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NIH Single Project, Competitive Grant Application Checklist R01/R03/R21/R24/R33/R34/R35/RC2/RF1/R50/R61/ DP1/DP2/U01/U24/UG1/UG3/UH3/UM1

rev. 9/12/23

GCO ASC Checklist

NIH Annotated Form Set

NIH Sample Applications

NIH SF424 Guide

GCO is highlighting particular fields & sections that are prone to error. This checklist does NOT comprise the entirety of the SF424 application. Please consult the NIH SF424 Guide plus additional Mount Sinai resources below.

Please use this checklist with GCO's Overall Application Submission Checklist.

Please read the NIH SF424 Guide for instructions.

Please review the NIH annotated from set for quick reference.

Notice of Funding Opportunity (NOFO) instructions always supersede these instructions.

Principal Investigator(s):

Proposal Title:

NOFO #:

Overall

All sections must conform to these instructions.

The NIH has very specific attachment formatting requirements. Failure to follow these requirements may lead to application errors upon submission or withdrawal of your application from funding consideration.

- [] <u>Citations</u>: Remember to comply with our public access policy by including the PMC reference number (PMCID) when citing applicable papers that you author or that arise from your NIH-funded research.
- [] <u>Filenames</u>: Save all document attachments with descriptive filenames of 50 characters or less (including spaces).
- [] Use unique filenames for all attachments in an application (or within a component of a multi-project application).
- [] Use any of the following characters: A-Z, a-z, 0-9, underscore, hyphen, space, period, parenthesis, curly braces, square brackets, tile, exclamation point, comma, semi colon, apostrophe, at sign, number sign, dollar sign, percent sign, plus sign, and equal sign.
- [] If including spaces, use one space (not two or more) between words or characters and do not begin the filename with a space or include a space immediately before the .pdf extension.
- [] Avoid the use of ampersand (&) since it requires special formatting (i.e., &).
 When saving the individual files this naming convention can be used: Last Name_Application Section_Mechanism_Date. Example: Jones_Abstract_R01_100522
- [] <u>File Size</u>: Ensure file size is greater than 0 bytes the NIH does accept a 0 byte attachment. Keep attachment file size to 100 MB or less.
- [] <u>Headers and Footers</u>: Do not include headers or footers in any of your attachments. Headers, footers, page numbers, bookmarks, and a table of contents are added when the grant application is assembled upon submission. *Headings (e.g., Significance, Innovation) within the text of your attachments improve readability and are encouraged.*
- [] <u>Images</u>: Digital images of material such as electron micrographs or gels must only be included within the page limits of the Research Strategy. The maximum size of images to be included should be approximately 1200 x 1500 pixels using 256 colors. Figures must be readable as printed on an 8.5" x 11" page at normal (100%) scale. Investigators must use image compression such as JPEG or PNG.
- [] <u>Margins</u>: Provide at least one-half inch margins (½") top, bottom, left, and right for all pages. No applicant-supplied information can appear in the margins.
- [] Language and Style: Use English. (See 45 CFR § 75.111 English language)

45 CFR 75.111 link

Avoid jargon. Spell out acronyms the first time they are used in each application section/attachment and note the appropriate abbreviation in parentheses. The abbreviation may be used in the section/attachment thereafter.

- [] <u>Paper Size</u>: Use paper (page) size no larger than standard letter paper size (8 ¹/₂" x 11").
- [] <u>Security Features:</u> Do not encrypt or password protect your documents.

Using these features to protect your documents prevents the NIH from opening and processing them.

[] Single vs. Multi-column Page Format

A single-column page format easily adapts to various screen sizes and is highly encouraged.

Multi-column formats, especially for information spanning multiple pages, can be problematic for online review.

- [] <u>Video</u>: Videos cannot be imbedded in an application, but are accepted under limited circumstances as post-submission Material. See these notices. • NOT-OD-12-141 Page Limits & Lines of Text Limits
- Page Limits

NOT-OD-20-061

Table of Page Limits 0

See Research Plan section of this checklist.

Font (size, color, type density) and Line Spacing [] Font: General

Must be 11 points or larger.

Smaller text in figures, graphs, diagrams and charts is acceptable, as long as it is legible when the page is viewed at 100%. [] Font: Recommended

NIH recommends Arial, Georgia, Helvetica, Palatino Linotype fonts, although other fonts (both serif and non-serif) are acceptable if they meet the requirements of font size, type density, line spacing, and text color.

- [] <u>Type density</u>: Must be no more than 15 characters per linear inch (including characters and spaces).
- [] Line spacing: Must be no more than six lines per vertical inch.
- [] Text color: No restriction. Though not required, black or other high-contrast text colors are recommended since they print well and are legible to the largest audience.

Hypertext, Hyperlinks, and URLs

[] Do not use hypertext, hyperlinks, and URLs unless specifically noted in the NOFO and/or form field instructions. It is highly unusual for a funding opportunity to allow links in Specific Aims, Research Strategy, and NOT-20-174 page-limited attachments.

PDFs

[] <u>Font</u> : Checking after PDF conversion

Some PDF conversion software reduces font size. It is important to confirm that the final PDF document complies with the fc requirements.

- [] <u>Combining Information into a Single Attachment</u>: Ensure all information is directly visible in your PDF. If you need to combine information from different sources into a single document prior to uploading, do not use "bundling or "portfolio" features which combine multiple documents into a single file by providing links to the individual files.
- [] Electronic Signature

Unflattened electronic signatures on PDF attachments within your application are not allowed.

[] To adhere to policies requiring electronic signatures on PDF attachments (e.g., electronically-signed other support format pages), you can electronically sign the document and then "flatten" the PDF. See "Flattening PDF" tab for instructions.

Documents with signatures (e.g., letters of support) can be printed, signed, scanned and attached in PDF format. GCO's Guidance document on signing Other Support pages provides instructions on electronic signatures. •GCO Guidance Please use the instructions in the GCO Guidance document for signing documents

- [] Flattened PDFs: Many simple PDFs are already flattened. See tab for further instructions.
- [] Marking Up Attachments: Do not mark-up your PDF documents with comments, sticky notes, or other features that are added on top of your PDF document content. This information may not be retained in your final application image.
- [] Scanning: Avoid scanning text documents to produce the required PDFs. It is best to produce documents using your word-processing software and then convert the documents to PDF. Scanning paper documents may hamper automated processing of your application for agency analysis and reporting. The NIH recognizes that sometimes scanning is necessary, esp. when including letters of support or other signed documents on business letterhead.
- [] <u>Security</u>: Disable all security features in your PDF documents.
- [] <u>InfoEd</u>: Check and fix technical errors before submitting to the GCO. InfoEd XML Validation Instructions Use the "XML Validation" and the "NIH Commons Validation Submit" features to check early for any technical errors which can delay your application from being accepted and can prevent it from being rejected by the funding agency.

	Section of Application	Format Restriction	s Reso	urces	
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	4b. Agency Identifier Number				,
LJ	Are you applying for a Notice of Spe	acial Interest (NOSI)? Enter		-71-###) in this fi	eld
٢1	8. Is this application being submitte				GCO Guidance
[]	11. Descriptive Title of Applicant's P	-	200 characters, incl	uding spaces and	
	This is a Set Up tab question you an			0	
[]	21. Cover Letter Attachment (optio	nal)			
[]	Do not use the cover letter to comm	nunicate application assigr	ment preferences. The	e Assignment Rec	quest Form is provided
	for that purpose.				
[]	A cover letter must not be included	with post-award submission	ons, such as administra	tive supplement	s, change of grantee
	institution, or successor-in-interest				
	The letter should contain any of the	-	applicable:		
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	Required Agency Approval Docume			0	•
	If there is any required agency appr			hat is attached.	
	Example: Approval for applications	that request \$500,000 or r	nore. It is recommend	ed that you inclu	de the official
	communication from an NIH official	as part of your cover lette	r attachment.		
[]	Videos: When intending to submit	a video as part of the appli	cation, include informa	ation about the ir	ntent to submit it.
	If this is not done, the video will not	•			Application Material
[]	Proposed studies that will generate	-	human genomic data a	as detailed in the	NIH Genomic Data
	Sharing Policy: Include such a stater				enomic Data Sharing
[]	Proposed studies that will involve h				
	Human Subjects are involved and/o				Fetal Tissue Research
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Οτ	her Project Info		Keso	urces	
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[]	6. Does this project involve activitie	s outside of the United Sta	tes	•GCO Foreign C	omponents Guidance
	or partnerships with international c			> IV. Competitiv	ve Grant Applications
[]	If yes, please include "foreign justifi		e link for complete info	ormation.	
	Please check your letters of support			-	
[]	7. Project Summary/ Abstract	30 lines maximum	 Project Summary vs 		
	8. Project Narrative	3 sentences maximum			

- [] 9. Bibliography & References Cited No page limit
- [] Reminder: Active hyperlinks are not allowed. See "Print to Image" for instructions on deactivating hyperlinks. Please review SF424 Instructions and/or excerpt in Bibliography & References Cited" tab.
- I 10. Facilities & Resources Required ORS Standardized Language
 Include the facilities for ISMMS and the subaward(s). Combine those documents and include in one PDF.
 Please put the applicable institution at the beginning of the section describing their facilities/resources.
- [] 11. Equipment Required If your application does not utilize any existing major equipment, please provide an Equipment document stating such.
- []
 12. Other Attachments

 Attach a file to provide additional information only in accordance with the NOFO and/or agency specific instructions.

Partial Other Project Info questions are listed above. Please review the SF424 Guide for instructions on all the questions.

Performance Sites	Resource	S	
	NIH	Research	GCO
		Roadmap	

- [] Performance Sites: Report the primary location and any other locations at which the project will be performed.
- [] Include any VA facilities and foreign sites. GCO Foreign Components Guidance > IV. Competitive Grant Applications
- Please check your letters of support and facilities and resources page(s) for a site for performance site information.
 See GCO link for foreign components instructions.

Re	search Plan		Resources	S	
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				Roadmap (RR)	
Pag	e Limits: If page limits in the Notice o	of Funding Opportunity (NC	OFO) differ from info belov	v, follow the N	IOFO.
	earch Plan Section				
٢١	1. Introduction	1 page max For	resubmission or revision a	oplications only	У
[]	2. Specific Aims	1 page max			
	3. Research Strategy	•	NIH Rigor and Reproducib	ility Site	
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	R03/R21/R35 - 6 page max DP1: 5 pages max; DP2: 10 pages m	- N			
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r 1	8. Consortium / Contractual	If applicable			baward Guidance
	Arrangements (Subawards)			• <u>dco 3u</u>	
٢ı	9. Letters of Support				
	Combine all letters of support into a	single PDF file and attach th	nis information here. Do no	t place these I	etters in the Appe
	Reminder: Use of hyperlinks and UR	-		·	
	Reminder: Make sure letters of supp				
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[]	Reminder - Do not overstuff. Applica	ations may be rejected if inf	ormation that does not fol	low the instruc	ctions are included
[]	Please see SF 424 or Letters of Suppo	ort tab for complete instruc	tions		
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[] [] <u>App</u> []		P): that will ge	● <u>NIH R</u> e	ab or NIH SF 424		
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	Use only if you wish to communicate speci			-	•	
	There is no requirement that all fields or all		•		•	single entry or to
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-	Budget Tab	[] Biosketch	
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•GCO Foreign Components Guidance

See Foreign Component tab and GCO Guidance link for complete information. Reminder - Review NIH definition, which is on the Foreign Component tab and in link. This definition is very broadle

Links to important NIH training and other resources are included in the cover sheet of the InfoEd instructions. [] Reminder - Review NIH definitions and take the NIH training. NIH's definition of clinical trials is very broad!

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> IV. Competitive Grant Applications

Upload Subaward Justification in "Consortium Justification." If modules are different

each year, justify in "Additional Narrative Justification." Add DMSP justification (even if none) in the "Additional Narrative Justification."

 <u>NIH Supplemental instructions</u> InfoEd Instructions

Bibliography & References Cited

9. Bibliography & References Cited

Who must complete the "Bibliography & References Cited" attachment:

The "Bibliography & References Cited" attachment is required unless otherwise noted in the FOA.

Format:

Attach this information as a PDF file. See the <u>Format Attachments</u> page. Use of hyperlinks and URLs in this section is not allowed unless specified in the funding opportunity announcement.

Content:

See the following instructions for which references to include in the "Bibliography and References Cited" attachment.

Additional Instructions for Research:

The "Bibliography & References Cited" attachment should include any references cited in <u>G.400 - PHS 398 Research Plan Form</u> and in the <u>G.500 - PHS Human Subjects</u> and Clinical Trials Information form.

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 <u>list of such journals</u>.

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.

Active hyperlinks in this section are not allowed. The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

You are allowed to cite interim research products. Note: interim research products have specific citation requirements. See related <u>Frequently Asked Questions</u> for more information.

Flattening PDFs

6. When submitting PDFs to eRA Commons, particularly for RPPRs and Just-in-Time, I am getting an error telling me to "ensure all files are flattened PDFs." What does "flattening" a PDF mean and how do you do it?

A PDF that has fillable fields, electronic signatures, text boxes or images inserted, becomes layered with each of these elements representing a layer. Flattening a PDF merges these separate elements into one flat layer. There are a number of methods to flatten a PDF, the easiest of which is to print it as a PDF.

To do this, go to File>Print, select the printer option from the menu that has a PDF option. Depending on the software available to you, the specific option may vary from the one shown below. Click the Print button and name the file.



Figure 1: A print dialog box with the Printer field set to Adobe PDF

In this process, you are exporting the layered PDF to the printer and saving it as a simple (flattened) PDF.

NIH Foreign Components Definition



Please refer to this GCO Guidance document for more information.

<u>GCO Foreign Components Guidance</u> > IV. Competitive Grant Applications

Letters of Support

9. Letters of Support

Content:

Attach a file with all letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application.

Letters should stipulate expectations for co-authorship, and whether cell lines, samples, or other resources promised in the letter are freely available to other investigators in the scientific community or will be provided to the particular investigators only.

For consultants, letters should include rate/charge for consulting services and level of effort / number of hours per budget period anticipated. In addition, letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service.

Material Transfer Agreements may be included in this section.

Letters must focus on the topics listed above and not contain data / figures / tables / graphs, preliminary data, methods, background and significance details that are expected to be found in Research Strategy section of the application. Letters of Support serve to describe terms of a collaboration or consultation and also are not de facto letters of reference from persons not actively participating in the project. Applications with letters containing such excess information may be withdrawn from the review process.

Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project.

Do not include consultant biographical sketches in the "Letters of Support" attachment, as consultant biosketches should be in the "Biographical Sketch" section.

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Printing to Image deactivates hyperlinks. Please follow these instructions.

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Step 2

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Recommendation: Print at minimum of 300 dpi. Lower than 300 dpi produces blurry images.

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Resource Sharing Plan

10. Resource Sharing Plan(s)

• Note: Effective for due dates on or after January 25, 2023, Data Management and Sharing (DMS) Plans are now included in Section 11. Other Plan(s). Plans for Genomic Data Sharing should be provided as part of the Data Management and Sharing Plan.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Sharing Model Organisms: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible. **For more information**, see the <u>NIH Grants Policy Statement</u>, <u>Section 8.2.3.2</u>: <u>Sharing Model Organisms</u>.

Research Tools:

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds, and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. For more information, see the Research Tools Policy on the NIH Scientific Data Sharing Website and the NIH Grants Policy Statement, Section 8.2.3: Sharing Research Resources.

Single IRB (sIRB)

Consider if a sIRB is required and decide if you would like ISMMS or an external IRB.

If you would like ISMMS to consider serving as the sIRB, PIs must consult with the PPHS regarding fees and include the cost in their budget.

• Please fill out the HRP-230 form and email to irb@mssm.edu for consideration at least two weeks prior to grant submission.

• If the ISMMS IRB agrees to serve as the sIRB, PPHS staff will provide sIRB fees to include in the budget and a letter of support from the PPHS Executive Director.

- Additional information is available at: https://icahn.mssm.edu/research/pphs/guidance/r2s
- E-Mail <u>Jennifer.Kucera@mssm.edu</u> with any questions.