Requirements & Instructions: NIH Research Training Grant Application D43 or D71

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 GMO **as per agreed submission timeline**. Only then the GMO 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 & all KP: 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 - See earliest start date of the FOA	
4	**Project Performance Site(s)** - complete template provided for all sites/sub contracts involvec	
5	**Profiles of all KP** - complete template provided with **ALL** the required information	
6	**Completed Conflict of Interest** (**COI**) 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 & Consultants 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 and to the GMO 6 weeks before the submission date	

Documents (separate documents)

1	**Training Program Plan:** 25 pages for D43. Read the FOA for specific instructions. Background, Program Administration; Program Faculty; Proposed Training; Program Evaluation; Trainee Candidates; Institutional Environment and Commitment; Qualifications of Trainee Candidates and Admissions and Completion Records. Note that Data Tables may be referred to or summarized in this section; however, the actual tables are not to be included in this attachment	
2	**Bibliography & References Cited:** NO page limit. Include all references as they appear in the Training program Plan and in the Human subjects section. Cite references supporting the need, rationale, and approach. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant, and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal – In Process." NIH maintains a list of such journals. Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference. The references should be limited to relevant and current literature. It is important to be concise and to select only those literature references pertinent to the proposed research.	
3	**Project Summary/Abstract** (max **30 lines of text** targeted to scientists in the field) Summarize the objectives, rationale and design of the research training program. Provide information regarding the research areas and scientific disciplines.Include a brief description of the level(s) (i.e., undergraduate, predoctoral, postdoctoral, faculty) and duration of the proposed training, and the projected number of participating trainees. Do not include confidential information. Include a sentence e.g. "**The overall impact** of this study .." A summary that exceeds the 30-line limit will be flagged as an error by the Agency	
4	**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. Describe how, in the short or long term, the research would contribute to fundamental knowledge	
5	**Equipment List** and describe available equipment at **all performance sites** to execute the research. If appropriate, identify the equipment's location and pertinent capabilities.	
6	**Facilities and Resources** available and relevant to execute your plan. Include this for each performance site. Example available from GMO. 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. Indicate how the applicant organization will support the program, financial or otherwise. This could include, for example, supplementation of stipends, shared space and/or laboratory facilities and equipment, funds for curriculum development, support for student activities, release time for the PD/PI and participating faculty (e.g., protected time for mentoring), support for additional trainees in the program, or any other creative ways to improve the environment for the establishment and growth of the research training program.	
7	**Training Advisory Committee if required by FOA.** If required, attach under "Other attachments"	
8	**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. Attach this document to the ***Other Attachments*** tab.	

9	**Biosketches for Key Personnel** in ***WORD*** format (max 5 pages per bio). PIs and all KP's must be registered on eRA Commons. Use the tool SciENcv to create your NIH biosketch: http://www.ncbi.nlm.nih.gov/sciencv/ senior/key personnel are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested. Consultants should be included in this "Senior/Key Person Profile (Expanded)" Form if they meet this definition. See also the Biosketch instructions document. For **participating faculty**, combine all participating faculty biosketches into a single PDF and attach to "Participating Faculty" tab. **but read the FOA for specific instructions**.	
10	**Multiple PI Leadership Plan** (if applicable) , all such individuals must be assigned the PD/PI role (and not co-PI). The emphasis in a training grant's Multiple PD/PI Leadership Plan should be on how multiple PD/PIs will benefit the program and the trainees. 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. The roles and administrative, technical, and other responsibilities for the training program should be delineated for the PD/PIs and other collaborators.	
11	**Training in the responsible conduct of Research:** 3 Pages. https://grants.nih.gov/grants/policy/nihgps/HTML5/section_11/11.3.3_application_requirements_and_receipt_dates.htm#Training3 **Include:** Format of instruction; Subject Matter; Faculty Participation; Duration of Instruction; Frequency of Instruction	
12	**Plan for instruction in Methods for enhancing reproducibility.** 3 Pages. Describe how trainees will be instructed in principles important for enhancing research reproducibility. These principles include, at a minimum, the following: evaluation of the foundational research underlying a project (i.e., the rigor of the prior research); rigorous experimental design and data interpretation; consideration of relevant biological variables such as sex; authentication of key biological and/or chemical resources; and transparency in reporting.Not required for D71, unless otherwise noted in the FOA. Applications lacking a Plan for Instruction in Methods for Enhancing Reproducibility will not be reviewed.	
13	**Data Tables:** The instructions for the required Data Tables (1-8) are located on the NIH's Data Tables page: https://grants.nih.gov/grants/forms/data-tables.htm **.** Please read the "Introduction to Data Tables" before beginning to prepare your data tables. The Introduction to Data Tables includes important definitions that should be used consistently both in the "Data Tables" attachment of your application and in all other parts of the application. The Data Tables must be included in the "Data Tables" attachment to avoid being counted against the page limits of other attachments. Read the FOA to ensure the correct Tables are completed.	
14	**Human Subjects & Clinical Trials information (FORMS G) :**The designation of your FOA will determine how to use these instructions, and subsequently, how to fill out this form. All applicants must use the PHS Human Subjects and Clinical Trials Information form regardless of your answer to the question "Are human subjects involved?" If you are proposing any human subject studies in your application, then at the time of application, you must use the PHS Human Subjects and Clinical Trials Information form to submit***delayed onset studies***. Do not fill in Study Records. Follow the instructions in your FOA. Post award, you will submit Study Records if applicable.Generally, for any study that you include as a delayed onset study in this section, you will provide a study title, indicate whether the study is anticipated to include a clinical trial, and include a justification attachment. Since by definition, information for a delayed onset study is not available at the time of application, you will not be given the option to complete a full Study Record for a delayed onset study. For delayed onset studies, the Delayed Onset Study Record is sufficient.Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). Refer to the NIH Glossary definition of Delayed Onset Study and Delayed Start. If you anticipate multiple delayed onset studies, you can include them together in a single Delayed Onset document.	
	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	
14	**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	
15	**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. **Combine all Letters of Support into a single PDF file**. Make sure all letters are in LETTER format.	
16	**Consortium/Contractual Arrangements** explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization. Contractual documents must contain a signature of the authorized organization representative and a statement e.g.: *The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency's consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.* See the NIH policy statement on consortium agreements: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15.1_general.htmTo be included for each institution : 1) Signed Institutional contractual agreement (Template available) 2) Scope of Work 3) NIH Checklist (PDF before combining). Combine all documents in one LETTER format PDF	
17	All additional documents as per special instructions e.g. '**Introduction**" for Resubmissions, Revision, Renewal Applications	
18	**Only Allowable Appendices** - NOT-OD-18-126 https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-126.html 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. Use filenames for attachments that are descriptive of the content.**Applications will be withdrawn and not reviewed if they do not follow the appendix requirements in these instructions or in your FOA.**	
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 timeline*		
1	**Biosketches for Key Personnel As described above**	
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 templat	
8	**Completed Checklist Form Page**	
9	**Financial Conflict of Interest forms** - Complete Appendix 2	