Requirements & Instructions: NIH Research Grant Application (R01,U01, R03, R21; R34)

The list below is a list of requirements and might differ from one Funding Opportunity Announcement (FOA) to the next. Itis the responsibility of the PI to READ the FOA , with special reference to Section IV of the FOA, and confirm that all additional rules, regulations and documents that are not listed below, are included in the application.

It is the responsibility of the PI to verify ALL Key Personnel (KP) or project leads are registered with eRA commons and that the affiliation on the KPs is up to date.

PI's must agree with ALL Key Personnel (KP) the % Effort and whether this effort will be paid for or not.

Read the NIH instructions available: http://grants.nih.gov/grants/How-to-Apply-Application-Guide.htm

All NIH submissions will be made at least ***2 Workdays before the NIH application due date*** to avoid any technical problems and to allow for changes

*The **final** documents in **WORD** format must reach RGMO as per agreed submission timeline. Only then the RGMO will be able to verify and check the documents before they PDF'ed and uploaded to the application.*

NB ***Page set-up for all docs :*** *Letter (not A4) , margins=1.27cm, Font=Arial 11. Single spacing. No headers and footers. No page numbers.* Documents will be uploaded as Letter PDF

The following is required to initiate the application

1	**PI eRA Commons ID**, details & Institution affiliation must match details filed at eRA commons	
2	**Descriptive long title of the project**. The title is **limited to 200** characters including letters, numbers, spaces and punctuation	
3	**Project Start** & End dates	
4	**Project Performance Site(s)** - complete template provided for all sites/sub contracts involved	
5	**Profiles of all KP** - complete template provided with **ALL** the required information	
6	**Completed Conflict of Interest** (**COI**) declaration forms for all Key Personnel. Forms are completed before submission (US Government requirement), again when receiving the Notice of Award (NOA) and then annually thereafter or as soon as FCOI occurs. SU KP complete Appendix 1 and OtherKP complete Appendix 2	
7	**NIH Financial Conflict of Interest online training certificate**. The certificate is valid for 3 years. PI's & KP must complete the certificate before the application can be submitted to NIH. This is in addition to the FCOI declarations that must be signed. If you have submitted a certificate, make sure it is still valid. **Link to the training:** https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html	
8	**Letter of Intent (LOI)** to NIH 30 days before submission due date	

Documents (separate documents)

1	**Research Strategy** R21=6 pages; RO1/U01=12 pages R03=6 pages. **Structure:** Significance, Innovation, Approach, Investigators, Environment, Timeline	
2	**Bibliography & References Cited:** (in the same sequence in which they appear in the publication) NO page limit	
3	**Specific Aims** 1 page - ***Include Rigor, Reproducibility and Transparency***	
4	**Project Summary/Abstract** (**30 lines of text or less** targeted to scientists in the field of the research). Do not include confidential information. Include a sentence e.g. "**The overall impact** of this study …."	
5	**Project Narrative** (3 sentences to describe the relevance of this project to public health. Use plain language that can be understood by a general, lay audience = public health relevance statement)	
6	**Equipment List** and describe available equipment at **all performance sites** to execute the research	
7	**Facilities and Resources** available and relevant to execute your plan. Include this for each performance site. Example available from RGMO. Applicants should clearly describe the **relevant** scientific environment that will contribute to the success, indicate access to the proposed patient population, institutional support, physical resources, intellectual rapport. Discuss how the proposed plan will benefit from the unique features e.g. scientific environment, subject populations, collaborative agreements. Describe resources available at all performance sites. How will applicant organisation support the plan e.g. protection of time, space, shared laboratory facilities & equipment, or any other creative ways to improve the environment for establishment and growth of the program.	
8	**Authentication of Key Biological and/or Chemical Resources** - briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. These include but are not limited to cell lines, antibodies, speciality chemicals and other biologicals. Standard laboratory reagents are not expected to vary and do not need to be included in the plan e.g. buffers.	
9	**Resource Sharing Plan** must include https://www.niaid.nih.gov/grants-contracts/resource-sharing-plan and https://grants.nih.gov/policy/sharing.htm	
10	**Data Management and Sharing Plan (DMSP)** must be included. There must also be a line item in the budget and full justification of all the cost associated with the DMSP https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Genomic	
11	**Foreign Justification:** Describe whether the project represents special opportunities e.g. use of unusual talent, resources, equipment. techniques, populations, disease or environmental conditions that are not readily available in the US or that augment exisisting US Resources. Describe whether similar research is being done in the US and whether ther is a need ofr additional research in this area.	
12	**Biosketches for Key Personnel** in ***WORD*** format (max 5 pages per bio). PIs must be registered on eRA Commons. Use the tool SciENcv to create your new format NIH biosketch: http://www.ncbi.nlm.nih.gov/sciencv/	
13	**Multiple PI Leadership Plan** (if applicable)Must address the following elements: 1. Designation of a contact PD/PI who is located at the grantee institution. 2. Roles/areas of responsibility of all of the PD/PIs. 3. Describe governance and organizational structure of leadership team, including communication plans, plans for handling publications and intellectual property, and process for making decisions on scientific direction and procedures for resolving conflicts	
14	**Human Subjects & Clinical Trials information (FORMS G) :** https://grants.nih.gov/policy/humansubjects.htm	
	Is the Project Exempt from Federal regulations? Yes/No https://humansubjects.nih.gov/human-specimens-cell-lines-data https://humansubjects.nih.gov/sites/hs/public_files/exemption_infographic_v4_hs_internet.pdf	
	If you answered "Yes" to the question "Are Human Subjects Involved?"	

	Add a study record for ***each*** proposed study involving human subjects by selecting "Add New Study" or "Add New Delayed Onset Study," as appropriate.	
	Any instructions in your FOA to determine whether you are permitted to include the "**Other Requested Information**" attachment. Content is limited to what is described in your FOA or in these instructions. Study Record is used to collect human subjects study data. Use unique file names for each. All attachments must be PDF files.	
	If you answered "No" to the question "Are Human Subjects Involved?"	
	Does the proposed research involve human specimens and/or data? Applications involving the use of human specimens or data may not be considered to be research involving human subjects, depending on the details of the materials to be used. https://grants.nih.gov/grants/policy/hs/PrivateInfoOrBioSpecimensDecisionChart.pdf If Yes, provide an explanation of why the application does not involve human subjects research.This justification should include: 1) information on who is providing the data/biological specimens and their role in the proposed research; 2) a description of the identifiers that will be associated with the human specimens and data; 3) a list of who has access to subjects' identities; and 4) information about the manner in which the privacy of research participants and confidentiality of data will be protected.	
	Clinical Trial Questionnaire: If you answered "Yes" to all the questions in the Clinical Trial Questionnaire, this study meets the definition of a clinical trial. https://grants.nih.gov/ct-decision/index.htm	
	1 Does the study involve human participants? **Yes/No**	
	2 Are the participants prospectively assigned to an intervention? **Yes/No**	
	3 Is the study designed to evaluate the effect of the intervention on the participants? **Yes/No**	
	4 Is the effect that will be evaluated a health-related biomedical or behavioral out-come? **Yes/No**	
	Provide the ClinicalTrials.gov identifier if applicable	
	Study Population Characteristics. (Not required for Expemtion 4 or if study does not include human subjects)	
	1) Conditions or Focus of Study: Identify the name(s) of the disease(s) or condition(s) you are studying, or the focus of the study. If available, use appropriate descriptors from NLM's Medical Subject Headings (MeSH) https://www.nlm.nih.gov/mesh/ so the application can be categorized. Include an entry for each condition.	
	2) Eligibility Criteria: List the study's inclusion and exclusion criteria. To provide a bulleted list, use a dash (or other character) followed by a space ("- ") at the start of each bullet. Be sure to check the formatting in the assembled application image. Further explanation or justification should be included in the ***Recruitment and Retention plan.*** Your text entry is limited to 15,000 characters.	
	3) Age Limits: ***Minimum Age*** - Enter the numerical value for the minimum age a potential participant can be to be eligible for the study. Provide the relevant units of time (i.e., years, months, weeks, days, hours, or minutes). If there is no lower limit or no lower limit is known, enter "N/A (No Limit)" and do not enter a unit of time. ***Maximum Age:*** Enter the numerical value for the maximum age a potential participant can be to be eligible for the study. Provide the relevant units of time (i.e., years, months, weeks, days, hours, or minutes). If there is no upper limit or no upper limit is known, enter "N/A (No Limit)" and do not enter a unit of time.	
	Inclusion Enrolment Report - In the Humans subject from, click to expand the form and complete	
	Attachments:	
	1. **Inclusion of Individuals Across Lifespan**	
	2. **Inclusion of Women, Minorities & Children**	
	3. **Recruitment & Retention Plan**	
	4. **Study Timeline**	
	5. **Protection of Human Subjects**	
	6. **Data Safety Monitoring Plan**	
	7. **Overall structure of the study team**	
	8. **Statistical Power and Design (Required of Clinical Trials only)**	
	9. **Dissemination Plan (Required for Clinical Trials only)**	
	10. **Other** Clinical Trial-related Attachments. Required if specified in the FOA	
15	**Vertebrate Animals (if Applicable) - euthanasia method required.** Describe how institution will only participate in IACUC approved animal research. Description of procedures, Justifications, Minimization of pain and distress	
16	**Letters of Support** (**with index**) must contain specific information re support required for the study e.g. letter of supporting laboratories and collaborators. If co-funding or in-kind support is planned from non-NIH sources, e.g. drug supplier, outline the details of the commitment type, amount and source, signed by a business official on an organizational letterhead. You can also request LoS from all KP	
17	All additional documents as per special instructions e.g. "**Introduction**" for Resubmissions and Revision Applications	
18	**Allowable Appendices** - NOT-OD-18-126 https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-126.html **For all other applications**: Blank informed consent/assent forms; Blank surveys, questionnaires, and/or data collection instruments; Other items only if they are specified in the FOA as allowable	
Budget		
1	**Budget** - All KP must be on budget with % effort even if no $ paid.	
2	**Budget Justifications for all periods** - Include the roles of all staff. Be specific.	
Subcontract Documents **NB These documents must reach GMO as *per agreed timelime***		
1	**Biosketches for Key Personnel in *WORD* format** (max 5 pages per bio). All PI's must be registered on eRA Commons. To prepare your biosketch use the tool (SciENcv) : http://www.ncbi.nlm.nih.gov/sciencv/	
2	**Profile of Key Personnel** - Complete template with **ALL** the required information	
3	**Project and performance site location** - Complete template	
4	Subcontract collaborator **Budget** for all periods of the application	
5	Budget **Justifications** for all periods	
6	**Letters of support** form the other PI's and the Departmental Head of the collaborator.	
7	**Institutional Contractual Agreement** containing the following: PI name, Institutional DUNS number Budget Amount, Period of Award, Scope of work (what will the collaborator do). This is additional to the letters of support. - See template	
8	**Completed Checklist Form Page**	
9	**Conflict of Interest forms** for non-SU collaborators and consultants - Complete Appendix 2	