Operational Excellence
Proposal Research Playbook
GUIDANCE ON PROPOSAL PROCESS

Updated | April 26, 2021
## TABLE OF CONTENTS

### PROPOSAL INTRODUCTION
- Overview
- Central Offices
- Roles and Responsibilities
- Key Terms
- Keyword Guidance
- Budgeting Categories
- General Tips & Tricks
- General FAQs
- System Submissions
- Compliance Guidance

### FEDERAL
- Process Overview
- Proposal Creation
- Proposal Submission
- Keyword Guidance
- Budgeting Guidance
- Federal Sponsor Info
- Tips & Tricks
- FAQs
- Summary
- Compliance

### NON-PROFIT
- Process Overview
- Proposal Creation
- Proposal Submission
- Keyword Guidance
- Budgeting Guidance
- Tips & Tricks
- Summary

### APPENDIX
- Office of Sponsored Research
- Compliance
- Proposal Specific
The Proposal Research Playbook will provide you the tools and information to complete each step of the proposal process. By following the summary lists (not all-inclusive) and process maps, you will take advantage of best practices designed by research leaders across campus units and central offices and be informed on when it is necessary to engage various compliance units. Additionally, you will have an opportunity to enhance the quality and completeness of the initial submission, which directly impacts award set-up response time.

While this playbook is meant to capture the standard process for proposals by sponsor type, it is not all inclusive. By thoroughly reading the proposal guidelines first, you can 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 proposal guidelines.

Always consult with your Office of Sponsored Research - Sponsored Projects Specialists or Sponsored Programs Office (School of Medicine only) - Grants Manager if you have questions not addressed in this playbook or if you think your situation is unique or differs from what is stated here.
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.
CENTRAL RESEARCH OFFICES
<table>
<thead>
<tr>
<th>Office</th>
<th>Responsibilities</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Conflict of Interest</strong></td>
<td>Provides training in identification and management of conflicting relationships connected to research at the University</td>
<td><a href="mailto:coi@unc.edu">coi@unc.edu</a></td>
</tr>
<tr>
<td><strong>Corporate Foundation Relations</strong></td>
<td>Provides a single point of contact for corporate foundations working with the University</td>
<td><a href="mailto:cfr@unc.edu">cfr@unc.edu</a></td>
</tr>
<tr>
<td><strong>Div Comparative Medicine</strong></td>
<td>Provides care for vertebrate animals used in research at the University</td>
<td><a href="mailto:dg@unc.edu">dg@unc.edu</a></td>
</tr>
<tr>
<td><strong>Environment, Health &amp; Safety</strong></td>
<td>Provides health/safety oversight and training on biological, environmental, chemical, occupational, and workplace safety at UNC</td>
<td><a href="mailto:ehs@unc.edu">ehs@unc.edu</a></td>
</tr>
<tr>
<td><strong>Office of Animal Care &amp; Use</strong></td>
<td>Reviews all animal care applications that use vertebrate animals and oversees applicable training and education programs</td>
<td><a href="mailto:iacuc@unc.edu">iacuc@unc.edu</a></td>
</tr>
<tr>
<td><strong>Office of Clinical Trials</strong></td>
<td>The central resource for UNC faculty, staff, and departments involved in clinical trial research and for sponsors of clinical trials at UNC.</td>
<td><a href="mailto:oct@unc.edu">oct@unc.edu</a></td>
</tr>
<tr>
<td><strong>Office of Human Research Ethics</strong></td>
<td>Provides ethical and regulatory oversight for research involving human subjects at the University</td>
<td><a href="mailto:irb_questions@unc.edu">irb_questions@unc.edu</a></td>
</tr>
<tr>
<td><strong>Office of Research Development</strong></td>
<td>Supports University researchers pursuing convergence science and a culture of innovation</td>
<td><a href="mailto:ord@unc.edu">ord@unc.edu</a></td>
</tr>
<tr>
<td><strong>Office of Sponsored Research</strong></td>
<td>Partners with research community at UNC for all sponsored programs and research administration management needs</td>
<td><a href="mailto:resadminosr@unc.edu">resadminosr@unc.edu</a></td>
</tr>
<tr>
<td><strong>Office of Technology Commercialization</strong></td>
<td>Provides management of all aspects of intellectual property and partners with campus to effectively manage inventions and technologies</td>
<td><a href="mailto:otc@unc.edu">otc@unc.edu</a></td>
</tr>
<tr>
<td><strong>Research Compliance Program</strong></td>
<td>Provides guidance that advances the highest standards of ethics, integrity, and honesty in compliance with all applicable laws, regulations, and policies governing research</td>
<td><a href="mailto:research_compliance@unc.edu">research_compliance@unc.edu</a></td>
</tr>
<tr>
<td><strong>Sponsored Programs Office</strong></td>
<td>Reviews, approves, and submits School of Medicine’s grant proposals to the NIH, foundations and non-profit organizations</td>
<td><a href="mailto:grants@unc.edu">grants@unc.edu</a></td>
</tr>
</tbody>
</table>
ROLES AND RESPONSIBILITIES

Reference the OSR Roles and Responsibilities matrix online HERE.

PRINCIPAL INVESTIGATOR (PI)

Pre-Award/Proposal

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

Post-Award (Acceptance and Set-Up)

- 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

DEPARTMENT RESEARCH ADMINISTRATOR (RA)

Pre-Award/Proposal

- 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)
- Completes and routes IPF in RAMSeS and submits other administrative components at least 5 business days prior to sponsor deadline
- Partners with PI to develop the budget and justification, F&A waivers, and other documents per sponsor guideline
- Obtain statement of work, budget, budget justification, letter of intent, and other required documents for subagreements
### ROLES AND RESPONSIBILITIES

#### DEPARTMENT RESEARCH ADMINISTRATOR (RA)

**Post-Award (Acceptance and Set-Up)**

- Review sponsor agreement and provide input where necessary
- Review and make budget modifications in partnership with OSR/SPO following agreement terms and conditions

#### SCHOOL DEAN/DEPARTMENT CHAIR

**Pre-Award/Proposal**

- 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 in the role of PI despite part-time employment status where applicable

#### CORPORATE AND FOUNDATION RELATIONS (CFR)

**Pre-Award/Proposal**

- Serve as UNC liaison, or single point of contact, to non-profit partners for successful collaborations with sponsored research and philanthropy
- Communicate non-profit partners’ priorities, guidelines, and requirements to University constituents; helping to inform pre-award, award setup, and post-award processes
- Work closely with faculty, staff, and central offices to develop, finalize, and submit proposals
- Coordinate communication between non-profit partners and the University regarding award negotiations and reporting
- Consults with the PI on their intent to submit a proposal, identification of funding mechanism, and development of technical proposal
- Consults with PI and unit RA to develop/obtain the budget, budget justification, F&A waivers, and administrative documents per sponsor guidelines
### OFFICE OF RESEARCH DEVELOPMENT (ORD)

**Pre-Award/Proposal**

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

### OFFICE OF SPONSORED RESEARCH (OSR)/SPONSORED PROGRAMS OFFICE (SPO)

**Pre-Award/Proposal**

- Provides institutional review and approval of the proposal
- Checks that all compliance requirements have been obtained
- 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 SPONSORED RESEARCH (OSR)

**Post-Award (Acceptance and Set-Up)**

- Review and negotiate contract terms, confidentiality agreements, and data use agreements with the sponsor (Industry Contracting Managers – for industry sponsored partnerships; Sponsored Projects Specialist – for all other sponsors)
- Confirm all regulatory compliance requirements have been met by the department
- Review and make budget modifications in partnership with department RA following terms and conditions
- 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
### CONFLICT OF INTEREST PROGRAM (COI)

- 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. With schools, implements monitoring oversight for PIs
- 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

### 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

### 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 Just-in-Time (JIT)/118 review and provides certification of IRB approval
- Conducts review of all initial, revised, annual renewals and new safety information. Activities should not begin until approval is obtained.
- Responds to questions regarding the protection of human subjects and OHRE/IRB processes and procedures

### OFFICE OF ANIMAL CARE AND USE (OACU) - Also called the IACUC Office

- Provide IACUC review and approval of animal care protocols
- Checks that all compliance, veterinary pre-review, hands-on training and lectures, Environmental, Health and Safety (EHS) requirements, and Institutional Biosafety Committee (IBC) approvals have been obtained prior to 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
- Performs federally mandated semiannual inspections of animal housing facilities and investigator laboratories
INFORMATION TECHNOLOGY SERVICES – DATA SECURITY

• Provides review of information security requirements of the proposal
• Provides guidance to researchers and IT support staff on completing risk assessment documentation required in proposal
• Provides 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

INFORMATION TECHNOLOGY SERVICES – PRIVACY

• Responsible for the general oversight and compliance with 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
• Aids Covered Entities in obtaining information required for their compliance with HIPAA regarding University 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
KEY PROPOSAL TERMS
## KEY PROPOSAL TERMS

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<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td><strong>Animal Subjects/Animal Care and Use</strong></td>
<td>Animals that are utilized in the process of research that are protected by Animal Welfare regulations and legislation. Protection of animal subjects in research is monitored by the Institutional Animal Care and Use Committee.</td>
</tr>
<tr>
<td><strong>Authorized Representative/Institutional Official</strong></td>
<td>Authorized Representative means the individual, named by the institution, who is authorized to act on its behalf and to assume the obligations imposed by any laws, regulations, requirements, and conditions that may apply to the proposal or award. Also called Authorized Official, Signing Official, and Institutional Official.</td>
</tr>
<tr>
<td><strong>Budget</strong></td>
<td>The financial plan for the project or program that the awarding agency or pass-through entity approves during the award process or in subsequent amendments to the award.</td>
</tr>
<tr>
<td><strong>Co-Investigator</strong></td>
<td>An individual involved with the PD/PI in the scientific development or execution of a project. The Co-Investigator (collaborator) may be employed by, or be affiliated with, the applicant/recipient organization or another organization participating in the project under a consortium agreement.</td>
</tr>
<tr>
<td><strong>Conflict of Interest (COI)</strong></td>
<td>A situation where financial or personal considerations, circumstances, and relationships may compromise or appear to compromise the objectivity of an individual performing research duties or responsibilities.</td>
</tr>
<tr>
<td><strong>Congruence</strong></td>
<td>The determination that the scientific procedures detailed in a funded sponsored project directly correlate to the research protocol being used to facilitate animal or human subjects’ research for that project. This approval is provided by the IACUC is required as part of the compliance review for having an approved protocol.</td>
</tr>
<tr>
<td><strong>Cost Reimbursable</strong></td>
<td>Cost-Reimbursement references a method of billing, were costs that are deemed to be applicable and appropriate are then reimbursed by the Sponsor after they have been incurred by the Recipient.</td>
</tr>
<tr>
<td><strong>Consultant</strong></td>
<td>An individual who provides professional advice or services for a fee, but normally is not engaged as an employee of the recipient institution.</td>
</tr>
<tr>
<td><strong>Cost Sharing</strong></td>
<td>Cost sharing or matching means the portion of project costs not paid by research funds.</td>
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<tr>
<td>Debarment and Suspension</td>
<td>Suspension is utilized in cases of immediate need of less than twelve months and are usually due to pending investigation or indictments. Debarment is more permanent with an average length of three years and based on confirmed evidence such as a conviction.</td>
</tr>
<tr>
<td>Deliverable</td>
<td>An action that must be completed for the sponsor per the terms and conditions. May need to be done prior to or in conjunction with a financial report.</td>
</tr>
<tr>
<td>Effective Date</td>
<td>The date when rights and obligations under an agreement become operational. This may not be the same as the date in which an agreement or contract is executed.</td>
</tr>
<tr>
<td>Expanded Authorities</td>
<td>The operating authorities provided by certain Federal Agencies to recipients that waive the requirement for prior approval for specified actions.</td>
</tr>
<tr>
<td>Financial Guarantee (Letter of Credit)</td>
<td>A request to establish a pre-award spending account. This is submitted via RAMSeS.</td>
</tr>
<tr>
<td>Fixed price</td>
<td>A type of agreement where the awarding agency or pass-through entity provides a specific level of support without regard to actual costs incurred under the award. This reduces some of the administrative burden and record-keeping requirements for both entities.</td>
</tr>
<tr>
<td>Foreign Component</td>
<td>The performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended.</td>
</tr>
<tr>
<td>Human Subject</td>
<td>Human Subject is an individual about whom a researcher obtains data through intervention or interaction with the individual or obtains identifiable private information.</td>
</tr>
<tr>
<td>Indirect (F&amp;A) Costs</td>
<td>Those costs incurred for a common or joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted without effort disproportionate to the results achieved.</td>
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<td>Term</td>
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<tr>
<td>Internal Processing Form (IPF)</td>
<td>The UNC document generated in RAMSeS for all proposed sponsored projects. It is a compilation of the financial, personnel, and scientific details of a project and serves as the internal proposal document.</td>
</tr>
<tr>
<td>Just-in-Time (JIT)</td>
<td>NIH specific policy that allows the submission of certain elements of a competing application (e.g. Other Support, Research Subjects Approvals) to be deferred until later in the application process, after review when the application is under consideration for funding.</td>
</tr>
<tr>
<td>Letter of Intent</td>
<td>A letter provided by prospective applicants that indicates their intent prior to the submission of a grant application.</td>
</tr>
<tr>
<td>Milestone</td>
<td>This is the page in ConnectCarolina where payment schedules are entered for each fixed price project.</td>
</tr>
<tr>
<td>Modular Budget</td>
<td>A budgeting capability available to certain NIH grants in which the direct costs are requested in specified increments that does not require a detailed budget or supporting documentation.</td>
</tr>
<tr>
<td>Non-Competitive Continuation</td>
<td>The interim request for further financial assistance for subsequent budget periods previously approved within a project period. This process does not require the recipient to compete with other applicants while within the originally authorized project period.</td>
</tr>
<tr>
<td>Other Support/Current and Pending Support</td>
<td>The disclosure of all financial sources—whether Federal, non-Federal, commercial—available in direct support of an individual’s research endeavors, including but not limited to research grants, cooperative agreements, contracts, and institutional awards.</td>
</tr>
<tr>
<td>Participant support costs</td>
<td>Participant support costs means direct costs for items such as stipends or subsistence allowances, travel allowances, and registration fees paid to or on behalf of participants or trainees (but not employees) in connection with conferences, or training projects.</td>
</tr>
<tr>
<td>Pre-Award Spending</td>
<td>Any cost incurred prior to the beginning date of the project period or the initial budget period of a competitive segment (under a multi-year award), in anticipation of the award and at the applicant’s own risk, for otherwise allowable costs.</td>
</tr>
</tbody>
</table>
## KEY PROPOSAL TERMS

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</thead>
<tbody>
<tr>
<td>Program Announcement (PA)</td>
<td>An unsolicited funding announcement utilized by the Federal government that identifies areas of priority and remains open for submissions for an extended period of time, typically several years.</td>
</tr>
<tr>
<td>Program Director/Principal Investigator (PD/PI)</td>
<td>The individual(s) designated by the applicant organization or recipient to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award.</td>
</tr>
<tr>
<td>Programmatic Report/Technical Report</td>
<td>Any required report to a sponsor that covers the programmatic activities and results for a sponsored project. Submission may be required on an interim, annual, or final basis.</td>
</tr>
<tr>
<td>Project Period/Period of Performance</td>
<td>The time during which the recipient may incur new obligations to carry out the work authorized under the award.</td>
</tr>
<tr>
<td>Proposal/Application</td>
<td>The document created by the completion of an application process for funding provided by a Sponsor such as a governmental agency, corporation, foundation or trust.</td>
</tr>
<tr>
<td>Renewal Application/Competitive Continuation</td>
<td>An additional funding request for a period subsequent to that provided by the current award. Renewal applications compete for funds with all other applications and must be developed as fully as though the applicant is applying for the first time. Previous funding does not ensure funding for a new competitive submission.</td>
</tr>
<tr>
<td>Request for Application (RFA)</td>
<td>A funding announcement used by the Federal government that identifies a narrow subject and has set aside funds for the awarding of grants. It usually has a single submission cycle and has a specifically convened review board for the applications.</td>
</tr>
<tr>
<td>Request for Proposal (RFP)</td>
<td>A solicitation used by the Federal government for proposals that will be funded by a contract mechanism.</td>
</tr>
<tr>
<td>Salary Cap</td>
<td>A limitation placed on the salary rate that can be charged to a sponsored project by the funding agencies, set by NIH. This is independent of the amount of personnel effort that can be devoted to a project.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
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</tr>
<tr>
<td>Scope of Work (SOW)</td>
<td>The aims, objectives, and purposes of a grant application; as well as the methodology, approach, analyses or other activities; and the tools, technologies, and timeframes needed to meet the grant’s objectives.</td>
</tr>
<tr>
<td>Senior/Key Personnel</td>
<td>The PD/PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant.</td>
</tr>
<tr>
<td>Specific Aims</td>
<td>A component of an application’s Research Plan which describes the goals of the proposed research and summarizes the expected outcomes, including the impact that the results of the proposed research will exert on the research fields involved.</td>
</tr>
<tr>
<td>Sponsor/Awarding Agency</td>
<td>Any organization that provides funding for a set purpose developed in a proposed project.</td>
</tr>
<tr>
<td>Subrecipient</td>
<td>An entity that receives a subagreement from a pass-through entity to carry out part of the SOW for an award; but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other Federal awards directly from a Federal awarding agency.</td>
</tr>
<tr>
<td>Terms and Conditions</td>
<td>All legal requirements imposed on a project, whether based on statute, regulation, policy, or other document referenced in the award, or specified by the award document itself. The Notice of Award may include both standard and special conditions that are considered necessary to attain the project’s objectives, facilitate post award administration of the project, conserve project funds, or otherwise protect the sponsor’s interests.</td>
</tr>
<tr>
<td>Trainee</td>
<td>An individual that is undergoing training for a particular job, profession, or position. Fellows can be students, post-doctoral fellows, or faculty members. This requires additional management of the method of payment for Trainees.</td>
</tr>
<tr>
<td>Tuition Remission</td>
<td>A practice of subsidizing the tuition of a student in lieu of salary and benefits provided for educational or research activities. Funding for the subsidy on sponsored programs is proportional to the amount of effort being dedicated by the student.</td>
</tr>
</tbody>
</table>
KEYWORD GUIDANCE
<table>
<thead>
<tr>
<th>Topics</th>
<th>Guidance</th>
</tr>
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<tbody>
<tr>
<td>Budgeting</td>
<td>Reach out to your <a href="#">OSR SPS or SPO Grants Manager</a></td>
</tr>
</tbody>
</table>
|                                             | • *Keywords*  
|                                             |   ▶ Direct Limitations / Indirect Rates  
|                                             |   ▶ Patient Capitation or Patient Care Costs                           |
| Individual Conflict of Interest (COI)       | Contact [COI program](#) and [OSR SPS or SPO Grants Manager](#)       |
|                                             | • *Keywords*  
|                                             |   ▶ Financial COI  
|                                             |   ▶ Personal COI                                                       |
| Organizational Conflict of Interest (OCI)   | Contact [COI program](#) and [OSR SPS or SPO Grants Manager](#)       |
|                                             | • *Keywords*  
|                                             |   ▶ Institutional COI  
|                                             |   ▶ Organization COI                                                  |
| PI Eligibility                              | Review policy [HERE](#); for questions, contact [OSR SPS or SPO Grants Manager](#) |
|                                             | • *Keywords*  
|                                             |   ▶ PI eligibility                                                    |
| Research data                               | Reach out to your [OSR SPS or SPO Grants Manager](#)                    |
|                                             | • *Keywords*  
|                                             |   ▶ Data management plan  
|                                             |   ▶ Publication Restrictions                                            |
| Foreign influence / interference            | Reach out to your [OSR SPS or SPO Grants Manager](#)                    |
|                                             | • *Keywords*  
<p>|                                             |   ▶ Foreign influence / interference                                   |</p>
<table>
<thead>
<tr>
<th>Topics</th>
<th>Guidance</th>
<th>Keywords</th>
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</tr>
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<tbody>
<tr>
<td>Export control</td>
<td>Reach out to your OSR SPS or SPO Grants Manager</td>
<td>• International Traffic in Arms Regulations (ITAR)</td>
<td>• Information systems</td>
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<td>• Export Administration Regulations (EAR)</td>
<td>• Privacy</td>
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<td>• NIST 800-171 / 800-53 / 800-173</td>
<td>• Access Control</td>
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<td>• ISO 27002</td>
<td>• Risk vulnerabilities</td>
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<td>• Data Security</td>
<td>• Security Assessment</td>
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<td>• Data Protection</td>
<td>• Controlled Unclassified Information</td>
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<td>• Data Share</td>
<td>• Processes, stores, transmits information</td>
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<td>• Safeguarding</td>
<td>• Cybersecurity</td>
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<td>Intellectual Property (IP)</td>
<td>Contact OTC if the Intellectual Property of UNC is involved</td>
<td>• Innovation</td>
<td>• Patent</td>
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<td>• Royalty</td>
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<td>Confidentiality</td>
<td>Reach out to your OSR SPS or SPO Grants Manager</td>
<td>• Proprietary</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Trade secrets</td>
<td></td>
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<td></td>
<td></td>
<td>• Non-disclosure</td>
<td></td>
</tr>
<tr>
<td>Limited submission</td>
<td>Route your submission through the Office of Research Development; details HERE</td>
<td>• Limited submission</td>
<td></td>
</tr>
</tbody>
</table>
BUDGETING CATEGORIES
<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuition &amp; Fees</td>
<td>A practice of subsidizing the tuition of a student in lieu of salary and benefits provided for educational or research activities. Funding for the subsidy on sponsored programs is proportional to the amount of effort being dedicated by the student.</td>
</tr>
<tr>
<td>Person Months</td>
<td>The unit use to express effort (amount of time) personnel devote to a specific project. The effort is based on the type of appointment of the individual such as a 12 month or 9 month.</td>
</tr>
<tr>
<td>Salary Caps</td>
<td>A limitation placed on the salary rate that can be charged to a sponsored project by the funding agencies, set by NIH. This is independent of the amount of personnel effort that can be devoted to a project.</td>
</tr>
<tr>
<td>Fringe Rate</td>
<td>Applicable rates of employee benefits that can be charged to a project. These calculations should use the most recent rates from OSR.</td>
</tr>
<tr>
<td>Equipment</td>
<td>Tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-Federal entity for financial statement purposes, or $5,000.</td>
</tr>
<tr>
<td>Detailed budget</td>
<td>The financial plan for the project or program that the awarding agency or pass-through entity approves during the award process or in subsequent amendments to the award.</td>
</tr>
<tr>
<td>Modular budget</td>
<td>A budgeting capability available to certain NIH grants in which the direct costs are requested in specified increments that does not require a detailed budget or supporting documentation. Modules are divided into $25,000 increments with a maximum of $250,000 per year.</td>
</tr>
<tr>
<td>Indirect (F&amp;A) Rate</td>
<td>Those costs incurred for a common or joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted without effort disproportionate to the results achieved.</td>
</tr>
<tr>
<td>Category</td>
<td>Definition</td>
</tr>
<tr>
<td>----------------------------------</td>
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</tr>
<tr>
<td>Consultants</td>
<td>An individual who provides professional advice or services for a fee, but normally is not engaged as an employee of the recipient institution.</td>
</tr>
<tr>
<td>Effort</td>
<td>The measurement of personnel time devoted towards a specific task. Time provided to sponsored projects is required to be monitored and documented to guarantee the amount of pledged time is equal to the time spent. The percentage of salary paid by a sponsored project must not exceed the amount of time spent on the project.</td>
</tr>
<tr>
<td>Incentives/Subject Payments</td>
<td>Payments made to participants who participate in research studies, does not apply only to clinical trials. Amount paid may be restricted by the sponsor.</td>
</tr>
<tr>
<td>Services</td>
<td>Something that cannot be provided by UNC-CH and must be obtained from an outside vendor. Services DO NOT include data analysis or other actions that complete part of the scope of work.</td>
</tr>
<tr>
<td>Subrecipients</td>
<td>An agreement provided by a pass-through entity to a subrecipient in order to carry out part of an award received by the pass-through entity. A subaward may be provided through any form of legal agreement. For Federal awards F&amp;A cannot be taken after the first $25,000 per 5-year segments.</td>
</tr>
<tr>
<td>Travel</td>
<td>Any travel that occurs to benefit the project. This can be outside of the U.S. (foreign) travel and does have additional restriction both from the sponsor and the University.</td>
</tr>
<tr>
<td>Participant support costs</td>
<td>Participant support costs means direct costs for items such as stipends or subsistence allowances, travel allowances, and registration fees paid to or on behalf of participants or trainees (but not employees) in connection with conferences, or training projects.</td>
</tr>
</tbody>
</table>
GENERAL TIPS & TRICKS
As soon as possible, **read and ensure understanding of proposal submission guidelines**

Create customized checklist for Proposal Creation based on submission guidelines

Create and share with PI a timeline of activity, with internal deadlines, starting with Proposal Creation and through the Proposal Submission process

Determine responsible parties for each element of the proposal (e.g., for when multiple PIs work on one proposal simultaneously)

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, COI terms) and incorporate into checklist

Understand and adhere to **version control** and file storage processes in place for documents (e.g., budgets, budget justifications, research strategy, etc.)

If subagreement(s) are involved, **connect with the business manager of the subrecipient(s) as early as possible**

Determine early in the process which agreement template (UNC or sponsor) will be used. If using the sponsor contract template, upload the contract with the IPF in RAMSeS

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**

Check ahead of time which **electronic system is used for proposal submission and ensure access** to the agency

**As needed, schedule a call / meeting with your OSR Sponsored Projects Specialist / SPO Grants Analyst** 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
PROPOSAL COMPLIANCE

- Check **PI eligibility** per UNC policy.

- The University requires **PIs have a minimum of 1% effort** for 1 effort period either directly charged or provided as pre-approved cost share on most sponsored projects. See [UNC policy](#).

- If any **Organizational Conflict of Interest (OCI) language** is identified in the submission guidelines, contact your OSR SPS and the COI office immediately. OCI approval may be required prior to proposal submission for non-profit sponsors that seek OCI disclosure.

- Gather the **name and email (non-.edu) 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**:
  - Did this person substantially contribute to the design of the study?
  - Is this person conducting any experiments or activities?
  - Is this person directly involved in or have control over the collection of data?
  - Is this person involved in the analysis of the data?

- 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 your study involves **biospecimens** (e.g. tissue, blood, etc.), please contact OHRE to determine if the “Human Subjects” checkbox should be checked.

- If the **study involves human subjects, radioactive / hazardous chemicals / biological materials, 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.

- If your study **involves animal research**, 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 IACUC.
RA should work with PI to develop a **realistic budget amount**

The PI should not share the budget or price with the sponsor unless the RA and OSR/SPO has reviewed it.

Confirm you are **using the most up to date rates for budgets** (e.g., Salary Cap, Fringe Rates, Tuition Fees, Faculty Salaries, etc.).

Confirm if the F&A rate is based on Total Direct Costs (TDC) Modified Total Direct Costs (MTDC).

Confirm that sponsor will allow fringe benefits and/or tuition costs. If not, notify the Department Business Manager to determine if the costs can be paid from another source.

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.

Review the proposal guidelines via the website rather than just print since federal sponsors frequently add updates after the initial posting.

**Cross-check the addition of subagreement budgets** to ensure they **match with the justification dollar amounts and the total dollar amount proposed** to the sponsor.

Review subagreement budgets and justifications to ensure that the first and last name of personnel proposed are provided to ensure timely compliance checks upon award and issuance of subagreements.
FREQUENTLY ASKED QUESTIONS
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. 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 that 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 subjects research), IRBIS (human subjects research), ALICE (industry contracts/clinical trials) and CRMS (clinical research), Cayuse (system to system application for Grants.gov). A list of research systems and their use may be found [HERE](#).

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 will require an internal budget that matches the budget in the agreement.

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 found [HERE](#).

Q: What if the proposal guidelines are unclear?
A: Confirm that there’s not a single point of contact at UNC for the sponsor (mostly managed by the Corporate and Foundation Relations Office). If not, contact the sponsor directly or OSR/SPO.
**PROPOSALS 101**

- **Q: What action should I take if I am unclear on the appropriate F&A rates for the project?**
  A: Please see [HERE](#) for more details.

- **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](mailto:globaloperations@unc.edu)

- **Q: How do I get access to the electronic systems used for proposal submissions**
  A: For Cayuse424, please contact [ORIS](#). For RAMSeS, contact your department’s [Backbone Role Manager](#). For eRA Commons, contact OSR at [ResAdminOSR@unc.edu](mailto:ResAdminOSR@unc.edu). For all other external sponsor portals, follow proposal guideline instructions or information provided on sponsor websites.

- **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: When do PIs or department research administrators submit the proposal?**
  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.
EXPEDITING PROPOSAL PROCESSES

1. Review the RFA and specific agency guidelines
2. Collaborate with your PI often, especially during proposal creation
3. Contact your OSR / SPO representative early in the pre-award process
4. Start compliance applications as soon as JITs are submitted
5. Always read the terms and conditions in the NOA
INTERNAL SYSTEM SUBMISSIONS
<table>
<thead>
<tr>
<th>SECTIONS REQUIRED FOR IPF SUBMISSIONS IN RAMSeS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Note: Some units use an intake form to gather the required information ahead of time when meeting with the PI.</td>
</tr>
</tbody>
</table>
| **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  
  • CFR representative may be selected from dropdown options |
| **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 *(Federal)* |
| **Regulatory Compliance** | • No funding may be used for human/animal research until the appropriate approved protocols are in place  
  • If human are involved and no submission to IRB have been made, the study team is not permitted to perform any human research  
  • Note that the JIT status will need to be selected once OSR is notified that funding/award is imminent *(Federal)* |
| **Budget** | • Always check with the sponsor if you are required to use their budget template.  
  • 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  
  • 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 |
| **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. |
| **Other Categories** | • Export control, subrecipients, community engagement, location of sponsored activities, application abstract, approving departments, and attachments |
### Intellectual Property

- If you have any IP questions, please contact your SPS and consult the [Office of Technology Commercialization](#) for more information.
- If your proposal is an SBIR of STTR, please see the [Office of Technology Commercialization](#) for more information.

### Required attachments

- Internal Budget and Budget Justification
- Subrecipient Required Documents when applicable

Please review the comprehensive list of items to include in the IPF for submission in RAMSeS [HERE](#).
COMPLIANCE GUIDANCE
**COMPLIANCE SUBMISSIONS PROCESS**

**Responsible party**

- **PI / Study Team and Department RA**
  - PI Learns of site selection
  - Both parties: Review relevant compliance submission requirements

- **Compliance Offices**
  - PI / Study Team: Submit to relevant compliance offices
  - Review *compliance submissions*
  - Approve once submission requirements have been met
  - Notify OSR / OCT of approved compliance submissions
  - Approve once submission requirements have been met

**Timeline**

- **PI Learns of site selection**
- **PI / Study Team:** Submit to relevant compliance offices
  - **REMEMBER:** Quality and completeness of initial submission directly impacts response time!
  - Review *compliance submissions*
  - Approve once submission requirements have been met
  - Notify OSR / OCT of approved compliance submissions

*Note - Some compliance processes may require negotiation with the sponsor:*
- Privacy
- Export Control
- Data Security
- Other Compliance requirements may also not be determined until terms are finalized
CONFLICT OF INTEREST REVIEW PROCESS MAP

**COI Disclosure Receipt**
- Investigators submit COI Disclosure through AIR when prompted by RAMSeS or IRBIS Actions
- System automatically evaluates disclosure
- Potential COI indicated?
  - NO - 96% of all disclosures
  - YES - 4% of all disclosures

**COI Program Review (Initial Stage)**
- Disclosures triaged:
  1) IRB disclosures assigned to staff's queue for review
  2) RAMSeS disclosures assessed: some placed in queue for review; others placed in "hold" bucket pending funding
- Staff review disclosure
  - Significant COI exists?
    - No conflict/Acknowledged/Transparency COI finalization letters sent to investigator
    - Staff reviews with COI Officer
      - 1) Staff send Case Summary to COI Committee Chair or Designated Reviewer. Either one can request full committee review after their initial analysis.
      - 2) Staff/COI Officer determine case needs full committee review based on investigators’ financial interest or risk of study.
      - ~60% (~98% (Designated or Chair review))

**Chair/Designated/Full Committee Review**
- COI Officer reviews and confirms draft COI Finalization Letter which includes determination and study specific management
- Report to sponsor if needed
- If new conflict, staff obtain signed management plan from investigator
- Staff create draft COI Finalization letter; disclosure text for IRB if needed
- Send COI finalization emails (systems reflect results)
- Letter visible to IRB
- Determination from COI Committee, including management
- ~1% are passed on to full committee review by Chair
- Designated review by Dean/Director
- ~1% (Designated or Chair review)

**School/Units**
- SOM meets monthly; CAS meets monthly during academic year; others 1x semester
- IRBIS submissions are triaged for review regardless of funding status
- RAMSeS submissions are triaged reviewed if a NOA is received, if it’s a 2+ year of multi-year award, or if it’s an industry contract with no additional grant sponsorship
- ~1% are passed on to full committee review by Chair
- Designated review by Dean/Director
- ~1% (Designated or Chair review)

**COI Program Review (Final Stage)**
- COI Officer reviews and confirms draft COI Finalization Letter which includes determination and study specific management
- Report to sponsor if needed
- If new conflict, staff obtain signed management plan from investigator
- Staff create draft COI Finalization letter; disclosure text for IRB if needed
- Send COI finalization emails (systems reflect results)
- Letter visible to IRB
- Determination from COI Committee, including management
- ~1% are passed on to full committee review by Chair
- Designated review by Dean/Director
- ~1% (Designated or Chair review)

**Close**
- No conflict/Acknowledged/Transparency COI finalization letters sent to investigator
- Staff reviews with COI Officer
  - 1) Staff send Case Summary to COI Committee Chair or Designated Reviewer. Either one can request full committee review after their initial analysis.
  - 2) Staff/COI Officer determine case needs full committee review based on investigators’ financial interest or risk of study.
  - ~60% (~98% (Designated or Chair review))

**End**
- Staff may query investigator, tech transfer, etc. on information in disclosure.
- End
GUIDELINES ON CONFLICT OF INTEREST 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
- 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. 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
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.

▪ **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
FREQUENTLY ASKED QUESTIONS

▪ Q: When are COI disclosures reviewed?
  A: If COI disclosures are tied to a human subject’s 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.
IACUC INITIAL REVIEW PROCESS MAP

**All protocols are reviewed monthly**

1. **IACUC Submission**
   - Submit application to OACU via ACAP system

2. **Admin Review***
   - Advised of EHS and training certification requirements

3. **Revisions needed?**
   - Yes
     - Make revisions
   - No
     - Request revisions

4. **OACU / DCM Veterinarians / EHS**
   - Pre-review notification sent to:
     - EHS
     - DCM
     - OACU admin
     - E&O

5. **Process application for meeting**
   - Yes
     - Send revised application to review
   - No
     - Make revisions

6. **Assign protocol to prime reviewer and veterinarian to review 1 week before meeting**

7. **FRC**
   - Revisions needed?
     - Yes
     - Application withheld?
       - Yes
         - Review revised application
       - No
         - Submit EHS and training completion forms

8. **DMR**
   - Revisions needed?
     - Yes
     - Application withheld?
       - Yes
         - Submit EHS and training completion forms
       - No
         - Submit EHS and training completion forms

9. **IACUC Meeting**
   - All items addressed?
     - Yes
       - Approve application
     - No
       - Verify completion

Note: *Admin Review includes DCM, EHS, and E&O review.
GUIDELINES ON IACUC SUBMISSION

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-Regulated 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.

Θ TIPS TO ACCELERATE THE PROCESS

▪ If a subagreement contains animal work, OACU should be notified ASAP so the process of approval can begin.

▪ Send a notification email to iacuc@med.unc.edu as soon as it is known that animal work will take place outside of UNC.

▪ OACU requires notification if animal work will be conducted at UNC. Complete or amend animal applications in ACAP.

▪ Contact OACU at iacuc@med.unc.edu to request an informational packet for new or existing PIs new to performing vertebrate animal work at UNC. A printable checklist is also available on the “Getting Started” page of the IACUC website.

▪ Plan ahead and register for required hands-on training and lectures as soon as you finalize what procedures and techniques will be performed.

Θ FREQUENTLY ASKED QUESTIONS

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. PI’s should begin work on their animal care applications as soon as they have established an ONYEN.
GUIDELINES ON IRB SUBMISSION

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), Good Clinical Practice Education Certification (GCP-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.
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: 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. Both exempt and expedited require a submission in IRBIS for IRB review/determination.
1) 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 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.
2) 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. See "Expedited Review Categories"
FREQUENTLY ASKED QUESTIONS

▪ **Q: If I am part of a multi-site study, what actions do I need to take?**
  A: 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.

  - **UNC is the Reviewing IRB?**
    A: Once the study receives initial IRB approval the participating sites are on boarded via subsequent modifications in IRBIS.

  - **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: 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:

  - Identify the individual in the "Project Personnel" section of the application,
  - Select "Edit" on their personnel record
  - Indicate their need to receive IRB correspondence by selection of the checkbook.

▪ **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.
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, click HERE to more information

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

- Q: How often is COI training required?
  A: Every 4 years
HELPFUL TIPS ON OTHER COMPLIANCE

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 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 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.
Federal Sponsors
FEDERAL PROPOSAL PROCESS

ENGAGE OSR EARLY IN THE PROCESS AND WORK WITH CFR AS NEEDED

Study conception
Principal Investigator (PI) conceives idea and determines funding source

Review submission guidelines
School / unit RA reviews submission guidelines and provide PI with appropriate checklists and timeline

Develop budget and technical proposal
PI and RA collaborate on budget development

Submit IPF
RA uploads all necessary documents to RAMSeS

Prepare final package
RA to complete package on sponsor portal

STOP IF FUNDABLE SCORE IS NOT RECEIVED

Proposal submission
OSR / SPO to review and submit final proposal package

Receive JIT requests from the sponsor
Sponsor notifies the PI and OSR on JIT requests

Submit all compliance forms
Departments may need to submit applications prior to NOA to ensure timely award setup

Respond to JIT requests
RAs to gather and submit JIT requests to OSR / SPO

Receive Notice of Award (NOA)
Sponsor notifies award is granted to PI or OSR

Review and setup award
OSR creates project ID after compliance checks and approval of budget and terms
**PROPOSAL CREATION PROCESS**

<table>
<thead>
<tr>
<th>Responsible Party</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI</td>
<td>Study conception</td>
</tr>
<tr>
<td></td>
<td><strong>Please follow internal school / unit deadlines</strong></td>
</tr>
<tr>
<td>Department RA</td>
<td>Review RFA and provide guidelines to PI for proposal creation</td>
</tr>
<tr>
<td></td>
<td>OCI disclosure triggered by department RFA review</td>
</tr>
</tbody>
</table>
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.

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**PROPOSAL SUBMISSION PROCESS**

<table>
<thead>
<tr>
<th>Responsible party</th>
<th>Timeline</th>
<th>5 business days before deadline</th>
<th>2 business days before deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department RA</td>
<td>Proposal developed</td>
<td>Submit IPF in RAMSeS</td>
<td>COI disclosure triggered</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prepare final administrative package in sponsor portal</td>
<td>Prepare final proposal package in sponsor portal (add technical component)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Approve IPF by administering department¹</td>
<td>Notify OSR / SPO that final package has been uploaded</td>
</tr>
<tr>
<td>OSR / SPO</td>
<td>Perform initial review on submitted content</td>
<td>Perform final review; approve and submit proposal to sponsor unless portal requires PI or CFR to submit</td>
<td>Pause until sponsor responds</td>
</tr>
</tbody>
</table>

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.
### SPECIFIC KEYWORD AND BUDGET GUIDANCE

#### KEYWORD GUIDANCE

<table>
<thead>
<tr>
<th>Topics</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Research data</strong></td>
<td>Reach out to your <a href="#">OSR SPS or SPO Grants Manager</a></td>
</tr>
</tbody>
</table>
| • **Keywords**                     | ▶ Data management plan  
|                                    | ▶ Publication Restrictions                                               |
| **Foreign influence / interference**| Reach out to your [OSR SPS or SPO Grants Manager](#)                      |
| • **Keywords**                     | ▶ Foreign influence / interference                                       |
| **Limited submission**             | Route your submission through the Office of Research Development; details [HERE](#) |
| • **Keywords**                     | ▶ Limited submission                                                     |
### SPECIFIC KEYWORD AND BUDGET GUIDANCE

#### BUDGETING GUIDANCE

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
</tr>
</thead>
</table>
| **Salary Caps**                   | ▪ OSR provides the latest information on salary caps for PHS funded agencies [HERE](#).  
                                          ▪ Refer to RFA for sponsor specific Salary Caps                                                                                                                                                                 |
| **Equipment**                     | ▪ 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                                                                 |
| **Graduate Student Fees**         | ▪ See OSR guidance on budgeting and charging graduate student fees that are allowable on federal funding sources [HERE](#).                                                                                                                                                 |
| **G-ship**                        | ▪ Consult the [Finance website](#) to identify current and up to date Yearly Rate                                                                                                                                                                                        |
| **Modular vs. detailed budget**   | ▪ Whether a modular or detailed budget is requested by the sponsor, a detailed budget is required for OSR/SPO proposal submission                                                                                                                                              |
| **Subrecipients vs. Consultants vs. Suppliers** | ▪ See OSR guidance on Subrecipient vs. Vendor and Subrecipient vs. Contractor found [HERE](#).                                                                                                                                                                           |
| **Effort**                        | ▪ Ensure PI has capacity to execute requirements of research outlined in the proposal and meets min. submission guidelines reqs.  
                                          ▪ Translate effort into weekly hours to ensure effort estimated can be reasonably be accomplished  
                                          ▪ There is a 1% minimum effort requirement for Lead PI’s. For more information, see [HERE](#)
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](https://www.grants.gov).

<table>
<thead>
<tr>
<th>Major Sponsor</th>
<th>Sponsor Specific Resource Links</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Institutes of Health (NIH)</td>
<td>• Apply: Application Guide</td>
</tr>
<tr>
<td></td>
<td>• Forms/Formats: Forms Library</td>
</tr>
<tr>
<td></td>
<td>• Systems: Systems and System Access Roles</td>
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<tr>
<td></td>
<td>• Other Resources: FAQs</td>
</tr>
<tr>
<td></td>
<td>• COVID-19: Resources</td>
</tr>
<tr>
<td>National Science Foundation (NSF)</td>
<td>• Apply: PAPPG</td>
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<tr>
<td></td>
<td>• Forms/Formats: Grants.gov Forms</td>
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<td></td>
<td>• Systems: Research.gov</td>
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<tr>
<td></td>
<td>• Other Resources: Fastlane Help &amp; FAQs</td>
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<tr>
<td></td>
<td>• COVID-19: Resources</td>
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<tr>
<td>Department of Defense (DOD)</td>
<td>• Apply: Application Instructions</td>
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<td>• Forms/Formats: Forms &amp; Formats</td>
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<td>• Systems: ebrap</td>
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<td></td>
<td>• Other Resources: Tips for Success</td>
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<td></td>
<td>• COVID-19: Resources</td>
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<tr>
<td>Department of Energy (DOE)</td>
<td>• Apply: How to Apply to Grants.gov</td>
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<tr>
<td></td>
<td>• Forms/Formats: EERE Forms</td>
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<tr>
<td></td>
<td>• Systems: EERE Exchange</td>
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<td></td>
<td>• Other Resources: DOE Offices</td>
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<tr>
<td></td>
<td>• COVID-19: Resources</td>
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<tr>
<td>Agency for Healthcare Research and Quality (AHRQ)</td>
<td>• Apply: Application Guide</td>
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<tr>
<td></td>
<td>• Forms/Formats: Forms Library</td>
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<tr>
<td></td>
<td>• Systems: Workspace-Grants.gov</td>
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<tr>
<td></td>
<td>• Other Resources: Tips for Success</td>
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<tr>
<td></td>
<td>• COVID-19: Resources</td>
</tr>
<tr>
<td>Major Sponsor</td>
<td>Sponsor Specific Resource Links</td>
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<td>---------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------</td>
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<tr>
<td>DHHS Health Resources and Services Administration</td>
<td>• Apply: <a href="#">Application Guide</a></td>
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<tr>
<td>(HRSA)</td>
<td>• Forms/Formats: <a href="#">Grants.gov Forms</a></td>
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<td></td>
<td>• Systems: <a href="#">Workspace-Grants.gov</a></td>
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<td></td>
<td>• Other Resources: <a href="#">Tips &amp; Process</a></td>
</tr>
<tr>
<td></td>
<td>• COVID-19: <a href="#">Grantee FAQs</a></td>
</tr>
<tr>
<td>National Aeronautics and Space Administration (NASA)</td>
<td>• Apply: <a href="#">Application Guide</a></td>
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<tr>
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<td>• Forms/Formats: <a href="#">Forms</a></td>
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<tr>
<td></td>
<td>• Systems: <a href="#">NSPIRES</a></td>
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<td></td>
<td>• Other Resources: <a href="#">Grant Resources</a></td>
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<td></td>
<td>• COVID-19: <a href="#">Resources</a></td>
</tr>
<tr>
<td>Centers for Disease Control and Prevention (CDC)</td>
<td>• Apply: <a href="#">Grants &amp; Cooperative Agreements</a></td>
</tr>
<tr>
<td></td>
<td>• Forms/Formats: <a href="#">Grants.gov Forms (HHS)</a></td>
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<td></td>
<td>• Systems: <a href="#">Workspace-Grants.gov</a></td>
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<td></td>
<td>• Other Resources: <a href="#">Grant Tips</a></td>
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<tr>
<td></td>
<td>• COVID-19: <a href="#">Resources</a></td>
</tr>
<tr>
<td>Department of Education (DOED)</td>
<td>• Apply: <a href="#">Discretionary Grants</a></td>
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<tr>
<td></td>
<td>• Forms/Formats: <a href="#">Forms</a></td>
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<tr>
<td></td>
<td>• Systems: <a href="#">Workspace-Grants.gov</a></td>
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<tr>
<td></td>
<td>• Other Resources: <a href="#">Grants Process Overview</a></td>
</tr>
<tr>
<td></td>
<td>• COVID-19: <a href="#">Resources</a></td>
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</tbody>
</table>
ADDITIONAL RESOURCES FOR FEDERAL SPONSORS

**General Resources**
- Primer on Federal Awards
- Grant Eligibility
- Grant Terminology
- Federal Awarding Agencies
- Systems Supporting Federal Awards
- Federal Grant Policies
- Uniform Guidance

**Grants.gov**
- Workspace Resources
- Grants.gov Alerts
- Grants.gov Support

**eRA Commons**
- eRA Commons
- eRA Commons FAQs
- eRA Commons Help & Tutorials

**Federal Contract Resources**
- Acquisition.gov (FAR)
- General Services Administration
- SAM.gov Contracting Resources
- USA.gov Contracting Resources

**Federal Grant Policy Manuals**
- HHS Grants Policy Statement
- NIH Grants Policy Statement
- NSF PAPPG

**Federal Demonstration Partnership**
- thefdp.org
- Subaward Forms

**Council on Government Relations**
- Cogr.edu
- COGR Resources
TIPS & TRICKS

- Be aware of specific peer review requirements for that proposal/sponsor
- Set realistic scope of work, keeping in mind the budget, sponsor goals and the timeframe of the project
- In the same vein, you should set a realistic budget for what you are proposing, it is not recommended to underestimate the budget in order to be considered ‘competitive’
- Do not propose voluntary cost share on federal proposals. Unless specifically required by the sponsor proposal guidelines, the federal sponsors do not want to see cost share.
- Always include all foreign components that you are proposing for the project, if you are uncertain of what to include please contact your department’s SPS or SPO. This can include foreign subrecipients, work in a foreign country, travel to a foreign country, collaborations, etc.
- Other Support specifications for NIH are detailed and rapidly changing, it is important to be aware of the changes that are applicable to the proposal you are submitting. See HERE for additional guidance from OSR.
- If you are proposing research with multiple PIs it is important to check the sponsor’s website and read the proposal guidelines carefully to ensure all requirements are met for a successful application
FREQUENTLY ASKED QUESTIONS

- **Q: Does each federal agency have separate guidelines for proposals?**
  A: Yes. Each agency will have specific guidelines, typically located on their websites, in additional to those for the specific proposal. Please check the sponsor's website for additional information.

- **Q: Are there separate systems for proposal submissions for federal sponsors?**
  A: There are many different systems that are used by federal agencies for proposal submissions but, typically the major UNC federal applications need to be submitted via Workspace. UNC uses Cayuse which interfaces with Grants.gov.

- **Q: Is there one document that contains all Federal proposal regulations/guidance?**
  A: While each sponsor has their own guidelines, all federal sponsors are subject to Code of Federal Regulations (CFR) Part 200: Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards, also known as Uniform Guidance (UG). This is the definitive regulations that UNC bases their policies and Operating Standards on for sponsored projects.

- **Q: Whom do I contact in the central offices for general proposal questions?**
  A: Contact either your department’s OSR Sponsored Projects Specialist or SPO Grant Manager, depending on the sponsor. You can also email the general inboxes for either, ResAdminOSR@unc.edu for OSR or grants.unc.edu for SPO.
TIPS & TRICKS

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 **1181/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.
### Five (5) Business Days Prior to Sponsor Deadline

**Proposal Attachments (UNC)**
- Internal Budget
- Budget Justification
- Proposal application with all final sponsor portal attachments and drafts of the technical components
- Provide access to your proposal 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 for subrecipient
  - SOW
  - Budget
  - Budget Justification
  - PHS 398 forms
  - Agency guidelines for the submission

**Proposal Attachments (Sponsor)**
- Non-federal: follow submission guidelines
- Federal:
  - 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)

### Two (2) Business Days Prior to Sponsor Deadline

**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**
- Final completed application package that is ready to submit
- Mentor biosketches and tables due at this time (Federal Training Grants Only)
A fully developed plan is NOT required at the JIT stage

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 an 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.
**GUIDELINES ON IRB SUBMISSION**

**FREQUENTLY ASKED QUESTIONS**

- **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 an 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.

Please note that if your award/grant is for a new project, or your aims, design, or scientific questions are different, then this should be submitted as a new project and not added to an existing IRB application.
GUIDELINES ON IACUC SUBMISSION

TIPS TO ACCELERATE THE PROCESS

▪ 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.

FREQUENTLY ASKED QUESTIONS

▪ Q: Is a grant congruency review required?
A: The IIA form issued will require a grant congruency review be conducted. These are issued for industry sponsored research where NIH is funding the sponsor and the sponsor is contracting UNC to conduct animal research. A congruency review is required for all federally funded grants where UNC is the Prime, and when UNC is issued an IIA from OLAW/NIH because of an industry sponsor agreement. All animal research requires an approved UNC animal care protocol. Additional information about this process can be found HERE.

▪ 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.

NOTE: A more comprehensive set of FAQs can be found on the IACUC website.
Non-Profit Sponsors
**NON-PROFIT PROPOSAL PROCESS**

**Project conception**
PI conceives idea and determines funding mechanism

**Review submission guidelines**
Department reviews submission guidelines and provides PI with appropriate checklists and timeline

**Develop budget and narrative**
PI and RA collaborate on budget development

**Submit IPF**
RA uploads all necessary documents to RAMSeS

**Prepare final package**
RA to review and approve package on sponsor portal

---

**Proposal submission**
OSR/SPO to review and submit final proposal package

**Receive notice of intent to fund from the sponsor**
Submit all compliance forms and respond to sponsor requests

**Receive Award**
Sponsor notifies award is granted. If PI or CFR receives notice, OSR should be notified immediately

**Review and setup award**
OSR creates project ID after compliance checks and approval of budget and terms

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**ENGAGE OSR EARLY IN THE PROCESS AND WORK WITH CFR AS NEEDED**
PROPOSAL CREATION PROCESS

<table>
<thead>
<tr>
<th>Responsible party</th>
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<tr>
<td>PI</td>
<td></td>
</tr>
<tr>
<td><strong>Project conception</strong></td>
<td>Determine funding mechanism / source</td>
</tr>
<tr>
<td><strong>Department RA</strong></td>
<td>Review submission guidelines and provide guidelines to PI for proposal creation</td>
</tr>
</tbody>
</table>
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 PROCESS

**Responsible party**

<table>
<thead>
<tr>
<th>Responsible party</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Department RA</strong></td>
<td><strong>5 business days prior to deadline</strong></td>
</tr>
<tr>
<td>Proposal developed</td>
<td>Submit IPF in RAMSeS (CFR contact if applicable)</td>
</tr>
<tr>
<td></td>
<td>Prepare final administrative package in sponsor portal</td>
</tr>
<tr>
<td></td>
<td>Approve IPF by administering department¹</td>
</tr>
<tr>
<td><strong>OSR / SPO</strong></td>
<td><strong>2 business days prior to deadline</strong></td>
</tr>
<tr>
<td></td>
<td>COI disclosure triggered</td>
</tr>
<tr>
<td></td>
<td>Prepare final proposal package in sponsor portal (add technical component)</td>
</tr>
<tr>
<td></td>
<td>Notify OSR / SPO that final package has been uploaded</td>
</tr>
<tr>
<td></td>
<td>Perform final review; approve and submit proposal to sponsor, unless portal requires PI or CFR to submit</td>
</tr>
<tr>
<td></td>
<td>Pause until sponsor responds</td>
</tr>
</tbody>
</table>

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.
<table>
<thead>
<tr>
<th>Topics</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Organizational COI</strong></td>
<td>Contact COI program</td>
</tr>
<tr>
<td>• <strong>Keywords</strong></td>
<td>• Institutional COI</td>
</tr>
<tr>
<td></td>
<td>• Organization COI</td>
</tr>
<tr>
<td><strong>Research data</strong></td>
<td>Reach out to your OSR/SPO contact</td>
</tr>
<tr>
<td>• <strong>Keywords</strong></td>
<td>• Data management plan</td>
</tr>
<tr>
<td></td>
<td>• Publication Restrictions</td>
</tr>
<tr>
<td><strong>Export control</strong></td>
<td>Contact your OSR contact if you see any of the keywords on the left</td>
</tr>
<tr>
<td>• <strong>Keywords</strong></td>
<td>• International Traffic in Arms Regulations (ITAR)</td>
</tr>
<tr>
<td></td>
<td>• Export Administration Regulations (EAR)</td>
</tr>
<tr>
<td></td>
<td>• NIST 800-171 / 800-53 / 800-173</td>
</tr>
<tr>
<td></td>
<td>• ISO 27002</td>
</tr>
<tr>
<td></td>
<td>• Data Security/Share/Protection</td>
</tr>
<tr>
<td></td>
<td>• Safeguarding</td>
</tr>
<tr>
<td><strong>Intellectual Property (IP)</strong></td>
<td>Contact OTC if the IP of UNC is involved</td>
</tr>
<tr>
<td>• <strong>Keywords</strong></td>
<td>• Innovation</td>
</tr>
<tr>
<td></td>
<td>• Invention</td>
</tr>
<tr>
<td></td>
<td>• Ownership</td>
</tr>
<tr>
<td></td>
<td>• License</td>
</tr>
<tr>
<td><strong>Confidentiality</strong></td>
<td>Reach out to your OSR/SPO contact</td>
</tr>
<tr>
<td>• <strong>Keywords</strong></td>
<td>• Proprietary</td>
</tr>
<tr>
<td></td>
<td>• Trade secrets</td>
</tr>
<tr>
<td></td>
<td>• Non-disclosure</td>
</tr>
<tr>
<td><strong>Limited submission</strong></td>
<td>Route your submission through the Office of Research Development; details <a href="#">HERE</a></td>
</tr>
<tr>
<td>• <strong>Keywords</strong></td>
<td>• Limited submission</td>
</tr>
</tbody>
</table>
### BUDGETING GUIDANCE

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Incentives/ Subject Payments</strong></td>
<td>Consult the following links for more information on: <a href="#">Payment to research subjects</a>, <a href="#">Collection of SSN for payment purposes</a>, and <a href="#">Recruitment incentives</a></td>
</tr>
</tbody>
</table>
| **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       |
| **Inpatient / Outpatient cost** | • Federal grants typically cannot pay for anything that is standard of care  |
| **Hospital Employees**          | • To learn more about hospital employees as research staff, consult the webpage [HERE](#) |
| **Milestone**                   | • Negotiate at least partial payment upon contract execution                |
| **Deliverable**                 | • Negotiate at least partial payment upon contract execution                |
| **Cost reimbursable**           | • You can negotiate for upfront payment                                     |
| **Fixed price**                 | • This is the preferred option over cost reimbursable with the appropriate risk assessment |
TIPS & TRICKS

- Set **realistic scope of work**, keeping in mind the budget, sponsor goals and the timeframe of the project.
- In the same vein, you should set a **realistic budget** for what you are proposing, it is not recommended to underestimate the budget in order to be considered ‘competitive’.
- Always include **all foreign components** that you are proposing for the project, if you are uncertain of what to include please contact your department’s SPS or SPO. This can include foreign subrecipients, work in a foreign country, travel to a foreign country, collaborations, etc.
- If you are proposing research with **multiple PIs it is important to check the sponsor’s website** and read the proposal guidelines carefully to ensure all requirements are met for a successful application.
### Five (5) Business Days Prior to Sponsor Deadline

<table>
<thead>
<tr>
<th>Proposal Attachments (UNC)</th>
<th>Proposal Attachments (Sponsor)</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Internal Budget</td>
<td>□ Non-federal: follow submission guidelines</td>
</tr>
<tr>
<td>□ Budget Justification</td>
<td></td>
</tr>
<tr>
<td>□ Proposal application with all final sponsor portal attachments and drafts of the technical components</td>
<td></td>
</tr>
<tr>
<td>□ Provide access to your proposal one of two ways:</td>
<td></td>
</tr>
<tr>
<td>□ your application is being submitted in hardcopy.</td>
<td></td>
</tr>
<tr>
<td>□ Allow access to Proposal application if using agency web portal to prepare and submit application. (e.g., Cayuse, NSF Fastlane, NASA NSpires)</td>
<td></td>
</tr>
<tr>
<td>□ F&amp;A waiver request (as applicable)</td>
<td></td>
</tr>
<tr>
<td>□ PI waiver form (as applicable)</td>
<td></td>
</tr>
<tr>
<td>□ Subagreement proposal documents (as applicable):</td>
<td></td>
</tr>
<tr>
<td>□ LOI signed by an authorized signing official of the sub’s institution</td>
<td></td>
</tr>
<tr>
<td>□ SOW</td>
<td></td>
</tr>
<tr>
<td>□ Budget</td>
<td></td>
</tr>
<tr>
<td>□ Budget Justification</td>
<td></td>
</tr>
<tr>
<td>□ Agency guidelines for the submission</td>
<td></td>
</tr>
</tbody>
</table>

### Two (2) Business Days Prior to Sponsor Deadline

<table>
<thead>
<tr>
<th>Technical Components</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Abstract</td>
<td>□ Final completed application package that is ready to submit</td>
</tr>
<tr>
<td>□ Project Description/Science</td>
<td></td>
</tr>
<tr>
<td>□ References Cited</td>
<td></td>
</tr>
<tr>
<td>□ Sections on Human and Animal Subjects (as applicable)</td>
<td></td>
</tr>
<tr>
<td>□ Human Subjects – recruitment plans (as applicable)</td>
<td></td>
</tr>
<tr>
<td>□ Other items regarding the technical/scientific aspects of this proposal per the guidelines for this submission (as required)</td>
<td></td>
</tr>
</tbody>
</table>
Appendix
ADDITIONAL RESOURCES: OFFICE OF SPONSORED RESEARCH

- Information Sheet
- Operating Standards & Procedures
- Forms & Tools
- Resources and Guidance
- Award Lifecycle

- SBIR / STTR Guidance
- Guidance on Science and Security
- Training

ADDITIONAL RESOURCES: COMPLIANCE

Human Subject Research
- Standard Operating Procedures
- Online Submission Guide and FAQ
- Consent templates

Animal Subject Research
- Standards and Policies
- Grant Congruency Self-Request Form
- Getting Started with Animal Research

Conflict of Interest
- Standards and Policies
- COI Decision Tree
ADDITIONAL RESOURCES: PROPOSAL RELATED

Proposal Preparation

- [SPO Tools](#)
- [OSR Prior Approval & Waiver Forms](#)
- [OSR Proposal Related Forms](#)
- [Grant Writing Tips](#) from the Writing Center

Operating Standards and Policies

- [Operating Standards](#)
- [Using RAMSeS for IPF submission](#)
- [Pre-submission compliance requirements](#)
- [Proposal submission deadlines](#)
- [F&A Waivers Point of Contact](#)