RUTGERS
School of Nursing

Office of Research Services, Contracts and Grants (ORSCG)
Summary of NIH R01-R21-R03-R18 Application Components and Internal Due Dates

Component	Guidance	Max length	Resp. Person(s)	Notes	Internal Due Date (# work days/ weeks before sponsor due date)
SF-424	Administrative content	Title: 81 char.	ORSCG, PI	Send us a title and project period. He's start a RAPSS application, which will include this form.	3 weeks
Cover Page Supplement	Asks about • Vertebrate animals • Program Income • Human embryonic stem cells • Inventions & patents (for renewal applications)		PI, ORSCG	Inform us as to whether your project involves program income of any of the other items listed to the left.	3 weeks
Performance Sites	For each, organizational name, address, and congressional district needed.		PI, ORSCG	We can look up congressional districts. Please send rest of info to Ben.	3 weeks before deadline
Human Subjects and Clinical Trial Information	Are human subjects involved? ▪ If yes, you'll need to create a study record: ○ Basic Information, including which, if any, exemptions apply. ○ Study population characteristics (required unless the research is falls under exemption class 4 and no other exemption class). Input/upload the age limits and other eligibility criteria, inclusion of women, minorities, and children document, a recruitment and retention plan, timeline, etc. ○ Inclusion Enrollment Report(s) (unless study falls under exemption class 4 and no other exemption class) ○ Protection and Monitoring Plans ○ Protocol Synopsis (only needed if the answers to all questions in the Basic Information section's Clinical Trials Questionnaire is yes).		PI, ORSCG	If no human subjects and no biospecimens or human subjects data are involved, inform Ben by the due date. **If human subject, biospecimens, OR human subjects data are involved, the PI must login to RAPSS and provide information through the interactive forms appearing in the Compliance Review, section 5.** Detailed guidance from NIAID	2 weeks before deadline

	○ If you cannot provide detailed humans subjects information at this time and your study meets the definition of a Delayed Onset study, enter a Delayed Onset study record, including a justification as to why human subjects study information cannot be provided yet. ○ Delayed Onset status does NOT apply to studies that can be described, even if they won't start immediately. (Where possible, avoid this designation.) ○ For clinical trials, other additional material may be requested for some R01 competitions. (Check the solicitation.) ▪ If no, does the research involve specimens and/or human subjects data? ▪ If no and specimens/human subjects data will be collected, you will be asked to explain why it's not human subjects research.				
Key Personnel	For each: Name, position/title, organization and division, address, phone number, email, role, and eRA Commons ID (needed for all PIs).		PI, ORSCG	Let us know right away if a key person lacks a Commons ID, so we have plenty of time to help secure one. FYI, for NIH/CDC/HRSA, there are no co-PIs, just multiple PIs. Other investigators are referred to as Collaborators or by their field: Nurse, Chemist, etc. Avoid the terms co-PI or co-I.	3 weeks before deadline
Biosketches	Must include the following: • Name & title • Education/training beginning with initial degrees and including postdoctoral and residency training, if applicable. For each degree Institution and location, degree, date of degree (MM/YY), field of study. • Personal Statement (why person's experience and qualifications make them well suited for project role) • B. Positions & Honors (chronological order; include clinical licensures) • C. Contributions to Science. Five max. For each: ▪ the historical background; ▪ the central finding(s);	5 each	PI	NIH instructions are here.	5 work days (by noon)

	▪ the influence of the finding(s) on the progress of science or their application of to health or technology; and ▪ your specific role in the described work. ▪ For each, you can cite up to four publications. Optional: • D. Additional Information Research support (ongoing and completed projects during past 3 years. Begin with most relevant projects. Indicate the goals and your responsibility/ role.)				
Budget	Detailed budget required for RAPSS review even if a modular budget will be submitted with the application.		PI,HD	Ten working day before the sponsor deadline, send a detailed, complete budget justification to Heidi, who will translate it into an Excel spreadsheet. Guidance: • How to write a justification. • NIH budget development guidance • Sample NIH Justification Inform Heidi in advance if you intend to provide yourself of another Rutgers employee with supplemental pay. **Consortium budgets should be requested well in advance of this deadline. See section on Consortium Contracts.**	10 work days for complete justifica-tion 6 work days for final budget info
Other Project Information (OPI)	Asks about • Proprietary information • Environmental impact • Historic site destinations • International collaborations Requires these standard documents described in the next six rows. .		PI, ORSCG	Let us know whether your study involves proprietary information, environmental impact, performance sites that are designated as historic sites, or international collaborations. If international collaborations are involved, you will need to prepare a justification, which will be due 5 working days before the sponsor deadline. If your study includes vertebrate animals, you will need to login to RAPSS and provide information about the IACUC review in section 5, the Compliance Review. This is due 5 working days before the sponsor deadline	3 weeks 5 work days (by noon) for foreign-collab. just. and IACUC info

OPI: Abstract	Summary/abstract should include the info discussed here.	30 lines			5 work days (by noon)
OPI: Project Narrative	Explains to a lay person the public health relevance of this project—why they should care about it (and why it's a good investment of federal dollars).	3 sentences			5 work days (by noon)
OPI: Bibliography	Specifications are here.				5 work days (by noon)
OPI: Facilities & Other Resources	Guidance is here. New and Early State Investigators may describe: • Resources for classes, travel, or training • Collegial support • Logistical support • Financial support, such as protected time		PI	HD to boilerplate document upon request. Should start with the statement that you have all resources necessary to complete the project, either at Rutgers or through arrangements with entities/individuals serving as consortium partners or providing commitment letters. Describe resources for each performance site.	5 work days (by noon)
OPI: Equipment	List of available major equipment. (May not be applicable.)	(none)			5 work days (by noon)
OPI: Other attachments	Include a foreign collaboration justification and other attachments specifically required by the solicitation. Additional attachments aren't needed for R01, R21, and R03 applications to the parent (investigator-initiated) grant programs.	(none)			5 work days (by noon)
Research Plan: Intro	Introduction to Application attachment required for renewal and resubmission applications.	1 p		Guidance and samples from NIAID	5 work days (noon) Earlier for line editing
RP: Specific Aims	State goals and summarize expected outcomes. Include objectives (test stated hypothesis, create novel design, solve specific problem, change existing clinical paradigm, etc.)	1 p	PI	Guidance and samples from NIAID	5 work days (noon) Earlier for line editing
RP: Research Strategy	Organize into these sections: 1. Significance 2. Innovation 3. Approach	12 pp for R01 6 pp for R03, R21	PI	Guidance and samples from NIAID	5 work days (noon) Earlier for line editing

	Include preliminary studies and progress report (for renewals) in one of the above sections. Instructions				
RP: Pub list	For renewals only. Instructions	(none)	PI		5 work days (noon)
RP: Vert. An.	The vertebrate animals attachment is usually optional, even for studies involving such animals. Instructions	(none)	PI		5 work days (noon)
RP: Select Agents	Needed only for select agent research. Instructions	(none)	PI	Let us know if your research involves select agents	3 weeks (at least)
Multi-PI Leadership Plan	Required if more than one PI. Instructions	(none)	PI	Examples can be found here. (Again, there is no such thing as an NIH co-PI.)	5 work days (noon)
Consortium Contracts /SOI	Needed for each non-Rutgers institution submitting a budget.	(none)	PI/HD	Send us a list partners. Indicate the role and provide administrative contact info. A Rutgers subrecipient commitment form should be signed by each consortium partner. This document won't be part of the submitted application, but is required by the University as a means of documenting the due diligence required by federal sponsors. It can take weeks for another institution to provide an approved budget and statement/letter of intent and the other to participate in the application. **Determine consortium budgets early!**	3 weeks (or earlier)
LOS	Letters of Support/Commitment LOS for collaborators at consortium institutions and other institutions, and for consultants. ▪ For collaborators, stipulate expectations for co-authorship. ▪ For consultants, specify what will be done, at what rate, and duration (days/hrs) . Include commitment letters from consortium and other institutions for which access, resources, or cooperation is required.		PI/ORSCG	Please send these to us to upload.. Or send us bullet points of content, and we'll draft the letters.	3 weeks to request drafts 5 work days (noon**)** signed letters due
Resource Sharing Plan	Generally, investigators seeking $500K or more in direct costs for any year are expected to include a 1-para description of how final research data will be shared, or explain why data-sharing is not possible.	(none)	PD	• General guidance on data sharing plans; example • Guidance from NIAID	5 work days (noon)

	If you will collect public health data, also include a Data Management Plan, including at minimum: ▪ Descriptions of data to be produced ▪ Description of how data will be provided, including provisions for privacy, confidentiality, IP, security… ▪ Use of data standards that ensure that all released data have appropriate documentation that described method of collection, what the data represent, and potential limitations for use ▪ Plans for archival and long-term preservation (or explanation why this can't be justified) Other plans are needed for genomic and model organism research. Instructions				
Appendix	Only 10 docs allowed. The only allowable appendix materials are as follows: ▪ Blank data collection forms, blank survey forms, and blank questionnaire forms - or screenshots thereof ▪ Simple lists of interview questions (Do not include items such as: data, data compilations, lists of variables or acronyms, data analyses, publications, manuals, instructions, descriptions or drawings/figures/diagrams of data collection methods or machines/devices. ▪ Blank informed consent/assent forms ▪ Up to 3 publications that are not publically available (as per the NOFO). An intro summary sheet is encouraged.	25 pp	PD	FAQ and additional info	5 work days (noon)
PHS Assignment Request Form	Optional. Used to request an institute and/or study section assignment based on required expertise.	(none)	PD	Guidance from NIAID List of CSR Panels and Groups	5 days (noon)
Format Specs	Font: 11 pt or larger; Ariel Georgia, Helvetica, or Palatino Linotpye recommended. Spacing – single is the norm Margins: ½ or larger Citation instructions File names – 50 characters/spaces or less; avoid "&" Instructions		PD, ORSCG to check	Smaller font can be used for figures, but must be legible when viewed at 100% (normal size). Note: Hyperlinks are generally not allowed. Use only when explicitly permitted in funding announcement.	