the project has been reviewed and meets criteria for 45 CFR 46.111 approval.
- **Subrecipients** will need to be **involved at the JIT request** received stage for Other Support and Human Subject Education Certification. If a **subagreement contains animal work, OACU should be notified ASAP** so the process of approval can begin

FREQUENTLY ASKED QUESTIONS

- **Q: How are JIT documents submitted to the agency?**
- A: You will submit your JIT documents to your OSR / SPO representative via email or through a portal (e.g., ERA Commons). Submission method is specified in the email sent by the agency when you receive the JIT request.

- **Q: What do I need to do if there is a personnel change at JIT?**
- A: Notify your OSR / SPO representative on the change. Once the representative adds the personnel to RAMSeS, a COI disclosure will be triggered for the added personnel depending on his / her role. If a new key personnel is added, a biosketch and other support will need to be included in the JIT submission. If any key personnel is removed, include a justification letter in the JIT submission.

- **Q: What is the Human Subjects Education Certification letter and where do I find it?**
- A: Human Subjects Education Certification covers all individuals listed in the proposal who are engaged in human subjects research. This letter certifies that these individuals have completed the necessary training required for human subjects research activities. The certification generation website can be found HERE. For more information on training, click HERE. Subrecipients and consultants outside of UNC will have to provide their own letter.

1 For more information on the definition of a 118 and when it is applicable, consult webpage HERE

GUIDELINES ON COI DISCLOSURES

TIPS TO ACCELERATE THE PROCESS

- **Less than 2%** of COI disclosures submitted **require manual review** (i.e. Program, Chair or Committee review)
- Plan ahead - **submit COI disclosures early** because committees typically only convene 1 time per month; some committees 1x per semester
- If a faculty member from your unit is **considering establishing a start-up company, licensing, or performing any other commercial activity**, please direct them to contact the COI Program and OVCR prior to making the final decision
- An **identified COI typically does NOT prevent a study from taking place**; a review is required and additional steps may be needed. If it's a human study however, there are higher standards in place for the investigator's involvement and more detailed review (see COI Policy, Compelling Circumstances)
- **SBIR and STTR** – Required for STTRs and possible for SBIRs upon COI Chair/Committee review, a **Data Confirmation form** is required to be completed prior to the submission of a progress or final report when the University is a sub-recipient. The Department Chair is responsible for certifying the accuracy of such form
- If there is an investigator, particularly a PI, whose **start-up** company is the sponsor or involved in the research project, please contact the COI Program early in the proposal development process to proactively work on structure and managing possible COI concerns.
- If any Organizational Conflict of Interest (**OCI) language is identified in the RFA**, contact your SPS and the COI office immediately. (For specific keywords to look for, see p.20.) OCI approval is generally required prior to proposal submission
- **COI training needs to be renewed every 4 years**
- **Project specific COI disclosures are required in IRBIS and RAMSeS.** Please ensure BOTH disclosures are submitted as IRB studies can have multiple sources of funding; Ramses can fund more than one IRB study with different intents.

ADDITIONAL RESOURCES

- Aids link (to help with navigating the process)
- SBIR / STTR guidance, including Data Confirmation form

GUIDELINES ON COI DISCLOSURES

FREQUENTLY ASKED QUESTIONS

- **Q: How often do I need to submit COI disclosures?**
- A: UNC policy (which stems from federal regulations) requires that project specific COI disclosures be submitted at the time of proposal or IRB submission, then be renewed at least annually.

- **Q: What factors are considered when a management plan is built?**
- A: Annual compensation received through royalties, consulting, etc., board memberships, etc. are examples of elements considered as well as the investigator's activities on the study. For more details, please view the Aids link on p.31 under "Additional Resources."

- **Q: Why did I receive the management plan that is different from the one sent by the COI Program?**
- A: The COI committees review conflicts and determine what the appropriate management plan should be in order to manage a conflict. That said, for projects involving human subjects, the Institutional Review Board (IRB) can place additional requirements on a faculty member that it believes are necessary to protect human subjects.

- **Q: When are COI disclosures triggered?**
- A: COI disclosures are triggered under four circumstances:
  - A proposal is submitted in RAMSeS
  - An individual is added to a funded project or added to an IRB study
  - A protocol is submitted in IRBIS
  - New funding is added to an IRB study

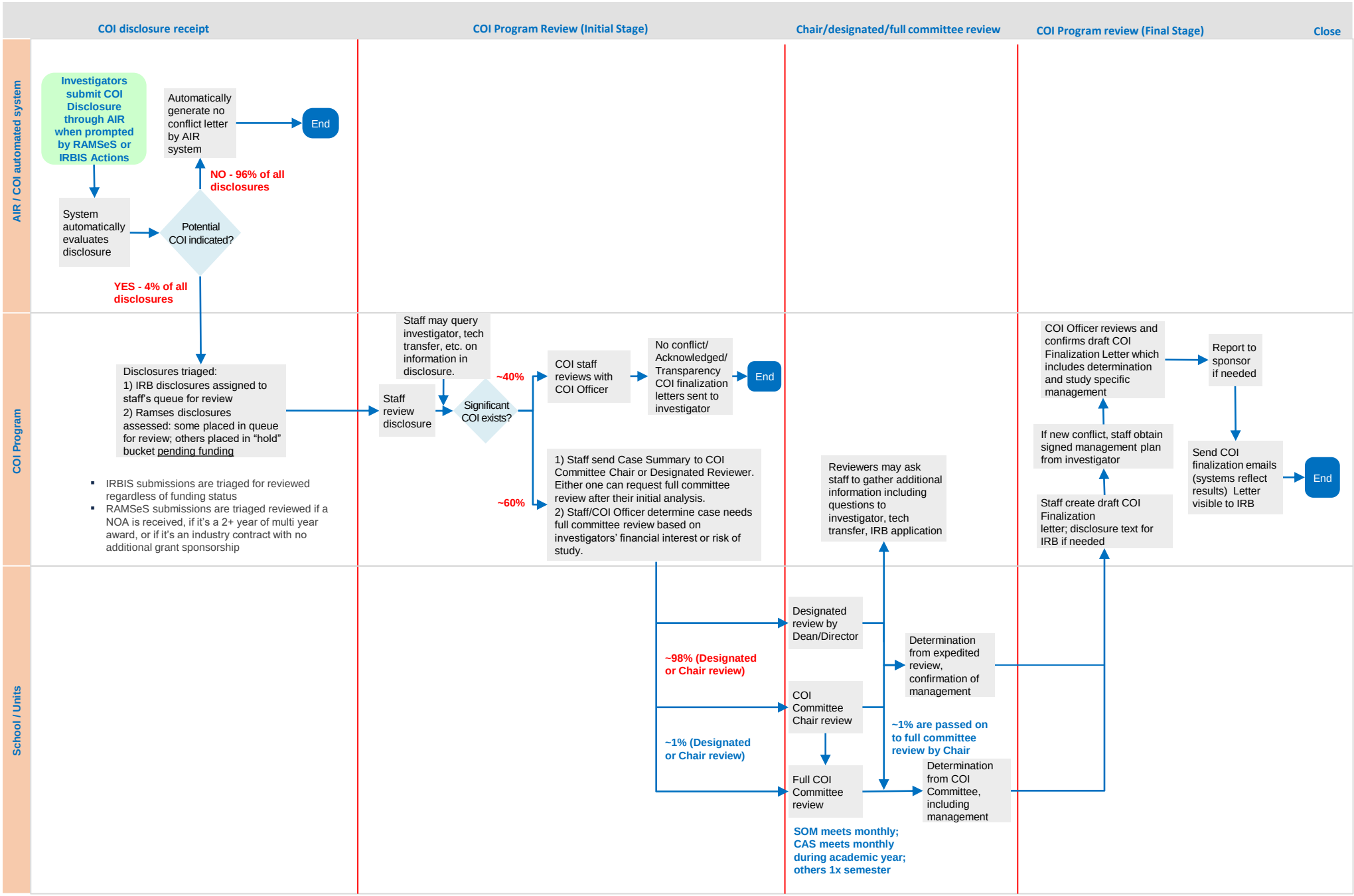
  COI Disclosures are self-generated when:
  - A faculty or staff is engaged in consulting engagements and submits an EPAP form; the submitter indicates potentially overlap with their University work and COI questions are added to the EPAP form
  - A faculty or staff member has new information regarding a financial interest or relationship and submits a self-initiated COI disclosure

- **Q: When are COI disclosures reviewed?**
- A: If COI disclosures are tied to a human subjects protocol, they are reviewed upon submission. For COI disclosures linked to a proposal, they are reviewed when the proposal status changes to "Award Received."

- **Q: How can I check the status of the COI for the sponsored project or research study?**
- A: COI status or training can be checked for sponsored projects in RAMSeS in the compliance tab or for IRB applications in IRBIS on the Personnel tab.

- **Q: Why do investigators have to complete a COI disclosure every year for a multiple year award? Or for a No Cost Extension?**
- A: The federal regulations [laws] for PHS/NIH and NSF require a project specific COI review before funding begins and require annual review since people's financial interests can change. In the case of PHS/NIH, if there has been a submitted FCOI report, the agency will not release the next year of funding (even for the non-competitive renewals) until the next FCOI report is submitted. For PHS/NIH, they are very specific that this COI review must also occur for any No-Cost Extensions.

COI REVIEW PROCESS MAP



GUIDELINES ON IRB SUBMISSION

Related to JIT submissions

TIPS TO ACCELERATE THE PROCESS

- If you have a **project similar to one that had previously been submitted** in IRBIS, there is a **copy function** located in the “My Studies”.
- If a study team in your unit is **in jeopardy of losing funding due to review of human subject research being required**, please call OHRE immediately
- **Once you have developed a “scientific plan”** (including protocol, consent forms, and IND/IDE documentation as required**), submit your full application prior to NOA**
- The review of a full application can take between **14-21 days for expedited review** and **30-45 days for full board review** based on current submission volume and responsiveness from study teams.
- Beware of the time required to receive approval on a full application; please **submit early to prevent delays** in setting up the Project ID
- The **IRB cannot view your application until all departments involved in the research have approved the study in IRBIS**. If you have any questions on who your department approver is, please find your department designee on IRBIS
- The IRB checks for **Human Subjects Education Certification (CITI)**, as well as **applicable ancillary reviews** (e.g., COI, radiation safety subcommittee, SRC).
- It is recommended to **engage the PI** in IRB submissions as they are **ultimately responsible for the conduct of the research**.
- Sign up for the **NRP listserv to receive the latest communications**, updates, and news on trainings from the IRB. Click HERE
- **A fully developed plan is NOT required at the JIT stage**

ADDITIONAL RESOURCES

- OHRE website
- Online Submission Guide and FAQ
- Consent templates
- Reliance agreement (relevant for multi-site studies, independent contractors, external investigators, etc.)
- SOPs

GUIDELINES ON IRB SUBMISSION

FREQUENTLY ASKED QUESTIONS

- **Q: Does my study need IRB oversight/approval?**
- A: If your project meets the definition of human subject research as defined by DHHS then IRB oversight is required, the "Determine whether IRB review is required" webpage can be reviewed. The investigator is primarily responsible for this determination as they will be held responsible if the determination is not correct. Investigators are urged to request a confirmation that a project is not human subject research (NHSR) from the OHRE by completing an application in IRBIS.

- **Q: What are Human Subject Research Activities?**
- A: Human subject research activities are not limited to interventions; they may also include the following,
  - Interactions, such as communication (e.g.,phone call, electronic surveys) or interpersonal contact
  - Obtain, utilize, study, or analyze identifiable private information or identifiable biospecimens (e.g., medical record review, specimen repository, data analysis of existing data sets).

- **Q: How do I know if my study qualifies for Exempt of Expedited review?**
- A: Exempt and expedited studies are two different review types as defined by OHRP each with their own list of acceptable research activities. Both exempt and expedited require a submission in IRBIS for IRB review/determination.
  - Exempt studies are exempt from the Common Rule, however they do require a determination/confirmation of exemption status and is not exempt from ethical considerations as described in the Belmont Report.
    - If all research activities do not fit within the defined "Exempt Categories" then expedited or full board review is required.
    - If your project meets the "Revised Common Rule" Exempt Categories, please submit an exempt application in IRBIS.
  - Expedited review procedures are for certain kinds of research involving no more than minimal risk and are not exempt from the Common Rule. If all research activities do not fit within the defined "Exempt and Expedited Categories" then full board review is required.
    - "Expedited Review Categories"

- **Q: Who is notified when a determination has been made or when stipulations are required?**
- A: PIs, Co-Is, and faculty advisors (when applicable) are notified via automated e-mails from IRBIS. Others can receive notification by following the following steps if listed as project personnel:
  1. Identify the individual in the "Project Personnel" section of the application,
  2. Select "Edit" on their personnel record
  3. Indicate their need to receive IRB correspondence by selection of the checkbook.

GUIDELINES ON IRB SUBMISSION

Related to JIT submissions

FREQUENTLY ASKED QUESTIONS

- **Q: Can I extend the approval of an application?**
- A: All expedited and full board approval letters either have an administrative or expiration date listed. In order to continue to conduct research activities (including data-analysis) past this administrative or expiration date a renewal submission, review and approval is required. The OHRE recommends submitting approximately 45 days prior to mitigate any risk of expiration. If you are done with your study and no longer conducting any human subject research activities, please submit a closure. Studies that the IRB determines to be exempt do not require a renewal, however if there are modifications that may impact the exempt determination (e.g., change to study design, activities conducted, or addition of vulnerable populations) a modification submission is required to be reviewed by the IRB prior to implementation.

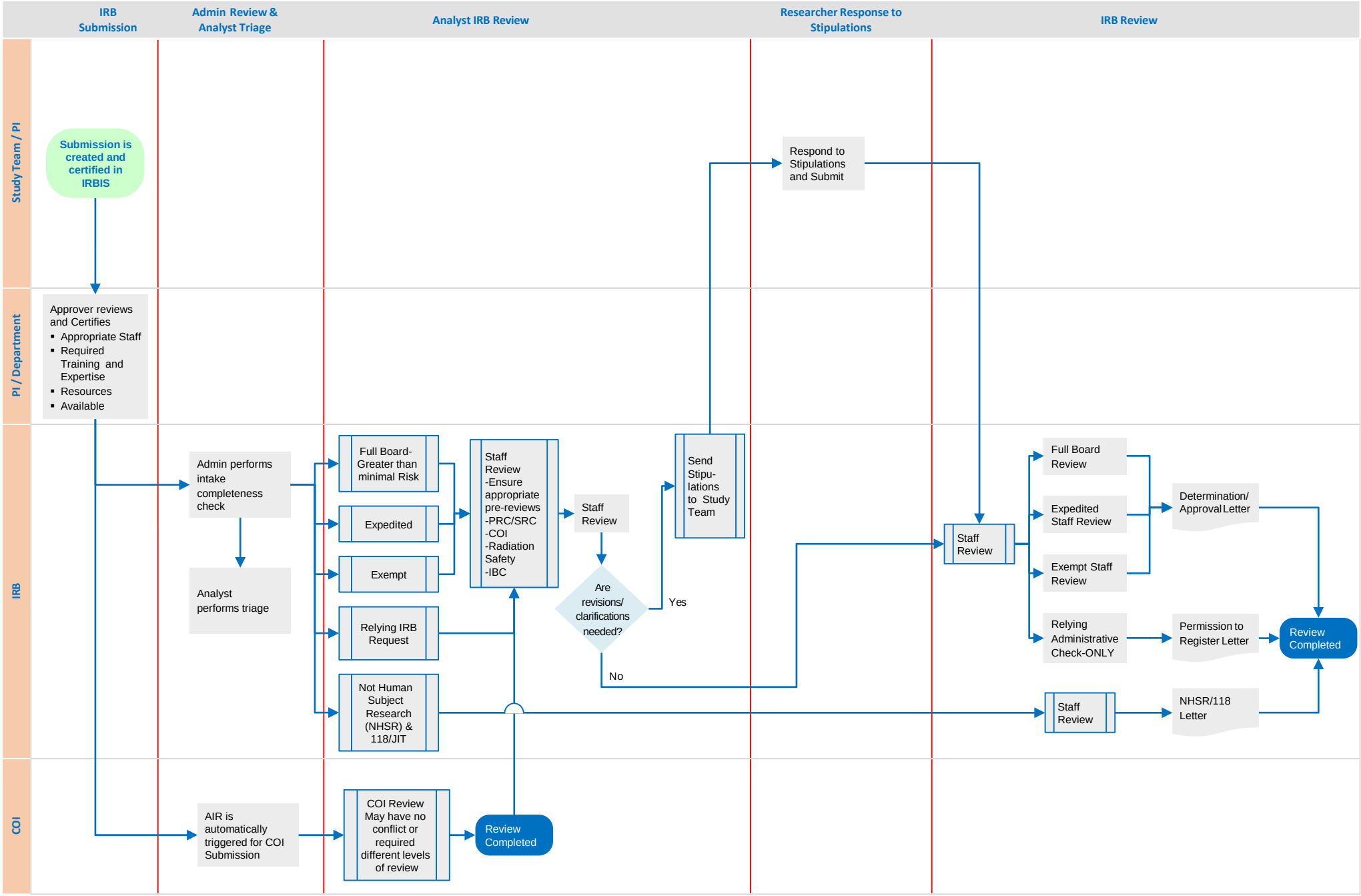
- **Q: If I am part of a multi-site study, what actions do I need to take if:**
  - Typically if UNC is the prime awardee, the UNC-Chapel Hill IRB will serve as the reviewing IRB, unless other arrangements have been made with the Reliance Team at the UNC OHRE/IRB. If UNC-Chapel Hill is not the prime awardee, then UNC-Chapel Hill may rely on an external IRB (e.g., Duke, Wake Forest, Johns Hopkins). We recommend consulting with the Reliance Team to help facilitate the process.
  - **1) UNC is the Reviewing IRB?**
  - A: Once the study receives initial IRB approval the participating sites are onboarded via subsequent modifications in IRBIS.
  - **2) UNC is the Relying IRB?**
  - A: At the JIT stage the Reliance Team can issue a Letters of Support (cede decision to rely on an external IRB) if required. The reliance team will assist in determining what is required by the reviewing IRB and an abbreviated IRBIS application will be required.

- **Q: What do I need to do if new personnel will be conducting human subject research activities?**
- A: Submit a modification in IRBIS to update the project personnel section and note the change in the modification description. A COI disclosure for the added personnel may be required depending on his / her role. Human Subjects Protection Training (CITI) is a requirement for all individuals listed in the "Project Personnel" section. Notify your OSR / SPO representative on the change to determine if agency prior-approval is needed.

- **Q: When do I submit a full application vs. a 118?**
- A: Submit the 118/JIT in IRBIS when a JIT request is received from the federal funding entity if a application has not been previously approved and we are the prime awardee. A full application/relying application to the OHRE/IRB is required prior to commencement of human subject research activities.

- **Q: What actions do I need to take if I already have an IRB-approved study and now receive JIT federal funding?**
- A: In cases where the IRB study is already active at the JIT stage because the study was ongoing before funding was proposed and/or received, the PI would be advised to submit a modification to add the IPF number and funding source in IRBIS. It would not be recommended to start the full modification process if additional changes are needed (e.g., COC language to the Consent Form) to the IRB until a notice of award is received or there is a true intent to fund received – i.e. letter, PO confirmation by email, etc.

IRB INITIAL REVIEW PROCESS MAP



GUIDELINES ON OCT COMPLIANCE REVIEW

TIPS TO ACCELERATE THE PROCESS

- Ensure **all personnel listed on the IRB** application have taken **Good Clinical Practices (GCP) Training through CITI** and training is current, must be **renewed every 3 years**.
- **IRB approval must be obtained** before conducting any clinical trials.
- **The Billing Coverage Analysis (BCA) must be completed in CRMS and certified by the PI.**
- Use the UNC **Standard Subject Injury Language** in the informed consent.
- Check the approved informed consent form and BCA with the fully executed agreement to **ensure congruency across all documents**.
- **COI training, disclosure and review must be completed** for all those listed on the IRB application.
- COI must also be complete on those listed on the IPF; NOTE: **there are 2 COI disclosures and review, IRB and RAMSeS**
- The agreement with the funding entity must be fully executed.

FREQUENTLY ASKED QUESTIONS

- **Q: Is GCP training the same as the Human Subjects Protection (HSP) Training taken for the IRB submission?**
- A: No, there are two required CITI trainings, GCP and HSP, link HERE to more information

- **Q: Where do I find information on completing the BCA?**
- A: Link HERE

- **Q: How often is COI training required?**
- A: Every 4 years

ADDITIONAL RESOURCES

- Office of Clinical Trials website

CLINICAL TRIAL CHECKLIST: SOLICITED OR UNSOLICITED FULL PROPOSALS

School / Unit RA

- ❑ Create and submit IPF

PI / Study Team

- ❑ PI certifies IPF
- ❑ Create CRMS record
  - ❑ BCA
  - ❑ IDS as applicable
- ❑ Conduct feasibility assessment
- ❑ Submit to the Scientific Review Committee or Protocol Review committee as applicable
  - ❑ Submit to the IRB
- ❑ Establish EPIC research record

OSR

- ❑ Review IPF
- ❑ Confirm PI eligibility and review budget
- ❑ Notify OCT for compliance checks
- ❑ Assign PS project ID once all compliance checks complete and agreement executed

OCT

- ❑ Run compliance checks
- ❑ Create EPIC billing calendar

For more information, please consult the Office of Clinical Trials website

GUIDELINES ON IACUC SUBMISSION

Related to JIT submissions

WHO TO CONTACT TO KICKSTART THE PROCESS

- **OACU** and **Division of Comparative Medicine (DCM) serve as the points of contact for all questions on animal research**. Please contact their offices directly for animal research questions.
- For assistance with **study design** and determining **lab space requirements**, **call 919-962-5335** to be put in touch with a DCM veterinarian. This is highly recommended if using a USDA-covered species.
- **Contact EHS at 919-962-5507 to discuss what is needed for your study** (Lab Safety Plan, hazard and IBC Schedule forms, etc.) so IACUC approval is not delayed for EHS requirements.

TIPS TO ACCELERATE THE PROCESS

- Send a notification email to iacuc@med.unc.edu as soon as it is known that **animal work will take place outside of UNC**. The approval process for this may take extra time.
- OACU requires notification if animal work will be conducted at UNC. A **new animal application should be completed in ACAP.**
- Contact OACU at iacuc@med.unc.edu to **request an informational packet for new or existing PI's** who will now be performing vertebrate animal work at UNC. This packet will include all of the information they need to get their animal research set up at UNC (how to get animal space and an animal protocol in place, information on EHS items needed, etc.)
- Plan ahead and **register for required hands-on training** and lectures as soon as you finalize what procedures and techniques will be performed.
- If a grant containing animal study has been submitted and there is no animal protocol in place, this should be remedied ASAP because the **JIT process requires an IACUC approved protocol be in place**.
- A **congruency review** is required when a JIT request is received. This review **requires an approved animal protocol.**

GUIDELINES ON IACUC SUBMISSION

Related to JIT submissions

FREQUENTLY ASKED QUESTIONS

NOTE: A more comprehensive set of FAQs can be found on the IACUC website

- **Q: How long will it take to receive IACUC approval for my animal care protocol?**
- A: Most applications are approved within 2 months of submission, but certain circumstances may prompt a longer review period. It is recommended that new PI's begin work on their animal care applications as soon as they have secured their PID number, ONYEN and password.

- **Q: When is a grant congruency review required?**
- A: A grant congruency review is required for all federally funded grants. **This review requires an approved UNC animal care protocol.** If no JIT request is received, please submit a self-request congruency review. If the agency issues a JIT request, an auto-notification is triggered when the proposal status in RAMSeS changes to "JIT request received." Additional information about this process can be found HERE.

- **Q: What actions should I take if I have an approved UNC animal care protocol and receive a JIT notice?**
- A: All federally funded grants containing animal work require a congruency review. Once the OACU is alerted to the existence of the proposal, the PI will be contacted via email to see if further action is required. An amendment to the protocol may be required.

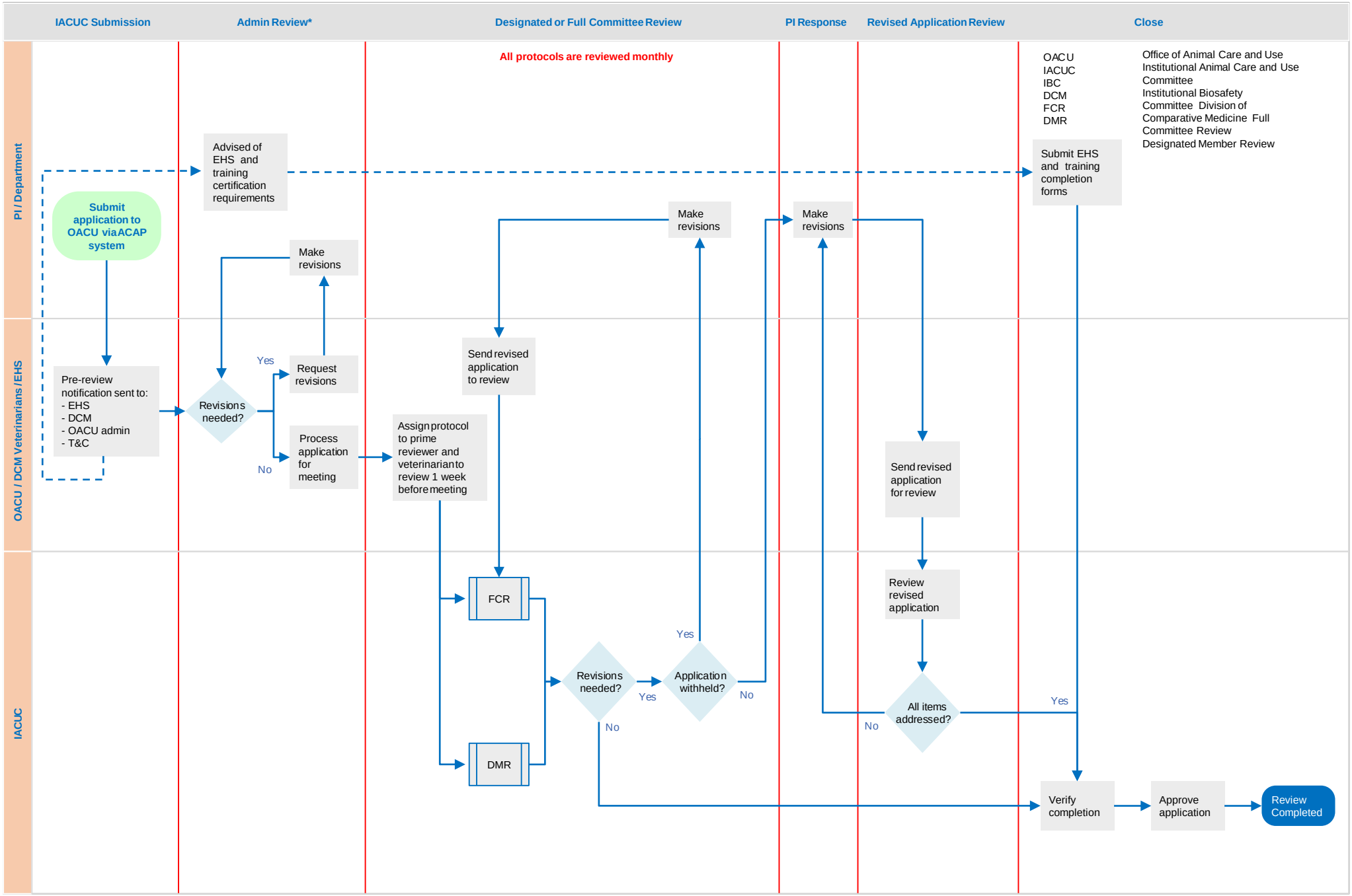
- **Q: Who receives a notification when protocol congruency reviews are complete?**
- A: The lead PI will receive an email directly from the OACU Grants Manager. Other personnel included in the funding inquiry will be cc'd.

ADDITIONAL RESOURCES

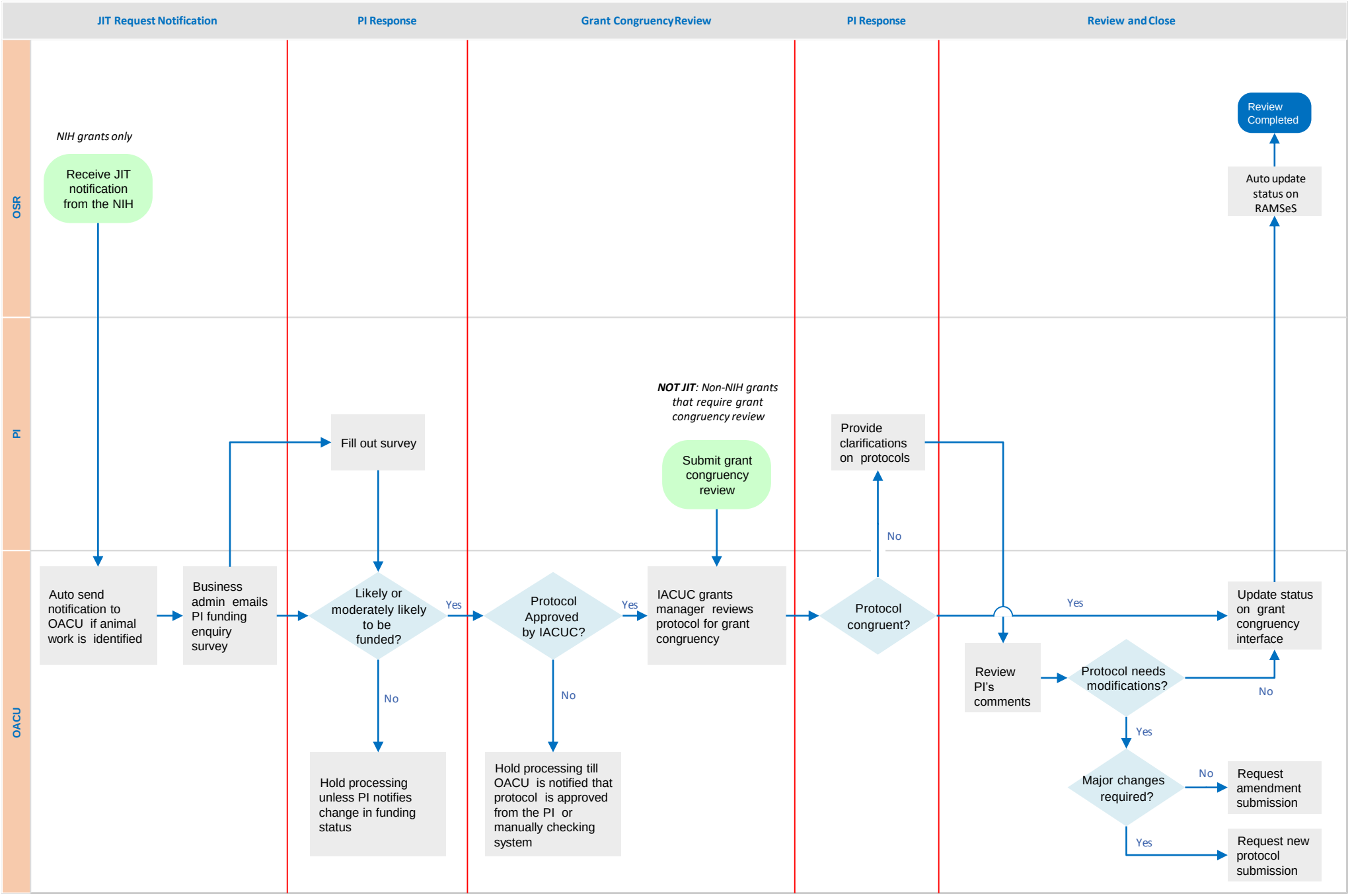
Please be aware that access to certain pages require a UNC ONYEN and password.

- IACUC Website
- Grant Congruency Self-Request Form
- Division of Comparative Medicine (DCM)
- Environment, Health and Safety (EHS)
- UNC Animal Care Application System (ACAP)

IACUC INITIAL REVIEW PROCESS MAP



IACUC JIT REVIEW PROCESS MAP



HELPFUL TIPS ON OTHER COMPLIANCE SUBMISSIONS

DATA SECURITY

- Contact your OSR / SPO representative early when / if your project involves any of the following:
  - **Reference to FISMA, HIPAA, or any reference to data security requirements like 800.171, etc.** If you have any questions, please contact the **ITS Security Office at (919) 962-4357.**
- Note: The Data Security office is part of Information Technology Services (ITS); in the near future, the data security office will receive notifications from RAM Tracker when an application requires review.

EXPORT CONTROL

- Contact your OSR / SPO representative early when if your project involves any of the following:
  - **Collaborations with foreign countries or individuals from foreign countries**
  - **Shipping or transferring any materials or equipment to any foreign entity**
  - **Any travel to a foreign country**
- If you have any questions, please contact the **Export Compliance Office at (919) 962-4102.**

PRIVACY

- Contact your OSR / SPO representative early when / if your project involves any of the following:
  - **The use or transfer (to an external entity) of Protected Health Information (PHI)**
  - **The need for a Business Associates Agreement (BAA)**
- If you have any questions, please contact the **Privacy Office at (919) 445-0232.**

AWARD SETUP READINESS – Process deep dive

Responsible party

Timeline

PI / Department RA

Obtain final IRB / IACUC approval that is consistent with the grant proposal if not already completed*

Notify SPS the IRBIS # of the IRB application

Check that approved IACUC protocol and congruency review reflected in the Compliance tab in RAMSeS

**Note: If IRB / IACUC approval is not obtained yet and you want to start non-human subjects research, submit an IRB waiver. IACUC approval is required prior to obtaining animals or commencing animal work under your animal care protocol.*

Review the agreement and communicate any important observations to the PI

Details on p.42

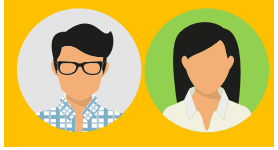
Resolution workflow

Details in FAQs on p.41

If adjustments are needed

NOA received

OSR / SPO



Change IPF status to “Award received”

If IPF does not exist, department will be asked to create one

Assign to SPS for review

COI disclosure automatically triggered

OCI disclosure potentially triggered

If checks are all clear including budget changes

Create Project ID and setup contract

END

AWARD SETUP READINESS

ADDITIONAL RESOURCES

- How to review the NOA from major federal sponsors:
  - NIH
  - NSF
- Recent example of an NOA received

TIPS TO ACCELERATE THE PROCESS

- Check that the **right person is selected** in the RAMSeS IPF to be **notified when Project ID is setup**
- Ensure the correct **IPF# is reflected in your IRBIS** submission
- **Review for any restriction requirements in the NOA** and continue to follow the stated requirements imposed by the agency. Follow up with your SPS at least 6-months before project closeout
- Make note of all the **deadlines specified in the NOA** (e.g., invoices, technical reports, etc.). While not necessary prior to Project ID setup, it will help with post-award management
- Review for references to **additional terms and conditions** that may apply outside the NOA
- A **Letter of Guarantee (LoG)** can be created upon receipt of confirmation that an award is going to be issued. The LoG allows a Project ID to be set up in advance of the award so spending can begin without requiring journal transfers after the award comes in

FREQUENTLY ASKED QUESTIONS

- **Q: What actions do I need to take when:**
  - **1) There are restrictions tied to the award?**
    - A: Department RA notifies PI of any administrative / technical restrictions and expected response times required by the sponsor (if applicable). OSR SPS communicates with the sponsor regarding administrative and financial restrictions and any technical restrictions that are tied to award performance and compensation, including changes to the scope of work and milestones. Other than a change to the scope of work, the PI communicates all scientific requirements to the sponsor. Department RA should notify the SPS if we are unable to meet the sponsor timelines for administrative components (e.g., IRB, budgets, changes in scope of work, etc.) and the SPS will communicate with the sponsor to request an extension.
  - **2) There is a budget mismatch between the NOA and the submitted proposal?**
    - A: Prepare a revised internal budget in partnership with the PI and submit it to the SPS
  - **3) There are pending compliance checks (currently requires manual checks in RAMSeS to determine the statuses)?**
    - A: Check which compliance checks are pending in the Compliance tab in RAMSeS (for instructions, click HERE). Take action on ensuring the appropriate compliances are completed or approved.

Note: Typically a Project ID cannot be setup until #2 and 3 above are cleared.

GUIDANCE ON KEYWORDS TO LOOK OUT FOR IN the NOA

It is best practice to review the NOA and make a record of the language flagged below. While this is NOT required for Project ID setup, they will be important to keep in mind in the post-award phase.

When reviewing an NIH NOA, pay close attention to the Special Terms and Conditions section to review any special language

Topics	Keywords in NOA
Spending restrictions	▪ Cost share ▪ Carryover ▪ Expanded authorities ▪ Funding restriction ▪ Pre-award spending ▪ Salary cap ▪ FDA requirements
Budget	▪ Re-budgeting authority ▪ F&A rates ▪ Program income
Key personnel	▪ Effort ▪ Sponsor-defined effort restrictions or limitations ▪ Names of investigators listed in the NOA
Prior approval	▪ Any foreign component ▪ Extension ▪ No cost extension
Reports	▪ Interval of reporting ▪ Inventions ▪ Milestone-based reporting ▪ Technical requirements ▪ Invoice ▪ Progress report

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of NORTH CAROLINA
at CHAPEL HILL