NIH PROPOSAL DOCUMENTS
PI GUIDE

The checklist below is to assist the principal investigator (PI) with preparing an NIH proposal using either ASSIST or the Forms D application package (pdf). This is *not* a required form, nor is this list all-inclusive. Please refer to your solicitation/funding opportunity for specific proposal requirements. Populate your proposal using the NIH Research Instructions for NIH and Other PHS Agencies for the Forms D Series. This is also known as the SF424 Application Guide. Be sure to check the NIH website for the most current version. Follow all page limits.

Prior to December 2017, the grants.gov pdf package can be downloaded by the PI through the funding opportunity announcement. All proposal components are populated by the PI and attached to the main pdf package. By the internal deadline, this completed pdf package is sent to the Sponsored Programs Office (SPO) analyst for review and submission to NIH. Note, with the current grants.gov pdf packages there is no way to ensure an initial error-free submission. A grants.gov package submitted with errors will be "bounced-back" to SPO and the PI for corrections that must be completed and re-submitted to the sponsor prior to the sponsor deadline. SPO strongly recommends that all PI's familiarize themselves with NIH ASSIST and prepare proposals for submission through this system. ASSIST allows for ease of collaborative preparation and pre-submission validation to ensure a successful submission through grants.gov.

Required Document	Document Requirements
ERA Commons ID	– To obtain a user ID contact the Sponsored Programs Office at 487-2226
SF424 Form	– Must be Forms D – Complete the SF424 Form; all yellow fields are required – Cover Letter, not required, also see PHS Assignment Request Form, below
PHS 398	– Complete Cover Page
Other Project Information	– Complete the required questions – Include the Project Summary/Abstract, Project Narrative, Bibliography & References Cited, Facilities & Other Resources, Equipment (see individual sections below for details)
Project/Performance Site Location(s)	– Include Michigan Tech's project/performance site location **If off-campus, must specify location of work – Include the project/performance site location for each subaward
Senior/Key Persons Profile	– Complete a profile for each PI, co-investigator, consultant, subawardee, and senior personnel involved in your project – eRA Commons ID is required for PI
Budget Forms (Modular or R&R)	– Refer to the funding opportunity to determine the budget to use
Summary/Abstract	– Limited to 30 lines of text
Project Narrative	– Limited to no more than 2 or 3 sentences
Bibliography & References Cited	– All author names are listed and fully written out (i.e. no "et al")
Facilities & Other Resources	– No special form is required – There is no page limit

	− The funding opportunity may ask you to include additional information
Equipment	− Include a document if applicable
Specific Aims	− This document is required unless otherwise stated in the funding opportunity − Follow the [page limits](#)
Research Strategy	− Follow the [page limits](#) for your funding opportunity − Include the Significance, Innovation and Approach *in the required order*
Biographical Sketch	− Follow the specific NIH guidelines for each sub-section and use the [current form;](#) or use the template provided by Michigan Tech's Research Development Office − PD/PI must include his/her eRA Commons User name − Include the Consultant(s) biographical sketch in current NIH format − This document is limited to 5 pages − You may provide a URL to a full list of your published work. NIH recommends My Bibliography − Refer to your funding opportunity. It may ask you for additional information in this document
Budget Forms	− Modular – budgets requesting $250,000 or less <u>per year for direct costs</u>. For all modular budgets, request total direct costs in modules of $25,000 − R&R – budget requesting $250,001 - $300,000 per year for direct costs − Refer to the funding opportunity. It may include additional instructions when completing these forms
Subaward/Consortium Budget	− Separate budgets are required for each subawardee/consortium organization, if submitting an R&R budget for Michigan Tech − Use the budget extracted from your current application. Do not use old budgets, they will error upon submission − When including subawards, Michigan Tech SPO strongly suggests utilizing ASSIST for proposal preparation and submission − Name the file using the first ten letters of the consortium organization's name − Files must be in pdf format
Budget Justification	− Follow the NIH guidelines and the funding opportunity. You may be required to include a Personnel Justification or a detailed Budget Justification − Consortium Justification is requested for each Subawardee − The funding opportunity may require additional information to be added to this document
PHS Assignment Request Form	− This form is optional if you don't want your proposal to go to a specific area − However, if you include a cover letter that indicates requested funding or review areas, this form is required

Human Subjects	− Complete this section if you answered "yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form
	− Follow the instructions in the SF424 Application Guide and include the following documents:
	  • Protection of Human Subjects
	  • Data Safety Monitoring Plan (if Clinical Trial)
	  • Inclusion of Women and Minorities
	  • Inclusion of Children
	− PHS Inclusion Enrollment Form (see separate instructions, below)

Vertebrate Animals	– Complete this section if you answered "yes" to the question "Are Vertebrate Animals Used?" on the R&R Other Project Information form – Follow the instructions in the SF424 Application Guide
Select Agent Research	– Complete this section if this project involves hazardous biological agents or toxins
Consortium/Contractual Arrangements	– Include this document in this section if you have a subaward/contractual arrangement – See the SF424 Application Guide for required verbiage
Letters of Support	– Attach all appropriate letters of support necessary to demonstrate the support of consortium participants and collaborators such as senior key personnel and other significant contributors included in the grant application – Consultant letters should include a rate/charge for consulting and level of effort/number of hours per year anticipated – Letters should be combined into one single pdf
Resource Sharing Plan	– Required if requesting $500,000 or more in direct costs **or** if a model organism is anticipated to be developed, **or** if genomic data will be generated
Appendix	– Do not use this section to circumvent page limits – A maximum of 10 PDF attachments is allowed in the appendix – Follow the SF424 Application Guide as to what kind of attachments are allowable
PHS Inclusion Enrollment Report	– Complete the form when Human Subjects are involved