

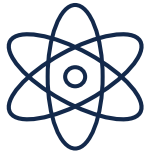
Operational **Excellence** Industry Research Playbook

Updated | November 17, 2020



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

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CLINICAL AGREEMENTS

Coming Soon!



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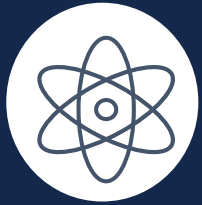


OVERVIEW – INTRODUCTION AND REMINDERS

The Industry Contracting Playbook will provide you the tools and information to complete each step of the project process for industry sponsors. 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.

Always consult with your Office of Sponsored Research – Industry Contracting Contract Manager/Sponsored Projects Specialists if you have questions not addressed in this playbook or if you think your situation is unique or differs from what is stated here.

While this playbook is meant to capture the standard process, it is not all inclusive.

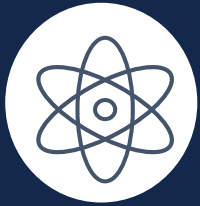


CENTRAL RESEARCH OFFICES



CENTRAL RESEARCH & COMPLIANCE OFFICES

Office		Responsibilities
Conflict of Interest	COI	Provides training in identification and management of conflicting relationships connected to research at the University coi@unc.edu
Industry Relations	IR	Leads and supports life cycle of research business development for industry partners working with the University industry@unc.edu
Div Comparative Medicine	DCM	Provides care for vertebrate animals used in research at the University. dg@unc.edu
Environment, Health & Safety	EHS	Provides health/safety oversight and training on biological, environmental, chemical, occupational, and workplace safety at UNC ehs@unc.edu
Office of Animal Care & Use	OACU	Reviews all animal care applications that use vertebrate animals and oversees applicable training and education programs. iacuc@med.unc.edu
Office of Clinical Trails	OCT	The central resource for UNC faculty, staff, and departments involved in clinical trial research and for sponsors of clinical trials at UNC. oct@unc.edu
Office of Human Research Ethics	OHRE	Provides ethical and regulatory oversight for research involving human subjects at the University irb_questions@unc.edu
Office of Research Development	ORD	Supports University researchers pursuing convergence science and a culture of innovation ord@unc.edu
Office of Sponsored Research	OSR	Partners with research community at UNC for all sponsored programs and research administration management needs resadminosr@unc.edu
Office of Technology Commercialization	OTC	Provides management of all aspects of intellectual property and partners with campus to effectively manage inventions and technologies otc@unc.edu
Research Compliance Program	RCP	Provides guidance that advances the highest standards of ethics, integrity, and honesty in compliance with all applicable laws, regulations, and policies governing research research_compliance@unc.edu



ROLES & RESPONSIBILITIES



ROLES AND RESPONSIBILITIES

Reference the OSR Roles and Responsibilities matrix online [HERE](#).

PRINCIPAL INVESTIGATOR (PI)

Project Development and Submission

- Works with industry sponsor to develop a project
- Partners with the unit research administration (RA) to develop / obtain the budget, budget justification, F&A waivers, and administrative documents per sponsor guidelines
- Identify subrecipients
- Responsible for accurate compliance disclosures
- 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 (Agreement Negotiation and Set-Up)

- 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

UNIT RESEARCH ADMINISTRATOR (RA)

Project Development and Submission

- Coordinates with the PI and central / compliance offices to ensure timely submissions
- Initiates requests to central / compliance offices if assistance is required on submissions
- Partners with PI to develop / obtain the budget and justification, F&A waivers, and other documents
- Obtain statement of work, budget, letter of intent, and other required documents for subagreements
- Complete and route IPF in RAMSeS and submit other administrative components

Post-Award (Agreement Negotiation and Set-Up)

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



ROLES AND RESPONSIBILITIES

SCHOOL DEAN / DEPARTMENT CHAIR

Project Development and Submission

- Determine if proposed project is an appropriate activity for the department and supports the mission of the University
- Responsible for providing resources identified in the scope of work, 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

INDUSTRY RELATIONS (IR)

Project Development and Submission

- Serve as UNC liaison or single point of contact to industry partners for successful collaborations with sponsored research and philanthropy
- Advance industry research partnership by developing engagement strategies, including sponsored research, gift/in-kind, intellectual property management and licensing
- Communicate corporate priorities and interests to University constituents
- Work closely with faculty and staff to develop, finalize, and submit project
- Coordinate communication between industry partners and University regarding agreement negotiations and reporting

OFFICE OF RESEARCH DEVELOPMENT (ORD)

Project Development and Submission

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

OFFICE OF SPONSORED RESEARCH (OSR)

Project Development and Submission

- SPS provides institutional review and approval of the IPF
 - Assists on questions related to eligibility, allowable costs and other administrative elements
-



ROLES AND RESPONSIBILITIES

Post-Award (Agreement Negotiation and Set-Up)

- Industry Contracting team reviews and negotiates contract terms with the sponsor
- Confirm all regulatory compliance requirements have been met by the department
- Review and make budget modifications in partnership with unit RA following agreement terms and conditions
- Checks that all compliance requirements have been obtained
- Ensures compliance with COI management plans, as applicable
- Notify PI and unit RA of award setup via RAMSeS email; provide chartfield and Project ID(s)
- Complete award, project, budgets, contract, and bill plan setup in ConnectCarolina
- Activate the ConnectCarolina contract

INFORMATION TECHNOLOGY SERVICES – DATA SECURITY

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

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
 - Provides assistance to Covered Entities in obtaining information required for their compliance with HIPAA regarding UNC-Chapel Hill research access and use of PHI in the Covered Entities' designated record sets
 - Serves as the University's contact person for all patient requests for further information regarding research projects listed in an accounting of disclosures of the patient's PHI
-



ROLES AND RESPONSIBILITIES - COMPLIANCE

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 investigators
 - Conducts organizational COI and reports as required by sponsors either upon proposal or award, per project
 - Supports Institutional COI Committee which reviews projects, with an emphasis on human studies, involving University-owned licensed Intellectual Property and/or a faculty start-up company
-

OFFICE OF CLINICAL TRIALS (OCT)

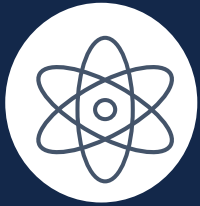
- Responsible for the Clinical Trial Quality Assurance Program, conducts routine and directed audits of clinical trials
 - Responsible for Clinical Research Billing Compliance, oversees the Billing Coverage Analysis process and conducts audits of clinical trials with subject billing through the UNC Health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

OFFICE OF 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 provide certification of IRB approval as part of the JIT federal funding process
 - Completes initial or modification submission reviews, as activities should not begin until the reviews is completed
 - Respond to questions regarding the protection of human subjects and OHRE/IRB processes and procedures
-

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

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



KEY TERMS



KEY TERMS

Term	Definition
Animal Subjects/Animal Care and Use	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.
Authorized Representative/ Institutional Official	Authorized Representative means the individual, named by the institution, who is authorized to sign agreements on behalf of the University. Also called Authorized Official, Signing Official, and Institutional Official.
Budget	The financial plan for the project or program that the sponsor approves.
Conflict of Interest (COI)	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.
Debarment and Suspension	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.
Deliverable	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 payment.
Effective Date	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.
Fixed price	A type of agreement where the sponsor provides a specific level of support without regard to actual costs incurred.
Foreign Component	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 project funds are expended.



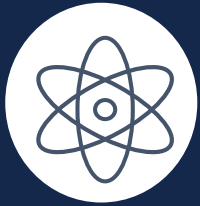
KEY TERMS

Term	Definition
Human Subject	Human Subject is an individual about whom a researcher obtains data through intervention or interaction with the individual or obtains identifiable private information.
Indirect (F&A) Costs	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.
Internal Processing Form (IPF)	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.
Milestone	This is the page in ConnectCarolina where payment schedules are entered for each fixed price project.
Participant support costs	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.
Principal Investigator (PI)	The individual(s) designated by the University to have the appropriate level of authority and responsibility to direct the project or program.
Project Period/Period of Performance	The time during which the recipient may incur new obligations to carry out the work authorized under the agreement.
Scope of Work (SOW)	The aims, objectives, and purposes of a project; as well as the methodology, approach, analyses or other activities; and the tools, technologies, and timeframes needed to meet the project's objectives.
Sponsor	Any organization that provides funding for a set purpose developed in a proposed project.



KEY TERMS

Term	Definition
Subrecipient	An entity that receives a subagreement from a pass-through entity to carry out part of the SOW for a project; but does not include an individual that is a beneficiary of such program.
Terms and Conditions	All legal requirements imposed on a project, whether based on statute, regulation, policy, or other document referenced in the agreement.
Trainee	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.
Tuition Remission	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.



KEYWORD GUIDANCE



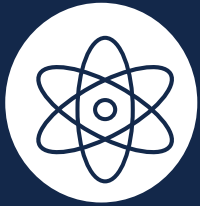
KEYWORD GUIDANCE

Topics	Guidance
Budgeting	Reach out to your OSR SPS /Contract Manager
	<ul style="list-style-type: none">• <i>Keywords</i><ul style="list-style-type: none">❖ Direct Limitations / Indirect Rates❖ Patient Capitation or Patient Care Costs
Individual Conflict of Interest (COI)	Contact COI program Review information on HERE
	<ul style="list-style-type: none">• <i>Keywords</i><ul style="list-style-type: none">❖ Financial COI❖ Personal COI
Organizational Conflict of Interest (OCI)	Contact COI program and OSR SPS /Contract Manager
	<ul style="list-style-type: none">• <i>Keywords</i><ul style="list-style-type: none">❖ Institutional COI❖ Organization COI
PI Eligibility	Review policy HERE ; for questions, contact OSR SPS
	<ul style="list-style-type: none">• <i>Keywords</i><ul style="list-style-type: none">❖ PI eligibility
Research data	Reach out to your OSR Contract Manager
	<ul style="list-style-type: none">• <i>Keywords</i><ul style="list-style-type: none">❖ Data management plan❖ Publication Restrictions
Foreign influence / interference	Reach out to your OSR SPS /Contract Manager
	<ul style="list-style-type: none">• <i>Keywords</i><ul style="list-style-type: none">❖ Foreign influence / interference



KEYWORD GUIDANCE

Topics	Guidance
Export control	Reach out to your OSR SPS /Contract Manager
• <i>Keywords</i>	<ul style="list-style-type: none">❖ International Traffic in Arms Regulations (ITAR)❖ Export Administration Regulations (EAR)❖ NIST 800-171 / 800-53 / 800-173❖ ISO 27002❖ Data Security❖ Data Protection❖ Data Share❖ Safeguarding❖ Information systems❖ Privacy❖ Access Control❖ Risk vulnerabilities❖ Security Assessment❖ Controlled Unclassified Information❖ Processes, stores, transmits information❖ Cybersecurity
Intellectual Property (IP)	Contact OTC if the Intellectual Property of UNC is involved
• <i>Keywords</i>	<ul style="list-style-type: none">❖ Innovation❖ Invention❖ Ownership❖ License❖ Patent❖ Materials❖ Equity❖ Royalty
Confidentiality	Reach out to your OSR Contract Manager
• <i>Keywords</i>	<ul style="list-style-type: none">❖ Proprietary❖ Trade secrets❖ Non-disclosure
Gift	Reach out to Industry Relations
• <i>Keywords</i>	<ul style="list-style-type: none">❖ Gift❖ Unrestricted❖ In-Kind❖ Donation❖ Philanthropy❖ Partnership



BUDGETING CATEGORIES



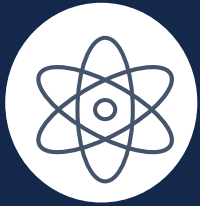
COMMON BUDGETING CATEGORIES

Category	Definition
Incentives/ Subject Payments	Payments made to participants who participate in research studies, does not apply only to clinical trials. Amount paid may be restricted by the sponsor.
Indirect (F&A) Rate	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.
Milestone	Definition: A measurable achievement or event during a project that is often tied to payment timing (e.g. deliverable-based payment schedule) Negotiate at least partial payment upon contract execution
Participant support costs	Participant: the recipient of a service or training associated with a workshop, conference, or other short-term instructional or information-sharing activity (e.g. may include students, scholars, scientists, private sector or state / local government individuals) Uniform Guidance states that participant support costs are typically exempt from F&A on federally sponsored projects
Person Months	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
Services	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.
Subrecipients	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.
Subrecipients vs. Consultants	See OSR guidance on Subrecipient vs. Vendor Guidance
Travel	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.



COMMON BUDGETING CATEGORIES

Category	Definition
Tuition & Fees	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.
Deliverable	Definition: A tangible product given to the sponsor Negotiate at least partial payment upon contract execution
Effort	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.
Equipment	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.
Fringe Rate	Applicable rates of employee benefits that can be charged to a project. These calculations should use the most recent rates from OSR.
Hospital Employees	To learn more about hospital employees as research staff, consult the webpage HERE



GENERAL TIPS & TRICKS



DEVELOPMENT & SUBMISSION PROCESSES

- 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
- Consider appropriate **payment terms and potential risks** especially if partnering with small industry sponsors (e.g., startups)
- Consult the Industry Contracting team in OSR to determine if there are any readily available industry agreement templates applicable for your project or a **master agreement** with a particular industry partner
- **Ensure a detailed SOW is submitted** so that central research offices can understand the proposed work
- **If you have questions related to whether the proposed work is research or service, please contact OSR and/or IR**
- Identify circumstances that require additional attention earlier on in the project conception process (e.g., licensing and IP issues, subrecipients, export control and compliance, large procurements)
- Determine **responsible parties** for each element of the project (e.g., for when multiple PIs work on one project simultaneously)
- If subagreement(s) are involved, connect with the business manager of the subrecipient(s) as early as possible. A sample email can be found [HERE](#)
- If applicable, attach the **subagreement package at the point of IPF submission**
- After SPS approves IPF and sends approval to the industry contracting team, the **PI and department contact will receive notification** when the agreement has been assigned to a contract manager in [ALICE](#)
 - The email will contain the name of the **Contract Manager (CM)** who the PI and the department contact can reach out to with additional relevant information

AWARD READINESS SETUP

- Check that the right person is selected in the RAMSeS IPF to be notified when Project ID is setup
- Ensure the correct IPF# is reflected in your IRBIS submission



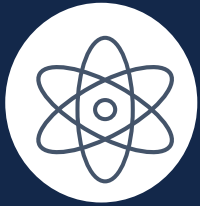
COMPLIANCE

- 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.
- If your study involves **any animal work that will take place outside UNC**, subagreement or otherwise, please contact the IACUC office



BUDGET

- Unit 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 has reviewed it**
- Confirm you are **using the most up to date rates for budgets** (e.g. Fringe Rates, Tuition Fees, Faculty Salaries, etc.)
- Confirm if the F&A rate is based on Total Direct Costs (TDC) or Modified Total Direct Costs (MTDC)
- **There are no salary caps for industry agreements**
- 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.**
- **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



Agreements/Research Administration 101

- **Q: What is an agreement?**

- A: Legal instrument by which entities define roles, responsibilities, and obligations to carry out the project or program.

- **Q: What is a Data Use Agreement (DUA)?**

- A: Contractual document used for the transfer of data that has been developed by nonprofit, government or private industry, where the data is nonpublic or is otherwise subject to some restrictions on its use.

- **Q: What is a Confidential Disclosure Agreement (CDA)?**

- A: legal agreement between a minimum of two parties which outlines information the parties wish to share with one another for certain evaluation purposes but wish to restrict from wider use and dissemination. The parties agree not to disclose the non-public information covered by the agreement. CDAs are commonly executed when two parties are considering a relationship/collaboration together and need to understand the other's processes, methods, or technology solely for the purpose of evaluating the potential for a future relationship. Also referred to as Non-disclosure Agreement (NDA)

- **Q: What is the difference between the Facility Use Fee Model and Budget Pool?**

- A: Facility Use Fee Model – an optional budgeting model that can be used to present costs to For-Profit for lab-based projects. The model provides for the inclusion of a 'facility use fee' (calculated based on a University-provided formula) that would be budgeted as a direct cost. A 28% General & Administrative (G&A) cost is also included. Both of these items are then treated as standard indirect costs by the University.

Budget Pool – will no longer require detailed budgets when the sponsor does not require them. Projects that do not require detailed budgeting will use the budget pool in account code 501000 – Other Expenses. This account code is used when all direct costs are pooled together into a single line item when loaded at project set-up. It is at the discretion of the department to utilize this method and can be used when the sponsor does not require detailed budgeting.



Agreements 101

- **Q: What action should I take if I am unclear on the appropriate F&A rates for the project?**

A: Consult OSR for clarification. Currently updating definitions for sponsored activity types.

- **Q: Why is the following question on international activity added to the IPF submission, and what are the implications for answering “Yes”: “Will the proposed project involve activities primarily focused outside of the United States?”**

A: Your answer to this question helps the University better support faculty and reduce institutional liability overseas. For all questions concerning this question, please contact globaloperations@unc.edu

- **Q: 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.

- **Q: 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, department administrator, OSR, and serves as the internal proposal of record. It is recommended that when answering the questions within the IPF form that the PI is consulted if the answer is unclear in any of the sections.

- **Q: What are the primary research systems I should learn to use?**

A: The main research systems used for research administration purposes include RAMSeS (all research types), RAMTracker (viewing award transactions), AIR (COI disclosures), ACAP (animal care research), IRBIS (human subjects research), ALICE (industry contracts/clinical trials) and CRMS (clinical research).



Agreements 101

- **Q: There are pending compliance checks (currently requires manual checks in RAMSeS to determine the statuses)?**
A: Check which compliance checks are pending in the Compliance tab in RAMSeS (for instructions, click [HERE](#)). Take action on ensuring the appropriate compliances are completed or approved.

- **Q: What do I need to do if personnel has changed during the negotiation process?**
A: Notify your OSR 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.

- **Q: Am I required to have both an IPF in RAMSeS and an ALICE submission?**
A: No. Once the SPS approves the IPF, the approval will be sent to the Industry Contracting team to establish an ALICE record.

- **Q: What is the departmental Research Administrator's role in developing the scope of work or project plan?**
A: It depends on department and PI; could range from no responsibility to coordination of the project.



EXPEDITING the PROCESSES



Review the [UIDP guidebook](#) on working with Industry



Collaborate with your PI often, especially during IPF creation:



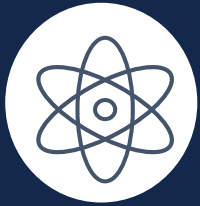
Contact Industry Contracting and IR early in the project development process



Obtain agreement as soon as possible and start compliance applications as soon as intent to submit is clear



Always read the terms and conditions in the agreement



INTERNAL SYSTEM SUBMISSIONS



SECTIONS REQUIRED FOR IPF SUBMISSIONS IN RAMSeS

Note: Some units use an intake form to gather the required information ahead of time when meeting with the PI.

General Information

- If you have questions about the dropdown options and option descriptions under activity type - chess code, reach out to your SPS 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

Personnel

- The first role that MUST BE entered is the Lead Principal Investigator

Regulatory Compliance

- No funding may be used for human/animal research until the appropriate approved protocols are in place
- If human/animal subjects are involved and no submission to IRB/IACUC have been made, the study team is not permitted to perform any human research

Budget

- Make sure to include appropriate F&A rate

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



SECTIONS REQUIRED FOR IPF SUBMISSIONS IN RAMSeS

Note: Some units use an intake form to gather the required information ahead of time when meeting with the PI.

Intellectual Property

- If you have any IP questions, please contact your SPS/Contract Manager and consult the [Office of Technology Commercialization](#) for more information

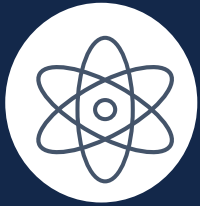
Required attachments

- Scope of Work
- Internal Budget, if applicable
- Draft Agreement, if applicable
- External contacts for negotiations

Other Categories

- Export control, subrecipients, community engagement, location of sponsored activities, application abstract, approving departments

Please review the comprehensive list of items to include in the IPF for submission in RAMSeS [HERE](#)



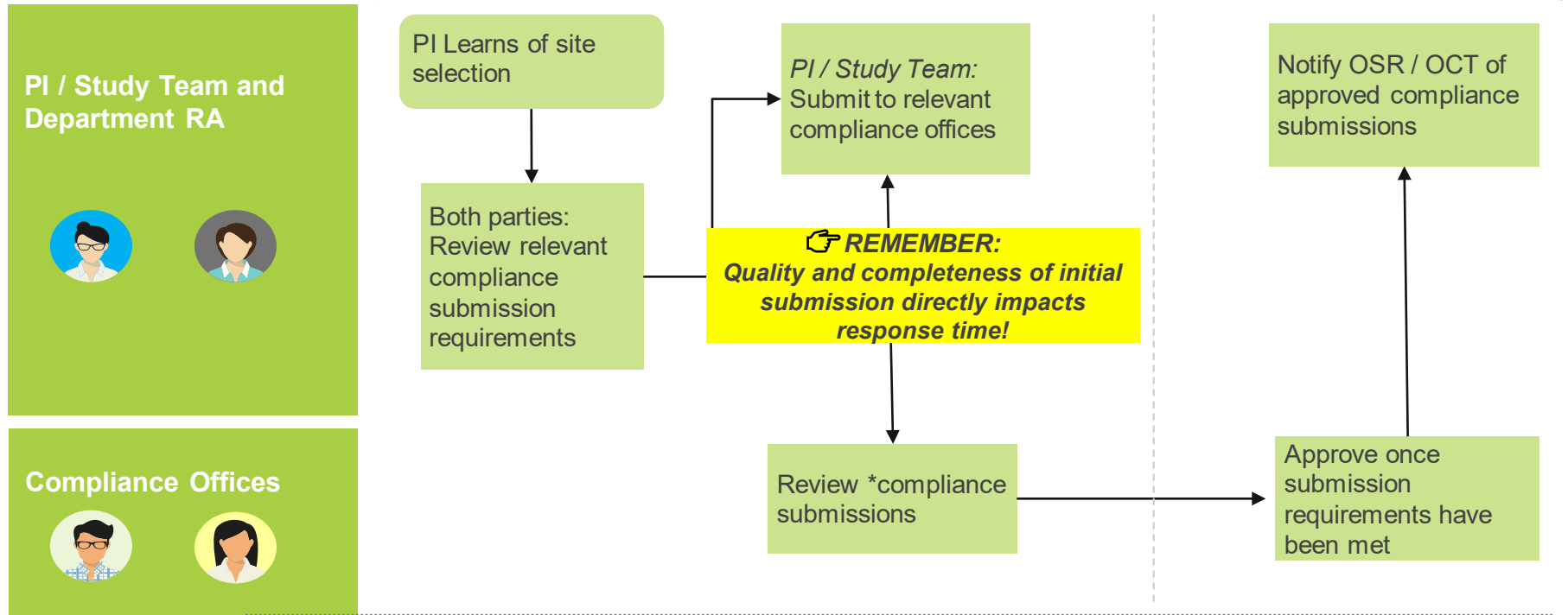
COMPLIANCE GUIDANCE



COMPLIANCE SUBMISSIONS PROCESS

Responsible party

Timeline

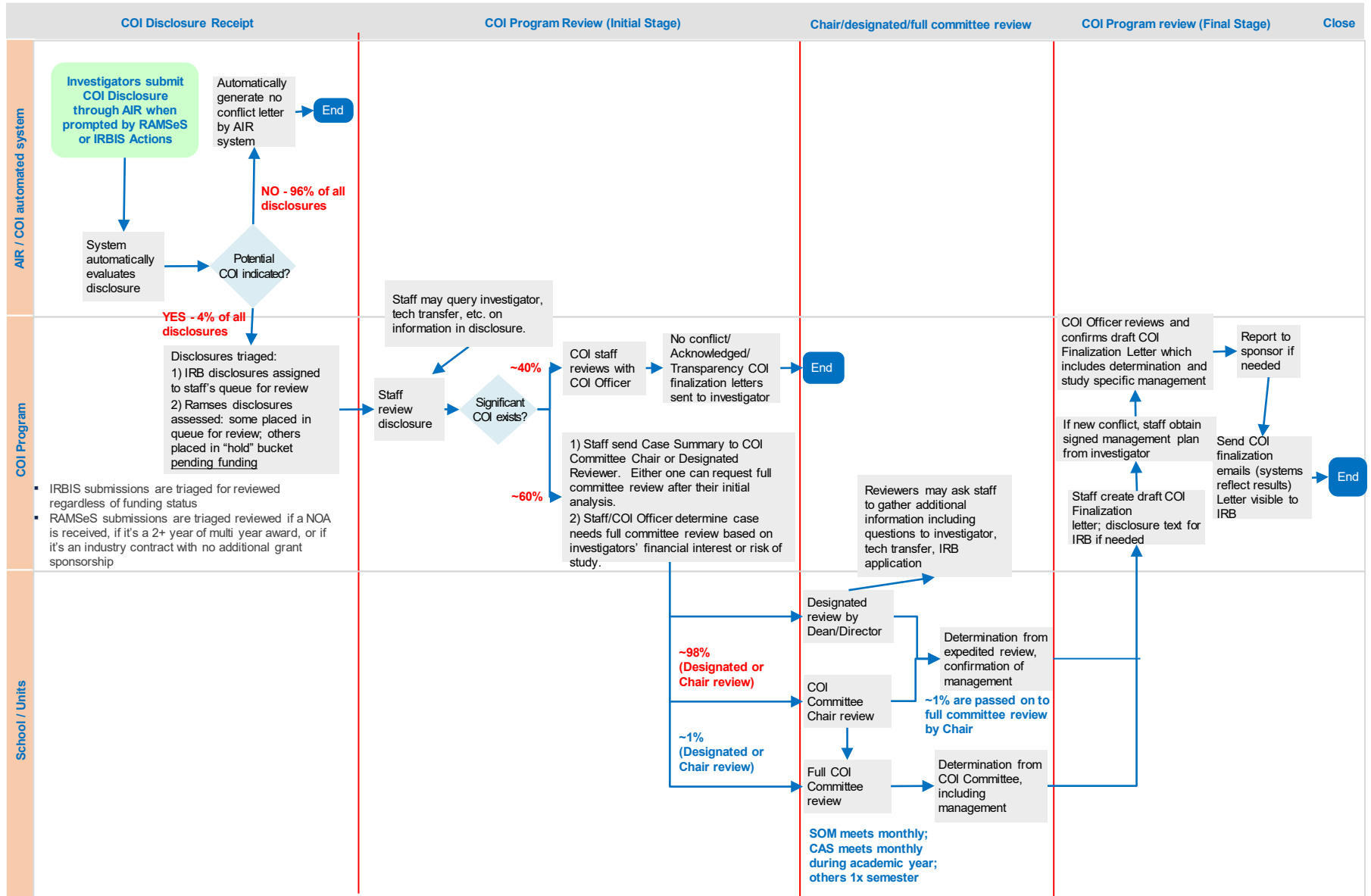


***Note - Some compliance processes may require negotiation with the sponsor:**

- Privacy
- Export Control
- Data Security
- Other Compliance requirements may also not be determined until terms are finalized



CONFLICT OF INTEREST REVIEW PROCESS MAP





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 project 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



GUIDELINES ON CONFLICT OF INTEREST DISCLOSURES



FREQUENTLY ASKED QUESTIONS

▪ **Q: How often do I need to submit COI disclosures?**

A: UNC policy (which stems from federal regulations) requires that project specific COI disclosures be submitted at the time of IPF 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:

- An IPF 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



GUIDELINES ON CONFLICT OF INTEREST DISCLOSURES



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 an IPF, they are reviewed when the IPF is submitted.

- **Q: How can I check the status of the COI for the sponsored project or research study?**

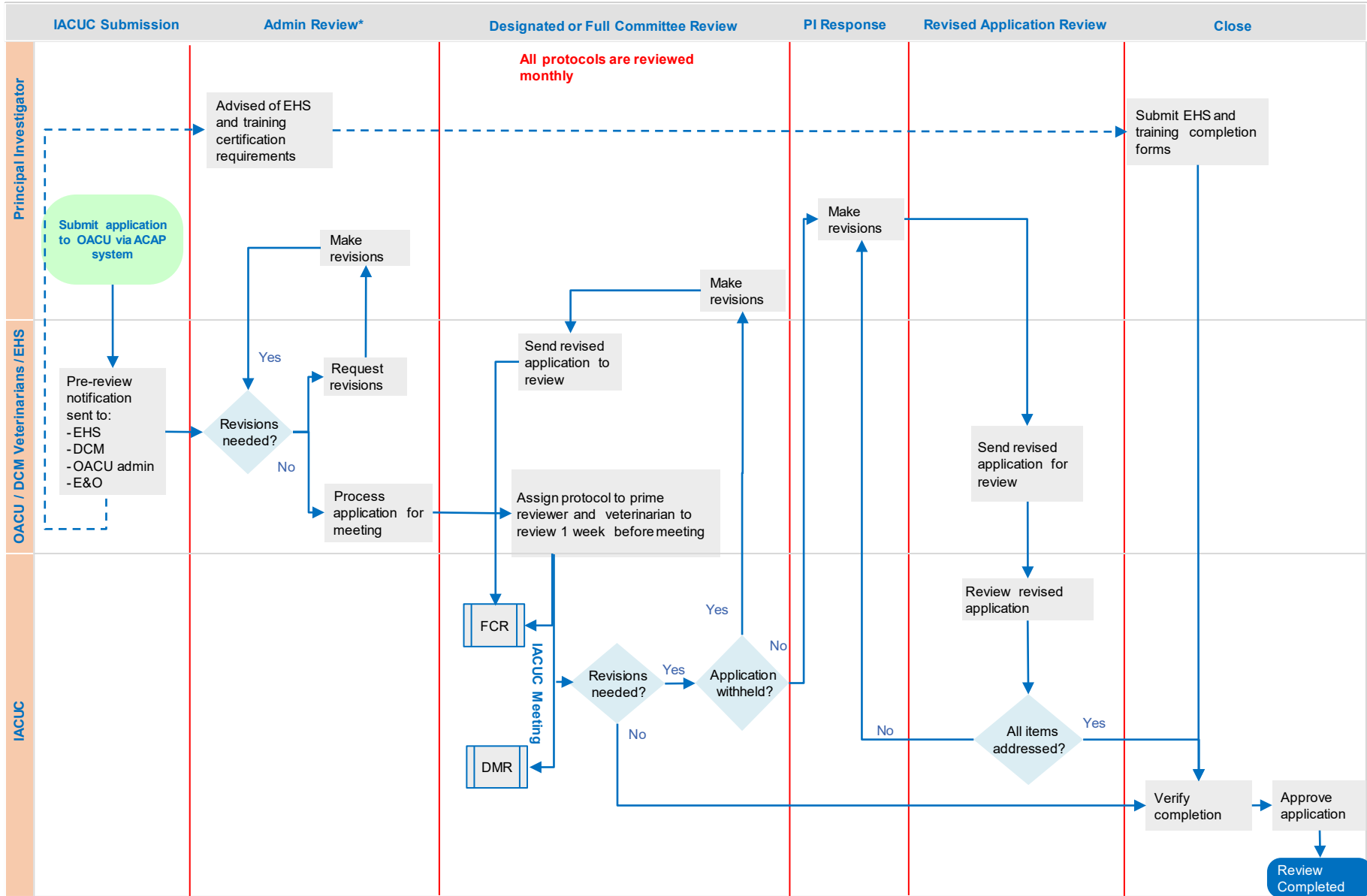
A: COI status or training can be checked for sponsored projects in RAMSeS in the compliance tab or for IRB applications in IRBIS on the Personnel tab.

- **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





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-covered species.
 - **Contact EHS at 919-962-5507 to discuss what is needed for your study** (Lab Safety Plan, hazard and IBC Schedule forms, etc.) so IACUC approval is not delayed for EHS requirements.
-



TIPS TO ACCELERATE THE PROCESS

- 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 a new animal application in [ACAP](#)**.
 - Contact OACU at iacuc@med.unc.edu to **request an informational packet for new or existing PI's** 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.
-



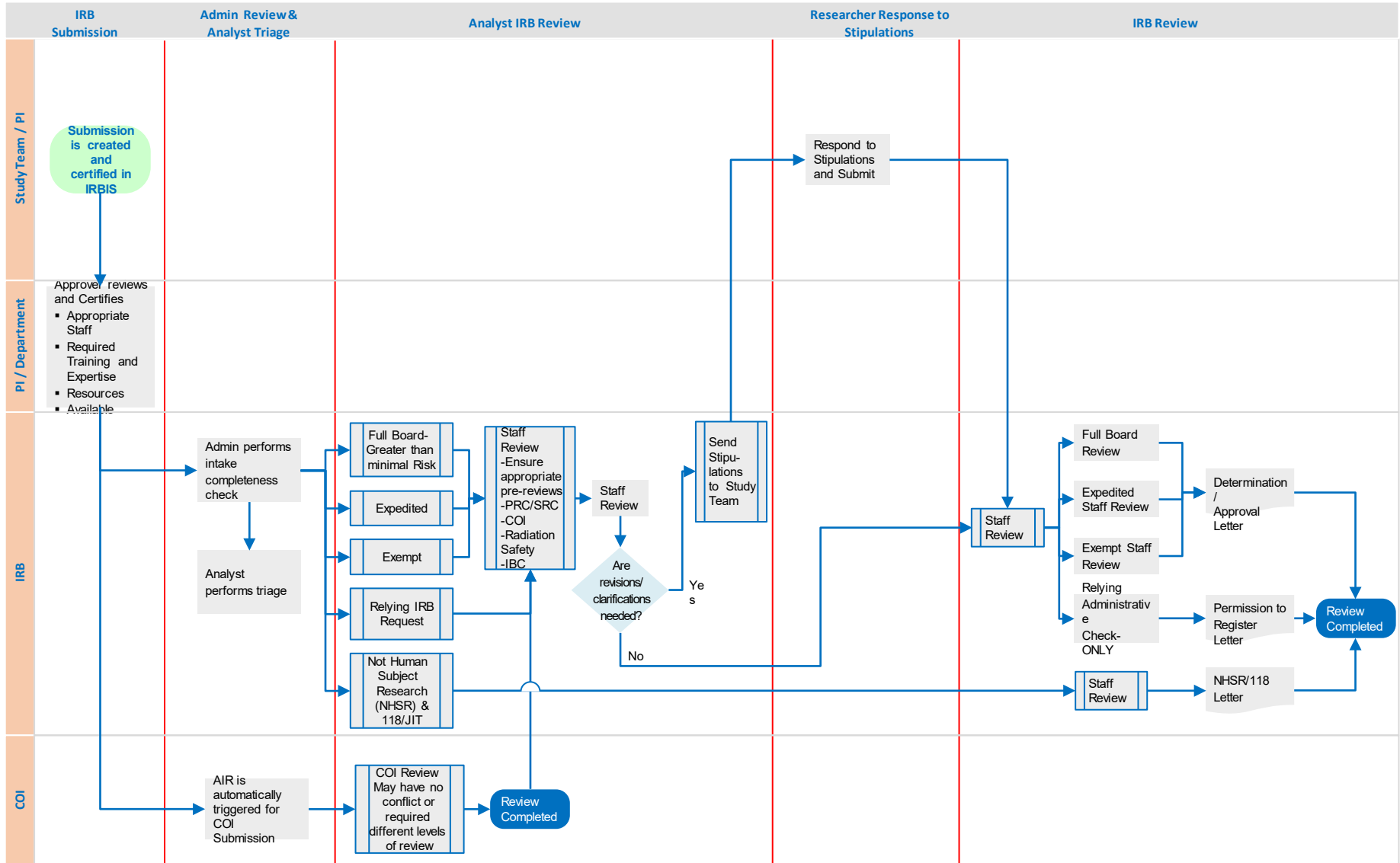
FREQUENTLY ASKED QUESTIONS

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.



INITIAL IRB PROCESS REVIEW MAP





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)**, 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](#)



GUIDELINES ON IRB SUBMISSION



FREQUENTLY ASKED QUESTIONS

▪ **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 (NHRS) 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](#)"



GUIDELINES ON IRB SUBMISSION



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 onboarded 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 when if your project involves any of the following:

- **Collaborations with foreign countries or individuals from foreign countries**
- **Shipping or transferring any materials or equipment to any foreign entity**
- **Any travel to a foreign country**

If you have any questions, please contact the **Export Compliance Office at (919) 962-4102.**



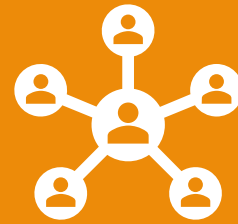
PRIVACY

Contact your OSR / SPO representative early when / if your project involves any of the following:

- **The use or transfer (to an external entity) of Protected Health Information (PHI)**
- **The need for a Business Associates Agreement (BAA)**

If you have any questions, please contact the **Privacy Office at (919) 445-0232.**

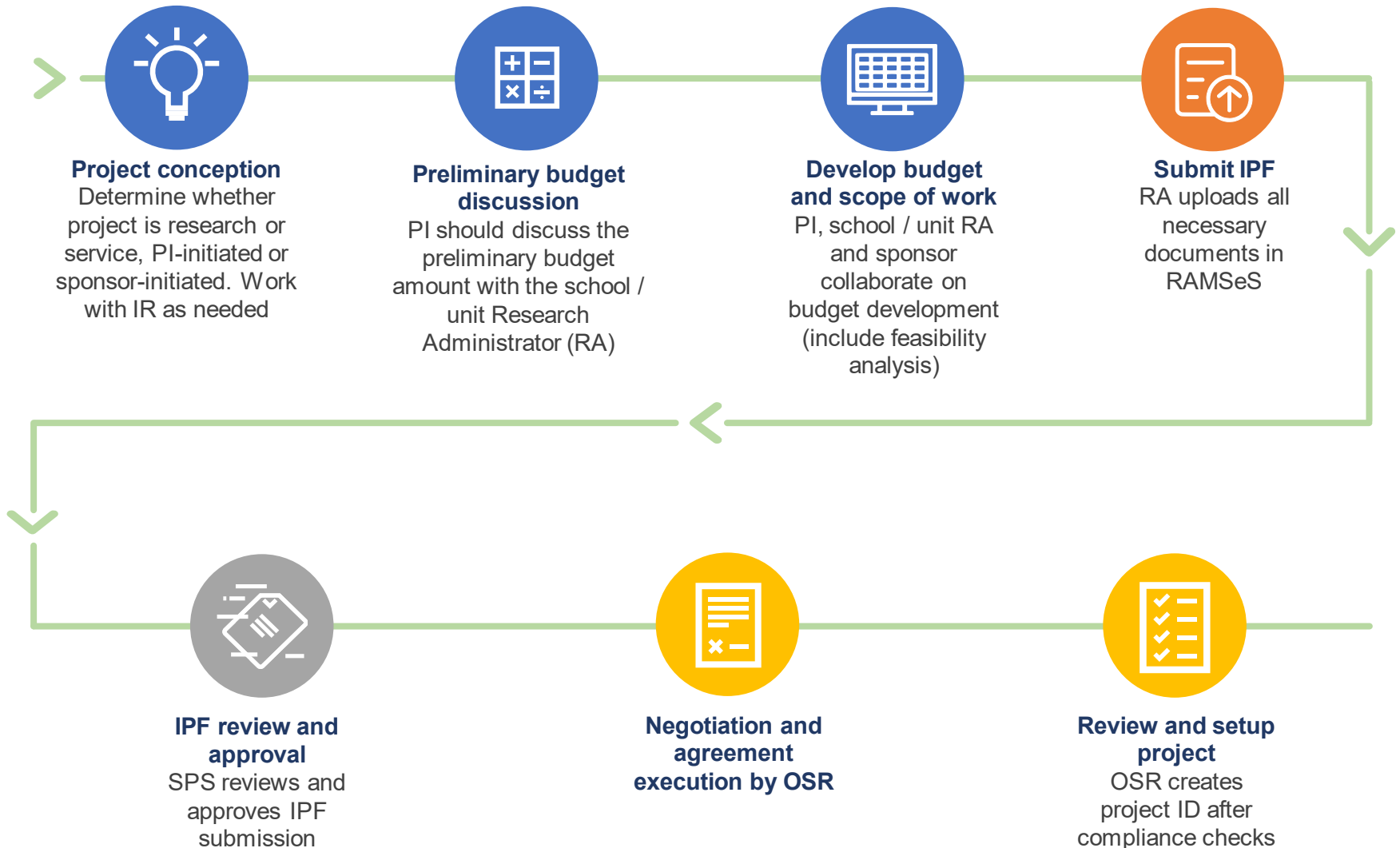
Non-Clinical



INDUSTRY PROJECT DEVELOPMENT & SUBMISSION PROCESS



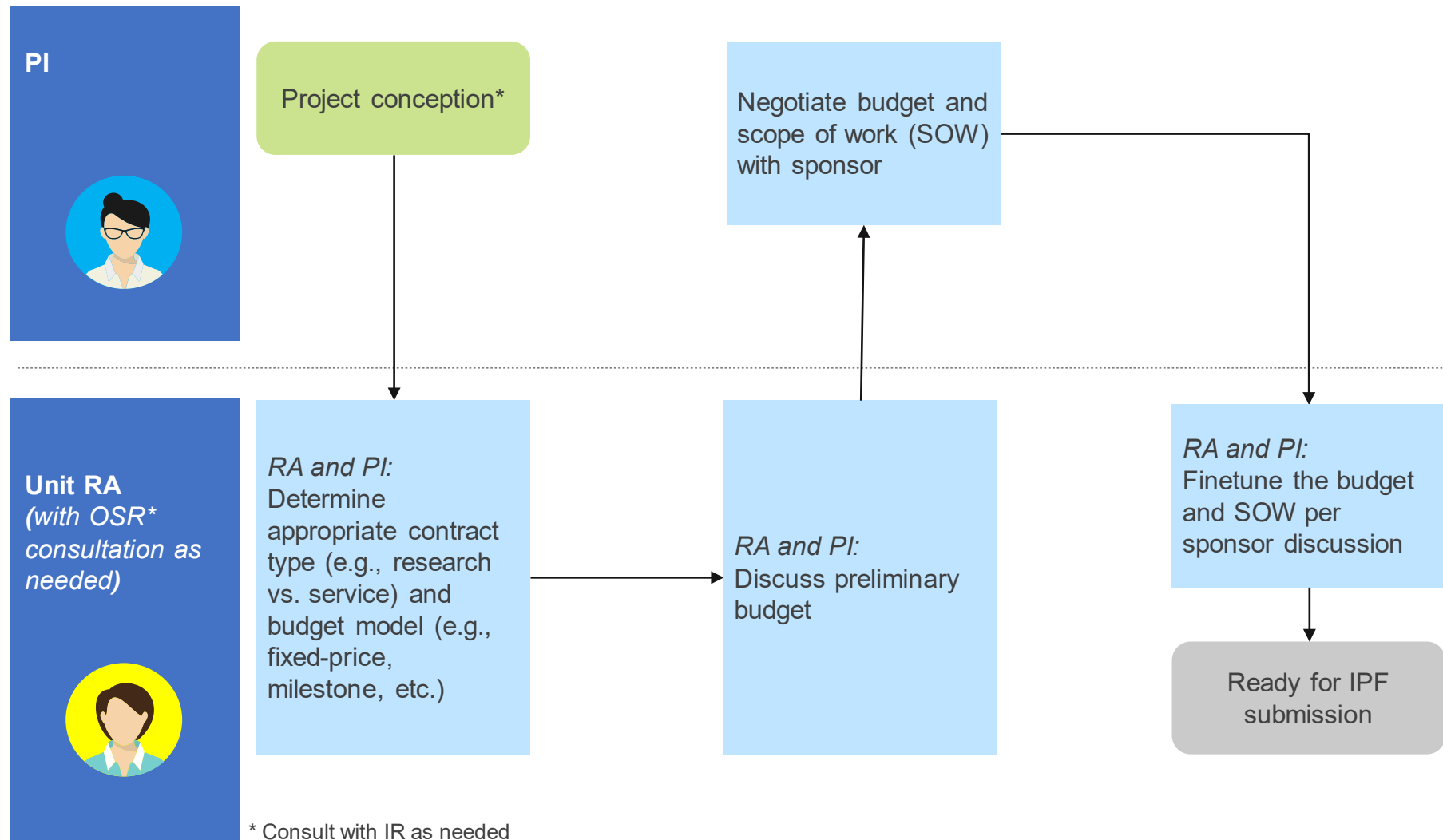
START COMPLIANCE SUBMISSIONS WHEN THE INTENT TO FUND IS CLEAR OR WHEN COMPLICATING FACTORS OCCUR





PROJECT DEVELOPMENT PROCESS

Responsible party Timeline

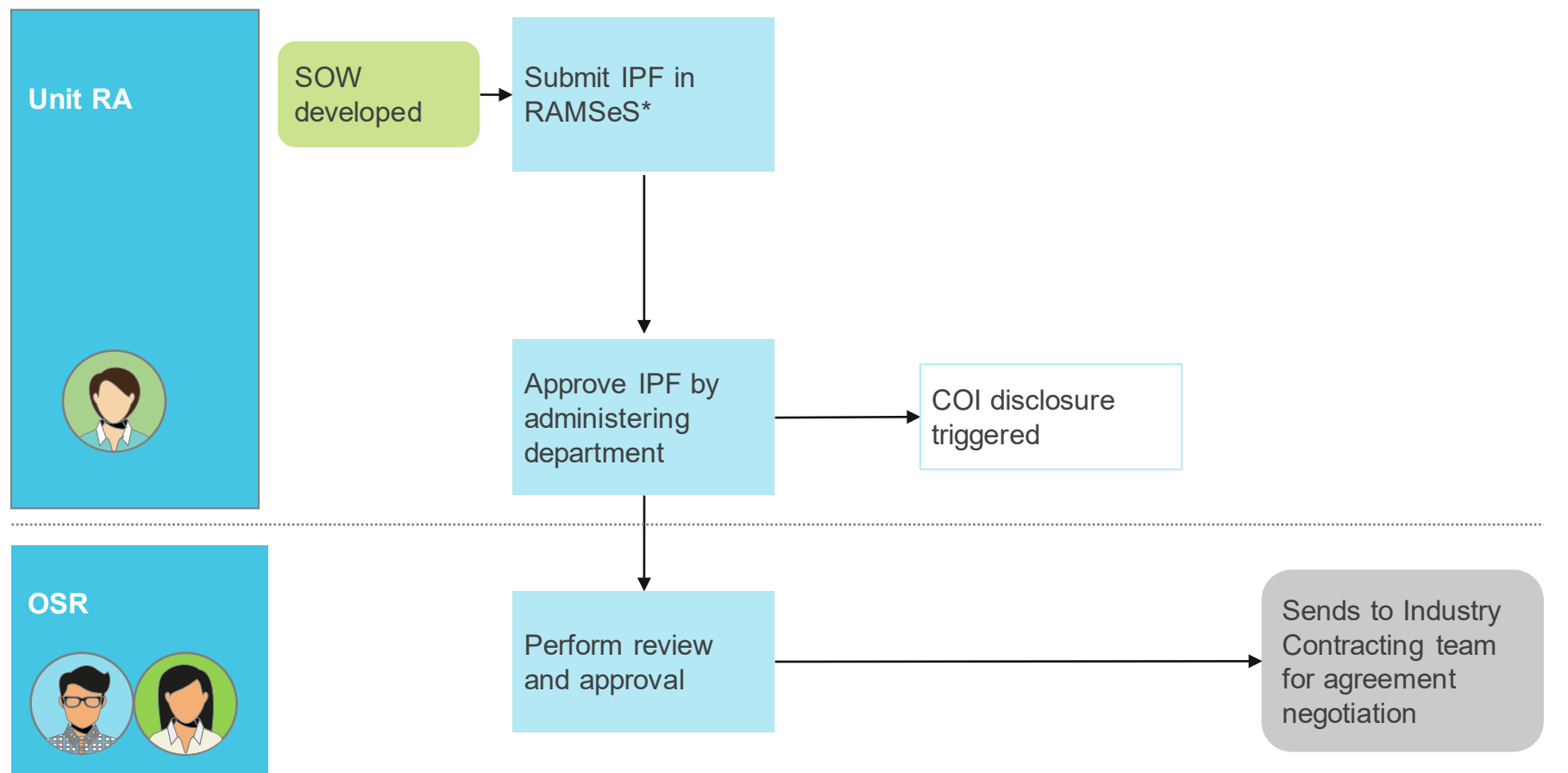




IPF SUBMISSION PROCESS

Compliance can be triggered at various stages during the submission process. For more guidance on the requirements of compliance offices (e.g., COI, IRB, IACUC, etc.),

Responsible party Timeline



* Complete submission includes a detailed scope of work, budget with appropriate F&A rate, a draft agreement if provided by sponsor, and the external contact for negotiations.



SUMMARY

IPF Attachments

- Detailed scope of work
- Internal Budget
- Budget Justification
- Draft agreement (if provide by sponsor) and drafts of the technical components
- PI waiver form (as applicable)
- Subagreement documents (as applicable):
 - LOI signed by an authorized signing official for subrecipient
 - SOW
 - Budget
 - Budget Justification
- External contact for negotiations



AWARD SETUP READINESS

Responsible party Timeline

PI / Unit RA

Obtain final IRB / IACUC approval for the project if not already completed

Notify SPS the IRBIS # of the IRB application

Check that approved IACUC protocol is reflected in the Compliance tab in RAMSeS

Review the agreement and communicate any important observations to the PI

OSR

Agreement executed by IC

Change IPF status to "Award received"

Assign to SPS for setup

Create Project ID and setup contract

Appendix



ADDITIONAL RESOURCES: OFFICE OF SPONSORED RESEARCH

- [Information Sheet](#)
- [Operating Standards & Procedures](#)
- [Forms & Tools](#)
- [Resources and Guidance](#)
- [Award Lifecycle](#)
- [Guidance on Science and Security](#)
- [Training](#)
- [Glossary](#)



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: INDUSTRY RELATED

Project Preparation

- [OSR Prior Approval & Waiver Forms](#)
- [ALICE](#)
- [UIDP Guidance](#)
- [UNC Industry Partnership](#)
- [Sample email to subrecipient](#)
- [OSR industry budget template](#)

Operating Standards and Policies

- [Award General Operating Standards](#)
- [Project Development & Submission](#)
- [Using RAMSeS for IPF submission](#)
- [Determining Consultants](#)