

NIH R01 (Parent R01 Clinical Trial Not Allowed)
Proposal Guidelines & Checklist 2022

Purpose of R01 funding mechanism: The NIH Research Project Grant supports a **discrete, specified, circumscribed project** in areas representing the specific interests and competencies of the investigator(s). The proposed project must be related to the programmatic interests of one or more of the participating NIH Institutes and Centers (ICs) based on their scientific missions.

Budget limit: Application budgets are not limited but need to reflect the actual needs of the proposed project.

Project duration limit: up to 5 years

Note: All blue links are hyperlinks to NIH webpages

	<p>NIH guidelines for R01 PA-20-185</p> <p><u>General formatting</u></p> <ul style="list-style-type: none"> <input type="checkbox"/> File names: 50 characters or less, including spaces; no “&”; 1 space between words <input type="checkbox"/> Recommended fonts: Arial, Helvetica, Palatino Linotype, Georgia; black; 11 pts + <input type="checkbox"/> Margins: ½” + <input type="checkbox"/> Header/Footer: clear of any information, including page numbers
	<p><input type="checkbox"/> <u>Cover letter:</u> Optional; <i>PI recommendations regarding study section assignment for proposal review are now included in the PHS assignment request form, no longer in the Cover letter</i></p>
	<p><input type="checkbox"/> <u>Project Summary/Abstract:</u> no more than 30 lines of text, understandable to a scientifically/technically literate lay reader</p>
	<p><input type="checkbox"/> <u>Project Narrative:</u> 2-3 sentences summary in plain language</p>
	<p>Budget and Budget Justification: If greater than \$250,000 in Total Direct Costs (<i>excluding indirect costs</i>) per project period:</p> <ul style="list-style-type: none"> <input type="checkbox"/> R&R/detailed budget form <input type="checkbox"/> Detailed budget justification <p>If \$250,000 or less in Total Direct Costs (<i>excluding indirect costs for prime and Subrecipient if applicable</i>) per project period:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Modular budget form <input type="checkbox"/> Modular budget justification (Personnel, Consortium [Subaward], Additional) <p>NIH has a longstanding policy that states any applicant requesting \$500,000 or more in direct costs (excluding consortium F&A costs) <i>in any one budget period</i> within a competitive segment is required to contact the NIH Institute or Center (IC) Program Official (PO), in writing or by telephone, as early as possible during development of the application but no later than 6 weeks before submission for prior approval.</p>
	<p><input type="checkbox"/> Facilities and Other Resources</p>
	<p><input type="checkbox"/> <u>Equipment</u> (Optional): List major items of equipment already available and identify location & pertinent capabilities</p>

	<p><u>Biosketch(es)</u> for each senior personnel (Instructions, Samples, Template):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Up to 5 pages in length for each <p><u>PHS 398 Research Plan Form</u></p> <ul style="list-style-type: none"> <input type="checkbox"/> Introduction (Resubmission or Revision only) <p><u>Research Plan Section</u></p> <ul style="list-style-type: none"> <input type="checkbox"/> Specific Aims: 1-page limit <input type="checkbox"/> Research Strategy Page limit: R01 = 12 pages; 3 separate sections: Significance, Innovation, Approach <input type="checkbox"/> Progress Report Publication List (Renewal applications only)
	<p><u>Human Subjects Section</u></p> <ul style="list-style-type: none"> <input type="checkbox"/> Protection of Human Subjects (if Human Subjects is YES) <input type="checkbox"/> Human Subjects and Clinical Trials Information <p><u>Other Research Plan Section</u></p> <ul style="list-style-type: none"> <input type="checkbox"/> Vertebrate Animals (if Vertebrate Animals is YES) <input type="checkbox"/> Select Agent Research (if applicable) <input type="checkbox"/> Multiple PD/PI Leadership Plan (if more than one PD/PI is specified) <input type="checkbox"/> Consortium/Contractual Arrangements (if applicable) <input type="checkbox"/> Letters of Support (if applicable; would include consultants) <input type="checkbox"/> Resource Sharing Plan: Describing dissemination <input type="checkbox"/> Authentication of Key Biological/Chemical Resources – <i>new as of January 25, 2016</i> (if applicable)
	<p><u>PHS Assignment Request Form</u> (Optional; Effective May 25, 2016):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Award Component Assignment Request: up to three NIH Institutes/Centers can be requested using their abbreviations (PI can also chose 3 “do not assign”). First choice should be #1. <input type="checkbox"/> Study Section Assignment Request: up to three study sections or special emphasis panels (use short abbreviations) can be requested (PI can also choose 3 “do not assign”). First choice should be #1. <input type="checkbox"/> List of individuals who should not review and why <input type="checkbox"/> Expertise needed to review your application (Each field can have a maximum of 40 characters)

Updated 10.13.22