Mastering NIH Grant Proposal Preparation

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Introductions: Presenters

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Introductions: Participants

What is your NIH proposal experience?

a) New to NIH proposal submissions

b) Some experience

c) Used to submit NIH proposals & need a refresher

Learning Objectives

1 **Key Components**

2 **Best Practices**

- Understand the key components of NIH grant mechanisms & policies to effectively guide faculty through the pre-award & submission process.

- Learn best practices in budget development, compliance checks, & post-submission support to improve NIH proposal success rates & streamline administrative workflows.

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Topics

NIH Grant Mechanisms and Policies

Pre-Award Best Practices for NIH Grants

NIH Submission Strategies & Avoiding Common Pitfalls

Post-Submission & Resubmission Support

Discussion: Q&A

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Key NIH funding Mechanisms/Activities

- Research and Development (R)
- Training (T)
- Fellowships (F)
- Career Development (K)
- Centers (P)
- Cooperative Agreements (U)

Notice of Funding Opportunity (NOFO)

- ○ RFA-Request for Application (Solicited – Usually a Grant)

- ○ RFP-Request for Proposal (Solicited – Contract/Service)

- ○ PA-Program Announcement (Ongoing Program/Activity)

- ○ PA-Parent Announcement – Unsolicited

Eligibility & Due Dates

- Determining PI and Institutional Eligibility

  - What is the sponsor's requirement for PI eligibility?

  - What is your institutional policy on PI Eligibility?

  - Does the NOFO limit the number of submissions?

- Understanding due dates and review & award cycles

  - Standard due dates, review and award cycles

  - Specific dates as described in the FOA
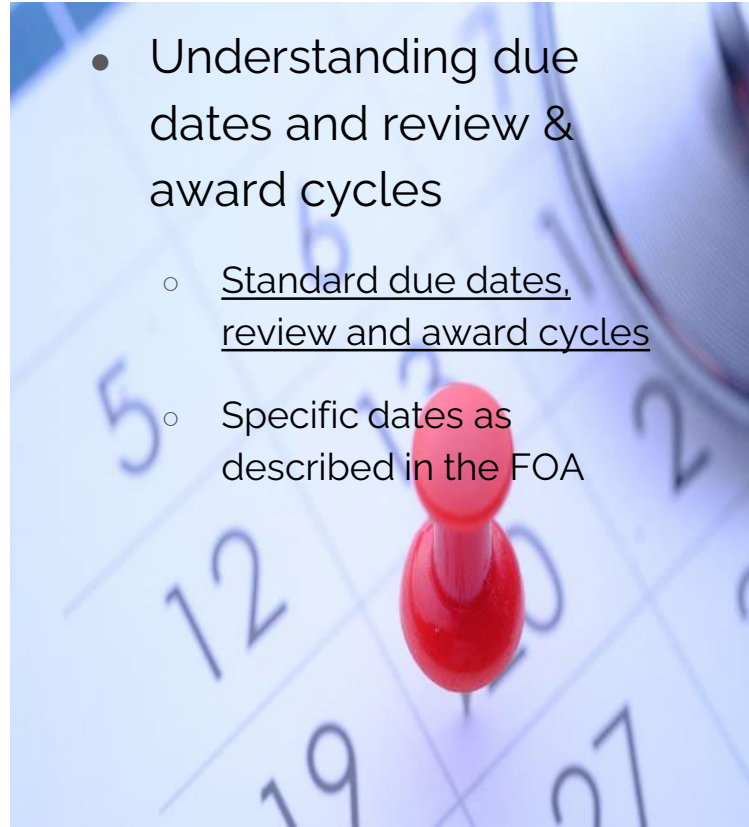
Letters of Intent & Pre-Proposals

- LOI

  - Optional or Required

  - Assists NIH determine reviewers

- Pre-Proposal

  - More detailed to gauge interest of sponsor

  - Formal proposals are invited

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"Ask Early, Ask Often"

- **Ask the Principal Investigator:**

  - Will this be a Multi-PI submission?

  - Are there subaward(s)?

  - Will there be consultant(s)?

  - Is there an equipment request?

- **Establish Early Internal Deadlines**

  - Set deadlines for subaward(s) and/or consultant(s) to allow time to integrate material

  - Allow time to collect vendor quotes

Follow the Instructions!

- Adhere to all page limits & formatting

- Do not include hyperlinks or URLs unless specifically allowed in FOA

- Ensure that all requested sections requested are included

Create a Checklist

- **Research Plan/Scientific Narrative**

- **Introduction**

- **Specific Aims**

- **Research Strategy**

- **Human, Clinical, Animal, Select Agents**

- **Letters of Support, Reference Letters**

- **Resource Sharing**

- **Budget and Budget Justification**

- **Biographical Sketches**

- **Bibliography/References Cited**

- **Cover Letter/PHS Assignment Request Form**

- **Appendices**

- **Other? Click on all links in the FOA**

Budget Considerations

- **Are There Budget Limitations and/or Caps?**

    o **Total Project Cap**

    o **Direct Cost Cap**

    o **NIH Salary Cap: $221,900 ($225,700 pending NIH Approval)**

- **Type of Budget: Modular vs. Detailed**

    o **See Prior Approval to Exceed $500K in Direct Costs per grant year**

Budget Considerations cont.

Follow the Cost Principles

ALLOWABLE | REASONABLE | ALLOCABLE | CONSISTENT

Budget Considerations cont.

| ALLOWABLE | REASONABLE | ALLOCABLE | CONSISTENT |

Allowable - Must conform to sponsor regulations

- Eligible for reimbursement by the sponsor

- May be an appropriate institutional expense but not allowable on a sponsored project

Allocable - Necessary to advance project aims

- Directly benefits the project

- Assignable or chargeable to one or more cost objectives

- NOT determined by fund availability

Budget Considerations cont.

| ALLOWABLE | REASONABLE | ALLOCABLE | CONSISTENT |

Reasonable - What a "prudent person" would pay in like circumstances

Treated Consistently - Similar costs should be treated the same in similar circumstances

- Inflationary increases across cost categories

- Consistent treatment across grant years unless there is an extenuating reason (budget justification)

Budget Considerations cont.

- **Direct Costs**
  - Identified specifically with a particular sponsored agreement and incurred to advance the work under that sponsored agreement
  - Assigned to a sponsored agreement with relative ease and a high degree of accuracy

- **F&A (Indirect Costs/Overhead)**
  - Benefits common or joint research activities
  - Cannot readily be identified with a particular sponsored agreement
  - Cannot be proportioned to benefit a group of sponsored agreements with relative ease or a high degree of accuracy

Budget Considerations cont.

- F&A Rates
  - Negotiated with the Federal government
  - De Minimis (15%)
- Indirect cost types
  - MTDC, TDC, Salary & Wages
- Typical activity types
  - Organized research
  - Instruction
  - Other sponsored activities (service)
  - On-campus vs. Off-campus
- Applicable to all proposal unless sponsor instructs on a different rate
  - Fellowship and Equipment (0%)
  - Training (8%)

Direct Cost Categories

Indirect Bearing*	Not Indirect Bearing*
Salaries & Wages, Fringe Benefits	Capital Equipment
Materials & Supplies	Subawards
Human/Animal Subjects	Renovations
Consultants	Leases
Travel	Patient Care Costs
Recharge fees	Tuition
Subawards up to $25K**	Subawards over $25K**

*For Modified Total Indirect Cost (MTDC) calculations

** Depending on NICRA

Budget Justification

- Provides a more detailed breakdown of proposed spending in each category as well as a justification supporting the numbers provided in each budget category

- Explains:

    - why each cost is essential to performing project

    - how project costs were estimated

    - any special circumstances applicable to the project

- Helpful in audit and in post-award

Pre-Award Best Practices - Summary

1. Ask questions

2. Follow instructions

3. Create a checklist

4. Budgetary compliance

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Institutional Routing, Review, & Approvals

Ensure proper routing for internal approvals **before** submission deadline.

1.   Internal Deadlines

2.   Budget Accuracy & Compliance

3.   Personnel Effort & Cost Share Commitments

4.   COI & Compliance Certifications

System Checks & Troubleshooting Errors

1) ASSIST

 - Use ASSIST's built-in validation check throughout the proposal preparation.

2) Grants.gov

 - Always download the application package directly from the NIH FOA page to avoid outdated forms.

 - Monitor the submission status to confirm handoff to eRA Commons occurs (within 24 hours typically).

System Checks & Troubleshooting Errors cont.

3) eRA Commons

- Double-check all personnel eRA Commons credentials before initiating the application.

4) System to System

- Manually review the PDF generated by the S2S system for formatting/missing data.

Meeting NIH Requirements

- Current Form, Page Limits, & Formats
  - Margins: 0.5 inch minimum
- Biosketch
  - May 25, 2025 – SciENcv
- Facilities & Other Resources and Equipment
- Human Subjects/Vertebrate Animals

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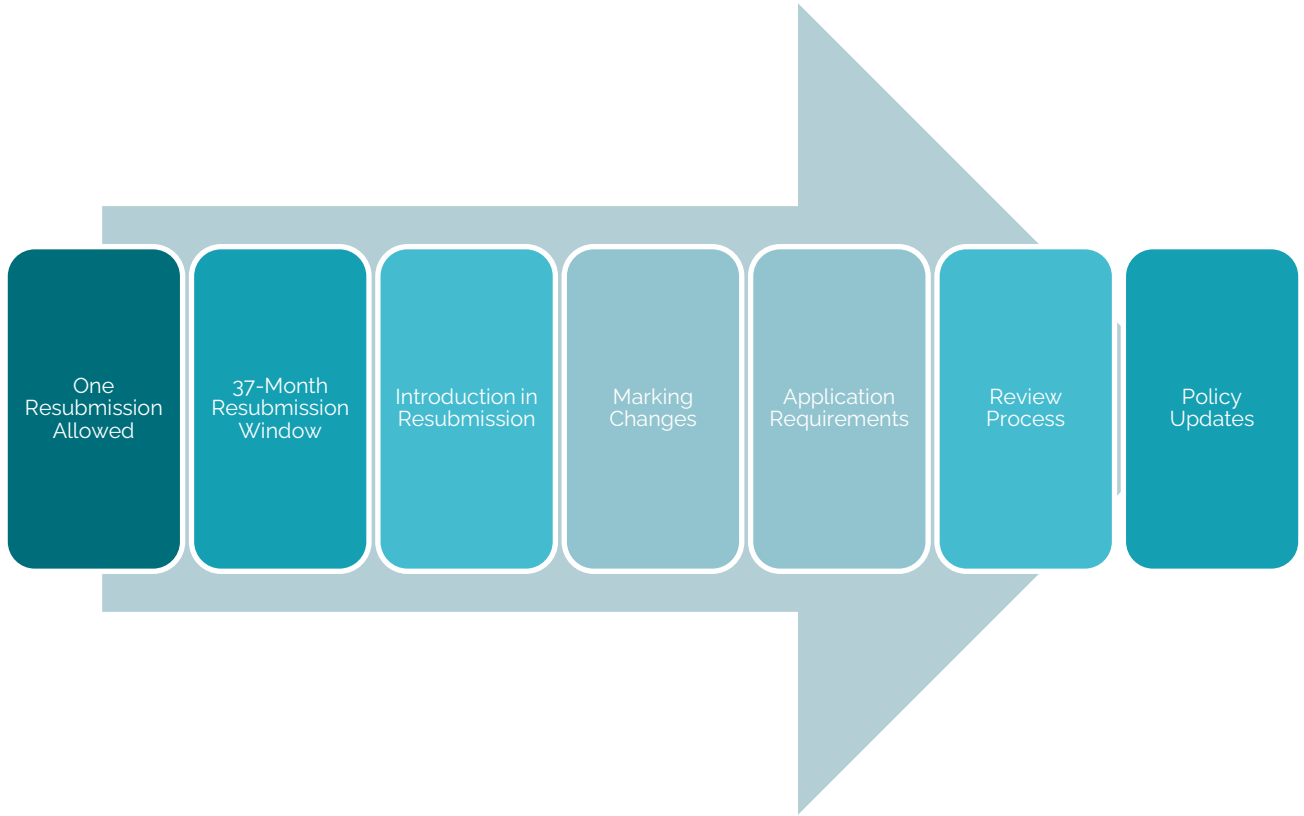
Discussion: Q&A

Post-Submission Materials

- Send to SRO **at least 30 days before** scheduled review meeting
- Must be submitted by the AOR
  - Publication
 - Patent
  - Video
  - Etc.

Resubmission: Things to Consider

One Resubmission Allowed

37-Month Resubmission Window

Introduction in Resubmission

Marking Changes

Application Requirements

Review Process

Policy Updates

Just-in-Time (JIT)

- Notified primarily by email when JIT information is required.

- Common Requested Items

  1. Other Support
  2. IRB Approval including Human Subjects Education
  3. IACUC Approval
  4. Etc.

- Must be submitted through the JIT module in the eRA Commons.
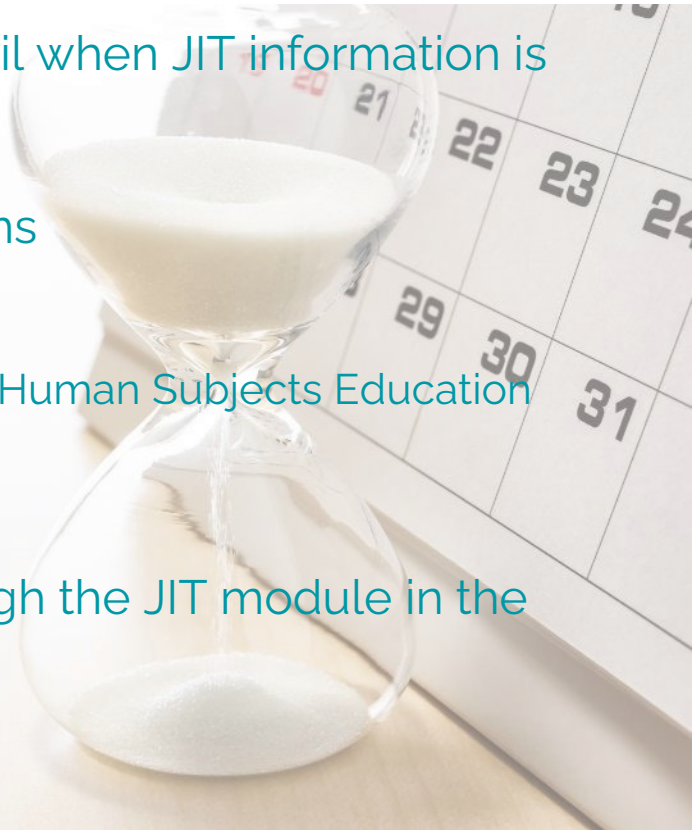
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Open Discussion: Q & A

Helpful Resources & Links

- NIH websites:

  - https://grants.nih.gov/grants-process

  - https://grants.nih.gov/policy-and-compliance/nihgps

  - https://www.era.nih.gov/files/Deciphering_NIH_Application.pdf

- Other Academic Institution websites (private, state, etc.)

Thank you!

Contact Information

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