APPLICATION FORMS	REQUIRED DOCUMENTS (Upload into the APPLICATION FORMS)	SF 424 (R&R) APPLICATION GUIDE
SF 424 (R&R)	☐ <b>Basic Info</b> : Title, PI Info, Union Info, Start/End Dates, Funding Amount, Congressional District, AOR Info, Certifications, etc.	Pages 56-72
	☐ Cover Letter: Request for SRG, list of reviewers not to include, etc.	Pages 72-73
Project/Performance Site Location	☐ <b>Primary Site Info</b> : Org Name, DUNS, and address, Congressional District	Pages 74-78
	☐ Additional Site(s) Info: Org Name, DUNS, and address, Congressional District	1 4 6 5 7 1 7 5
Research & Related Other Project Information	☐ <b>Basic Info</b> : IRB approval, IACUC approval, Proprietary info, Foreign collaboration, etc.	Pages 79-84
	☐ <b>Project Summary/Abstract</b> : The application's broad, long-term objectives and specific aims, referencing the health relatedness of the project. Describe concisely the research design and methods for achieving the stated goals. MAXIMUM 30 lines of text.	Page 84
	☐ <b>Project Narrative</b> : Describe the relevance of this research to public health. MAXIMUM 3 sentences.	Page 85
	☐ <b>Bibliography &amp; References Cited</b> : Must include author names (same sequence as they appear in the pub), article/journal title, book title, volume number, page numbers, and year of publication. See additional NIH guidelines for references cited.	Page 85

APPLICATION FORMS	REQUIRED DOCUMENTS (Upload into the APPLICATION FORMS)	SF 424 (R&R) APPLICATION GUIDE
Research & Related Other Project Information (Con't.)	<ul> <li>□ Facilities &amp; Other Resources: Include the information required per the SF 424 Application Guide         <ul> <li>including information on Early Stage Investigators.</li> <li>Applicants MUST also include information required per the AREA PA-13-313:</li> <li>A profile of the students of the applicant institution/academic component and any information or estimate of the number who have obtained a baccalaureate degree and gone on to obtain an academic or professional doctoral degree in the health-related sciences during the last five years.</li> <li>A description of the special characteristics of the institution/academic component that make it appropriate for an AREA grant, where the goals of the AREA program are to: (1) provide support for meritorious research; (2) strengthen the research environment of schools that have not been major recipients of NIH support; and (3) expose available undergraduate and/or graduate students in such environments to research. Include a description of the likely impact of an AREA grant on the PD(s)/PI(s) and the research environment of the institution/academic component.</li> <li>Although it is expected that the majority of the research will be directed by the applicant investigator and conducted at the grantee institution, limited use of special facilities or equipment at another institution is permitted. For any proposed research sites other than the applicant institution, provide a brief description of the resources.</li> <li>If relevant, a statement of institutional support for the proposed research project (e.g., equipment, laboratory space, release time, matching funds, etc.).</li> </ul> </li> </ul>	Pages 85-86
	☐ <b>Equipment:</b> List major equipment available to the project, including pertinent capabilities.	Page 86

APPLICATION FORMS	REQUIRED DOCUMENTS (Upload into the APPLICATION FORMS)	SF 424 (R&R) APPLICATION GUIDE
Senior/Key Person Profile	<ul> <li>□ Basic Info: Name, address, email, project role for PI and all collaborators, consultants, senior personnel</li> <li>For the PI, enter eRA Commons User Name in the Credential field</li> <li>□ Biographical Sketch: Required for each person listed. MAXIMUM 5 pages.</li> <li>• Must use the NIH Format</li> <li>• For the PI, must include details required per PA-13-313:         <ul> <li>○ Include a summary of your previous and/or current experience in supervising students in research in the Personal Statement. Also indicate which peer-reviewed publications involved students under your supervision.</li> </ul> </li> </ul>	Pages 87-97 Template, Pages 96-97
Budget  Note: the Sponsored Programs Office will assist with budget development, to include requesting subaward budgets from collaborating institutions for	When total direct costs ≤ \$250,000 use:  □ PHS 398 Modular Budget □ Budget Justification:  • Include Personnel Justification per PA-13-313 and SF 424 Application Guide • Include additional budget narrative per SF 424 Application Guide	Pages 131-136
	When total direct costs ≥ \$250,001 to \$300,000 (maximum) use:  □ R&R Budget □ Budget Justification:  • Include Personnel Justification per PA-13-313 and SF 424 Application Guide • Include additional budget narrative per SF 424 Application Guide	Pages 98-117

APPLICATION FORMS	REQUIRED DOCUMENTS (Upload into the APPLICATION FORMS)	SF 424 (R&R) APPLICATION GUIDE
PHS 398 Cover Page Supplement	☐ <b>Basic Info:</b> PI info, Disclosure, Human Subject clinical trial, program income, etc.	Pages 124-131
PHS 398 Research Plan	☐ Introduction: For Revision or Resubmission applications only.	Pages 36-38, 139
	<ul> <li>Specific Aims: MAXIMUM 1 page</li> <li>State goals of proposed research</li> <li>Summarize expected outcome(s), including impact that the results of proposed research will exert on research field(s) involved</li> <li>List specific objectives of the research proposed</li> </ul>	Page 140
	<ul> <li>Research Strategy: MAXIMUM 12 pages</li> <li>Organize the Research Strategy document using the exact order and section headings as listed below.</li> <li>Include, as applicable, Preliminary Studies for New Applications or Progress Report for Renewal and Revision Applications keeping within the three sections listed below.</li> <li>A. Significance         <ul> <li>Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.</li> <li>Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.</li> <li>Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved</li> </ul> </li> </ul>	Pages 141-142

APPLICATION FORMS	REQUIRED DOCUMENTS (Upload into the APPLICATION FORMS)	SF 424 (R&R) APPLICATION GUIDE
PHS 398 Research Plan, Con't.	<ul> <li>B. Innovation</li> <li>Explain how the application challenges and seeks to shift current research or clinical practice paradigms.</li> <li>Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.</li> <li>Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.</li> </ul>	
	<ul> <li>C. Approach</li> <li>Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 15 (Resource Sharing Plan), include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.</li> <li>Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.</li> <li>If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.</li> <li>Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of select agents should appear in the Select Agent document.</li> <li>If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be identified, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time.</li> </ul>	
	☐ Progress Report Publication List: For <u>Renewal</u> applications only	Page 143

APPLICATION FORMS	REQUIRED DOCUMENTS (Upload into the APPLICATION FORMS)	SF 424 (R&R) APPLICATION GUIDE
PHS 398 Research Plan, Con't.	☐ Protection of Human Subjects: If applicable	Page 143
	☐ Inclusion of Women and Minorities: If applicable	Page 144
	☐ Inclusion of Children: If applicable	Page 144
	□ Vertebrate Animals: If applicable	Page 145-146
	☐ Select Agent Research: If applicable	Page 147-148
	☐ Multiple PD/PI Leadership Plan: If applicable	Page 148
	☐ Consortia/Contractual Arrangements: If applicable	Page 149
	<ul> <li>Letters of Support:         <ul> <li>Include letters necessary to demonstrate support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors.</li> <li>For consultants, letters should include rate/charge for consulting services and level of effort/number of hours per year anticipated.</li> <li>Letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service.</li> </ul> </li> <li>THIS CAN INCLUDE INSTITUTIONAL LETTERS OF SUPPORT (FACILITIES, COST-SHARING, ETC.)</li> </ul>	Page 149

APPLICATION FORMS	REQUIRED DOCUMENTS (Upload into the APPLICATION FORMS)	SF 424 (R&R) APPLICATION GUIDE
PHS 398 Research Plan, Con't.	<ul> <li>□ Resource Sharing Plan(s):</li> <li>• Data Sharing ≥ \$500,000 requests; Model Organisms; Genomic Data, if applicable</li> </ul>	Page 150-151
	<ul> <li>Appendix:</li> <li>Adhere strictly to Application Guide list of allowable appendix materials</li> </ul>	Pages 152-153
Planned Enrollment Report	□ Planned Enrollment Report: If applicable	Pages 153-156
PHS 398 Cumulative Inclusion Enrollment Report	☐ Cumulative Inclusion Enrollment Report: If applicable	Pages 157-159