NIH R01/R03/R15/R21 Checklist
Please refer to RFA and NIH guidelines

READ THE PA/RFA SOLICITATION AND MAKE SURE YOU CHOSE THE RIGHT FUNDING OPPORTUNITY.
In January 2018 NIH changed their Funding Opportunity Announcements (FOA) to be either (a) clinical trial not allowed; (b) clinical trial optional; or (c) clinical trial required. Pay attention to the "Application and Submission Information" section.

- Individual NIH PA/RFAs take precedence over NIH SF424 general guidelines. The NIH SF424 Application Guide takes precedence over this document.
- Proposals MUST be submitted via Grants.Gov on or before 5:00 pm Local Time on Deadline Date. If an NIH "standard deadline" date falls on a weekend or federal holiday, the deadline is extended to the following business day. For RFAs with specific deadline dates, the deadline is fixed and does NOT change for any reason.
- eRA Commons username is required for all Senior/Key Personnel roles.

Notes:
For specific document requirements, see the Forms Version H General (G) instructions and the funding opportunity announcement (FOA).

If additional project/performance sites will be utilized (regardless of consortium/contractual arrangements), the following information must be supplied separately to OSP:

- Organization Name
- UEI Number, if available
- Full physical address of site location, including country
- Congressional District of performance site *(if domestic entity)*.

For All Documents

- Black or high-contrast text colors recommended.
- 11 point or larger font, recommended fonts - Arial, Georgia, Helvetica, Palatino Linotype.
- Use at least ½" margins.
- Do not use headers, footers or page numbers.
- Save documents as PDF files. All file names must be under 50 characters in length, and may include letters, numbers, underscores and hyphens. No special characters.
- Recommended naming convention: *PILastName_DocumentTitle*
- If personnel have effort without salary, that is cost sharing.
- Be aware of the NIH salary cap in effect. For a categorical budget, can request salary in excess of the cap and NIH will reduce at award time. Salary caps are based on 12-month appointments. https://grants.nih.gov/grants/policy/salcap_summary.htm
- In general, modular budgets are used only for R01, R03, R15, R21, and R34 applications.
- Foreign subawardee F&A is limited to 8%
- Hyperlinks and URLs are only allowed when specifically noted in FOA and form field instructions. The use of hyperlinks is typically limited to citing relevant publications in biosketches and publication lists. Refer to NOT-OD-20-174 and NIH SF424 (R&R) Application Guide.

SECTIONS OF THE APPLICATION

Cover Page and Other Project Information

1) Cover Letter *PILastName_CoverLetter*

Required ***only*** if *any* of the following apply:

- Late Application;
- Changed/Corrected Application submitted after deadline;
- If subaward budget components not active for all budget periods;
- Inclusion of agency approval documentation (i.e. budget request of $500,000 or more, approval of Conference Grant or Cooperative agreement);
- Video to be included as part of application;
- Collection of large-scale genomic data;
- Research involving Human Fetal Tissue.

Cover letter must be addressed to the Division of Receipt and Referral, in accordance with FOA and Forms H instructions. Include application title, funding opportunity title, and information, explanation, and/or documentation of required items. Do **not** use cover letter for requesting institute or review assignment. Requests should be made with the Assignment Request Form.

2) Project Summary *PILastName_Summary*

Maximum of 30 lines of text.

3) Project Narrative *PILastName_Narrative*

Maximum of 2-3 sentences.

4) Bibliography & References Cited *PILastName_References*

PMCIDs/NIHMSIDs should be included if citations co-/authored by applicant and fall under Public Access Policy. Be careful with PubMed references; they can generate an error and prevent submission. Active hyperlinks are not allowed.

5) Facilities & Other Resources *PILastName_Facilities*

Identify the facilities available to the program to demonstrate capability of research site to complete the proposal, including all performance sites. Describe any special facilities used for working with biohazards and any other potentially dangerous substances. For early stage investigators (ESIs), describe institutional investment in the success of the investigator.

6) Equipment *PILastName_Equipment*

List major items of equipment available to the project to demonstrate capability of research site, including all performance sites. If no equipment, please provide document stating that there is no equipment applicable to the project.

7) Other Attachments *(if applicable)*

Foreign Justification: *PILastName_ForeignJust*

Required if project involves activities outside of the US or partnerships with international collaborators.

HFT Sample IRB Consent Form: *PILastName_HFT_IRB*

Provide blank sample of the IRB-approved consent form with proposal if project involves Human Fetal Tissue (HFT).

HFT Compliance Assurance: *PILastName_HFTCompliance*

PI letter assuring the HFT donating org adheres to the requirements of the informed consent process and documentation that HFT was not obtained or acquired for valuable consideration.

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Key Person Profile

8) Biographical Sketches *PILastName_Biosketch*

Required for all senior/key personnel or other significant contributor (OSC). *Note: OSCs are "Individuals who commit to contribute to the scientific development or execution of the project, but do not commit any specified measurable effort (i.e., person months) to the project."*

- 5 page maximum.
- Personal Statement – Brief description of experience and qualifications for the role in project:
  - the historical background that frames the scientific problem;
  - the central finding(s);
  - the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and
  - your specific role in the described work.
- Positions, Scientific Appointments, and Honors- list in reverse chronological order all previous positions/scientific appointments both domestic and foreign, including affiliations with foreign entities and governments.
- Contributions to Science – describe up to 5 most significant contributions to science, each no longer than half a page, including citations.
- Cite up to 4 products under Personal Statement; 4 Products per Contribution. Use of hyperlinks and URLs is not allowed for citations.
- Only provide ".gov" URL link only for List of Published Work (My Bibliography recommended by NIH). No other URLs are allowed.
- No graphics/figures/tables allowed in biosketch (tables built into the template are only allowed tables).
- Use most current template. Template available at: https://grants.nih.gov/grants/forms/biosketch.htm.

Budget

9) Budget Justification *(submit based on budget type)* *PILastName_Justification*

a) R&R (Non-Modular) Budgets – Detailed Justification, 1 PDF file.
- Itemize and provide details for any materials and supplies categories (i.e. glassware, chemicals,
- animal costs, etc.) that are $1,000 or more.
- If research involves Human Fetal Tissue (HFT):
  - Budget must include one line in F.8-10 listed as "Human Fetal Tissue Costs", even if $0 requested *(in that case "0" must be listed in requested costs).*
  - Justification must include the quantity, type/s, and source/s of the HFT, including the stage of fetal development, even if $0 requested.
- If consortium (subaward) will be used, see Consortium Justification below. OSP will require additional documents from each institution; please contact your grant specialist.

b) Modular Budgets – 3 PDF files *(may need only 1 PDF)*
- ***Required for budgets with $250,000 or less in direct costs per year, excluding subcontract indirect costs (unless FOA states otherwise).***
- Not allowed for proposals with HFT research, even if under $250k.
- Personnel Justification *PILastName_Personnel*
  List all personnel including name, person months devoted to project and role. If participating students have not yet been individually identified, the number and academic level of those to be involved should be provided. If there are any Collaborators or Consultants for the project, provide their names, organizational affiliations, and the services they will perform.
- Consortium Justification – *if a consortium is involved* *PILastName_Consortium*
  State dollars of subaward rounded to nearest thousand for each year, state domestic or foreign entity, list personnel including name, effort and role
- Additional Narrative Justification *PILastName_AdditionalJust*
  required if modules change from year to year

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PHS 398 Research Plan and Assignment Request

10) Introduction (*Required for Revisions and Resubmissions only*) *PILastName_Introduction*
Maximum of 1 page.

11) Specific Aims *PILastName_SpecificAims*
Maximum of 1 page.

12) Research Strategy *PILastName_ResearchStategy*

- **R01/R15**: Maximum of 12 pages; **R03/R21**: Maximum of 6 pages.
- *Sections* – Must be labeled in this order and with each header: 1. Significance; 2. Innovation; 3. Approach.
- As applicable, also include preliminary studies for new applications and progress report for renewal and revision applications as part of the Research Strategy, keeping within the three sections listed above.
- If Human Fetal Tissue (HFT), include HFT info in 3. Approach section following NOT-OD-19-137.

13) Progress Report Publication List *PILastName_Publications*
Required for renewals. PMCIDs/NIHMSIDs should be included if citations co-/authored by applicant and fall under Public Access Policy.

14) Vertebrate Animals *PILastName_Vertebrate*
Required if vertebrate animals involved.

- *Description of Procedures*: Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the "Research Strategy" section. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed provide the source of the animals.
- *Justifications*: Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g. computational, human, invertebrate, in vitro).
- *Minimization of Pain and Distress*: Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain, and injury.
  For additional information, see http://grants.nih.gov/grants/olaw/VAChecklist.pdf

15) Select Agent Research *PILastName_SelectAgent*
Required of activities involve use of select agents (hazardous biological agents or toxins).

16) Multiple PI/PD Leadership Plan *PILastName_LeadershipPlan*
Required only if more than one PI, not applicable to Co-Investigators. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts.

17) Consortium/Contractual Arrangements *PILastName_Contractual*
Required if there is a subcontract; OCG template here.

18) Letters of Support *PILastName_SupportLetters*

- All letters of support in a single PDF document.
- Font and margin requirements do not apply to letters of support.
- Except for UARK persons being charged to the budget, include one for each person named in Senior/Key Persons to affirm their participation. If a consultant letter is included, ensure it states the rate and hours expected to dedicate to project

19) Resource Sharing Plan *PILastName_ResourceSharing*

- Strongly encouraged. *Required if:* $500,000 or more in direct costs in any one year; model organisms to be developed; or if FOA requirement.
- If applying to **NIMH with Human Subjects research**, Resource Sharing Plan is *required*.

- If applying to most parent FOAs (see NOT-AA-19-020) to **NIAAA with Human Subjects research**, you are required to include NIAAA Data Archive Sharing Plan as Resource Sharing Plan – use of NIAAADA DSP template encouraged. *Costs associated with with submitting data to the NIAAADA should be included in grant applications. A cost estimation tool ("NDA Cost Estimation Tool") for data sharing is available for this purpose.*

20) Data Management and Sharing (DMS) Plan *PILastName_DMS*
Required if research will generate scientific data per the NIH Data Management and Sharing Policy. Plans for Genomic Data Sharing should be provided as part of the DMS Plan. Applicants subject to both policies must attach a single plan including elements for both policies. A sample format is provided on the Data Management and Sharing Plan Format page. Additional resources are available through University Libraries.

21) Authentication of Key Biological and/or Chemical Resources *PILastName_Authentication*
Required for established key biological and/or chemical resources. If not applicable, include a brief statement indicating that none will be used. See NIH's page on Rigor and Reproducibility for more information.

22) Appendix
See NIH Appendix Policy for acceptable appendix materials.
Allowable Appendix Items for Inclusion:

- Blank data collection forms, blank survey forms and blank questionnaire forms (Do not include instruction pages).
- Simple lists of interview questions.
- Blank informed consent/assent forms.
- Other items ***only if*** they are specified in the FOA as allowable Appendix materials.

23) Assignment Request Form (optional)
Use to communicate specific application assignment and review requests. Do NOT include this information in Cover Letter. Ensure the institution you are requesting is accepting proposals for the program you are applying to. This information is usually detailed in the funding opportunity announcement.

Humans Subjects and Clinical Trials
*Refer to Forms H Research Instructions for information on Exemptions (section R. 500). If proposal has Human Fetal Tissue (HFT); review NOT-OD-21-111 for definition and requirements***.**

24) Human Specimens and/or Data *PILastName_HumanSpecimenData*
Required if no human subjects are involved, but human specimens and/or data will be used.

25) Delayed Onset Study *PILastName_DelayedOnset*
Required only when human subjects research is anticipated within the period of award but definite plans cannot be described in the application.

26) Study Record and Attachments

- Required for any project involving Human Subjects and/or Clinical Trails that does not include only delayed onset studies.
- One Study Record form required for each study.
- Use unique file names for each form and document.
- See table on next page for requirements based on type of human subject or clinical trial research.

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NIH Human Subjects (HS) and Clinical Trials (CT) Required Forms and Documents				
HS/CT Forms and Documents	**Human Subjects, Exemption 4**	**Human Subjects, no Clinical Trial**	**Clinical Trial**	**File Name** (if multiple study records, add _StudyRecord# to each file)
Study Record Form				*PILastName_StudyRecord*
Section 1: Basic Information	Required	Required	Required	
Section 2: Study Population Characteristics	Not required	Required	Required	
Section 3: Protection and Monitoring Plans	Required – only justification of exemption document	Required	Required	
Section 4: Protocol Synopsis	Do not complete	Do not complete	Required	
Section 5: Other Clinical Trial-Related Attachments	Do not complete	Do not complete	Required	
HS/CT Documents				***See list below:***
Inclusion of Individuals Across the Lifespan	Not required	Required	Required	*PILastName_Lifespan*
Inclusion of Women and Minorities	Not required	Required	Required	*PILastName_IWM*
Recruitment and Retention Plan	Not required	Required if study involves human participants	Required	*PILastName_RRPlan*
Study Timeline	Not required	Required if study involves human participants	Required	*PILastName_Timeline*
Inclusion Enrollment Report	Not required	Required	Required	
Protection of Human Subjects	Required – only justification of exemption document	Required for all non-exempt research. For exempt, provide justification for exemption.	Required	*PILastName_Protection*
Single IRB	Select N/A	For all exempt research, select N/A. For non-exempt research, required only for Multi-site study.	Required only for Multi-site study	*PILastName_IRBPlan*
Data and Safety Monitoring Plan	Optional	Optional	Required	*PILastName_DataSafety*
Overall Structure of the Study Team	Optional	Optional	Required	*PILastName_StudyTeam*
Statistical Design and Power	Do not include	Do not include	Required	*PILastName_StatisticalMethods*
FDA Regulated Intervention	Do not include	Do not include	Required for FDA-regulated intervention study	*PILastName_FDA*
Dissemination Plan	Do not include	Do not include	Required	*PILastName_Dissemination*
Other Requested Information	Do not include	Do not include	As required by the FOA	*PILastName_OtherHS*

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NIH Page Limits for R01, R03, R15, R21		
Section of Application	**Activity Codes**	**Page Limits (if different from FOA, FOA supersedes)**
Project Summary/Abstract	For all Activity Codes	30 lines of text
Project Narrative	For all Activity Codes	Three sentences
Introduction to Resubmission and Revision Applications	For all Activity Codes	1
Specific Aims	For all Activity Codes	1
Research Strategy	R03, R21	6
	R01, R15	12
Biographical Sketch	For all Activity Codes	5

For all other Activity Codes, please refer to the NIH Page Limits guidance.