



**OFFICE OF RESEARCH ADMINISTRATION**

**NATIONAL INSTITUTES 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-20-185](#)) along with the [Research Instructions for NIH and Other PHS Agencies \(Forms Version F Series\)](#). 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
- 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 [NIH Table of Page Limits](#)

**Application can be prepared by PI in [Grants.gov](#) Workspace**

<b><i>Proposal Element</i></b>	<b><i>Instructions</i></b>
<b><i>SF424</i></b>	<ul style="list-style-type: none"> <li>• See sample attached</li> <li>• Earliest start date and standard due dates can be found <a href="#">here</a></li> <li>• Maximum project period is 5 years</li> <li>• 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).</li> </ul>
<b><i>RR Performance Sites</i></b>	<ul style="list-style-type: none"> <li>• Include all project/performance site location(s) – generally the applicant organization is the primary location.</li> </ul>
<b><i>RR Other Project Information</i></b>	<ul style="list-style-type: none"> <li>• Answer questions 1-6</li> <li>• If human subjects are included – Human Subject Assurance # is <i>FWA00000215</i></li> <li>• If Vertebrate Animals are included – Animal Welfare Assurance # is <i>A3867-01</i></li> <li>• If the project involves foreign activities or international collaborations, you must upload a “Foreign Justification” to Field 12 – Other Attachments</li> </ul>
<b><i>Project Summary/Abstract</i></b>	<ul style="list-style-type: none"> <li>• Limited to 30 lines of text</li> <li>• Do not include proprietary, confidential information or trade secrets</li> </ul>
<b><i>Project Narrative</i></b>	<ul style="list-style-type: none"> <li>• 3 sentence max</li> </ul>
<b><i>References Cited</i></b>	<ul style="list-style-type: none"> <li>• Should include references cited in the Research Plan and Human Subject sections</li> <li>• 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.</li> <li>• 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</li> </ul>



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	reference
<b>Facilities</b>	<ul style="list-style-type: none"> <li>Describe the scientific environment in which the research will be done and how it contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport).</li> <li>If there are multiple performance sites, describe the resources available at each site.</li> <li>Early Stage Investigators (ESI) should include description of institutional investments such as resources for classes/travel/training, collegial support, logistical support, and financial support.</li> </ul>
<b>Equipment</b>	<ul style="list-style-type: none"> <li>List major items of equipment already available</li> <li>If there is 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.</li> </ul>
<b>RR Key Person Profile (including Bio)</b>	<ul style="list-style-type: none"> <li>Must complete all fields – it is critical to include the eRA Commons ID in the “Credential, e.g., agency login” field</li> <li>Must upload Biographical Sketch (5 page max) using <a href="#">NIH template</a></li> <li>Current and Pending Support is not required at proposal stage</li> </ul>
<b>Budget</b>	<ul style="list-style-type: none"> <li>Application budgets are not limited but need to reflect the actual needs of the proposed project – cost sharing is not required</li> <li>Must draft budget using <a href="#">ORA Internal Budget Template</a> which you will data enter in portal once ORA approves</li> <li>NIH has an annual <a href="#">salary cap</a>. 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 ORA Internal Budget Template.</li> <li>Cognizant Federal Agency Field - DHHS, Ryan McCarthy, 212-264-2069</li> <li>Generally, you must use the <a href="#">R&amp;R Budget</a> if you are applying for more than \$250,000 per budget period in direct costs, and you must use the <a href="#">Modular Budget</a> 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.</li> <li>Subaward Budgets have own R&amp;R Budget unless the proposal is using the Modular Budget Format</li> <li>Applicants requesting \$500,000 or more in direct costs in any year (excluding consortium F&amp;A) must contact a Scientific/ Research Contact at least 6 weeks before submitting the application</li> </ul>
<b>Detailed Budget Justification (Used for R&amp;R Budgets)</b>	<ul style="list-style-type: none"> <li>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.</li> <li>Justify any significant increases or decreases from the initial budget period.</li> <li>Justify budgets with more than a standard escalation from the initial to the future year(s) of support</li> <li>Subcontracts must also provide a detailed Budget Justification to be uploaded along with the subcontract budget.</li> </ul>
<b>Personnel Justification (Used for Modular)</b>	<ul style="list-style-type: none"> <li>Should include the name, role, and number of person-months devoted to this project for every person on the project.</li> <li>Do not include salary and fringe benefit rate in the justification</li> </ul>
<b>Consortium Justification (Used for Modular)</b>	<ul style="list-style-type: none"> <li>If you have a subcontract(s), include total costs (direct + F&amp;A) rounded to the nearest \$1,000 for each and identify any foreign consortiums.</li> <li>Should include the name, role, and number of person-months devoted to this project for every person on the project.</li> </ul>



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<p><b><i>Additional Narrative Justification (Used for Modular)</i></b></p>	<ul style="list-style-type: none"> <li>• Include explanations for any variations in the number of modules requested annually.</li> <li>• 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&amp;A rate.</li> </ul>
<p><b><i>PHS Human Subjects and Clinical Trials</i></b></p>	<ul style="list-style-type: none"> <li>• Video discussing how to complete the form, annotated form sets, and application instructions available <a href="#">here</a></li> <li>• Questions regarding Human Subject determinations (IRB) can be directed to <a href="mailto:IRB@uml.edu">IRB@uml.edu</a></li> </ul>
<p><b><i>PHS 398 Cover Page Supplement</i></b></p>	<ul style="list-style-type: none"> <li>• Answer questions 1-4 and 5-6 as applicable</li> </ul>
<p><b><i>Introduction</i></b></p>	<ul style="list-style-type: none"> <li>• Mandatory for resubmissions (1 page max)</li> </ul>
<p><b><i>Specific Aims</i></b></p>	<ul style="list-style-type: none"> <li>• Limited to 1 page</li> </ul>
<p><b><i>Research Strategy</i></b></p>	<ul style="list-style-type: none"> <li>• 12 page max</li> <li>• Organize the Research Strategy in the specified order starting each section with the appropriate heading – Significance, Innovation, Approach.</li> <li>• Detailed guidance and requirements provided in the <a href="#">Research Instructions for NIH and Other PHS Agencies</a></li> </ul>
<p><b><i>Progress Report Publications List</i></b></p>	<ul style="list-style-type: none"> <li>• Should be included for renewal submissions</li> </ul>
<p><b><i>Vertebrate Animals</i></b></p>	<ul style="list-style-type: none"> <li>• Must be included if vertebrate Animals are being used</li> <li>• 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</li> <li>• Questions regarding Vertebrate Animal determinations (IACUC) can be directed to <a href="mailto:IACUC@uml.edu">IACUC@uml.edu</a></li> </ul>
<p><b><i>Select Agent Research</i></b></p>	<ul style="list-style-type: none"> <li>• Include if your proposed activities involve the use of <a href="#">select agents</a> at any time during the proposed project period, either at the applicant organization or at any performance site</li> </ul>
<p><b><i>Multiple PD/PI Leadership Plan</i></b></p>	<ul style="list-style-type: none"> <li>• Must be included if multiple PIs have been designated in the RR Key Person Profile section</li> </ul>
<p><b><i>Consortium/Contractual Arrangements</i></b></p>	<ul style="list-style-type: none"> <li>• Must be included if you have consortiums/contracts in your budget</li> </ul>
<p><b><i>Letters of Support</i></b></p>	<ul style="list-style-type: none"> <li>• Include letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors</li> <li>• 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</li> </ul>
<p><b><i>Resource Sharing Plan</i></b></p>	<ul style="list-style-type: none"> <li>• Investigators seeking \$500,000 or more in direct costs (exclusive of consortium F&amp;A) in any budget period are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible</li> <li>• Additional requirements may apply depending on the project</li> </ul>



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<b><i>Authentication of Key Biological and/or Chemical Resources</i></b>	<ul style="list-style-type: none"><li>• 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.</li></ul>
<b><i>Appendix</i></b>	<ul style="list-style-type: none"><li>• NIH is VERY specific about what is allowed as an appendix. Please consult the <a href="#">Research Instructions for NIH and Other PHS Agencies</a></li></ul>
<b><i>PHS Assignment Request Form</i></b>	<ul style="list-style-type: none"><li>• 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 <a href="#">here</a>.</li><li>• It is <i>critical</i> to verify the <a href="#">Institute &amp; Center (IC)</a> you are targeting is participating</li></ul>

***Subcontract Organization(s) – Required Documents***

- Subrecipient Commitment Form (with 3b1 and 3b2-if applicable) or FDP Letter of Intent (if organization is registered in the FDP Clearing House)
- 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