2025 Grant Writing Boot Camp

Working with the Ochsner Grants Team

December 15, 2025

10:00 am – 10:50 am CT

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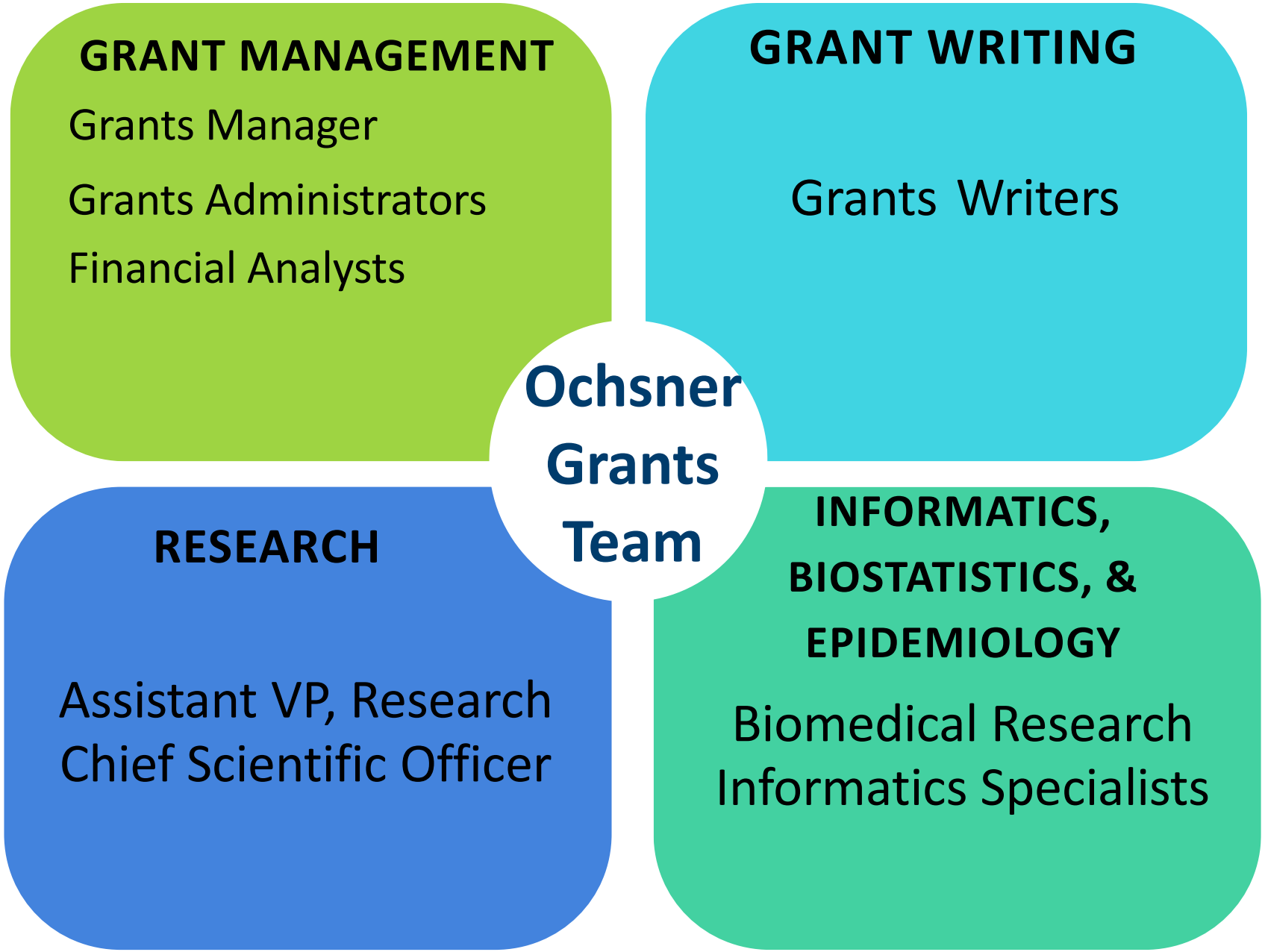

About Us

The Grants Team is an inter-departmental working group that provides comprehensive support - from ideation and preliminary data analysis to writing, submitting, and post-award financial management.

We consider several factors when prioritizing our services including but not limited to Ochsner's strategic initiatives, research fundability, project budget, timeliness of application, PI readiness, and resource capacity.

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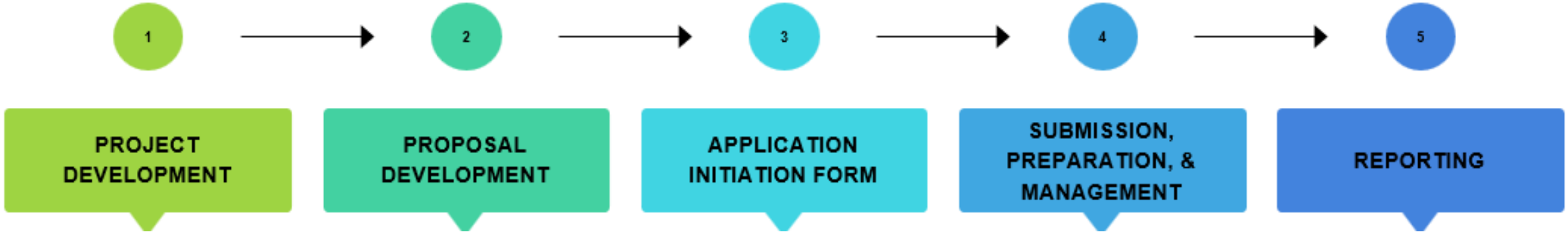
Ochsner Grant Process



When is the best time to start working with a Grant Writer? The sooner the better!
At a minimum, at least 60 days ahead of your deadline.

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PROJECT DEVELOPMENT

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1. Identify a FINER research question or unmet need
   - Feasible
   - Interesting
   - Novel
   - Ethical
   - Relevant
2. Consult with Research Director (RD) and Director of Clinical Research (DCR)
   - Confirm feasibility
   - Coordinate staff, services (biobank, informatics/biostatistical support)
3. Start drafting IRB protocol (if needed).

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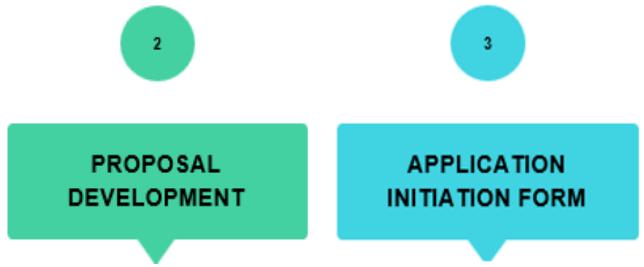

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4. Identify potential sources of funding – contact grant writers for help, if needed.

5. Request grant writer support. The sooner the better!
   - Contact grants@ochsner.org
   - Application Initiation Form (AIF)
   - Contact grant writers directly

6. Submit Application Initiation Form (AIF)
   - Needed for all applications
   - Must be submitted at least ≥ 30–90 before the proposal deadline (>21 days if subaward). Your grant writer can also submit the AIF on your behalf.

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APPLICATION INITIATION FORM

Ochsner Grant Process

The Application Initiation Form (AIF)

https://redcap.ochsner.org/surveys/?s=8CX3MD4EDY

Due Date (# Days before Sponsor Deadline)	Application Characteristics
90	Patient Care, Clinical Trial, Construction, Renovation, or Real Estate Purchase
60	Federal Sponsor, Collaborating Institution/Consortium Partner, or Equipment Lease/Purchase
30	None of the above

If a pre-application/Letter of Intent (LOI) is required and will include an approximate request amount, submit the AIF ≥30 days before the LOI due date.

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The AIF

- Alerts Grants Management of an upcoming submission
- Helps us determine readiness for grant writing support (if you're not already working with a writer)
- Serves as the foundation for a Concept Paper to engage Program Officers

- Sample questions on the AIF:
  - Who is your Research Director?
  - What is your research objective?
  - Does this project involve Human Subjects Research?
  - Who is on your team?
  - Are you collaborating with another institution?

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SUBMISSION, PREPARATION, & MANAGEMENT

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Grants Management

Grants Manager

Grants Administrators

Grants Writing

Grants Writers

- Identify research question
- Consult RD, DCR
- Find funding opportunity with **Grants Writing**

Grants Management sends timeline

Submit Budget Justification to **Grants Management**

Grants Management submits 1-2 days before due date

Submit AIF or have **Grants Writing** submit it for you

Work with **Grants Writing** team to draft application

Submit final documents to **Grants Management**

Note: **PI is ultimately responsible** for the accuracy and content of AIF and all application documents

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Sample Internal Timeline from Grants Management		
Internal Due Date	**PI Deliverable**	**Comments**
8/21/2025	**Statement of Work (SOW) for each partner**	This is needed to request a partner budget; once submitted, the SOW should not be revised. Elegant formatting isn't required; provide the information, and we 'll create a polished document.
9/5/2025	**Complete list of Performance Sites**	Please provide full names; include all sites for each consortium partner.
9/12/2025	**Ochsner budget justification**	For each contributor, provide name, role, responsibilities, and % effort—e.g., Jane Doe, CRC, will recruit & consent subjects @ 10% effort a year. Itemize non-personnel costs exceeding a total of $1K—e.g., incentive stipends @ $250 x 25 subjects, needles for acupuncture, $500. For contractors, specify name, skills, & responsibilities and break down costs ($100/hr x 200 hrs a year, or $250 per data set x 3 sets). Detailed bullet points are fine. We'll work them into a formal document.
9/12/2025	**Ochsner biosketch(es)**	For PI/PD and key personnel
9/26/2025	**Project narrative and all other PI documents (to be specified in a follow-up message).**	The grants team will complete all administrative and budget forms. Provide PI documents in final form. After this date, the only changes should be those initiated by grant administrators to address technical errors, inconsistencies, etc.

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SUBMISSION, PREPARATION, & MANAGEMENT

Working with Grant Writers

- Level of service assessed on a case-by-case basis, but in general:
- **Editing**
  - Review of narrative segments including introduction, summary, broader impacts, specific aims, significance, and innovation.
  - Review supporting documents such as biosketches, partner letters, facilities and equipment, etc.

- **Full**
  - In-depth editing and/or writing for clarity and impact
  - Ensure proposal fully addresses requirements
  - Coordination of statistical consultation/review, data management and analytics
  - Vision and storyline (one page concept paper) planning
  - Contact program officers
  - Draft letters of support/commitment
  - Planning for proposal revision and resubmission

Note: **PI is ultimately responsible** for the accuracy and content of AIF and all application documents

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SUBMISSION, PREPARATION, & MANAGEMENT

Working with Grant Writers

- **Full**
- 3–6-month project sprint
- We establish a timeline and track deliverables
- Weekly check-in meetings
  - Grant kickoff with full grant team: review Project Needs List and identify partners
  - Goals and objectives
  - Budget development
  - Iterative narrative development with time for comments and edits

Note: **PI is ultimately responsible** for the accuracy and content of AIF and all application documents

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REPORTING

Post-Award Process

- “Just-in-time” (JIT):
  - PI to coordinate with his/her research team, line up support
  - Ramp up efforts for protocol completion, approval
  - Other support
- The Grant Management Team handles all personnel and financial reports.
- PIs and Directors of Clinical Research are responsible for all other grant reporting requirements.

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Thank You!

Questions?

2025 Grant Writing Boot Camp

Introduction to Grants: How to find funding opportunities for your project and read funding opportunities

December 15, 2025

11:00 am – 12:00 pm CT

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How do I get started?

Identify Project

- Define research question, scope of work
- Think about how long your project will take
- Create ballpark budget estimates– consult your research director and grants management

Create list of grants

Sources of grant opportunities:

- Grants.gov – federal grants
- Google
- Email subscriptions
- GrantForward, Instrumentl
- CARGO (Ochsner database)

Prioritize

- Prioritize funding opportunities that best fit your:
  - Budget
  - Goal
  - Timeline
- Create a Grant Tracker for high-priority grants

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What is a Notice of Funding Opportunity (NOFO)?

- Announces the availability of funding for a specific program
- Outlines goals, eligibility requirements, application instructions, and deadlines
- Also sometimes referred to as:
  - Funding Opportunity Announcement = FOA
  - Request for Proposals = RFP
  - Request for Applications = RFA
  - Program Announcement = PA
  - Program Announcement with Referral Guidelines = PAR
  - Program Announcement with Set-Aside Funds = PAS
  - Request for Quote = RFQ
  - Broad Agency Announcement = BAA
  - Research Opportunity Announcement = ROA
  - Letter of Intent = LOI
  - Notice of Intent = NOI (posted before actual solicitation)

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Types of Funding Opportunities

- **Government**
  - NIH, NSF, ARPA-H, etc.
- **Private non-profit organizations**
  - Robert Wood Johnson, Hartford, MacArthur foundations
- **Private companies**
  - Pfizer, Merck, etc.
- **Internal**
  - Collaborative Intramural Research Program (CIRP) with LSU Health Shreveport

- Ochsner Research submits all **research** project grant applications.
- If you're proposing a **non-research project** (e.g. workforce development) to a foundation or corporation, contact the Program Coordinator **for Foundations & Corporate Relations**.

Not sure if your project is considered research? Ask us!

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Types of Federal Funding Opportunities

- **Grant (NOFO):**
  - Minimal agency involvement in project activities
  - Initiated by the Principal Investigator (PI)
  - Flexible in scope of work, budget

- **Federal Cooperative Agreement (RFA):**
  - Substantial federal involvement in project activities
  - Initiated by the PI
  - Scope shaped by federal involvement

- **Federal Contract (RFP or RFQ):**
  - For the direct benefit or use of the government
  - Scope defined by government
  - Rigid in scope of work, budget

- **Federal Other Transaction Agreement (BAA or ROA):**
  - Procurement mechanism primarily used for research and development and innovation
  - Scope defined by PI and government in collaboration

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Where to Find Opportunities

- Google
- Grants.gov
- NIH email alerts
- Listservs from professional societies
- Paid Search Engines: Instrumentl, Pivot-RP, GrantStation
- Ask Drs. Boyd and Pai for help

- Use keywords: specific disease, methods, audience (Early Investigator, etc.)

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Components

- Purpose
- Due Date(s)
- Description
- Eligibility
- Submission Requirements
- Review Process
- Contact

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Quickly Read a Funding Announcement

- **Eligibility**
  - PI eligibility – MD, PhD, junior vs. senior
  - Organization eligibility – Non-profit, consortium
    - For Ochsner Health, you're looking for: nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
  - Geography and/or population restrictions
    - Foreign components often not allowed for federal grants
    - NOTE: Non-US citizens on valid work visas are **not** foreign components
- **Mechanism**
  - Research, program, training
    - Clinical Trial: not allowed, required, optional
  - Grant, contract, cooperative agreement
- **Funding Level**
  - Total budget
  - Duration
  - Indirect cost rate

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Quickly Read a Funding Announcement

- **Deadline** and Submission Requirements – For Ochsner, Federal opportunities must be at least 60 days out. Others, at least 30 days out.
  - LOI required?
  - Resubmission allowed?

- **Project Scope**
  - Required activities
  - Priority populations/diseases
  - Required partnerships or community engagement

- **Review Criteria**

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Understanding NIH Series Grants

- **R series – Research**
  - R01 – common, supports investigator-initiated project
  - R03 – small grants, pilot studies, data collection, limited budget
  - R21 – exploratory and developmental, high-risk/high-reward
- **K series – Career Development**
  - Designed to support early-stage researchers
- **T and F series – Training and Fellowships**
  - Institutional and individual fellowships
- **P series – Program**
  - Supports a program of related projects or core infrastructure for a center
- **U Series – Cooperative Agreements**
  - NIH is a research partner

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NIH Institutes and Centers (ICs)

- 27 Institutes and Centers, each with a specific research agenda, often focusing on a particular disease or body system

- Check if your IC of interest participates in a NOFO

Components of Participating Organizations

National Institute of General Medical Sciences (NIGMS)

NIH Submission Cycles

Activity Codes	Program Description	Cycle I Due Date	Cycle II Due Date	Cycle III Due Date
P Series *All - new, renewal, resubmission, revisions*	**Program Project Grants and Center Grants** NOTE: Applicants should check with the relevant Institute or Center (IC), since some do not accept P series applications for all three receipt/review/award cycles.	January 25	May 25	September 25
R18, U18 R25 *All - new, renewal, resubmission, revision*	**Research Demonstration Education Projects**	January 25	May 25	September 25
T Series D Series *All - new, renewal, resubmission, revision*	***Institutional* National Research Service Awards** **Other Training Grants** NOTE: Applicants should check with the relevant Institute or Center (IC), since some do not accept T series applications for all three receipt/review/award cycles.	January 25	May 25	September 25
C06/UC6 *All - new, renewal, resubmission, revision*	**Construction Grants**	January 25	May 25	September 25
G07, G08, G11, G12, G13, G20, R24, S06, S11, S21, S22, SC1, SC2, SC3, UG1, U10, U19, U24, U2C, U41, U42, U45, U54, U56 *All - new, renewal, resubmission, revision*	**Other Activity Codes**	January 25	May 25	September 25

R01 *new*	**Research Grants**	February 5	June 5	October 5
U01 *new*	**Research Grants - Cooperative Agreements**	February 5	June 5	October 5
K series *new*	**Research Career Development**	February 12	June 12	October 12
R03, R21, R33, R21/R33, R34, R36, U34, UH2, UH3, UH2/UH3 *new*	**Other Research Grants and Cooperative Agreements**	February 16	June 16	October 16
R15 *All - new, renewal, resubmission, revision*	**Academic Research Enhancement Award (AREA)**	February 25	June 25	October 25
R01 *renewal, resubmission, revision*	**Research Grants**	March 5	July 5	November 5
U01 *renewal, resubmission, revision*	**Research Grants - Cooperative Agreements**	March 5	July 5	November 5
K series *renewal, resubmission, revision*	**Research Career Development**	March 12	July 12	November 12
R03, R21, R33, R21/R33, R34, R36, U34, UH2, UH3, UH2/UH3 *renewal, resubmission, revision*	**Other Research Grants and Cooperative Agreements**	March 16	July 16	November 16
F Series Fellowships *new, renewal, resubmission*	***Individual* National Research Service Awards (Standard)**	April 8	August 8	December 8
R13, U13 *All - new, renewal, resubmission, revision*	**Conference Grants and Conference Cooperative Agreements**	April 12	August 12	December 12
R41, R42, UT1, UT2 R43, R44, U43, U44, *All - new, renewal, resubmission, revision, AIDS and AIDS-related* SB1, UB1	**Small Business Technology Transfer (STTR)*** **Small Business Innovation Research (SBIR)*** **Commercialization Readiness Pilot (CRP) Program***	September 5	January 5	April 5

Creating a Personal Grant Tracker

Name	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Agency, Grant, Link, $				✓								
Agency, Grant, Link, $								✓				
Agency, Grant, Link, $						✓						
Agency, Grant, Link, $											✓	

✓ = submission deadline

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Addressing Key Review Criteria

- Common grant review criteria:
  - Significance – why is my problem important?
  - Innovation – what differentiates my approach?
  - Investigators – why is my team qualified for this?
  - Environment – how does institution and/or collaborating institution(s) provide the ideal environment for this project?
  - Approach – how is my approach scientifically robust?

- Listed under a separate heading in most NOFOs
  - NIH's simplified review framework:
    - Factor 1: Importance of the Research (Significance, Innovation), scored 1-9
    - Factor 2: Rigor and Feasibility (Approach), scored 1-9
    - Factor 3: Expertise and Resources (Investigator, Environment), to be evaluated as either sufficient for the proposed research or not

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Other Key Information

- Look up:
  - Success rates (if available)
  - Prior awardees
  - Review panel members

- Resources:
  - NIH RePORTER
  - NSF Award Search
  - NIH Matchmaker
  - NIH Assisted Referral Tool (ART)

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The Program Officer (PO)

- Identify the point of contact or PO
  - Usually listed as “Scientific Contact” for NIH NOFOs
- Create a one-page summary of your project and specific aims
  - Grant writers can help you with this!
- Email to request feedback on the idea
  - 15-30-minute virtual meeting
  - Be respectful of PO’s time
  - Say "thank you" a lot

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Plan Ahead

- Allocate at least 3-6 months for planning and preparation
- Plan to repurpose core application components for future applications (to be addressed in more detail on day 4)
- **Do not expect to get funded on your first attempt**
  - Reviewer feedback may take 3-6 months

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Thank You!

Questions?

2025 Grant Writing Boot Camp

Common Grant Components Part 1:
Specific Aims, Goals/Objectives, and Timelines

December 16, 2025
11:00 am – 11:50 am CT

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Guidelines are VERY Important

- Font styles, sizes, margins, and page numbers
- Figures and tables
- Reference formatting and limitations
- Required submission components

- **If you don't follow the guidelines perfectly, your proposal may be administratively disqualified before review.**

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Core Grant Components

- **Specific Aims**: 1 page

- **Research Strategy**: 6-12 pages
  - For a **12-page** Research Strategy:
    - Significance: 2-3 pages
    - Innovation: 1 page
    - Approach: 8-9 pages
      - Preliminary Studies: 2 pages
  - For a **6-page** Research Strategy:
    - Significance: 1-1.5 pages
    - Innovation: 0.5-1 page
    - Approach: 4 pages
      - Preliminary Studies: 1 page

- **References/Bibliography**:
  - Use reference management software:
    - Zotero and Mendeley (free)
    - EndNote (can be obtained through Ochsner)

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Generative AI tools merit caution

- While generative artificial intelligence (AI) tools such as ChatGPT can assist with various aspects of grant preparation, such as literature review, use it for grant content with caution.
  - Generative AI content is seldom usable for scientific grants as is without heavy editing and fact-checking, so if you find yourself copying from ChatGPT *en masse*, you are unlikely to generate compelling grant copy.

- AI tools may plagiarize, falsify, or fabricate information. You, as an applicant, share responsibility for ensuring integrity in the scientific review process, and the **NIH will hold you accountable even if AI technology is the source of noncompliance**.

- Read NIH's generative AI policy here and here.

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Examples of Grant Applications

- NIH grants:
  - National Cancer Institute (NCI) Division of Cancer Control and Population Sciences (DCCPS)
  - NCI Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants
  - National Institute of Allergy and Infectious Diseases
  - National Institute on Drug Abuse Small Business Grants
- Other Grants:
  - Open Grants

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The Specific Aims Page

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The Aims Page or Executive Summary

- 1-page summary of:
  - Background
  - Unmet need/unsolved problem
  - Goals
  - Impact
  - Next steps
- Serves as an “elevator pitch” to Program Officer (PO) or grant point of contact
- May be the *only* page of the grant some reviewers read! Try to address all review criteria.

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The First Paragraph

Viruses are thought to be involved in 15% to 20% of human cancers worldwide, thus providing critical tools to reveal common mechanisms involved in human malignancies. As the etiologic agent of adult T cell leukemia/lymphoma (ATLL), human T cell leukemia virus type I (HTLV-1) is just such a virus. HTLV-1 encodes a potent oncoprotein, Tax, which regulates important cellular pathways including gene expression, proliferation, apoptosis, and polarity. Over the years, Tax has proven to be a valuable model system in which to interrogate cellular processes, revealing pathways and mechanisms that play important roles in cellular transformation. Although the Tax oncoprotein has been shown to transform cells in culture and to induce tumors in a variety of transgenic mouse models, the *mechanism by which Tax transforms cells is not well understood*. A large number of Tax mutants have been generated and their biological activities have been thoroughly characterized, primarily in cell culture systems. *Currently, a major obstacle in the field* is that the transforming activity of Tax mutants cannot be compared using available transgenic models due to random transgene integration sites, variable transgene copy number, and inconsistent transgene expression levels, making it difficult to link the biological activities of Tax mutants with their transforming potential.

Color Key: Hook | Known Information | Gap in Knowledge | Critical Need

Source: Michelle S., Ph.D., E.L.S., The Anatomy of a Specific Aims Page

- **Key message:** Why is my research problem important?
- **Review Criterion Addressed:** Significance

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The Second Paragraph

To solve this problem we will develop an innovative mouse model system in which to study Tax tumorigenesis using targeting vectors containing wild-type or mutant Tax genes that are silenced by a preceding floxed stop cassette. These vectors will be knocked in to the *Rosa26* locus of recipient mice by recombination. After crossing these mice with Lck-CRE mice, the stop cassette will be specifically excised in developing thymocytes where the Lck promoter is active, allowing conditional expression of wild-type or mutant Tax proteins in T cells, the natural target of HTLV-1 infection. The feasibility of our proposed mouse model is supported by the fact that Lck-Tax transgenic mice have been developed and produce a leukemia that closely resembles ATLL. Thus, targeting of Tax expression in cells in which the Lck promoter is active is expected to produce a similar disease in our model. In our improved model system, insertion into the *Rosa26* locus will eliminate random integration sites and standardize gene copy number resulting in consistent levels of wild-type and mutant Tax protein expression.

Color Key: Long-term Goal | Proposal Objective | Rationale | Hypothesis | Pay-off

Source: Michelle S., Ph.D., E.L.S., The Anatomy of a Specific Aims Page

- **Key message:** Why is my research different from other approaches? How is my team qualified to address this?
- **Review Criteria Addressed:** Innovation, Environment, Investigators

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The Aims

Aim 1 will establish an innovative mouse model for HTLV-1 Tax tumorigenesis. Targeting vectors containing silenced wild-type or mutant Tax genes will be knocked in to the Rosa26 locus of C57BL/6 mice. These mice will then be crossed with homozygous Lck-CRE mice, thereby excising the stop cassette and generating mice that express wild-type or mutant Tax proteins specifically in T cells.

Aim 2 will examine the effect of mutations that disable specific biological functions of Tax on Tax-mediated tumorigenesis. Tax can bind to and regulate the activity of members of the SRF, CREB, NF-kB and PBM protein families, each of which has been implicated in oncogenesis. Mice established in Aim 1 will allow us to compare for the first time the tumorigenic potential of wild-type and mutant Tax proteins in an effort to identify pathways that are required for Tax tumorigenesis.

Color Key: Aim Title | Experimental Strategy | Outcome or Impact

Source: Michelle S., Ph.D., E.L.S., The Anatomy of a Specific Aims Page

- **Key message:** What is my team doing to address this important problem?

- **Review Criterion Addressed:** Approach

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The Conclusion

The proposed studies will establish a new mouse model that will overcome current limitations and provide greater insight into the mechanism of HTLV-1 Tax tumorigenesis, knowledge that is currently lacking and that promises to yield novel insights into viral and cellular biology. The new and improved mouse model for Tax tumorigenesis will provide a valuable resource for the wider scientific community to pursue a multitude of studies that have not previously been possible due to limitations of existing mouse models of Tax.

Color Key: Innovation | Expected Outcomes | Impact/Pay-off

Source: Michelle S., Ph.D., E.L.S., The Anatomy of a Specific Aims Page

- **Key message:** What are my next steps? What is the ultimate payoff?
- **Review Criteria Addressed:** Significance, Approach

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Target and Tailor

- **Target** your audience.
  - *Reviewers will likely have a PhD/MD but may not have the domain-specific knowledge you have.*
  - *Look up your reviewers' background*

- **Tailor** your Aims page to the Funding Opportunity (FO).
  - *If the FO emphasizes product development goals as opposed to hypothesis-driven research, you may not want to include a hypothesis.*

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Goals & Objectives

Goals and Objectives

- Often included in applied research or program grant proposals
- **GOAL/AIM** – a broad statement of what you hope to achieve.

- **OBJECTIVE/MILESTONE** - a concrete, measurable step you will take to reach that goal
  - SMART format: Specific, Measurable, Achievable, Relevant, Time-bound

Goals and Objectives

- **Example 1**

  - **GOAL 1**: Improve access to early screening and treatment for prostate cancer in underserved communities.
    - **Objective 1.1**: By month 6, establish mobile screening clinics in three rural parishes serving at least 1,000 men annually.
    - **Objective 1.2**: By Year 2, increase rates of PSA screening among Black men aged40+ by 20% over baseline

**Objectives are usually numbered and nested under goals.*

Goal 1, Obj 1.1, Obj 1.2, Obj 1.3, etc. Goals and objectives are tied to the logic model, timeline, milestones, and responsible parties in the work plan.

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Formatting Goals and Objectives in a Chart

GOAL 1: Establish two prostate cancer screening and treatment clinics to serve Louisiana's river parishes.			
	Timeline	*How Objective Will Be Measured*	*Responsible Party*
Obj 1.1. Repurpose existing clinical space at St. Charles Parish Hospital and LaPlace Medical Center in St. John the Baptist to become prostate cancer screening and treatment clinics, including telehealth rooms	Within 30 days of award	Clinical space equipped with intake area, screening rooms, and private telehealth rooms	PI
Obj 1.2. Train all RPP staff on program goals and objectives, grant operations, and procedures	Within 30 days of award	Training logs	PI
Goal 2: Increase the number of individuals who participate in PSA screenings within the river parishes.			
	Timeline	*How Objective Will Be Measured*	*Responsible Party*
Obj 2.1. Convene regular meetings with community-based organizations including Bayer and Rise St. James to increase awareness of new clinic operations and disseminate findings, outcomes, and health improvements.	Quarterly	Event invites, attendance logs, meeting notes	PI OXIHER
Obj 2.2. Conduct socio-culturally responsive engagement and outreach within the target area through events and marketing.	Ongoing	Event publications, attendance logs, contact notes	PI OXIHER
Obj 2.3. Two clinics will conduct at least 250 PSA screenings in Year 1 and 400 screenings in Year 2. At least 50% of individuals screened will be Black/African American (Hispanic and non-Hispanic) males.	Ongoing	# Screenings conducted at two clinics logged into Ochsner HER	ALL
Goal 3: Increase the number of Black/African American men enrolled in prostate cancer clinical trials.			
	Timeline	*How Objective Will Be Measured*	*Responsible Party*
Obj 3.1. Paradigm to screen Ochsner's EHR and identify patients eligible for participation in prostate cancer clinical trials	Ongoing	# Eligible patients identified	Paradigm PI
Obj 3.2. RPP staff will attempt to contact 100% of eligible patients to gauge their interest in participating in a prostate cancer clinical trial	Ongoing	# Eligible patients contacted	CRC

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Approach

Approach

- Consists of:
  - Preliminary Studies / Progress to Date
  - Experimental Design / Work Plan
  - Timeline
  - Conclusion, Future Directions, and/or Sustainability
- “Meat” of the application
- Most scrutinized by reviewers
- Describes what will be done to accomplish the project
- Tells how the data will be collected, analyzed, and interpreted
- Speaks to scientific rigor – mention control groups, statistical analysis, and mitigation strategies
- Addresses Feasibility

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Preliminary Studies

- Describe your team's prior work *or* work that forms the basis of your study
- Helps establish competence of the investigative team
  - Not required for all NOFOs – *read* the NOFO!
  - Also describe in your Biographical Sketch (Biosketch)
- Some NOFOs let you cite other teams' work in this section
- If you've published in the field, use this section to cite your work
- Highlight your team's ownership of the work- "our work"
- Figures should be as fleshed out as possible- error bars, statistical significance etc.

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Experimental Design/Work Plan

- Overview of study design
  - Observational, experimental, quasi-experimental, mixed methods
  - Justification for the design
- Population and sampling
  - Inclusion/exclusion criteria
  - Sample size with justification or power analysis
  - Recruitment and retention strategies
    - Always plan for attrition in your power analysis
    - Find references to justify this rate

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Experimental Design/Work Plan

- Data collection methods
  - What data will be collected (e.g., EHR, surveys, imaging, tissue samples, interviews)
  - How and when will data be collected
- Analysis plan
  - Primary and secondary outcomes
  - Statistical methods or analytical frameworks
- Existing infrastructure
  - Epic, REDCap, registries, etc.
- Rigor and reproducibility
  - Blinding, duplicates
- Alternative strategies
  - Describe your “Plan B” if things don’t work out

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Timeline

- Not just a list of dates. A good timeline signals to reviewers that your project is **realistic**, **organized**, and **ready to launch**.
- Timeline should align with aims, goals/objectives, budget, staffing, and available resources.
- Total funding period (1 year, 3 years, 5 years)
- Anchor timeline to aims or goals/objectives
  - Cross check: every aim or objective should have corresponding activities in your timeline
- Map out major milestones
  - IRB approval, participant recruitment, start and end dates, data collection and analysis reporting requirements, advisory board meetings, manuscript submission
- Assign responsible parties

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Timeline

- Use CLEAR FORMATTING (Table, Gantt chart)

Timeframe	Activity	Milestone	Lead
Y1 Q1	IRB submission and approval	IRB Approval Letter	Dr. Smith
Y1 Q2	Begin participant recruitment	Enroll first 10 participants	CRC
Y1 Q3–Q4	Conduct baseline assessments	50 participants enrolled	Dr. Lee
Y2 Q1	Launch intervention	25 patients start treatment	Dr. Smith
Y3 Q2	Complete data collection	Close database	Data Manager
Y3 Q4	Submit manuscript	Accepted for publication	PI

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Thank You!

Questions?

2025 Grant Writing Boot Camp

Common Grant Components Part 2:
Background/Introduction, Significance, Innovation, and Team

December 16, 2025
11:00 am – 12:00 pm CT

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Background/Introduction

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Background/Introduction

- Provides context for the research question or intervention
- Frames the problem, population, and setting
- Outlines current state of the science, programmatic need, or clinical gap
- Lays the foundation for your Specific Aims or Goals/Objectives

This is your chance to show the reviewers that you've done your homework.

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Background/Introduction

- **Where does this go in the application?**
  - Specific Aims: first 1-2 paragraphs
  - Summary/Abstract
  - Approach
    - Significance
    - Innovation

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Background Content

- Problem Statement
  - Clearly define the issue you are addressing
  - Use relevant statistics or citations
- Population and Setting
  - Who is affected? Where? Why does this matter?
  - If appropriate, identify health disparities or equity considerations
- Current Approaches
  - What has already been tried? What are the gaps?
  - Summarize relevant literature or prior studies
- Preliminary Work
  - Your team's prior work, pilot data, or institutional capacity

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Background Sources

- Peer-reviewed publications
- Clinical guidelines
  - CDC, WHO, professional societies
- Surveillance data
  - Worldwide, US, Louisiana, Parish, Zip code, possibly by race/ethnicity
- Institutional data
  - EHR, QA reports, internal pilots
- Prior grants or program evaluations
- Input from stakeholders or advisory groups

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Significance & Innovation

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Significance vs. Innovation

- **Significance:** why does this research MATTER?
- **Innovation:** what makes it NEW?

What is Significance?

- Significance is about *impact*.
  - WHY your research is important
  - Address real problem
  - Fill a critical knowledge gap
  - Affect public health

Example 1 (Disease-focused): *Pancreatic cancer has a 5-year survival rate below 10%, there are limited biomarkers for early detection, and existing therapies only extend survival by months.*

Example 2 (Unmet need): Despite decades of research, there is still no widely adopted protocol to address financial toxicity among patients undergoing cancer treatment.

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Tips - Significance

- Describe and ***quantify*** the problem using numbers
  - How many patients affected, $ burden on healthcare system/society etc.
  - Do not assume reviewers know about your topic
- Summarize current approaches (standard-of-care or state-of-the-art)
- Explain **unmet need:** why current approaches are inadequate.
- Describe your solution. State the impact your solution will have on all aspects of the problem (health, economic, and societal) in comparison with current practice.
  - Link your work to agency priorities: “This work directly aligns with SAMHSA’s goal to…”
  - Highlight what’s at stake: “Without this work, we will continue to…”
- **For NIH grants**: End with “Rigor of Prior Research”.
  - Strengths and weaknesses in the rigor of prior research (both published and unpublished) that serves as key support for the proposed project.
  - Plans to address weaknesses in rigor of prior research.

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What is Innovation?

- Tell the reviewers what's *new*.
  - Novel method
  - New application of an existing technique
  - Fresh conceptual framework
  - Doesn't have to be groundbreaking – but it must be *different* from what's already out there.

Example 1 (Method): *This is the first study to apply machine learning algorithms to predict 30-day readmission risk using both clinical and social determinants data.*

Example 2 (Conceptual): *This study introduces a novel biopsychosocial framework to explain disparities in treatment adherence among patients with chronic pain.*

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Tips - Innovation

- Explicitly label the innovation
  - *"This proposal is innovative because…"*
  - *"Our key innovation lies in…"*

- Compare to the *status quo*
  - What would others do and what are you doing differently?
  - Compare your solution with standard-of-care and emerging approaches to solving the unmet need and describe what features differentiate your idea from others
  - Use a table to lay out features that set your solution apart from others
  - Remember – there is *always* competition!

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Significance & Innovation

- A project can be innovative but not significant
  - A flashy new technique that doesn't solve a real-world problem
- A project can be significant but not innovative
  - Replicating known interventions in a new population
- We're aiming for both, *ideally*
  - *But* some NOFOs emphasize one over the other: do not submit a non-innovative project to a NOFO that seeks innovation, or vice versa
  - Your work addresses a critical problem AND your approach offers something new
- Before you submit, ask yourself:
  - Did I clearly explain why this matters? (Significance)
  - Did I make it obvious what's new and different? (Innovation)

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Let’s Practice – Significance, Innovation, or Both?

- Although motivational interviewing has been widely studied in substance use disorder treatment, its use in post-stroke rehabilitation is unprecedented.

Let’s Practice – Significance, Innovation, or Both?

- Although motivational interviewing has been widely studied in substance use disorder treatment, its use in post-stroke rehabilitation is unprecedented.
  - Innovation

Let’s Practice – Significance, Innovation, or Both?

- Although motivational interviewing has been widely studied in substance use disorder treatment, its use in post-stroke rehabilitation is unprecedented.
  - Innovation
- Sepsis affects over 1.7 million adults in the U.S. annually and costs the healthcare system an estimated $62 billion each year.

Let’s Practice – Significance, Innovation, or Both?

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- Sepsis affects over 1.7 million adults in the U.S. annually and costs the healthcare system an estimated $62 billion each year.
  - Significance

Let’s Practice – Significance, Innovation, or Both?

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  - Both

Building Your Team

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Building Your Team

- Main goal: show the reviewers your team is qualified
- As you define your aims, think about the gaps in your team's expertise
- Common gaps:
  - Biostatistical expertise
  - Clinical expertise
  - Regulatory expertise
- How to fill these gaps:
  - Consultants
  - Subawards
  - New personnel
- Type of role depends on amount of effort expended, organizational requirements, affiliations

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Key Personnel and Other Personnel

- Key Personnel:
  - Intellectual contribution
  - Integral to accomplishing aims
  - Includes consultants
  - Typically need biosketches

- Other Personnel:
  - Need not have any intellectual contribution
  - Could be integral to accomplishing aims, but are relatively easy to replace
  - Do not need biosketches

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Biosketch

- Each key personnel must submit an NIH biosketch (5-page max)
  - Education
  - Personal Statement
  - Positions and Honors
  - Contributions to Science
- Use the latest/correct template!
- Tailor the personal statement for every submission.
  - Describe role in project- be specific!
    - Example: *As a biostatistical consultant in this R01 project, I will contribute to the study design for Aim 1.*
  - Highlight relevant experience
  - Detail how your experience aligns with the goal of this grant
  - Mention prior collaborations with the research team
  - Explain any extenuating circumstances, if necessary
    - If you have a large gap in your employment history, you can thoughtfully address it here.
      - Example: *From 2015-2018, I took a leave of absence to care for my child who was diagnosed with…*

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Biosketch

- Drs. Boyd and Pai can assist with drafting/updating your biosketch
- SciENcv: Science Experts Network Curriculum Vitae
- In 2026, NIH will require all key personnel to generate a biosketch using SciENcv
  - Obtain ORCID ID and link to both eRA Commons and your NCBI/SciENcv account
  - Enter your personal data
  - Personal statements may move out of the biosketch and into a new supplementary attachments

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Letters of Support/Commitment

- Drs. Boyd and Pai can draft letters and coordinate with your partners
- Signed letters of support and commitment are often required to confirm partnerships
- Describe the type and length of relationship or partnership
- Clearly state what they are committing to the project
- Describe letter writer's technical expertise and background
- Confirms availability of resources
- Enthusiastic support and alignment.
- Must be signed – Allow plenty of time to secure approval
  - Some funding agencies require INKED SIGNATURES
  - Some allow DIGITAL SIGNATURES through Adobe Sign, DocuSign, etc.

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Other Application Components

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Clinical Research

- NIH definition of clinical research
  - HS research that is:
    - **Patient-oriented**. Research conducted with **human subjects** (or on material of human origin) for which an investigator **directly interacts** with human subjects. Excluded from this definition are *in vitro* studies that use human tissues that cannot be linked to a living individual.
    - **Epidemiologic and behavioral studies**.
    - **Outcomes research and health services research**.

- Examples:
  - Registries
  - Observational Studies
  - Retrospective Chart Review
  - Social/Behavioral Studies

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Human Subjects (HS) Research

- According to 45 CFR 46, a human subject is "a living individual about whom an investigator (whether professional or student) conducting research:
  - Obtains *information or biospecimens* through *intervention or interaction* with the individual, and uses, studies, or analyzes the information or biospecimens; or
  - Obtains, uses, studies, analyzes, or generates *identifiable private information* or *identifiable biospecimens*."
- The use of any **potentially identifiable data or biospecimens** from a **living human being** can be HS Research
- Not sure if you're doing HS Research? Use **NIH's decision tool**

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Human Subjects (HS) Research

- Examples of HS research include:
  - Collecting blood
  - Conducting a survey
  - Changing participants' environment
  - Interviewing
  - Administering a psychological test
  - Collecting data
  - Conducting a focus group
- Included in the NIH application:
  - Protection of Human Subjects attachment
    - Details how subjects will be protected from research risk
- If funded, grantees will need:
  - An Institutional Federal-Wide Assurance (FWA) with Office for Human Research Protections
  - IRB approval or determination of exemption
  - Human Subjects education (even for exemptions)

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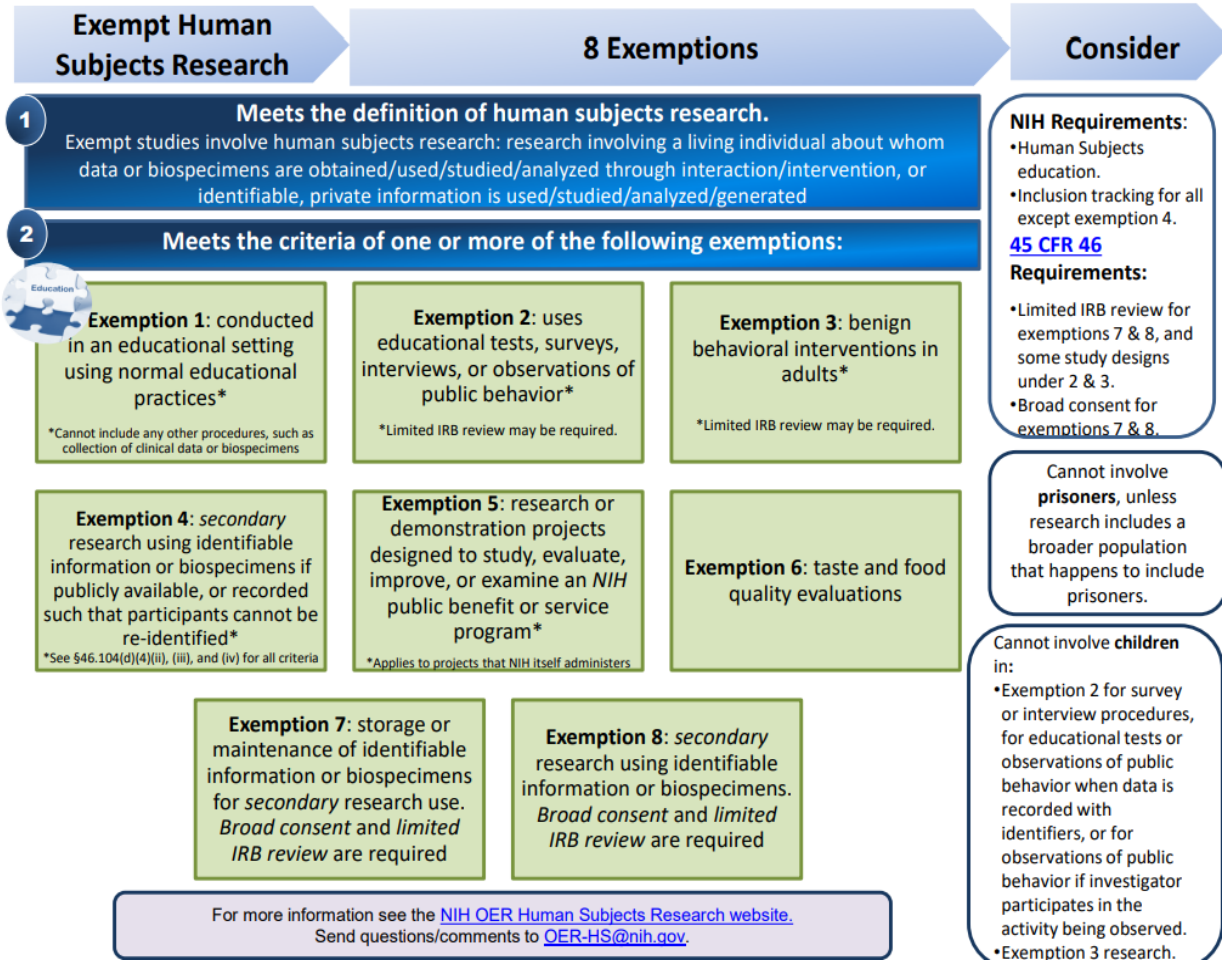
Human Subjects Research Exemptions



- If you qualify for an exemption, you may need fewer HS documents
- NIH Infographic on HS exemptions
- Contact the IRB to discuss and clarify exemption status

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Clinical Trials

- Per NIH, clinical research is a Clinical Trial when:
  - Human subjects are **prospectively assigned** to one or more **interventions** (which may include placebo/other control) to evaluate the **effects of those interventions** on health-related **biomedical or behavioral outcomes**.
- Can be **Investigator Initiated** and:
  - Federally Funded
  - Industry Funded
  - Privately Funded (Internal Awards, Private Foundations)
  - Single Site or Multi-site
- **Industry Sponsored** and:
  - Single Site or Multi-site
- Not sure if you're doing a clinical trial? Use **NIH'S Clinical Trial Decision Tool**
- NIH Clinical trial attachments more elaborate than HS

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Clinical Trials

- NIH requires the completion of a **Study Record** in the **PHS Human Subjects and Clinical Trials Information form**. This form contains a combination of text fields, narrative text boxes and attachment fields.
- Attachments include:
  - Inclusion Across the Lifespan
  - Inclusion of Women & Minorities
  - Recruitment & Retention Plan
  - Study Timeline
  - Inclusion Enrollment Report(s)
  - Protection of Human Subjects
  - Data and Safety Monitoring
  - Overall Structure of Study Team
  - Statistical Design and Power
  - Dissemination Plan
- Provide Recruitment status and Date first subject enrolled information via dropdown selections in form

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HS/Clinical Trials Resources

- NIH HS and Clinical Trial Form instructions
- NIH Clinical Trials & You: The Basics; For Researchers & Trial Sites
- Clinical Trial-Specific Funding Opportunities
- Human Subjects and Clinical Trials Information Form
- Division of Human Subjects Research (DHSR) Resources on Human Subjects, Clinical Trials, and Inclusion
- Research Patient Care Costs: Policy & Allowable Costs
- Sample NIH Clinical Trial section

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Let’s Practice – HS only or Clinical Trial?

- A study is interviewing 500 adults about their daily diet and exercise habits over a year to understand links to cognitive decline. The adults are the human subjects, providing data through interaction (interviews) and identifiable private info (their habits/health). Is this a:
  - Human Subjects Study
  - Clinical Trial
- A study testing a new "InPACT" classroom physical activity program (5-minute breaks) in schools to improve student health.

  Intervention: The InPACT program (behavioral/lifestyle) vs. a control group.

  Subjects: Students in randomized schools.

  Data: Physical activity levels, health outcomes.

  Goal: See if the intervention improves health compared to the standard.

  Is this a:
  - Human Subjects Study
  - Clinical Trial

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Other Material (NIH grants)

- **Resource Sharing Plan**
  - How you won't make gov't paid development proprietary
- **Data Management and Sharing Plan**
  - **Not scorable** by reviewers
  - Can ask for money in your budget (rare)- under "Other Direct Costs"
  - Examples **here**
- **Authentication**
  - How you will validate chemical/biological resources
  - 1-page limit
  - Example **here**
- **Project Summary/Abstract**
  - 30-line scientific summary- no proprietary information!
- **Project Narrative**
  - 3 sentence lay description
  - Include relevance to public- no proprietary information!
- **Facilities and Resources**
  - Description of institution and capabilities, core facilities
  - Get from Grants Office!
  - **People are also resources!** You can highlight institutional experts

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Thank You!

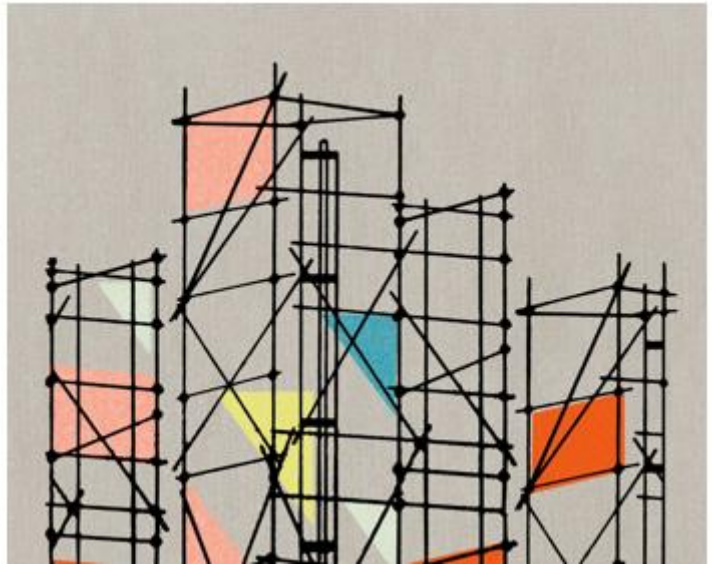
Questions?

Grant Budgeting

Grant Writing Bootcamp

12/17/25

Budgets



Collaboration is key!

Research Grant Partners

1. Research Directors/Managers – Nicole, Ansley, Wendy, Dan, Rachel
2. Grant Writers – Sarah, Priya
3. Grant Administrators (RFO) – Alyssa, Hillary, Cari (1/19/26)

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Grant Administrators

Financial aspects of applications

- Preparing budgets
- Reviewing cost allowability (for federal grants, a reg. requirement)
- Applying knowledge of institutional policies as well as sponsor requirements
    - Important for allowability determinations, troubleshooting
- Serving as your partner post-award

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A Strong Budget . . .

- Provides scaffolding
- Impresses reviewers
  - Demonstrates organization, responsibility, knowledge of fiscal management
- Protects against sponsor cuts
- Can result in fewer post-award delays

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Key Steps

- PI sends timely justification to grant administrator
- Grant administrator does the following:
  - Initiates two-phase RFO review,
  - Translates justification to xl budget,
  - Prepares formal, uniformly written justification, and
  - Input info into sponsor forms

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That was the homestretch . . .

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Prior Steps

PI coordinates with

- Research Director/Manager
- OCOR (if informatics, biostat, epi support is needed)
- Biobank Manager (Melyssa)
- Grant Writers

RD, OCOR, Biobank manager provide staffing info—planning/early communication is needed!

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RFO Timeline (Homestretch)

Justification—a complete justification—is due to RFO:

- 3 weeks before sponsor deadline (Ochsner is prime)
- 2 weeks before Ochsner materials are due (Ochsner is sub)
- Earlier if patient care cost are involved. Timeline TBD.

These are drop-dead dates—don’t wait this long!

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Ochsner Grant Process

Here's where we request justifications.

While the timeline may vary, what we're looking for is the same for all applications, whether Ochsner is the lead institution or a consortium partner. The PI should provide justifications and other deliverables directly to grants@ochsner.org, even if he/she is working with a grant writer.

Sample Internal Timeline from Grants		
Internal Due Date	**PI Deliverable**	**Comm**
8/21/2025	**Statement of Work (SOW) for each partner**	This is / should not be revised. Ele create a polished document.
9/5/2025	**Complete list of Performance Sites**	P er.
9/12/2025	**Ochsner budget justification**	For ea e.g., Jane Doe, CRC, will recruit & consent subjects @ 10% effort a year. Itemize non-personnel costs exceeding a total of $1K—e.g., incentive stipends @ $250 x 25 subjects, needles for acupuncture, $500. For contractors, specify name, skills, & responsibilities and break down costs ($100/hr x 200 hrs a year, or $250 per data set x 3 sets). Detailed bullet points are fine. We'll work them into a formal document.
9/12/2025	**Ochsner biosketch(es)**	For PI/PD and key personnel
9/26/2025	**Project narrative and all other PI documents (to be specified in a follow-up message).**	The grants team will complete all administrative and budget forms. Provide PI documents in final form. After this date, the only changes should be those initiated by grant administrators to address technical errors, inconsistencies, etc.

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Budget Justification: What We Need

- List of direct costs, specifying need for each
- Substance over form (bullet points are fine)
- Don’t focus on overhead. We’ll justify that.

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Common Question

"I've mastered arithmetic. Why can't I just send a budget?"

- Grant administrators have direct knowledge of appropriate rates, salaries, policies, etc.
- An institutionally authorized office must determine cost allowability – requires justifications. (I.e., a standalone budget isn't enough.)

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Allowable Costs

Requirements:

- Needed to complete the project,
- Allocable to project,
- Reasonably priced, and
- Consistent with institutional policies and practices

What's allowable at UAB may not be allowable here (and vice versa).

Is This an Allowable Cost?

From a Sub-awardee:

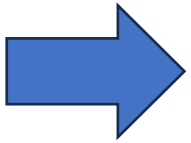
> "A personal computer is needed for our PI to work at home."

Issues?

PC Request

Issues:

- Need?
- Allocability?
- Consistent costing?



Not allowable as direct cost. (Overhead.)

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Is This an Allowable Cost?

NIH R01 Request:

“Each year, $3K is requested for domestic travel to a microbiology meeting, such as ASM Microbe or the Microbiology Society Annual Conference.”

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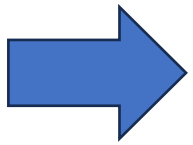
Travel Request

Issue: Why is travel needed in year 1?



Not allowable w/o more info.

Travel Justification, Revised

“In years 1, 4, and 5, $3K is requested for domestic travel. In year 1, the co-I will attend the annual ASM Microbe conference to partake in training modules on techniques X and Y, which will facilitate the timely completion of aim 2. In years 4-5, the PI or co-I will attend ASM Microbe, the Microbiology Society Annual Conference, or another national meeting to disseminate research findings .”

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What We'd Need from You, the PI

Travel

- Y1 – co-I travel to ASM Microbe annual mtg. for training on x & y (needed to conduct experiments for aim 2).
- Y 4, 5 – PI or co-I to conference (ASM Microbe, Microbiology Society, etc.) for dissemination.

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Other Good Examples

Travel

- Y3 – co-I travel to ASM Microbe annual mtg. for dissemination of Aim 1 results (expected after first 24 months).
- Y 4, 5 – PI or co-I to conference (ASM Microbe, Microbiology Society, etc.) for dissemination.

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Other Good Examples

Travel

- Y1-5 – PI or Project Manager to travel to DC for annual RFPW6 meeting, as required by sponsor.

Common Direct Cost Categories

Cost Type	Information to Provide
Personnel (Ochsner employees, current and TBH)	• Role • Tasks & responsibilities • Suitability/why essential • Who supervises their project-related work (for personnel other than PI) • Annual effort (hours/year or % of entire Ochsner effort)

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Personnel

Roles – PI, Co-I, CRC, Biostatistician, etc.

- Note: NIH doesn't recognize the term "Co-PI"

"Personnel" includes only Ochsner employees (or TBHs). People employed elsewhere are included via independent contractor, professional services, or subrecipient agreements.

Cost Type	Information to Provide
Materials & Supplies	• What's being purchased • Why needed • When needed (which year) • Which, if any, items will be obtained through Ochsner's Digital Medicine • (If $1K, itemize – quantity, unit price)

Cost Type	Information to Provide
Patient Incentives	• Number of patients • Patient requirements (blood draws, surveys, etc.?) • Special considerations? • Itemization: Number of patients, incentives/patient, unit cost
Travel	• Traveler(s) • Approximate date/year of trip • Event/Destination • Purpose

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Cost Type	Information to Provide
Subawardees	• SOW (needed early!) • Suitability • Need • Grant admin to request justifications/budgets
Consultants	• Whether Key Personnel or not • SOW (needed early!) • Need • Suitability/qualifications • Break down costs into unit price x estimated # units

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Cost Type	Information to Provide
Equipment	• Item name • Specify project-related use (to confirm specialized vs general-purpose use) • Why it's essential • Why existing shared resources aren't sufficient • Confirmation of 100% use for project • (Provide quote showing vendor, cost breakdown.)
Patient Care	• Protocol (draft is okay) with schema • (Coordinate with Research Director!)

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Practical Considerations

For Ochsner to direct charge a non-personnel cost to a federal grant, the following is needed:

- An invoice, a receipt (reimbursement), a contract, and/or a PO to/with/for an external entity, or
- A reimbursable invoice from the external entity

Note: Invoices from the Ochsner biobank or Digital Medicine are **not** generally reimbursable!

How to Handle these Costs?

Biobank:

- Contact Melyssa for budget justification. She'll identify staff and quantify expected efforts.

Digital Medicine:

- Work with your grant administrator early!

Thank you.

Questions/Suggestions? Grants@Ochsner.org

Web pages:

https://research.ochsner.org/grants/applications/start/

https://research.ochsner.org/grants/grant-writing-services/

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2025 Grant Writing Boot Camp

11am CT – Building a Budget Part 2:
Hands-on, guided activity to build a sample budget using a template

December 17, 2025
11:00 am – 12:00 pm CT

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What do you think are the most common budget categories?

Budget Categories

- Personnel Time – salary effort: Key, Other
- Consultants
- Equipment
- Travel & Meetings
- Subawards/subcontracts
- Clinical Trial Costs
  - Procedures: Technology
    - Imaging & labs
  - Procedures: Study-related Care & Intervention
    - Drugs & devices
  - Protocol-Related Fees
    - Start-up, close-out, & institutional fees
- Materials & Supplies
- Fee-for-service

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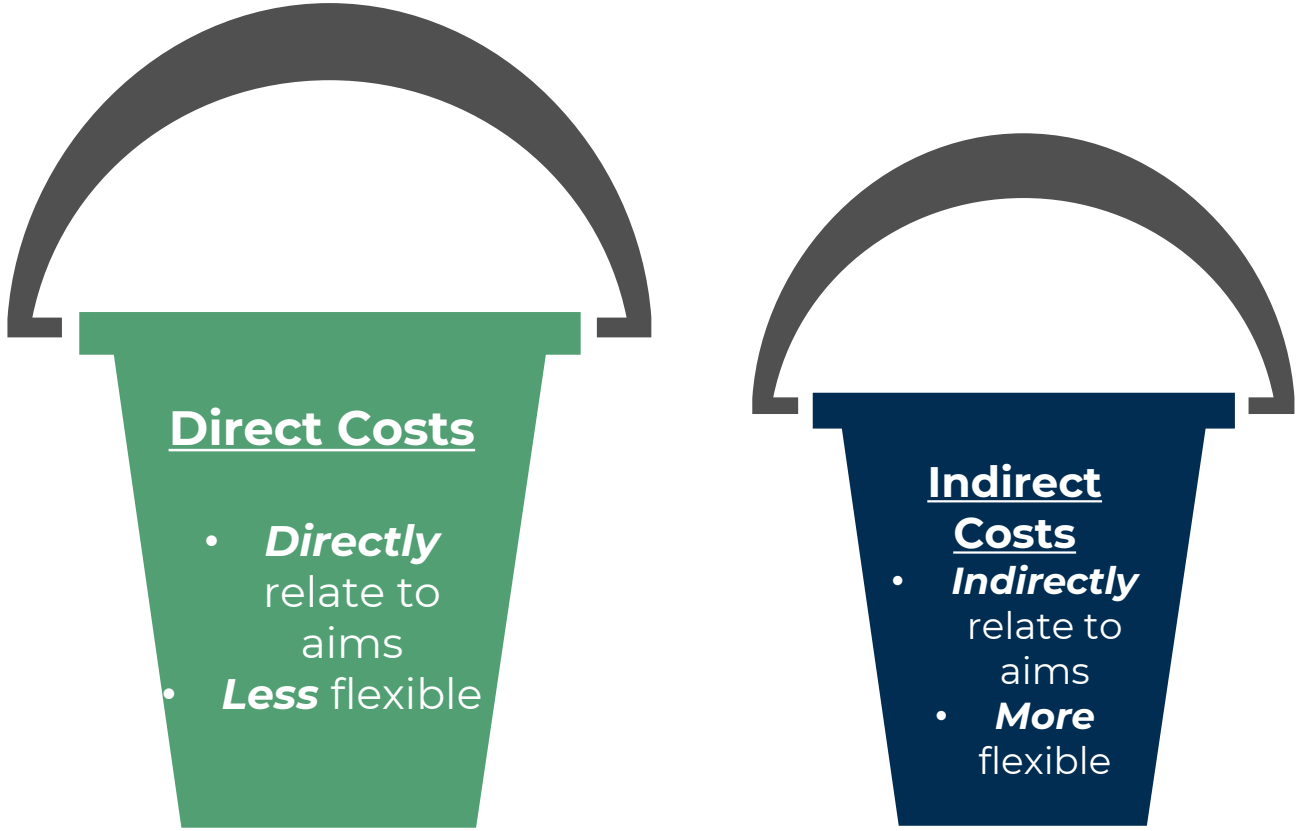
Direct Vs. Indirect Costs



- **NIH policy on allowable costs**
- Only include direct costs in your budget justification
- Different funders have different indirect costs policies.
- **You do not have to worry about indirect costs – the grants management team will handle indirect costs for you**

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Direct Vs. Indirect Costs

Electricity Bill: **Indirect Cost**
Not specific to your project

Tissue sections for your project: **Direct Cost**
Specific to your project

Subaward/Subcontract vs. Fee-for-Service

- A subaward is an award provided by a pass-through entity (prime) to a **subrecipient** for the subrecipient to carry out part of an award received by the pass-through entity.

Subaward/Subcontract

- Typically, a university or non-profit
- Has a subaward Principal Investigator (PI)
- Has a separate budget with its own indirect cost rate
- ***Key differentiator: intellectual contribution to project***

Fee-for-Service

- Typically, a contract research organization or for-profit entity
- Does not have a PI
- Provides a quote for services, but no separate budget
- ***Key differentiator: standard off-the-shelf service***

Both foreign Subawards and Fee-for-Service providers are heavily scrutinized for federal grants

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Consultant vs. Key Personnel

- **Consultants**
  - Offer services on an hourly basis
  - Not employed by applicant organization
  - Usually require a Letter of Support/Commitment
  - Check institutional policies on consulting

- **Key Personnel**
  - W2 Employees of applicant organization
  - Vital to accomplishing aims and have intellectual input
  - If PI, funder may have minimum effort requirement (often 10%)

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Consultant vs. Subaward

- Are institutional resources (equipment/facilities/data) being used?

Subaward

If:

- No institutional resources being used
- Organization allows employees to serve as consultants
- Contribution can be quantified in #hours/year

Consultant

Let’s Practice – Consultant, Fee-for-service or subaward?

- You’re collaborating with an entity that is making a device that is vital for your planned experiments. Your point-of-contact at the entity is working with you to refine the design of the device to your specifications. They are also a subject matter expert in the use of the device, and they are heavily involved in experimental design. You are writing a grant for this project. Is the entity a:
  - Subaward/subcontract
  - Fee-for-service
  - Consultant

Let’s Practice – Consultant, Fee-for-service or subaward?

- You’re collaborating with a contract research organization (CRO) that is performing efficacy experiments with mice using a drug you have developed in your laboratory for a grant application. The CRO supplies you with a quote. Is the CRO a:
  - Subaward/subcontract
  - Fee-for-service
  - Consultant

Let’s Practice – Consultant, Fee-for-service or subaward?

- You’re collaborating with a co-author on one of your published papers for a grant application. The co-author is employed at another university and will be advising on study design, in addition to performing some data analysis for you. This work will amount to about 20-30 hours in total. Is the co-author a :
  - Fee-for-service
  - Subaward/subcontract
  - Consultant

Guided Activity

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NOFO #1: Small Pilot Grant

- Award: $50,000
- Project Period: 1 year
- Funder Type: Regional Health Foundation
- Key Budget Rules
  - No indirect costs allowed
  - Equipment purchases capped at $5,000
  - Funds must be fully expended within 12 months

Your project needs: PI effort (0.10 FTE = 1.2 CM), project coordinator (0.5 FTE = 6.0 CM), mileage to and from pilot site monthly (100 miles round trip) for PI and coordinator.

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NOFO #2: Mid-Size Federal Grant

- Award: $500,000
- Project Period: 2 years
- Funder Type: Federal Agency
- Key Budget Rules:
  - Indirect costs allowed up to 10%
  - No more than $250,000 per year

Your project needs: PI effort (0.20 FTE = 2.4 CM), 2 CRCs (2.0 FTE = 24 CM) , subaward to Tulane totaling $50,000 per year, 10% indirect cost rate

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NOFO #3: Large Research Project

- Award: $2.0 Million
- Project Period: 5 years
- National Philanthropic Funder
- Key Budget Rules:
  - Federal negotiated indirect cost rate allowed
  - No more than $500,000 per year

Your project needs: Physician PI effort (0.20 FTE using NIH salary cap), Project Coordinator (0.5 FTE = 6.0 CM), CRC (1.0 FTE = 12 CM), subaward to LSU for $45,000 per year, Consultant fee of $25,000 per year, patient incentives ($50 per patient x 100 patients per year)

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Thank You!

Questions?

2025 Grant Writing Boot Camp

10am CT – Review, Repurpose, and Resubmit: Understanding NIH review cycles, how to incorporate reviewer feedback, and repurposing your written assets

10:00 am – 10:50 am CT

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Review Process

- Depending on agency, can take anywhere from 1-4 months
- Most funding opportunities have low success rates- **plan to resubmit**
- **If applying for NIH/federal grants, plan to resubmit *at least* 1-2 times before getting a fundable score.**
- Consider reviewer feedback as you plan next steps

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NIH Review Process

- **Application Assigned to a Review Group by Center for Scientific Review (CSR)**
  - 1-3 weeks after submission
  - CSR checks application for administrative and formatting requirements
  - Assigns application to an NIH institute or center (IC) and a review group.
- **First-Level Peer Review**
  - Chair— a committee member who leads the discussions.
  - Scientific review officer (SRO)— NIH staffer with Ph.D. in relevant field who manages the review.
  - Members of the committee assigned to your application.
  - Program officer to provide programmatic input.
- **Scoring and Summary Statements (SS)**
  - Overall impact score is the main basis for a funding decision by an NIH IC.
  - Your SS provides information about the review, the reviewers' critiques, and your score.
  - Scored review criteria: Significance, Innovation, Approach (score 1-9)
  - Judged for acceptability: Investigators, Environment
- **Second-Level Review: Advisory Council**
  - The main Advisory Council must recommend an application for funding
  - Looks at applications with potential barriers to funding such as human subjects and animal concerns, or renewal applications requesting more money than the limit.
  - PO part of council review

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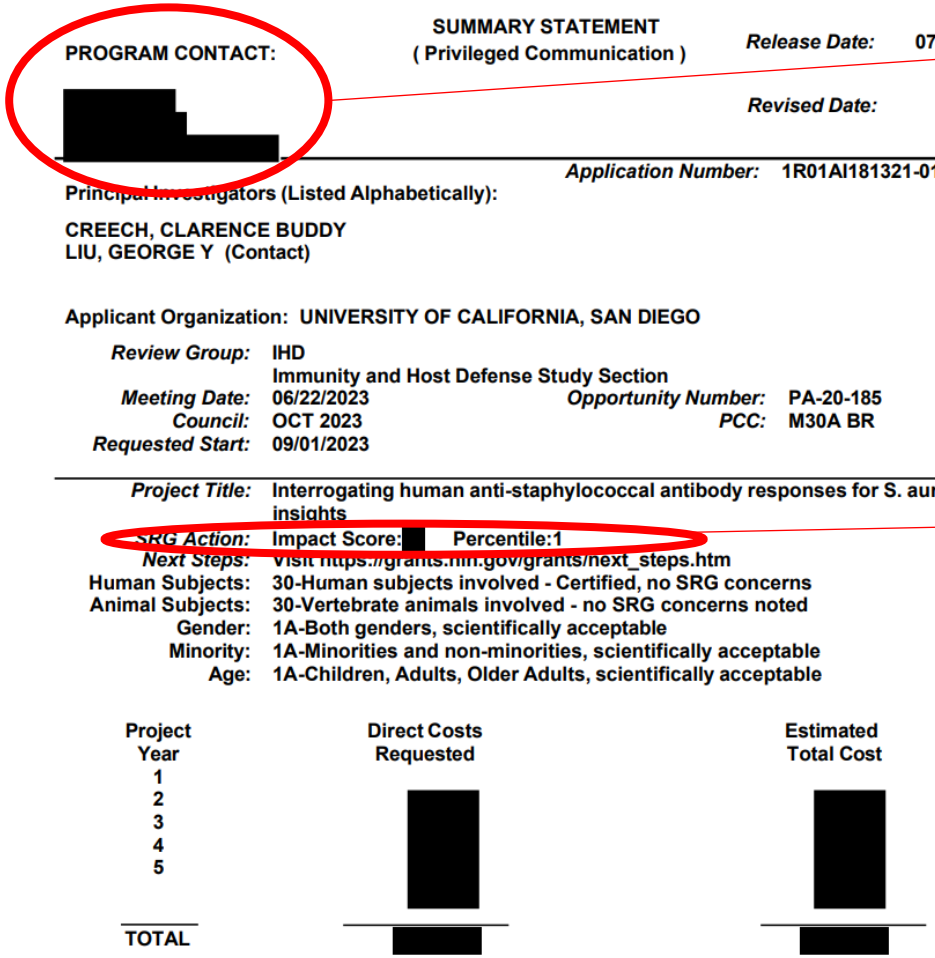
The Summary Statement



SUMMARY STATEMENT
(Privileged Communication)

PROGRAM CONTACT: [redacted]

Release Date: **07/08/2023**

Revised Date:

Application Number: **1R01AI181321-01**

Principal Investigators (Listed Alphabetically):

CREECH, CLARENCE BUDDY
LIU, GEORGE Y (Contact)

Applicant Organization: UNIVERSITY OF CALIFORNIA, SAN DIEGO

Review Group:	**IHD** Immunity and Host Defense Study Section		
Meeting Date:	**06/22/2023**	***Opportunity Number:***	**PA-20-185**
Council:	**OCT 2023**	***PCC:***	**M30A BR**
Requested Start:	**09/01/2023**		

Project Title:	**Interrogating human anti-staphylococcal antibody responses for S. aureus vaccine insights**
SRG Action:	**Impact Score:** [redacted] **Percentile:1**
Next Steps:	**Visit https://grants.nih.gov/grants/next_steps.htm**
Human Subjects:	**30-Human subjects involved - Certified, no SRG concerns**
Animal Subjects:	**30-Vertebrate animals involved - no SRG concerns noted**
Gender:	**1A-Both genders, scientifically acceptable**
Minority:	**1A-Minorities and non-minorities, scientifically acceptable**
Age:	**1A-Children, Adults, Older Adults, scientifically acceptable**

Project Year	**Direct Costs Requested**	**Estimated Total Cost**
1		
2		
3		
4		
5		
TOTAL	[redacted]	[redacted]

This is your PO – email them with any questions

This is your impact score. Will say “**” if not discussed

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The Summary Statement

1R01AI181321-01 LIU, GEORGE

RESUME AND SUMMARY OF DISCUSSION: This R01 application proposes to characterize the protective components of the human antibody response to *Staphylococcus aureus*, and to distinguish these from non-protective or suppressive responses, in order to elucidate critical mechanisms of anti-staphylococcal antibody protection. The reviewers agreed that defining the mechanisms underlying failure of vaccines against *S. aureus*, and identifying antigens that may not be impacted by pre-existing immunity against *S. aureus*, could have very significant impact on vaccine development. The rigor of the prior research strongly supports the significance and experimental approach. The Principal Investigators (PIs) of this multi-PI (MPI) application have complementary expertise, and an excellent track record of productivity. The MPIs and collaborators are well-suited for undertaking the proposed work. The MPI plan is well laid out. The application is conceptually and technically innovative. The research plan is rigorous with adequate statistical analysis and experimental replicates. Sex as a biological variable is appropriately addressed. Anticipated results, pitfalls and alternative approaches are thoroughly considered. No score-driving weaknesses were identified. Overall, the review committee expressed an exceptional level of enthusiasm for this application.

This is a written summary of the study section's discussion. Will be missing if application is not discussed.

Budget and Period of Support:
Recommend as Requested

CRITIQUE 3:

Significance: [redacted]
Investigator(s): [redacted]
Innovation: [redacted]
Approach: [redacted]
Environment: [redacted]

Overall Impact: This is a very well written proposal from a seasoned veteran and colleague of the *Staphylococcus aureus* (SA) and methicillin-resistant SA (MRSA) fields. The rigor of prior research with respect to both significance and approach is presented with inclusion of publications as well as a plethora of preliminary results. Scientific rigor is addressed with presentation of statistical analyses as well as defined cut-offs and the like throughout the aims. Sex as a biological variable is addressed with the use of female and male human samples and animals. This project deals with addressing the "original sin" of SA/MRSA. They have found with, at least IsdB, that a portion of the protein, while eliciting protection in naïve mice, causes immune evasion in pre-exposed mice. They intend to address this throughout the project as well as address this potential in other antigens. Anticipated results, pitfalls and alternative approaches are given throughout. This is an exciting project with a high potential of success. The potential impact of this project is high.

1. Significance:

Strengths

- SA and MRSA remains a highly significant public health issue.
- The rigor or prior research is strong with a number of publications noted as well as a plethora of preliminary results presented. Additionally, each aim is supported by these results.

Weaknesses

- No weaknesses noted.

- **All** applications get written critique from the 3 primary reviewers
- Budget, HS documents get yes/no for acceptability

What does my score mean?

- **Not discussed**= *roughly* bottom half of pile
  - PIs still get the Summary Statement with individual reviewer criteria scores and critiques
  - Don't be discouraged if your application is not discussed – reviewer feedback can inform your next submission
- **Scored** = top half (the lower the score, the better)
  - Number (10–90)
    - Scores 10–30: Very encouraging, potentially fundable
    - Scores 40–60: Somewhat encouraging, but probably not fundable on this submission
    - Scores 70–90: Considerably less encouraging, less fundable
  - Percentile Score: 10th percentile or lower is very good and potentially fundable
- **Paylines** are the funding cutoff points for grant applications
- ICs used to subscribe to defined paylines, but the **NIH is moving away from paylines**; effective the January 2026 Council round. Instead, impact scores will be considered in context of IC and NIH's priorities, strategic plans, and budgets

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Why Proposals are Rejected

- Inadequately presented statement of need (not significant or can't change)
- Lack of innovation, idea has already been tried and failed
- Lack of scientific rigor
- Objectives are ill-defined (vague goals)
- Poorly crafted proposal
- Team not qualified; not the appropriate investigator or institution
- Funder doesn't have enough information

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Planning your next steps

- NIH grants: regardless of your impact score (even if not discussed), it's always a good idea to reach out to your PO for a meeting
- Prepare a 1-2 page-rebuttal to reviewer critique ahead of the meeting with PO
- Solicit PO's advice on next steps
  - Resubmission may not always be a good idea
  - Ask if another NOFO may be more appropriate funding mechanism

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Resubmission vs. New Submission

- NIH/federal grants:
  - If scope of work largely the same – resubmission
  - If major changes to scope of work – new submission
  - If resubmission, leverage 1-page "Introduction to Application" to respond directly to reviewers
    - **Never** be aggressive or combative in your response to reviewers
    - Thank the reviewers a lot
    - Address all major critiques directly (I like to use separate sub-headings for each critique)

- Other grants
  - Consider resubmission if allowed
  - Consider repurposing core content for other grant applications

Try to fully address all reviewer critiques in a resubmission

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Repurpose

Name	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Project 1		PO mtng		✓			Review					
Project 2				PO mtng		✓		Review				
Project 1 resubmission								PO mtng		✓		
Project 2 resubmission									PO mtng		✓	

✓ = submission
Blue = application preparation

Remember to tailor your application to each funding opportunity!

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Thank You!

Questions?