



NATIONAL INSTITUES OF HEALTH (NIH) RESEARCH PROJECT GRANT (PARENT R01) CLINICAL TRIAL NOT ALLOWED FULL RESEARCH PROPOSAL CHECKLIST

When preparing NIH Parent R01 proposals, please follow the specific FOA (PA-25-301) along with the Research Instructions for NIH and Other PHS Agencies (Forms Version I Series). The FOA contains Related Notices which may include Notices of Special Interest (NOSI), additional proposal preparation guidance, and other important information. The guidance provided in the FOA will supersede the general Research Instructions. It is critical to verify the Institute & Center (IC) you are targeting is participating in the Parent Announcement. This checklist highlights, not replaces, the Parent R01 FOA and general Research Instructions. Please consult the guidelines for complete instructions.

REQUIRED FORMATTING

- All documents must be submitted in PDF format (100MB or less)
- Use Arial, Helvetica, Palatino Linotype or Georgia type 11 point font or larger. (Smaller font may be used for figures, graphs, diagrams, charts, tables, figure legends and footnotes but must be legible)
- ½ inch margins all around for all pages
- Filename: Length of uploaded document titles must not be more than 50 characters using the following characters: A-Z, a-z, 0-9, underscore, hyphen, space, period, parenthesis, curly braces, square brackets, tilde, exclamation point, comma, semi colon, apostrophe, at sign, number sign, dollar sign, percent sign, plus sign, and equal sign.
- No information in header or footer page numbers for the footer will be system-generated.
- Follow the <u>NIH Table of Page Limits</u>
- Hyperlinks/URLs are only allowed when specifically noted in the guidelines but are otherwise strictly prohibited. When allowed, you must hyperlink the actual URL text, so it appears on the page rather than hiding the URL behind a specific word or phrase (hypertext).
- Electronic signatures on PDF attachments within your application are not allowed. Standard forms requiring electronic signatures should be flattened prior to upload.

Application can be prepared by PI in Grants.gov Workspace

Proposal Element	Instructions
SF424 Cover Page Supplement	 Sample form available HERE – Be sure to use NIH EIN (1-043167352-E5) Earliest start date and standard due dates can be found HERE Maximum project period is 5 years Federal Identifier (Field 4.a.) is required for Resubmissions, Revision and Renewal applications. Include only the institute code and serial number of the prior application/grant number (e.g., use CA987654 extracted from full application/grant number 1R01CA987654-A1). Questions 1-4 are required. Questions 5 & 6 should be completed as applicable.
RR Other Project	Answer questions 1-6
Information	 Allswer questions 1-0 If human subjects are included – Human Subject Assurance # is FWA00000215 Enter the 8-digit number. Do not enter "FWA" before the number. If Vertebrate Animals are included – Animal Welfare Assurance # is A3867-01 Enter the latest IRB or IACUC approval date (if available). Leave blank if pending. If the project involves foreign activities or international collaborations, you must upload a file named "Foreign Justification" to Field 12 – Other Attachments
Project Summary/Abstract	 Limited to 30 lines of text Do not include proprietary, confidential information or trade secrets
Project Narrative	• 3 sentence max
References Cited	Should include references cited in the Research Plan and Human Subject sections



	Active hyperlinks in this section are not allowed
	• Citations that fall under the Public Access Policy (authored or co-authored by the applicant
	and arose from NIH support) provide the NIH Manuscript Submission reference number or
	the PubMed Central (PMC) reference number.
	• Citations not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference
Facilities & Other Resources	
	contributes to the probability of success (e.g., institutional support, physical resources, and
	intellectual rapport).
	• If there are multiple performance sites, describe the resources available at each site.
	• Early Stage Investigators (ESI) should include description of institutional investments such as
	resources for classes/travel/training, collegial support, logistical support, and financial
Fauinmant	support. • List major items of equipment already available
Equipment	If there are no equipment items to list, upload a pdf with the "Equipment" heading and state
	No major equipment will be used to complete the proposed work.
RR Performance Sites	Include all project/performance site location(s) – generally the applicant organization is
KK I erjormunce Sues	the primary location.
	UEI is a required field (UML UEI: LTNVSTJ3R6D5)
RR Key Person Profile	Must complete all fields – it is critical to include the eRA Commons ID in the "Credential,"
(including Bio)	e.g., agency login" field
(memmig 200)	Must upload Biographical Sketch (5 page max) using <u>NIH template</u> or <u>SciENcv</u>
	• On the Biosketch, you may provide a hyperlinked URL to a full list of your published work.
	This hyperlinked URL must be to a Federal Government website (a .gov suffix) and is the
	only allowable URL on this document.
	Current and Pending Support is not required at proposal stage unless specified in the NOFO
Budget	Application budgets are not limited but need to reflect the actual needs of the proposed
	project – cost sharing is not required
	Must draft budget using OSP Internal Budget Template which you will data enter in portal
	once OSP approves
	• Generally, you must use a <u>Detailed Budget</u> if you are applying for more than \$250,000 per
	budget period in direct costs, and you must use the Modular Budget if you are applying for
	less than \$250,000 per budget period in direct costs. However, some grant mechanisms or
	programs may require other budget forms to be used. Refer to your FOA and follow
	instructions for guidance on which Budget Form to use. There is also helpful
	Determination Table found <u>HERE</u> .
	• Direct cost requests equal to or greater than \$500,000 require prior approval from the NIH
	Institute/Center before application submission.
	• Split IDC rates must be entered on separate lines, as applicable. Should you require assistance
	with this step, please refer to the <u>How to Enter Multiple IDC Rates in Grants.gov</u> section or
	contact your College Research Administrator for support.
	• Subaward Budgets have their own <u>R&R Budget</u> uploaded to the application unless the
	proposal is using the Modular Budget Format.
	• Important Reminders - Check the solicitation carefully for budget requirements
	o NIH has an annual salary cap. Personnel with 9-month appointments should calculate
	the monthly salary for the current NIH cap and then multiply that amount by 9 to
	determine what to use as the base salary for the OSP Internal Budget Template.
	o Full-time Academic RAs require associated tuition and fees. (\$10K per 9 academic
	months)
	o UML's equipment acquisition threshold is \$5K
	Confirm whether there is required travel for conferences or meetings
	Absolutely no cost share unless solicitation requires
	o Cognizant Federal Agency Field - DHHS, Edwin Miranda, 212-264-2069
	o Include Data Management and Sharing Costs (as applicable). Costs to support these
	activities may be requested in the appropriate cost category. Details regarding Data



	Management and Sharing Costs must be specified in the Budget Justification attachment.
Detailed Budget Justification (Used for Detailed RR Budgets)	 Management and Sharing Costs must be specified in the Budget Justification attachment. Provide information justifying funds requested in each budget category and any other information the applicant wishes to submit to support the budget request, including quotes. Justify any significant increases or decreases from the initial budget period. Justify budgets with more than a standard escalation from the initial to the future year(s) of support Subcontracts must also provide a detailed Budget Justification to be uploaded along with the subcontract budget. NIH Specific Detailed Budget Justification Template is available HERE Details regarding Data Management and Sharing Costs must be separately justified under a clearly labeled section entitled "Data Management and Sharing Justification" within the budget justification followed by the estimated dollar amount (total direct costs). Provide a brief summary of type and amount of scientific data to be preserved and shared and the name of the established repository(ies) where they will be preserved and shared. Indicate general cost categories such as curating data and developing supporting documentation, local data management activities, preserving and sharing data through established repositories, etc., including an amount for each category and a brief explanation. Specify in the justification if no costs will be incurred for Data Management and Sharing, if applicable. The recommended length of the justification should be no more than half a page.
Personnel Justification (Used for Modular)	 Should include the name, role, and number of person-months devoted to this project for every person on the project, including Other Significant Contributors and Consultants who are committing effort. Do not include salary and fringe benefit rate in the justification
	NIH Specific Personnel Justification Template is available HERE
Consortium Justification (Used for Modular)	 If you have a subcontract(s), include total costs (direct + F&A) rounded to the nearest \$1,000 for each and identify any foreign consortiums. Should include the name, role, and number of person-months devoted to this project for every person on the project.
Additional Narrative	 NIH Specific Consortium Justification Template is available <u>HERE</u> Include explanations for any variations in the number of modules requested annually.
Justification (Used for Modular) PHS Human Subjects and	 Describe any direct costs excluded from the total direct costs (such as equipment, tuition remission) and any work being conducted off-site, especially if it involves a foreign study site or an off-site F&A rate. NIH Specific Additional Narrative Justification Template is available HERE Details regarding Data Management and Sharing Costs must be separately justified under a clearly labeled section entitled "Data Management and Sharing Justification" within the budget justification followed by the estimated dollar amount (total direct costs). Provide a brief summary of type and amount of scientific data to be preserved and shared and the name of the established repository(ies) where they will be preserved and shared. Indicate general cost categories such as curating data and developing supporting documentation, local data management activities, preserving and sharing data through established repositories, etc., including an amount for each category and a brief explanation. Specify in the justification if no costs will be incurred for Data Management and Sharing, if applicable. The recommended length of the justification should be no more than half a page. Video discussing how to complete the form, annotated form sets, and application
Clinical Trials	 Video discussing how to complete the form, annotated form sets, and application instructions available here Questions regarding Human Subject determinations (IRB) can be directed to IRB@uml.edu
Introduction	Mandatory for resubmissions or revisions (1 page max)
Specific Aims	Limited to 1 page (No figures allowed)
Research Strategy	 12 page max Organize the Research Strategy in the specified order starting each section with the appropriate heading – Significance, Innovation, Approach. Detailed guidance and requirements provided in the Research Instructions for NIH and Other PHS Agencies



Progress Report Publications List	Should be included for renewal submissions
Vertebrate Animals	 Must be included if Vertebrate Animals are being used Be sure to address 1.) Description of Procedures 2.) Justification 2.) Minimization of Pain and Distress 4.) Project Performance Sites 5.) When and How Animals are Expected to be Used Questions regarding Vertebrate Animal determinations (IACUC) can be directed to IACUC@uml.edu
Select Agent Research	• Include if your proposed activities involve the use of <u>select agents</u> at any time during the proposed project period, either at the applicant organization or at any performance site
Multiple PD/PI Leadership Plan	Must be included if multiple PIs have been designated in the RR Key Person Profile section
Consortium/Contractual Arrangements	Must be included if you have consortiums/contracts in your budget
Letters of Support	 Include letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors Consultants letters should include rate/charge for consulting services and level of effort/number of hours per budget period anticipated. In addition, letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for- service
Resource Sharing Plan	 Applicable to <u>Sharing Model Organisms</u> and <u>Research Tools</u> Additional requirements may apply depending on the project
Other Plans	 Include <u>Data Management and Sharing Plan</u> if applicable/required by the NOFO. Should include 1.) Data Type 2.) Related Tools, Software and/or Code 3.) Standards 4.) Data Preservation, Access, and Associated Timelines 5.) Access, Distribution, or Reuse Considerations 6.) Plans for Genomic Data Sharing (as applicable) 7.) Oversight of Data Management and Sharing
Authentication of Key Biological and/or Chemical Resources	• If applicable, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. A maximum of one page is suggested.
Appendix	• NIH is VERY specific about what is allowed as an appendix. Please consult the <u>Research Instructions for NIH and Other PHS Agencies</u>
PHS Assignment Request Form	 This form is optional. Use it only if you wish to communicate specific awarding component assignments or review preferences. PHS Assignment Information can be found here. It is critical to verify the Institute & Center (IC) you are targeting is participating

Subcontract Organization(s) – Required Documents

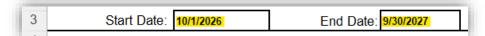
- Subrecipient Commitment Form (with 3b1 and 3b2-if applicable)
- Statement of Work
- Project/Performance Site Location(s)
- Research & Related Senior/Key Person Profile
- Research & Related Budget
- Budget Justification
- Facilities & Other Resources
- Equipment
- Letters of Support



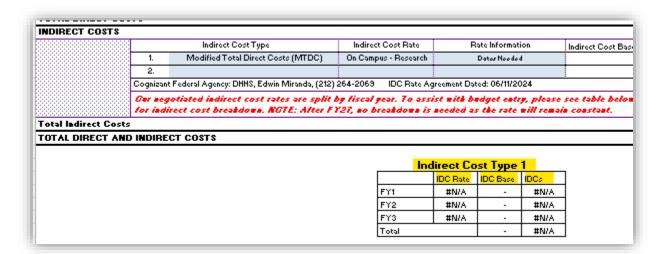
HOW TO ENTER MULTIPLE INDIRECT COST (IDC) RATES IN GRANTS.GOV

UML's Negotiated Indirect Cost (IDC) Rate Agreement has different yearly rates in the coming years. Multiple rates may apply to a single budget period due to how the fiscal year falls within the period of performance. The split rates must be detailed out on proposal budgets. To split the rates, follow the steps below:

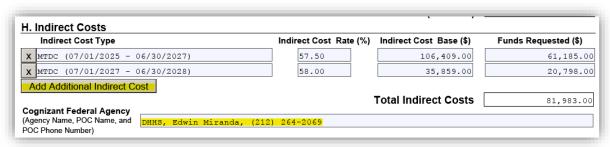
- 1. Ensure you are using the most current internal budget template found HERE.
- 2. Confirm the correct dates for the applicable budget period are entered in row 3 of the budget template.



3. On the newest internal template, the IDC breakdown is calculated under the budget on each tab. Please reference the table below when entering in the IDC in grants.gov.



Below is an example of how to complete this section on the RR Budget:



You can add as many Indirect Cost Rates as needed using the highlighted "Add Additional Indirect Cost." To calculate the IDC, multiply each portion of the MTDC by the applicable rate.

Be sure to add the Cognizant Federal Agency Information