

**Office of Sponsored Programs**

Phone: 617.919.2729

Email: [osp@childrens.harvard.edu](mailto:osp@childrens.harvard.edu)

**CHECKLIST FOR NIH APPLICATIONS: RESEARCH PROJECTS (R)**

*Updated for FORMS-E submission requirements (for applications due on or after 01/25/2019)*

This checklist is a general guidance tool to assist PIs and administrators in completing and compiling documentation for NIH application submissions. Please make sure to review Funding Opportunity Announcements (FOA) (i.e., PA-XX-XXX, PAR-XX-XXX, or RFA-XX-XX-XXX) for additional application requirements.

**Make sure to download the appropriate FOA:** [Comparison of Parent FOAs by Clinical Trial Allowability](http://web2.tch.harvard.edu/osp/Documents/Comparison_of_Parent_FOAs_by_Clinical_Trial_Allowability.docx)

**CHeRP:** Make sure that the Online Coversheet (OLCS) is approved by the PI & Department/Division/Program Chair.

**Conflict of Interest (COI):** Have all designated “investigators” completed COI disclosures and COI CITI Training? For COI disclosure purposes, investigator is defined as the principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of the proposed research.  **No  Yes**

**Adobe Version:** At minimum, Adobe Reader 11.0.10 is required.

**Formatting: Have the attachments been formatted to NIH specifications?  No  Yes**

Text Font: Recommended: Arial, Georgia, Helvetica, or Palatino Linotype. Other fonts may be used as

long as they meet the size, density, and spacing requirements.

Text Size: 11 or larger (figure text may be smaller).

Type Density: No more than 15 characters per linear inch (including characters and spacing).

Line Spacing: No more than six lines per vertical inch.

Text Color: Black or other high-contrast text colors are recommended since they print well and are legible to the largest audience.

Page Size: 8.5 x 11.

Margins: at least ½ inch on all four sides.

Hyperlinks and URLs: Allowable in Biosketches. Please check FOA to ensure allowability in other attachments.

Actual URL text must appear as the hyperlink (example: NIH (<http://www.nih.gov>)).

**File Size:** The file size must be greater than 0 bytes and less than 100MB per Grants.gov recommendation.

**Does the application include proprietary and/or privileged information?  No  Yes**

***If Yes***, clearly mark each applicable line or paragraph and include a statement similar to: “The following contains proprietary/privileged information that [name of applicant] requests not be released to persons outside the government, except for review and evaluation.” [NIH Freedom of Information Act Office](http://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office)

**Attachments (sorted by application section):**

**SF-424 (R&R) Form Page**

Cover Letter: Recommended. Required for: Late submissions; Applications requesting annual direct costs of $500,000 or more (excluding subaward F&A) must also attach NIH approval; Explanation of any subaward budget components that are not active for all proposed budget periods; when intending to submit a video; and when the proposed project will generate data as detailed in the [NIH Genomic Data Sharing Policy](https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/). Remember to include the application title and FOA. No page limit.

**Research & Related Other Project Information**

Are human subjects involved: Yes or No. Your response to this question will populate the first item (If No/Yes to Human Subjects) in the “PHS Human Subjects and Clinical Trials Information” form page where a response will be required *(even if your project does not involve human subjects).*

Project Summary/Abstract: Limited to 30 lines. An error message will be generated if more than 1 page.

Note: If awarded, this information becomes public.

Narrative: A 2-3 sentence description of the project’s relevance to public health. An error message will be

generated if more than 1 page. Note: If awarded, this information becomes public.

Bibliography: Include full citations. Comply with the [public access policy](https://publicaccess.nih.gov/) by including PMCIDs when

citing applicable papers that PI authors or that arise from his/her NIH-funded research.

**Research & Related Other Project Information, continued**

Facilities & Other Resources: Facilities/Resources to be used: Lab, Animal, Computer, Office, Clinical, etc.

Equipment: Items available for the proposed project.

Other Attachments: Include Other Attachments only when specifically requested in the FOA.

**Does the project include activities outside of the U.S. or international partnerships?  No  Yes**

NIH Definition of Foreign Component: The performance of any significant element or segment of the project outside the United States either by the grantee or by a researcher employed by a foreign institution, *whether or not grant funds are expended*. Activities include: The involvement of human subjects or vertebrate animals at a foreign site; Extensive foreign travel by grantee project staff for the purpose of data collection, surveying, sampling, & similar activities; and Any activity of the grantee that may involve the population, environment, resources, or affairs of a foreign country. Examples of other grant-related activities: collaborations with investigators at a foreign site anticipated to result in co-authorship; use of facilities or instrumentation at a foreign site; or receipt of financial support or resources from a foreign entity.

***If Yes***, identify the countries in section 6a and provide an explanation in section 6b and a Foreign Justification in section 12 (Other Attachments) of the Research & Related Other Project Information form. (Describe special resources or characteristics of the project, whether similar research is being done in the US, and if there is a need for additional research in this area)

**Research & Related Senior/Key Person Profile**

*PD/PI(s): Please remember to enter their eRA Commons IDs in the Credentials field.*

Biosketches: Limited to 5 pages. In Section C, please list no more than 4 publications per Contribution to Science. For more information, please refer to: [NOT-OD-15-032](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-032.html). Do not include figures, graphics, or tables. [Biosketch Template](http://grants.nih.gov/grants/forms/biosketch.htm)

Current & Pending Support: Provide Current & Pending Support only when requested in the FOA.

**Modular Budget**

Budget Justification: Personnel Justification (names, effort, roles on the project, and descriptions); Additional

Narrative Justification (to explain fluctuations in modules or Equipment costs, if applicable).

**Detailed Budget**

Budget Justification: Describe all cost categories. Please also include information about cost of living increases

and fringe benefits rate(s).

**Does the project include at least one subaward to another institution?  No  Yes**

***If Yes***, some or all of the following attachments will be required:

Facilities: include in BCH Facilities attachment

Equipment: include in BCH Equipment attachment

Budget and Detailed Budget Justification: Required for applications requesting more than $250,000 direct costs

per year (excluding subaward F&A costs)

Consortium Justification: Required for Modular budget submissions.

Consortium Arrangement: Explain programmatic, fiscal and administrative arrangements to be made between the

applicant and subaward/consortium organization(s).

Please request Statement of Intent or Subrecipient Commitment Form and Scope of Work documents from each

participating site and forward them to your OSP grant officer.

**PHS 398 Research Plan Form**

Introduction: Required for Resubmissions. Generally limited to 1 page, so please check the FOA. NIH policy allows a 37-month window for resubmissions (A1). [NOT-OD-12-128](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-128.html) and [NOT-OD-18-197](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-197.html).

Specific Aims: Limited to 1 page. Goals of proposed research and summarize expected outcome(s).

Research Strategy: Parent R01: 12 pages, Parent R03: 6 pages, Parent R21: 6 pages. Please check the FOA for specific requirements. New Requirement for Significance and Approach sections: Describe the strengths and weaknesses in the rigor of prior research that serves as key support for the proposed project. [Does the Strategy address Rigor & Transparency requirements?](https://grants.nih.gov/reproducibility/index.htm)

Progress Report Publication List: Required for Renewals. No page limit.

Letters of Support: Explain expectations for co-authorship, will resources/cell lines be freely available or limited to select investigators?; Consultants’ letters should include rates and numbers of hours/days needed per year; Core Services/Facilities’ letters should state if access is provided as a fee-for-service.

Resource Sharing Plan(s): Required for research projects. Please check the FOA for further requirements on

data sharing, model organisms, and genomic data sharing. [Sharing Research Resources](http://grants.nih.gov/policy/sharing.htm)

**Does the project involve** [**Select Agents**](http://www.selectagents.gov/SelectAgentsandToxins.html)**?  No  Yes**

***If Yes***, the Select Agent Research Attachment is required.

**Does the project include more than one PD/PI?  No  Yes**

***If Yes***, the Multiple PD/PI Leadership Plan Attachment is required.

Required Plan Components: governance and organizational structure of leadership team; communications plans; process for making decisions on scientific direction; procedures for resolving conflicts; and budget allocation.

Please make sure that multi PIs have the PD/PI role in the Senior/Key Person Profile section.

**Does the project involve key biological or chemical resources?  No  Yes**

***If Yes***, the [Authentication of Key Resources](https://nexus.od.nih.gov/all/2017/06/06/what-kind-of-information-should-i-include-in-the-authentication-of-key-biological-andor-chemical-resources-attachment/) Attachment is required (limited to 1 page). ***If No***, Upload an attachment stating that “no key biological and/or chemical resources will be used in the activities proposed in the application.”

**Does the project involve vertebrate animals?  No  Yes**

***If Yes***, the Vertebrate Animals Attachment is required.

Three Required Points: 1. Description of Procedures, 2. Justification, and 3. Minimization of Pain and Distress.

Euthanasia is covered in the PHS 398 Cover Page Supplement. [AVMA Euthanasia Guidelines.](https://www.avma.org/kb/policies/pages/euthanasia-guidelines.aspx)

**Does the project involve human subjects and a** [**clinical trial**](https://grants.nih.gov/policy/clinical-trials.htm)**?  No  Yes**

***For clinical trials, make sure to submit applications in response to FOAs stating that*** [***clinical trials are allowed.***](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-043.html)

***If Yes***, some or all of the following sections will need to be completed:

**PHS Human Subjects and Clinical Trials Information**

Intro page

Does the proposed research involve human specimens and/or data?  No  Yes

***If Yes***, provide an explanation of why the application does not involve human subjects research. Include information on who is providing data/specimens and their role in the research; a description of the identifiers; a list of who has access to research participants’ identities and information about how their privacy will be protected.

Other Requested Information: Please refer to the FOA for specific requirements.

Study Records: Add a study record for each proposed study involving human subjects and complete the form (up to 150). Sections 1 - 5 (detailed below) are accessed from each Study record.

Delayed Onset Studies: Upload an attachment explaining why human subjects study information is not available.

Section 1: Basic Information

Complete the Clinical Trial Questionnaire:

* Does the study involve human participants?  No  Yes
* Are participants prospectively assigned to an intervention?  No  Yes
* Is the study designed to evaluate the effect of the intervention on the participants?  No  Yes
* Is the effect that will be evaluated a health-related biomedical or behavioral outcome?  No  Yes

Answering “**Yes**” to all of these questions means that the study meets the definition of a clinical trial and these sections are required:

Section 2: Study Population Characteristics (includes Inclusion Enrollment Report)

Section 3: Protection and Monitoring Plans

Section 4: Protocol Synopsis

Section 5: Other Clinical Trial-related Attachments (check the FOA)

Answering “**No**” to any of these four clinical questions means that the study does not meet the definition of a clinical trial and only these sections are required:

Section 2: Study Population Characteristics (includes Inclusion Enrollment Report)

Section 3: Protection and Monitoring Plans

Section 2: Study Population Characteristics (includes Inclusion Enrollment Report)

*This section is not required if you selected Exemption 4.*

Inclusion of Women, Minorities, and Children: [(Children defined as individuals under 18 years old)](https://grants.nih.gov/grants/funding/inclusion-across-the-lifespan-faq.htm#5611). New

Requirement: In response to the [Inclusion Across the Lifespan Policy](https://grants.nih.gov/grants/funding/lifespan/lifespan/policyinfo.htm), applicants must now address age-related inclusion, including a rationale for the age range of study participants and justification for age-based exclusion.

Recruitment and Retention Plan: Describe how study participants will be recruited and retained. Address planned recruitment activities and proposed engagement strategies for engagement.

Study Timeline: Provide a general timeline (year one, year two, etc.) that does not include specific dates.

Section 2, continued

Inclusion Enrollment Report: Select “Planned” to provide information about individuals expected to be enrolled; Select “Cumulative” to provide information for new studies using existing Datasets or Resources where no contact with participants is expected or studies that will continue in a renewal application.  [Inclusion Enrollment Report Information](https://grants.nih.gov/grants/funding/inclusion-basis-on-sex-gender-race-ethnicity-faq.htm)

Section 3: Protection and Monitoring Plans

Protection of Human Subjects: Exempt: Describe how the proposed research meets the criteria for the exemption

claimed. Non-exempt: Describe risks to participants, adequacy of protection against risks, potential benefits to participants and others; and importance of the knowledge to be gained.

Single IRB Plan: Required if your application involves a multi-site study that will use the same protocol to conduct non-exempt human research at more than one domestic site. [NIH Single IRB FAQs.](https://grants.nih.gov/grants/policy/faq_single_IRB_policy_research.htm)

Data and Safety Monitoring Plan: Required for clinical trials; optional for all other human subjects research.

Overall Structure of the Study Team: Required for clinical trials; optional for all other human subjects research. Include a brief overview of the organizational structure of the study team, particularly the administrative sites, data coordinating sites, enrollment/participating sites, and any separate laboratory or testing centers.

Section 4: Protocol Synopsis

Statistical Design and Power: State the number of subjects you expect to enroll, the expected effect size, the

power, and the statistical methods that will be used in each outcome measure described in Section 4.3 (Outcome

Measures).

Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status:

Required if you answered “yes” to the question in section 4.6. Describe the availability of study agents and support for acquisition and/or administration of these agents. Also include information about the IND/IDE status and/or any interactions with the FDA.

Dissemination Plan: You may upload the same plan for all proposed studies, but they must have unique file names within the application. Provide assurance that the trial will be registered @ clinicaltrials.gov, informed consent documents will include a statement about posting clinical trials information @ clinicaltrials.gov; and the applicant institution’s policies and processes comply with the [NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html).

Section 5: Other Clinical Trial-related Attachments

Other Clinical Trial-related Attachments: Please check the FOA for specific requirements. A maximum of 10 PDF

attachments may be uploaded.

**Does the project include any** [**Appendix**](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-098.html) **items?  No  Yes**

Please check the FOA to ensure that Appendix items are allowable. ***If Yes***, no more than 10 attachments may be included.

**Blank** data collection forms, **blank** survey forms, **blank** questionnaire forms (screenshots are allowable)

**Blank** informed consent/assent forms

Simple lists of interview questions

FOA-specific items (The FOA will address review criteria for required materials. Applications submitted without these appendix materials will be considered incomplete and will not be reviewed.)

**Note:** In these blank forms and lists, do not include items such as: data, data compilations, lists of variables or acronyms, data analyses, publications, manuals, instructions, descriptions or drawings/figures/diagrams of data collection methods or machines/devices.

Updated 01.03.2019

R Application Checklist 01.23.18