Navigating the NIH Proposal Process Part 2

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Overview

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Overview

- **Part 2: Proposal Contents**
  - Format Guidance
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  - Budget Types
  - Subcontracts
  - Common Errors

Guideline Background

- Developing a proposal requires use of
  - Federal guidance (example 2 CFR)
  - NIH General Guidance
  - One or more specific program announcements
  - NIH Notices
  - State or Local information may also be applicable (for example your negotiated rate agreement)

NIH Guide to applying for grants
http://grants.nih.gov/grants/how-to-apply-application-guide.htm

Note the extracted versions of the General Guidelines.

Guideline Background

- General Guidelines
  - Title = General Instructions for NIH and Other PHS Agencies SF 424 Research & Related Application Packages (commonly called SF 424 R&R Forms F)
  - Current is Forms Version F Series (forms versions change every few years and there may be overlap)
  - Released Oct 16, 2020 (new release done every year to two)
  - Check the Significant Changes section **ONLINE** periodically
    - "Application instructions are updated 2-3 times per year as needed. Additionally, minor revisions may be made outside of these releases."
    - Notices can also be used to provide guidance changes or updates (NOT-xx-xx-xx)
    - If you print a copy it is usually good for some reference use but to be most current and correct you MUST check online especially as submission dates are approaching.

Guideline Background

Funding Opportunity Title	NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)
Activity Code	R01 Research Project Grant
Announcement Type	Reissue of PA-19-056
Related Notices	See Notices of Special Interest associated with this funding opportunity • **July 13, 2021** - NOSI: Academy of Finland (AKA) –Notice of NHLBI Participation in NOT-HD-21-027. See Notice NOT-HL-21-021. • **November 13, 2020** - NOSI: Academy of Finland (AKA) – National Institutes of Health (NIH) Partnership Program. See Notice NOT-OD-21-021. • **October 5, 2020** - Consolidated Notice on NIMH Clinical Trials Policies. See Notice NOT-MH-20-105. • **September 24, 2020** - Notice of Change to NIEHS target FOAs for NOT-HL-20-788. See Notice NOT-HL-20-015. • **August 26, 2020** - Notice of Correction to Eligibility in NIH Funding Opportunity Announcements. See Notice NOT-OD-20-171. • **August 26, 2020** - Notice of NIGMS Participation in NOT-ES-20-018. See Notice NOT-GM-20-046.
Funding Opportunity Announcement (FOA) Number	PA-20-185
Companion Funding Opportunity	PA-20-183 - NIH Research Project Grant (Parent R01 Clinical Trial Required) PA-20-184 Research Project Grant (Parent R01 Basic Experimental Studies with Humans Required)

Common Forms and Files

- SF 424 R&R Cover Form
  - Your PDS completes this form
  - Certified upon submission
  - Uses data from info sheet unless you specify differently
  - If data from info sheet changes, then check the routing and print forms (if you give time for a full print to be sent for review)
    - Check your address; especially if you are in Stephenson
    - Check the title
  - Cover letter is attached on this form; rarely needed
    - No longer allowed to be used for communicating application assignment preferences.

Common Forms and Files

- PHS 398 Cover Page Supplement Form
  - ORS completes form using information from PI
  - Used for all NIH grant applications except fellowships
  - If you answered yes to Vertebrate Animals on the Other Project Information Form then you have to answer Qs on euthanasia
  - Program Income anticipated (usually none)
  - Human embryonic stem cells section (and cell line registry information)
  - Change of PI or institution; Invention & Patent questions--only related to renewals and awards

Common Forms and Files

- Project/Performance Sites Form
  - Your PDS completes this form
  - Uses OU data plus (as appropriate)
  - Subcontracts and sometimes collaborators/consultant info is needed if they are Key Personnel AND if the PI wishes to indicate work is occurring at different locations
    - **PI** needs to help provide this information
    - Includes congressional district, county, and **zip plus four** required

Common Forms and Files

- R&R Other Project Information Form
  - Form part ORS does based on info sheet and questions to PI (questions are related to Human Subjects, Vertebrate Animals, Proprietary [note markings], Historical Performance Site, Environmental Impact, and International work or collaborators).
    - Human Subject and Vertebrate Animal answers may drive other questions or files becoming 'active' or being needed.
  - Files are needed from the PI to complete this form (we're going to go through these)
    - Project Summary/Abstract (also has link to font and margin specifications)
    - Project Narrative
    - Bibliography & References Cited
    - Other Attachments
    - Facilities and Other Resources
    - Equipment

Common Forms and Files

- R&R Other Project Information Form cont….
  - Files
    - Project Summary/Abstract
      - Succinct and accurate description of proposed work in first person; broad, long term objectives and specific aims and relevance to NIH mission; key focus of proposal
      - 30 lines (**not sentences**)
      - Releasable to public (no proprietary or confidential information)
      - Some solicitations will specify additional info to be included
    - Project Narrative
      - 3 sentences (error program appears to count the periods when NIH uses it)
      - Relevance of research to public health
      - Releasable to public

Common Forms and Files

- R&R Other Project Information Form cont....
  - Files
    - Bibliography & References Cited
      - Required on all submissions unless otherwise noted in solicitation
      - Should cite any reference included in the Research Plan form and the Human Subjects and Clinical Trials Information form (basically whole proposal)
      - No page limit but you are expected to be concise.
      - May include URLs or PubMed ID (PMID) numbers along with the full reference
    - Other Attachments
      - Attach a file here only in accordance with the solicitation or agency specific instructions
      - Common one is 'Foreign Justification (tied back to Q 6 on 'Other Project Info' form)
      - Do not use to get around page restrictions

Common Forms and Files

- R&R Other Project Information Form cont....
  - Files
    - Facilities and Other Resources
      - What is On Hand to assist with the proposed work (if multiple sites involved use information on all of them)
        - Scientific environment and how it contributes to probability of success (institutional support, physical resources, and intellectual rapport) Unique features of scientific environment or subject populations or collaborative arrangements.
      - Early State Investigators should describe institutional investment in success of PI (resources for classes/training, supervision, career enrichment programs, logistical support, administrative management and oversight, financial support such as protected time for research with salary support)
    - Equipment
      - What is On Hand and already available for this project; and if appropriate identify the equipment's location and pertinent capabilities
        - Don't laundry list - think about what your proposed work needs
        - Don't overlook items outside your lab and close to OU or with collaborator involvement

Common Forms and Files

- R&R Sr/Key Person Profile Form
  - PI info pulls into form from entry on cover page; All other key personnel must be added
    - Substantial, meaningful contribution to scientific development or execution of the project regardless of salary requested
    - If OU-Norman most info may pull from Cayuse system
    - **If person is not OU – Norman employee the PI needs to provide info to PDS for loading; this includes full address, with zip+four, phone, and email**
  - eCommons id is needed for PI (and anyone designated as PI; if you designate multiple PIs then you need Multiple PI Management Plan)
    - Profile for those loaded needs to match their role – can cause ERROR after submission
    - NIH does not use coPI designation – common to use Co-Investigator or to designate as 'other' and then put coPI
  - Zip **plus 4** required
  - For all Sr/Key Personnel a bio sketch file is needed – use current format; current instructions – Changed May/June 21; Jan 22 expectation
  - No Current & Pending support file needed at submission unless specifically requested in solicitation; if NIH wants it they request it (you may hear terms 'other support' and 'active and pending support')

Common Forms and Files

- PHS 398 Research Plan (no form entry -- it is all files from the PI)
  - Introduction File
    - Only required for resubmission or revision
    - 1 page (unless otherwise specified in solicitation)
    - Summarizes substantial additions, deletions, and changes to the application and responds to issues and criticisms of reviewers/program officers
  - Specific Aims File
    - Always required unless solicitation specifies otherwise
    - 1 page (unless otherwise specified in solicitation)
    - Concisely state goals and summarize expected outcomes including impact on the research field; list specific objectives

Common Forms and Files

- PHS 398 Research Plan cont.....
  - Research Strategy (Scientific Premise, Rigor, Consider relevant Biological Variables)
    - Page Length varies by solicitation (usually 6 or 12) you must check NIH link https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/page-limits.htm or it may be specified in the solicitation
    - Discuss overall strategy, methodology and analysis; do not duplicate information in the PHS Human Subjects and Clinical Trials Information Form
    - Unless told otherwise must organize into sections (and label sections) of Significance, Innovation, and Approach (general guidelines have specific things they are looking for in each section and the specific solicitation may also have guidance) (more info next slide)

Common Forms and Files

- PHS 398 Research Plan cont.....
  - Unless told otherwise must organize into sections (and label sections) of Significance, Innovation, and Approach
    - Significance (importance of problem or critical barrier that project addresses, describe scientific premise including strengths and weaknesses of published research or preliminary data; how will proposed project improve scientific knowledge, technical capability or clinical practice....
    - Innovation (how application challenges or seeks to shift current research or clinical practice paradigms; describe novel concepts, approaches, methodologies, instrumentation or interventions..., refinements, improvements, or new applications of theoretical concepts, approaches,.....
    - Approach (overall strategy, methodology, and analysis to accomplish specific aims; describe experimental design.....if not addressed in Resource Sharing Plan you must include how data will be collected and analyzed....discuss potential problems, trials, biological variables, safety concerns, ...

Common Forms and Files

- PHS 398 Research Plan cont.....
  - Vertebrate Animals File
    - Required if you answer yes to vertebrate animals on Other Project Information Form
    - You must address specific information in 3 criteria (Description of Procedures, Justifications, Minimization of Pain and Distress (see General Instructions)
    - Besides the criteria there are two other items to address (collaborating sites and when and how animals are expected to be used if the plans have not been finalized)
    - There is an NIH worksheet for animals that may help plus links to NIH's Office of Laboratory Animal Welfare and their policy statement on Animal Welfare Requirements

Common Forms and Files

- PHS 398 Research Plan cont.....
  - Consortium/Contractual Arrangements
    - Explain programmatic, fiscal, and administrative arrangements to be made between applicant and consortium organizations; if the consortium is significant explain why the applicant organization rather than the ultimate performer should be the grantee)
    - Normally the official subcontract letter is loaded here.
    - Most correct file for this section is one that includes the information in the first bullet (and don't use the bullet, look at the guidelines) PLUS the subcontract organizational official commitment letters

Common Forms and Files

- PHS 398 Research Plan cont.....
  - Letters of Support
    - All combined into one PDF (do not place in the Appendix)
    - Demonstrate support of consortium participants and collaborators
    - There is a lot of information about what the letters should include or not include
    - Do not include bio sketches with letters of support from consultants; if you want to include their bio sketch add them as Sr/Key personnel (there is an exception for STTR/SBIR applications)

Common Forms and Files

- PHS 398 Research Plan cont.....
  - Resource Sharing Plan
    - Usually optional but may be specified as required in specific solicitation
    - Contents: Data Sharing Plan, Sharing Model Organisms, and Genomic Data Sharing
    - Caveat on optional is that it falls outside of parameters listed in content for a Resource Sharing Plan ($500,000 or more in direct costs, model organisms, genomic data sharing)
    - In practice is a good idea to always provide unless solicitation says you can't (otherwise you must address at least data sharing in your research strategy)

Common Forms and Files

- PHS 398 Research Plan cont.....
  - Refer to solicitation to determine if there are any special appendix instructions for your application (for example: none allowed)
  - 10 PDF attachments are allowed; if you need more than 10 spaces then combine remaining info into Attachment 10.
  - Use file names that are descriptive of content.
  - Attachment one is encouraged to have a summary sheet of all the items included in the Appendix
  - What can be included as an Appendix is very restrictive/limited (see general guidelines)
  - Appendix section is closely looked at and if you are considered non-compliant or trying to circumvent page limits in other areas of the proposal the application will be withdrawn and not reviewed.

Common Forms and Files

- PHS Human Subjects and Clinical Trials Information
  - Human Subjects – **Be Aware –there are new forms and guidance** (and it will probably affect the solicitation you select if you are doing a parent solicitation).
  - You must complete the R&R Other Project Information Form first as it prefills parts of this form.
  - If you answer that no human subjects research is being done then you answer a few more questions on this form (ORS will send you the questions and then complete the form for you) and you send a file to upload on the form with your justification unless there are other instructions in the solicitation (specific info on what the justification must include is in the General Instructions)

Common Forms and Files

- PHS Human Subjects and Clinical Trials Information cont…
  - If you answer yes to the question 'are human subjects involved'; on the R&R Other Project Information Form then you need to provide additional files and information.
    - Other Requested Information File (only if a renewal or if the specific solicitation tells you to have this file)
    - You need to complete a Study Record Attachment File for each proposed study (your PDS will send you either a form extract or a list of what information is needed)
    - Each study record must have a unique name – use the guidance from the General Instructions to provide answers/build the study record (page 230-258)
    - Besides the study record you also need a justification file for delayed onset studies and you will need several other files and fields filled in (Recruitment and Retention Plan, Inclusion or Women and Minorities, Inclusion of Children, Inclusion Enrollment Reports, Planned Enrollment Tables, Protection and Monitoring Plan, Data Safety and Monitoring Plan.
    - **Do not assume you don't need to provide negative responses or that you don't need a file.**
    - There are also several links to other information and directions to NIH's Clinical Trial's Website https://grants.nih.gov/policy/clinical-trials.htm

Optional/Unusual Forms and Files

- Cover Letter
  - Usually optional (unless it is a changed/corrected proposal)
    - See General Instructions for when NIH wants one
  - Has specific items they want to see
- Progress Report Publication List (only needed for renewal application)
- SFLLL (Disclosure of Lobbying Activities)
  - If needed PDS will do (usually not needed)

Optional/Unusual Forms and Files

- Select Agent Research
  - No page limit but be succinct.
  - Only needed if your proposal involves use of select agents at applicant organization or any performance site
  - Select agents are hazardous biological agents and toxins identified by HHS or USDA as potential to pose severe threat to public health and safety, to animal and plant health or to animal and plant products
  - There is a list of agents via a link and there is also a list of excluded agents (these still require a file and statement)
  - You must address three points (Identify the select agents; Provide registration status of entities where used, Provide description of facilities where used [with specific info needed])

Optional/Unusual Forms and Files

- Multiple PD/PI Leadership plan
  - Needed if you designate more than one PI on submission
  - Includes rationale for choosing multiple PI approach, governance and organizational structure of the leadership team, communications plans, how to resolve conflicts, roles and administrative, technical, and scientific responsibilities for the project. If budget is allocated, then how it is being distributed and managed.
- PHS Assignment Request Form
  - Usually an optional form but may be specified in a particular solicitation
  - We recommend providing one as it can help determine the correct handling of your proposal by NIH (the study section)
  - You only need to complete the fields you want

Optional/Unusual Forms and Files

- Authentication of Key Biological and/or Chemical Resources File
  - Describes methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies
  - A factor in **Rigor and Reproducibility** (see link in General Instructions)
  - Needed if you are using any biological or chemical resource that isn't considered a standard laboratory item or reagent
  - Includes chemical or biological resources that may or may not be generated with NIH funds
  - A maximum of one page is suggested.
- NOTE: Interactive Forms
  - On occasion the solicitation my have or prescribe a form be downloaded from a website or the application that is interactive; sometimes they can be reloaded into the application file as interactive and sometimes they need to be saved as a pdf to load; - be sure to check guidance and work with your PDS

Determining Budget Type

- An NIH submission will have either an R&R Budget Form (called detailed budget) or PHS 398 Modular Budget Form (never both)
  - Sometimes the solicitation will mandate which form must be used (and could also specify another form)
  - Usually it is determined by the direct costs threshold (what direct costs you are requesting for the whole project)
  - Detailed = >$250,000 in direct costs in a budget period
  - Modular = < $250,000 in direct costs in a budget period

Other Budget Considerations

- If you are wanting to request more than $500,000 in direct costs in any one budget period you usually must get prior approval from the awarding component (no later than 6 weeks prior to submission)
- If you or someone on your proposal exceeds the current NIH salary cap ($199,300 for 12 mo.; $149,472 for 9 mo.) then the amount over the cap is automatic cost share (no income and must be tracked internally).

Other Budget Considerations

- Internally at OU you will have an OU spreadsheet which is a detailed budget that routes.
- In the Application we choose if we are filling out a Detailed budget or a Modular Budget based on the parameters mentioned.
- Your PDS loads the budget in the application based on the budget form needed or specified in the guidance and the data on the budget form that routes internally at OU.
- If you have a subcontract the data that is loaded for the budget depends on whether you have a detailed or modular budget (more information later)

Differences in Detailed & Modular Budget

- **Detailed Budget**
  - Has line by line entries for each amount/category of funds you are requesting for each year (for example: a salary entry = each OU PI/coPI name, position, base salary, percent of time, salary requested, fringe benefits, total)
  - Also has a detailed budget justification
  - If subcontracts are involved then they also have a full detailed budget form and justification that must be loaded

- **Modular Budget**
  - Budget total must be in increments of $25,000 in direct costs. Each year's entry has a modular total, info on subcontract, indirect cost entry, totals and rate agreement info.
  - The budget justification is reduced to just Personnel Information
  - If there is a subcontract there is an abbreviated Consortium budget justification that is loaded.
  - If your modules differ – for example one year is $200,000 and one year is $175,000 then you have to provide a sentence or two on why there is a difference (for example in the first year you bought equipment).

Subcontracts and Collaborations

- Determining Subcontract
  - A Subcontract is a person (usually at an organization) that is substantially involved in the proposal (helps make programmatic decisions and will be a co-author on any publications)
  - A Vendor is providing something anyone can order (like testing for a fee).
  - A Consultant is someone who is involved in a limited manner (short time like a few weeks in summer, or limited scope like an advisory board); usually a Vendor or Consultant is not involved in programmatic decisions; A Consultant may or may not be involved in publications.
- Normally NIH considers a Collaborator to be someone who is assisting you for no budget consideration; however, the term is still very broadly used; Co-Investigator is also very common; CoPI is normally not used.

Subcontracts and Collaborations

- Routing paperwork needed
  - Statement of work
  - Budget
  - Budget justification
  - Official letter of commitment from someone with authority to commit the organization (an authorized official)
  - Negotiated rate agreement or link info (if an idc rate is used)

Note that for a vendor we don't need anything (if you have a quote that is good to keep) and we recommend for consultants to have an email or letter from them on what they agree to do for you (but we don't need this at this time either).

Subcontracts and Collaborations

- Submission paperwork needed for both detailed and modular related submissions
  - Performance Site information (may not be needed if not a subcontract)
  - Bio sketch in correct format
  - Letter of Support from PI (normally if external to OU)
  - Official subcontract letter (part of subcontract package)
- Additional files needed for detailed submissions
  - Detailed budget justification (part of subcontract package)
  - **R&R Subcontract Budget Form** detailed budget extract (detailed budget loaded on importable form) usually must be provided by subcontract's ORS equivalent.

Avoid Common Errors:

- Missing Attachments
  - Specific question answers or form entries can drive the need for an attachment
    - Human Subjects
    - Vertebrate Animals
    - Multiple PD/PI Leadership Plan
    - Contractual Arrangements
- Page Limit Exceeded
  - May be determined by type of proposal or specified in FOA

Page Limits: http://www.grants.nih.gov/grants/forms_page_limits.htm#other

Avoid Common Errors:

- Incorrect Format
  - Format guidance overall
    - Font size 11 points or larger (text in figures and charts may be smaller but must be legible at 100% view) – watch conversions
      - Recommended fonts are Arial, Georgia, Helvetica and Palatino Linotype
    - Type density no more than 15 characters per inch; Line spacing no more than 6 lines per vertical inch
    - No restriction on text color but high contrast, easy to print preferred
    - Paper size is no larger than standard letter paper size
    - Margins are at least one-half inch on all sides

Format Attachments | grants.nih.gov

Avoid Common Errors:

- Incorrect Format
  - Use Format Templates/info given by NIH
    - Make sure they are current templates
    - Biosketch (format pages, instructions, and samples; dated 2023)
      - https://grants.nih.gov/grants/forms/biosketch.htm
    - Data Tables
      - https://grants.nih.gov/grants/forms/data-tables.htm
    - Additional info (senior personnel, performance site, other support)
      - https://grants.nih.gov/grants/forms/format-pages.htm

Avoid Common Errors:

- PDF
  - Use simple format; disable security features like password
- Keep file names 50 characters or less
  - File names must be unique within the application
  - Use meaningful names especially for 'other attachments'
  - Only use one space (not two or more) between words or characters; don't start with a space
- Hyperlinks and URLs are only allowed when specifically noted (typically only in citing publications)
- Do not use appendix or other sections to circumvent page limits
- Do not include headers or footers
  - Simple section headers as part of text (Significance, Approach) are encouraged; Some announcements will provide guidance on specific headings.

Take-a-Way

- Become familiar with General Guidelines; make sure you are using the most current guidelines
- Decide budget type for submission as soon as possible
- Send information to fill out the forms in the application as soon as possible
- Send files as soon as possible to test loading and display for issues
- Take advantage of validation window – submit at least 2 days before the due date
- Do ORCID, eRACommons, sciENcv registrations
- Use resources and information on the NIH website
  - https://www.nih.gov/grants-funding

Contacts for Help

- RIS@ou.edu will answer questions or put you in contact with who can answer your questions for anything pre-award/Office of Research Services (ORS) related.
- Submit an info sheet Office of Research Services - Proposal Information Sheet | | The University of Oklahoma (ou.edu) and someone from ORS will contact you
- Center for Faculty Excellence (CFE) provides proposal assistance to include SciENcv training cfe@ou.edu
- If your question is related to post award then contact Research Financial Services (ReFS) refsinfo@ou.edu