

National Institutes of Health (NIH) – K Series –GRAMS 424 Submission Checklist

Please review program specific solicitation for compliance and completeness. **Guidelines in the solicitation may supplement or deviate from guidelines below.**

GENERAL INFORMATION	
UNT Internal deadline	6 business days prior to sponsor deadline
Grant Application Guide	Review the SF424 Application Guide for full detail on proposal preparation: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/career-forms-h.pdf
eRA Commons Registration	NIH requires <u>ALL</u> Senior/Key Personnel to have an eRA Commons User ID. Contact your GCA Specialist if you do not have one.
Budget Restrictions	<ul style="list-style-type: none"> ✔ See solicitation for specific budget requirements and limitations ✔ Indirect Costs are limited to 8% MTDC
Background	Career Development Award (CDA) Program's purpose is to provide candidates at the postdoctoral, early career, and mid-career stages with opportunities to build on their initial research training and to further develop their research careers through individual or institutional awards.
Information	<p>Contact Institute/Center (IC): Applicants are encouraged to consult with the NIH Scientific/Research contact of the appropriate awarding component <i>prior</i> to submitting an application, as eligibility criteria, support levels, and availability of awards may vary among NIH Institutes or Centers.</p> <p>Reference Letters: If reference letters are required for your program, follow the instructions on NIH's Reference Letters page. Referees must submit reference letters through eRA Commons by the application due date.</p>

FORMATTING GUIDELINES	
Document formatting	<ul style="list-style-type: none"> ✔ PDF attachments only ✔ No headers or footers ✔ Headings within the text of attachments are encouraged
Font type/size	<ul style="list-style-type: none"> ✔ Arial, Georgia, Helvetica, Palatino Linotype are recommended ✔ Size 11 or larger (smaller font may be used for figures, charts, graphs)
Line spacing/Type Density	<ul style="list-style-type: none"> ✔ No more than 6 lines of type within a vertical space of 1 inch ✔ No more than 15 characters per linear inch (including spaces) ✔ Only single column formatting; Multi-column format is discouraged
Page size	✔ 8.5 x 11
Margins	✔ At least 0.5" all sides
URLs	✔ Most sections do not allow for the inclusion of URLs unless specified in the funding opportunity announcement.

GRAMS 424 PROPOSAL DOCUMENTS	
A.	<input type="checkbox"/> SF424 RR (Proposal Cover Page) – fillable <ul style="list-style-type: none"> ✔ Complete fields, including type of submission, proposed project dates (start date is typically at least 9 months after submission), project title (200 character limit), etc. ✔ GRAMS will auto-populate some of the sections for you. ✔ The individual candidate is considered the PI for career development award programs.
1.	<input type="checkbox"/> Pre-application (not typically used for NIH or other PHS agencies)
2.	<input type="checkbox"/> Cover Letter – Required for mentored CDA; Encouraged for Non-mentored CDA

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		<ul style="list-style-type: none"> ✔ Letter should contain a list of referees (including name, departmental affiliation, and institution). See NIH’s Reference Letters page. ✔ Cover letter is for internal use only and not shared with peer reviewers. Ensure it is attached in the appropriate location to ensure it is only made available to appropriate staff. ✔ Letter should be addressed to the Division of Receipt and Referral, and should reference the Application Title and the Funding Opportunity (PA or RFA) title of the NIH initiative.
B.	<input type="checkbox"/>	RR Performance Sites – fillable
		<ul style="list-style-type: none"> ✔ Information on Primary location and any additional sites at which the research and career development plans will be conducted. ✔ Add additional sites as necessary
C.	<input type="checkbox"/>	RR Other Project Information SF424 Guide, G.220
1-6.	<input type="checkbox"/>	✔ Complete RR Other Project Information section containing questions about this project.
7.	<input type="checkbox"/>	Project Summary/Abstract – 30 lines of text maximum
		<ul style="list-style-type: none"> ✔ State the application’s broad, long-term objectives and specific aims, making reference to the health relatedness of the project ✔ Describe the research design and methods for achieving the stated goals ✔ Describe the candidate’s career development plan, career goals, and the environment in which the career development will take place. ✔ Do not include proprietary information; if funded the project summary will become public information
8.	<input type="checkbox"/>	Project Narrative – 3 sentences, max
		<ul style="list-style-type: none"> ✔ Describe the relevance of this research to public health ✔ If funded, this public health relevance statement will be combined with the Project Summary and will become public information.
9.	<input type="checkbox"/>	Bibliography & References Cited – no page limit
		<ul style="list-style-type: none"> ✔ Include any references cited in the PHS 398 <i>Career Development Supplemental Form</i> and in the <i>PHS Human Subjects and Clinical Trials Information Form</i>. ✔ 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., PMID234567) for each article. ✔ 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. <u>Active hyperlinks are not allowed.</u>
10.	<input type="checkbox"/>	Facilities & Other Resources – no page limit
		<ul style="list-style-type: none"> ✔ Describe in detail, institutional facilities and resources available to the candidate. ✔ Identify how the scientific environment in which the research will be done contributes to the probability of success (i.e.: institutional support, physical resources, intellectual rapport) ✔ Discuss ways in which the proposed studies will benefit from unique features of the scientific environment or from unique subject populations ✔ Describe any special facilities used for working with biohazards and any other potentially dangerous substances.
11.	<input type="checkbox"/>	Equipment – no page limit
		✔ List major items of equipment already available for this project and if appropriate, identify location and pertinent capabilities
12.	<input type="checkbox"/>	Other Attachments – if applicable
		✔ Attach additional files only in accordance with the FOA and/or agency-specific instructions (i.e.: Foreign Justification).
D.	<input type="checkbox"/>	RR Senior/Key Personnel

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	<ul style="list-style-type: none"> ✔ The candidate should be considered the PD/PI. <u>The eRA Commons Profile associated with the username entered in the Credential field must include an ORCID ID linked to their profile.</u> ✔ Multiple PD/PI projects are not applicable to Career Development Award (CDA) applications ✔ Mentored CDAs require a primary mentor that should be identified as senior/key personnel, even if no measurable effort is committed to the proposed project. Select “Other Professional” as the Project Role and provide the text “Mentor” or “Co-Mentor” as applicable in the category field. ✔ Co-Mentors may also be included, and they should also be identified as Senior/Key Personnel. ✔ In addition to involving mentors, applications may also involve collaborators, consultants, & advisory committee members. These individuals are usually not considered senior/key personnel unless they contribute in a substantive, meaningful way to the project. In determining which individuals to identify as “Senior/Key”, applicants may wish to keep in mind that those listed as senior/key personnel on the application should <u>not be asked to provide reference letters</u>, as such letters are expected to be from individuals not directly involved in the application. For more information, see NIH’s Reference Letters page.
1.	<input type="checkbox"/> Biographical Sketch – 5 page limit each
	<ul style="list-style-type: none"> ✔ Must be included for all senior/key personnel and other significant contributors (OSCs) ✔ Use NIH biosketch format – https://grants.nih.gov/grants/forms/biosketch.htm - note additional instructions for postdoctoral and/or CDA applicants
2.	<input type="checkbox"/> Current & Pending Support – 3 page limit each
	<ul style="list-style-type: none"> ✔ For mentored CDA applications: Must be included for each mentor/co-mentor(s) - Current and Pending Support Format Page ✔ Does not need to be included for PI (candidate). ✔ Information on current and pending research support <i>relevant</i> to the candidate’s research plan should be provided. See SF424 Guide, G.240 for content requirement
E.	<input type="checkbox"/> RR Budget – SF424 Guide, G.300
	<ul style="list-style-type: none"> ✔ The RR Budget form is required for all career development applications. ✔ Refer to your solicitation for information regarding allowable costs for the candidate and any allowable research development or other costs. Amounts vary by awarding components. ✔ Typical minimum effort for the candidate is 75% or 9 Person Months. Base salary, person months and requested salary/fringe should be included in the Senior/Key Person section of the RR Budget Form. ✔ The total amount of “Research Development Support” being requested may be included on the “Material and Supplies” line of the RR Budget Form and all other budget field sections can be left blank. ✔ Indirect Cost rate is limited to 8% MTDC for career development award applications ✔ For Transitional Career Award applications (e.g., K22, K99/R00), follow instructions in your solicitation
1.	<input type="checkbox"/> Budget Justification - required
	<ul style="list-style-type: none"> ✔ Provide detailed description and justification for specified items within the Research Development Support costs (e.g., all equipment, supplies, and other personnel that will be used to help achieve the career development and research objectives of this award). ✔ Equipment quotes may be included here, if applicable.
2.	<input type="checkbox"/> RR Subaward Budget (if applicable)
	<ul style="list-style-type: none"> ✔ Includes budget detail on subaward ✔ Must be included for each subaward ✔ Subaward Budget Justification must also be included for each subaward budget
F.	<input type="checkbox"/> PHS Human Subjects and Clinical Trials Information
	<ul style="list-style-type: none"> ✔ Complete this form after questions on the <i>RR Other Project Information</i> section are completed. ✔ Required to be completed even if no human subjects are involved.

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	✓	Answer the question “Does the proposed research in the application involve human specimens and/or data? If you answer “yes”, provide explanation. Refer to SF424 Guide G.500, Human Specimens and/or Data for additional information and content requirements
	✓	If you answered “No” to “Are Human Subjects Involved?”, skip the rest of the form
	✓	If you answered “Yes” to “Are Human Subjects Involved?”, proceed in completing the form as required and attach all required documents. Refer to SF424 Guide, G.500 when completing this section and the separate checklist for HSCTI content and documents .
	✓	For CDA applicants proposing an independent clinical trial , follow standard instructions.
	✓	For CDA applicants who are proposing to gain clinical trial research experience under a mentor’s supervision (i.e.: NOT an independent clinical trial), follow the standard instructions but follow relevant <i>Additional Instructions for Career Development</i> where given in the SF424 Guide. Ensure you are applying to a FOA that does NOT allow independent clinical trials but does encourage clinical trial research experience.
G.	<input type="checkbox"/>	PHS 398 Cover Page Supplement
	✓	Complete RR Cover Page Supplement section containing questions about this project. If needed, refer to SF424 Guide, G.210 for additional guidance.
	✓	Skip “Inventions and Patents” & “Change of Investigator” section. Not applicable to CDAs.
H.	<input type="checkbox"/>	PHS 398 Career Development Award Supplemental Form
	✓	Upload documents listed below as applicable
1.	<input type="checkbox"/>	Introduction (for resubmissions/revisions only) – 1 page limit
	✓	Summarize substantial additions, deletions and changes to application
	✓	Respond to issues and criticism raised in the summary statement
Candidate Section (#2)		
2.	<input type="checkbox"/>	Candidate Information and Goals for Career Development – 12 page limit
	✓	12 page limit applies to this document in combination with Research Strategy document
	✓	Refer to the SF424 Guide, G.410, Section 2 and solicitation for content requirements
	✓	Should contain the below 3 sections with these headings and in the order below.
	○	Candidate’s Background
	○	Career Goals and Objectives
	○	Candidate’s Plan for Career Development/Training Activities During Award Period
Research Plan Section (#3-6)		
3.	<input type="checkbox"/>	Specific Aims – 1 page limit
	✓	State concisely the goals of the research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.
	✓	List succinctly the specific objectives of the research proposed
4.	<input type="checkbox"/>	Research Strategy – see “#2 Candidate Information and Goals for Career Development” above
	✓	Organize the Research Strategy in the specified order and use instructions provided in the SF424 Guide, G.410, Section 4 unless otherwise specified in your specific solicitation.
	○	Significance
	○	Innovation
	○	Approach
	✓	For Mentored CDA applications: Explain the relationship between the candidate’s research on the CDA and the mentor’s ongoing research programs.
	✓	For Non-Mentored CDA applications: include a brief description of currently funded research, along with a more extensive description of any new research to be supported by the CDA.
5.	<input type="checkbox"/>	Progress Report Publication List (for renewal applications only)
	✓	See SF424 Guide, G.410, Section 5 for full details on requirements.
6.	<input type="checkbox"/>	Training in the Responsible Conduct of Research – 1 page limit (3 page limit for K12 & KL2)

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- ✔ **Mentored CDA applications:** should describe a plan to acquire instruction in the RCR
- ✔ **Non-mentored CDA applications:** should describe a plan to obtain or provide instruction in RCR, depending on your level of experience with RCR.
- ✔ Refer to [SF424 Guide, G.410, Section 6](#) for content requirements
- ✔ Must address the five required components outlined in the NIH Policy on Instruction in the Responsible Conduct of Research (RCR), as more fully described in the [NIH Grants Policy Statement, Section 11.2.3.4: Responsible Conduct of Research](#)

Other Candidate Information Section (#7)

7. **Candidate’s Plan to Provide Mentoring** – 6 page limit

- ✔ Include only when required by the solicitation
- ✔ Refer to [SF424 Guide, G.410, Section 7](#) for content requirements

Mentor, Co-Mentor, Consultant, Collaborators Section (#8-9)

8. **Plans and Statements of Mentor and Co-Mentor(s)** – 6 page limit

- ✔ Required for mentored CDA applications
- ✔ Mentor and Co-mentor(s) must each document their willingness to participate in the project, and explain how they will contribute to the development of the candidate’s research career. Review [SF424 Guide, G.410, Section 8](#) for what should be included in statement(s).

9. **Letters of Support from Collaborators, Contributors, and Consultants** – 6 page limit

- ✔ Letters of Support are not Reference Letters, which are required for some applications
- ✔ Upload all letters as a single PDF
- ✔ If any collaborators, consultants, or advisors are expected to contribute to the scientific development or execution of the CDA application’s proposed project, attach letters of support from those individuals here, describing their anticipated role and contribution.
- ✔ Letters from consultants should include rate/charges for consulting services
- ✔ **Mentored CDA applications:** Should identify collaborators, contributors, and consultants involved with the proposed research and career development program, and not already included in the “Plans and Statements of Mentor and Co-Mentor(s)” section. Letter should briefly describe their anticipated contributions and document their role and willingness to participate in the project. The letters should also briefly describe research materials, data, guidance, or advice each person will provide.
- ✔ **Non-mentored CDA applications:** Should include letters from collaborators, consultants, and contributors. Letters should list proposed roles and document their willingness to participate in the project. The letters should also briefly describe research materials, data, guidance, or advice each person will provide.

Environment and Institution Commitment to Candidate Section (#10-12)

10. **Description of Institutional Environment** – 1 page limit

- ✔ Refer to [SF424 Guide, G.410, Section 10](#) for content requirements.

11. **Institutional Commitment to Candidate’s Research Career Development** – 1 page limit

- ✔ Document on institutional letterhead that describes its commitment to the candidate and their career development.
- ✔ Refer to [SF424 Guide, G.410, Section 11](#) for detailed information that is to be provided in this document and appropriate signature requirements.

12. **Description of Candidate’s Contribution to Program Goals**

- ✔ Required only for Applicants to diversity-related FOAs. All other CDA applicants should skip this section.
- ✔ Sponsoring Institution must provide document on institutional letterhead that explains how the candidate’s participation will further the goals of the career development program to promote diversity in health-related research. The letter should avoid revealing sensitive personally identifiable information, such as the candidate’s specific racial/ethnic background or type of disability.

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	<ul style="list-style-type: none"> ✔ Must be signed by an institutional official. In most cases, this will be the dean or chairman of the department. Signature must appear over the signer’s name and title at the end of the statement
Other Research Plan Sections (#13-18)	
13. <input type="checkbox"/>	Vertebrate Animals (if applicable) – no page limit
	<ul style="list-style-type: none"> ✔ Required if you answered “Yes” to vertebrate animal use in the <i>RR Other Project Information</i> section. Refer to the SF424 Guide, G.410, Section 13 for content requirements.
14. <input type="checkbox"/>	Select Agent Research – no page limit
	<ul style="list-style-type: none"> ✔ Required if your proposed activities involve the use of select agents at any time during the proposed project period, either at the applicant organization or at any performance site. ✔ If activities involve a select agent that which have been excluded from the list per 42 CFR 73.3, use this attachment to identify the strain(s) of the select agent that will be used and note that it has been excluded from this list. ✔ Refer to the SF424 Guide, G.410, Section 14 for document content requirements
15. <input type="checkbox"/>	Consortium/Contractual Arrangements – no page limit
	<ul style="list-style-type: none"> ✔ Required if your budget includes consortium/contracts ✔ Programmatic, fiscal, and administrative arrangements between the applicant organization and consortium organization(s) should be explained.
16. <input type="checkbox"/>	Resource Sharing – no page limit
	<ul style="list-style-type: none"> ✔ Individuals are required to comply with the instructions for the Resource Sharing Plans (Sharing Model Organisms) as provided in the SF424 Guide, G.410, Section 16 ✔ 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
17. <input type="checkbox"/>	Other Plan(s) – 2 page limit (recommended)
	<ul style="list-style-type: none"> ✔ Applicants proposing to conduct research that will generate scientific data are subject to the NIH Data Management and Sharing (DMS) Policy and must attach a DMS Plan. ✔ The NIH Genomic Data Sharing Policy expects applicants seeking funding for research that generates large-scale human or non-human genomic data to provide a plan for sharing of these data as part of their DMS Plan. ✔ Sample DMS Plan format can be found on the Data Management and Sharing Plan Format Page. Refer to SF424 Guide, G.410, Section 17 for full guidance.
18. <input type="checkbox"/>	Authentication of Key Biological and/or Chemical Resources – 1 page limit suggested
	<ul style="list-style-type: none"> ✔ If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies
19. <input type="checkbox"/>	Appendices (if applicable) – 10 PDF attachments max
	<ul style="list-style-type: none"> ✔ Review your solicitation for special appendix instructions ✔ If more than 10 appendix attachments are needed, combine remaining into attachment #10 ✔ File names should be descriptive of content ✔ Summary sheet is encouraged to be included in first appendix attachment summarizing items included in the Appendix. ✔ Review SF424 Guide, G.410, Section 19 for allowable appendix material (i.e., blank data collection forms, blank informed consent forms)
20. <input type="checkbox"/>	Citizenship
	<ul style="list-style-type: none"> ✔ Answer citizenship question(s) ✔ Note: K99/R00 applicants on temporary visas should document in the application that their visa will allow him/her to remain in the U.S. long enough to complete the phase of the award covered by the application.
I. <input type="checkbox"/>	PHS Assignment Request - optional

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- ✔ Allows selection of application assignment and review requests to the Division of Receipt and Referral (DRR) and to Scientific Review Officers (SROs).
- ✔ Also allows for identification of specific individuals who should not review your application and up to 5 types of expertise needed for the review of your application