Requirements & Instructions: NIH K43 Career Development

The list below is a list of requirements and might differ from one Funding Opportunity Announcement (FOA) to the next. It is 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 PI's or project leads are registered with eRA commons and that the affiliation on the PI's 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. Timeline must be signed by the PI.*

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. Headings can be Arial 12 or 13 , Bold All Caps and left aligned.* Documents will be uploaded as Letter PDF's.

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 - Please see the FOA for earlierst start date.	
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 Financial Conflict of Interest** (**FCOI**) 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 Other KP complete Appendix 2	
7	**Letter of Intent (LOI)** to NIH 30 days before submission due date. See FOA if it is required.	
8	Signed Project timeline	

Documents (separate documents)		
Candidate Information - Max 6 Pages		
1	**Candidate Background**	
2	**Career Goals**	
3	**Candidate Plan for Career Development**	
	Training in the Responsible Conduct of Research	

Environment and Insitutional Commitment to candidate		
1	**Description of Institutional Environment - 1 Page**	
2	**Institutional Commitment to Candidates Research Career Development - 2 Pages as per new FOA**	

Research Plan Section		
1	**Research Strategy** 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** 1)Sharing of Model Organisms https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy 2)Sharing of Unique Research Tools and Resources https://sharing.nih.gov/other-sharing-policies/research-tools-policy 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)** 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	
Biosketches of Mentors and Co-Mentors		
	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/	
	Other Support for PI, mentors and co-mentors NB See new Format	

Human Subjects Sections - Make sure whether clincial trials are allowed or not allowed		
1	**Human Subjects & Clinical Trials information (FORMS E from 25 Jan 2018):** https://humansubjects.nih.gov/ and https://humansubjects.nih.gov/sites/hs/pdf/HS-Scenarios-for-Forms-E.pdf	
2	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	
3	If you answered "Yes" to the question "Are Human Subjects Involved?"	

	3,1 **Add a study record** for ***each*** proposed study involving human subjects by selecting "Add New Study" or "Add New Delayed Onset Study," as appropriate.	
	3,2 **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.	
	3,3 For any study that you include as a **delayed onset study** in this section, do not fill out a full study record, as the delayed onset record is sufficient. Delayed onset **does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).** If you have multiple delayed onset studies, you can include them together in a single Delayed Onset Study. Study Title: maximum of 600 characters. Enter a brief, unique title that describes the study the participants will be involved in. Each study within your application must have a unique Study Title. The first 150 characters will display in the application image bookmarks.If you are including multiple delayed onset studies in one delayed onset study entry, you may enter "Multiple Delayed Onset Studies" as the title of this record. **Anticipated Clinical Trial? Read your FOA carefully to determine whether clinical trials are allowed in your application.** All delayed onset studies must provide a justification explaining why human subjects study information is not available at the time of application. this justification must also include the **dissemination plan.** If NIH's Single Institutional Review Board (sIRB) policy will apply to your study, this justification must also include information regarding how the study will comply with the policy and state that you will provide a single IRB plan prior to initiating any multi-site study.	
4	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.	
5	**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	
	5,1 **Study Population Characteristics.** (Not required for Expemtion 4 or if study does not include human subjects)	
	5,2 **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.	
	5,3 **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.	
	5,4 **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.	
	5,5 Inclusion Enrolment Report - In the Humans subject from, **click to expand** the form and complete	
6	**Attachments:**	
	Inclusion of Individuals Across the Lifespan	
	Inclusion of Women & Minorities	
	Recruitment & Retention Plan	
	Study Timeline	
	Single IRB Plan for multiple research sites	
	Inclusion Enrollment Report	
	Protection of Human Subjects	
	Data Safety Monitoring Plan: Required for Clinical Trial & Optional for Human Subjects study	
	Overall structure of the study team	
	Statistical Design and Power: Required for Clinical Trial	
	Dissemination Plan: Required for Clinical Trial	
	Other Clinical Trial-related Attachments. Required if specified in the FOA	
7	**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	

Statements and Letters of Support		
1	Plans and Statements of Mentor and Co-Mentor (s) - Max **6** pages	
2	Letters of Support from Collaborators, Contributors and Consultants - Max **6** Pages	

Other		
1	All additional documents as per special instructions e.g. "**Introduction**" for Resubmissions and Revision Applications	
2	**In most cases appendices are not allowable. 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	
3	**Reference Letters:** https://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/reference-letters.htm	

Budget		
1	**Budget** - All KP must be on budget with % effort even if no $ paid.	
2	**Very Strong Budget Justifications for all periods** - Include the roles of all staff. Be specific.	