

NIH R21 Checklist

DUE DATE AND AWARD INFORMATION	
Sponsor deadline	February 16, June 16, October 16
Internal deadline	3 business days prior to sponsor deadline
Budget period	\$275,000 in direct costs for up to two years; no more than \$200k per year
Anticipated Start Dates	December 1, April 1, July 1
PI Name	
Co-PI(s) and Senior Personnel	_____
Collaborative/subaward institution(s)	_____

FORMATTING INSTRUCTIONS	
Document format	PDF only; no headers or footers (no page numbers)
Font type/size	<ul style="list-style-type: none"> ✔ Arial, Helvetica, Palatino Linotype or Georgia ✔ Size 11 or larger ✔ Black font color
Line spacing	<ul style="list-style-type: none"> ✔ No more than 6 lines of type within a vertical space of 1 inch ✔ Only single column formatting ✔ Use section headings
Page size	8.5 x 11
Margins	.5" all sides
General NIH Guidelines	https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf
Formatting Guidelines	https://grants.nih.gov/grants/forms/all-forms-and-formats.htm
Page Limits	https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/page-limits.htm#other
R21 Solicitation	https://grants.nih.gov/grants/guide/pa-files/PA-16-161.html

eRA Commons INSTRUCTIONS	
1	<input type="checkbox"/> Register in eRA Commons with CofC affiliation Need:
2	<input type="checkbox"/> Login to Commons
3	<input type="checkbox"/> Commons ID(s) _____

PROPOSAL DOCUMENTS	
1	<input type="checkbox"/> Project Summary/Abstract- no more than 30 lines
	<ul style="list-style-type: none"> ✔ Concise description of project objectives and methodologies suitable for dissemination to the public ✔ Include broad, long-term objectives and specific aims, making reference to the mission of NIH

	<input type="checkbox"/>	<ul style="list-style-type: none"> ✔ Note: Will be public domain
2	<input type="checkbox"/>	Project Narrative- 3 sentences
		<ul style="list-style-type: none"> ✔ Describe relevance of research to public health in lay terms
3	<input type="checkbox"/>	Bibliography & References Cited- no page limit
		<ul style="list-style-type: none"> ✔ Each reference must include the names of all authors, article and journal title, book title, vol #, page #, year of publication ✔ When citing articles that fall under the Public Access Policy (peer-reviewed, accepted for publication since April 2008, and result of NIH funding) and were authored or co-authored by the application, provide the NIH Manuscript Submission reference number or the PubMed Central number for each article.
4	<input type="checkbox"/>	Facilities and Other Resources- no page limit
		<ul style="list-style-type: none"> ✔ Identify resources available to the program to demonstrate capability of research site to complete the proposal (include all performance sites)
5	<input type="checkbox"/>	Equipment- no page limit
		<ul style="list-style-type: none"> ✔ Provide list of major equipment items already available; location and pertinent capabilities
6	<input type="checkbox"/>	Biographical sketch- 5 page max per person
		<ul style="list-style-type: none"> ✔ Use template provide by NIH, available on ORGA website
7	<input type="checkbox"/>	Specific Aims- 1 page
		<ul style="list-style-type: none"> ✔ Concisely state goals and specific objectives of the proposed research and summarize expected outcomes, including the impact the results will exert on the research and health fields
8	<input type="checkbox"/>	Budget and Budget Justification (NIH forms)
		<ul style="list-style-type: none"> ✔ Budget forms: (to be created/completed by ORGA) <ul style="list-style-type: none"> Modular (PHS 398) for less than \$250k direct costs (in \$25k increments) R&R for more than \$250k in direct costs ✔ Budget Justification (created by ORGA, technical information completed by PI) <ul style="list-style-type: none"> Personnel justification (mandatory), consortium justification (if applicable) and additional narrative justification (usually used to explain different number of modules per year)
9	<input type="checkbox"/>	Research Strategy- 12 pages
		<ul style="list-style-type: none"> ✔ Significance ✔ Innovation ✔ Approach
10	<input type="checkbox"/>	Resource Sharing Plans (if applicable)
		<ul style="list-style-type: none"> ✔ Data Sharing Plan-required for PIs seeking \$500k + in direct costs; provide a brief paragraph immediately following Research Plan section ✔ Sharing Model Organisms- only applicable for novel mouse models ✔ Genomic Data Sharing Plan (if applicable)
11	<input type="checkbox"/>	Cover Letter (not required, but recommended)
		<ul style="list-style-type: none"> ✔ Include: funding opportunity announcement, application title; More suggestions from NIH: https://public.csr.nih.gov/ApplicantResources/PlanningWritingSubmitting/Pages/Cover-Letters-Help-Us-Refer-and-Review-Your-Application-.aspx ✔ Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in proposed research
12	<input type="checkbox"/>	Human Subject Sections (if applicable)- no page limit, separate attachments
		CofC FWA: 00000772

See ORGA IRB resources: <http://research.cofc.edu/administration/research-protections-and-compliance/human-participants-irb.php>

Four Required parts:

- ✔ Protection of Human Subjects
- ✔ Inclusion of Women and Minorities
- ✔ Inclusion of Children
- ✔ Planned Enrollment Table

13 **Vertebrate Animates (if applicable)- no page limit**

Assurance number: A4376-01

See ORGA IACUC resources: <http://research.cofc.edu/administration/research-protections-and-compliance/vertebrate-animals-iacuc.php>

[NIH Worksheet for Review of Animal Section](#)

- ✔ description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used
- ✔ justifications for the use of animals versus alternative models and for the appropriateness of the species proposed
- ✔ interventions to minimize discomfort, distress, pain and injury
- ✔ justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals

14 **Select Agent Research (if applicable)**

- ✔ Identify select agent(s) to be used; provide the registration status of all entities where select agent will be used; provide a description of facilities where select agent will be used

15 **Multi PI Leadership Plan (if applicable)**

- ✔ Rationale for multiple PI approach should be described, as well as organizational structure of the leadership team and research project, including communication plans, processes for making decisions on scientific direction, and procedures for resolving conflict
- ✔ Budget information

16 **Consortium/Contractual Arrangements (if applicable)**

- ✔ Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee.
- ✔ Signed by authorized representative

17 **Letters of Support (if applicable)**

- ✔ Consortium and consultant letters combined into single PDF file
- ✔ Attach a file with all letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application.
- ✔ For 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.
- ✔ Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project.

18 **Resubmission statement- 1 page (if applicable)**

- ✔ Introduction to the submission application

19 **ORGA Routing Sheet- submitted to ORGA**

- ✔ Must be signed by PI (and Co-PI, if applicable), department chair, and dean before the proposal can be submitted
- ✔ ORGA needs the following information to complete the routing sheet, before returning to the PI for signatures: solicitation, project title, projected dates, and basic budget information (including salary information)

20 **Financial Conflict of Interest- submitted to ORGA**

- ✔ Read the PHS Financial Conflict of Interest Procedures:
<http://research.cofc.edu/administration/documents/policies-documents/fcoi-procedures-phs.php>
- ✔ Complete the [NIH Financial Conflict of Interest Training](#).
- ✔ Submit a [Financial Interests Report eForm](#) at the time of submission of the grant proposal and, if funded, at intervals specified by the grant.