Requirements: NIH Research Grant Application (R01, R03, R21)

The list below is a general list and requirements might differ from one Funding Opportunity Announcement (FOA) to the next. It is the responsibility of the PI to study 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

NB ***Page set-up*** *for all docs: Letter (not A4) , margins=1.27cm, Font=Arial 11. No headers and footers. No page numbers*

*The **final** documents in **WORD** format must reach RGMO 7 workdays before submission date. Only then the RGMO will be able to verify and check the documents before the application package is submitted.*

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	
5	Profiles of 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 OtherKP complete Appendix 2	
7	Internal Letter of Intent (ILOI) & preliminary specific aims	
8	Letter of Intent (LOI) to NIH 30 days before submission due date	

Documents (separate documents)

1	**Research Strategy** R21=6 pages; RO1=12 pages R03=6 pages. **Structure:** Significance, Innovation, Approach, Timeline	
2	**Bibliography & References Cited:** Each reference must include the names of all authors (in the same sequence in which they appear in the publication)	
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 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 1. Data sharing plan 2. Sharing model organisms 3. Genomic Wide Association Studies and Genomic data sharing	
10	**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.	
11	**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/	
12	**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	
13	If **Human Subjects** are applicable (all clinical research) include the following documents:	
	a. Protection of Human Subjects	

	b. Data safety monitoring plan for clinical trials	
	c. Inclusion of Women & Minorities	
	d. Inclusion of Children	
	e. Inclusion Enrolment Report	
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.	
16	**Budget** - All KP must be on budget with % effort even if no $ paid.	
17	**Budget Justifications** - Include the roles of all staff. Be specific.	
18	All additional documents as per special instructions e.g. "**Introduction**" for Resubmissions and Revision Applications	
19	Allowable Appendices - NOT-OD-17-035 - For applications proposing **clinical trials:** Clinical trial protocols &Investigator's brochure from an Investigational New Drug Applications. **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	
Subcontract Documents NB These documents must reach RGMO *7 workdays* before the internal submission date		
1	**Biosketches for Key Personnel in *WORD* format** (max 5 pages per bio). All KP 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 must relate to the personal statement of KP). This is additional to the letters of support. - See template	
8	**Completed Face Page**	
9	**Completed Checklist Form Page**	
10	**Financial Conflict of Interest forms** - Complete Appendix 2	