HHS Office of Research (OOR) Timeline for Successful Grant Submission

Effective   9/13/2020

Revised 8/17/21; 9/6/23; 3/6/24 **Background:**

- The scientific contribution and writing of the investigators is key to the success of any grant proposal. However, successful submission of a grant also requires effective and advance communication with various offices on campus. The HHS OOR is charged with facilitating that process for HHS faculty, with many tasks that must be completed. Additional assistance and supports can be provided by the HHS OOR office, <u>if given adequate notice</u>.

- It takes time to route a grant through the needed approval process at UNCG. After a grant leaves HHS, it takes time to be reviewed and ultimately submitted by the Office of Sponsored Programs (OSP). <u>The OSP process is summarized here.</u>

- Many faculty within and beyond HHS submit grants at any one time. Schedules need to be coordinated to ensure that each planned submission is routed successfully.

- Given the increase in HHS and UNCG grant submissions, we must create and adhere to firmer deadlines than we have in the past.

- The goal of the HHS OOR is to assist all faculty with their grant submissions. But, moving forward, if many submissions are being routed at the same time, priority will be given to those in which the PI adhered to the timeline below. Exceptions may be made for rapid turnaround requests for applications (RFA) in which the PI can demonstrate the timing of the call and the deadline necessitated a shortened timeframe (e.g., RFA with 30-day turnaround from posting).

- In instances in which HHS OOR cannot assist faculty with a submission due to time constraints/volume, we will reach out to OSP to see if their staff can assist with the submission. *OSP does not complete the Cayuse portion*.

- We have provided the timeline below in multiple formats recognizing individual preferences may vary. o Simplified, bare bones timeline no enhancement/optional steps (Table 1, p. 2). Click 🗖 for details.
    - o Simplified, recommended timeline with all enhancement/optional steps included (Table 2, p. 3). Click 🗖 for details.
    - o Detailed overview of all optional and required steps with additional information and explanations to help investigators prepare (Table 3, p. 4)

If the Timeline is Not Followed:

In the event a Principal Investigator has not adhered to the HHS OOR timeline for effective grant submission and our workload prohibits us from providing our full suite of services in the needed time frame, we will reach out to OSP to see if their staff can assist with the submission. *Note: OSP does not complete the Cayuse portion. (clarified Aug. 2021).* Thus, the Principal Investigator is expected to complete the Cayuse application on their

own in its entirety. This would likely require watching the training video and/or reading the documentation, completing the budget in the required format, answering all questions, uploading all needed documents, etc. Our goal is to shield investigators from this burden, but this may not be possible if there are tight time constraints, and we are in a period of peak submissions. Should this happen, be prepared to devote a substantial amount of time to this. We estimate this could take an entire business day or more.

Table 1. Bare Bones Submission Timeline No Methodologist Support; No External Reviews **Not Recommended Especially for First-Time Submitters or Complex Proposals**				
Time before due date	**3 to 6 months**	**6 weeks**	**10 business days[1]**	**5 business days**
PI Responsibilities	Submit intent to apply form Notify department chair of submission plans	Meet with preaward specialist to discuss budget Complete investigator portions of Cayuse (before day 10) {complete HHS research space request}	**All final documents for the submission provided to preaward specialist in designated folder (day 10)** Be available to make requested revisions (day 6-9) {Complete Human Subjects Section of Assist (day 6-10)} Research-Based COI Disclosures done[2]	Be available to make needed revisions

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[1] M-F, 8 to 5, excludes University Holidays

[2] Research-based COI disclosures are required for all investigators prior to submission; ORI will check that COI training is current (expires after 4 years) and annual disclosures have been completed.

{The listed action in braces {} is only applicable for certain projects; check with Pre-Award Specialist}

Role				Make needed revisions				
HHS Pre-Award Specialist or Designee	Review sponsor requirements Add to list; alert OSP Create and start filling Cayuse Create and start filling External Application package	After meeting, send PI budget template with some information loaded Field questions, review multiple iterations of budget & justification as needed {Get docs from subs}	Review all documents, request revision if needed Route Cayuse for Internal Review Prepare External Application Package	Make needed revisions				
Chairs/ADRs	Discuss grant plans with investigators		Cayuse Review & Authorization					
ORI Compliance check[2]				X				
OSP **-Review & request revisions from PI** **-Submit**					X	X	X	X

Table 2. **Enhanced** Submission Timeline w/Methodologist Support & External Reviews **Recommended for Maximal Success and Especially for First-Time Submitters or Complex Proposals**					
	3 to 6 months	**8 to 10 weeks**	**6 weeks**	**3-5 weeks**	**10 business days[1]**	**5 business days**
PI Responsibility	Submit intent to apply form Notify department chair of submission plans	Meet with HHS OOR methodologist Coordinate with methodologist from this point out	Meet with pre-award specialist to discuss budget Complete investigator portions of Cayuse (before day 10) {complete HHS research space request}	Work with HHS OOR Assistant Dean to send draft to: scientific editor of your choosing (5 wks) technical editor we have on retainer (3 wks) Edit after each review	**All final documents for the submission in designated folder (day 10)** Be available to make requested revisions (day 69) {Complete Human Subjects Section of Assist (day 6-10)} Research-Based COI Disclosures done[2]	Be available to make needed revisions
HHS Pre-Award Specialist or designee	Review sponsor requirements Add to list; alert OSP Create and start filling Cayuse Create and start filling External Application package		After meeting, send budget template with some information Field questions, review budget & justification as needed {Get docs from subs; 4 wks}	Work on Cayuse Work on External Application Package with any documents in hand early	Review all documents, request revision if needed Route Cayuse for Internal Review Finalize External Application Package	Make needed revisions

[1] M-F, 8 to 5, excludes University Holidays   [2]Research-based COI disclosures are required for all investigators prior to submission; ORI will check that COI training is current (expires after 4 years) and annual disclosures have been completed.

{The listed action in braces {} is only applicable for certain projects; check with Pre-Award Specialist}

Chairs/ ADRs	Discuss submission plans with investigators				Cayuse Review & Authorization				
Comp check 2						X			
OSP					Review, request revisions		X	X	X
					Submit				X

Table 3. HHS OOR Detailed Timeline for Successful Grant Submission

Time before Deadline	Task
3 to 6 months in advance of sponsor deadline (even earlier helps us plan)	Alert HHS OOR via this form and **Department Chair** of potential grant/contract submission plans.
10 to 12 weeks before deadline is strongly encouraged; *failure to adhere to this deadline undermines the level of support provided*	Optional, enhancement: Meet with HHS Research Methodologist if you need guidance/consultation regarding design/analytic features (e.g., statistical power, needed sample size, etc.) and/or consultation on the creation of a Data Sharing and Management Plan. This information can inform your specific aims, research strategy, budget, etc. Refer to the Policy for HHS OOR Methodologist Effort on External Proposals.
If the HHS Research Methodologist becomes part of your team and writes sections of the proposal or ancillary documents, those sections are due at the deadlines noted below. In other words, you need to give them the information about aims, research questions, methods/design far enough in advance for them to generate the materials you need by the below noted deadlines/steps; this may be relevant prior to taking advantage of external reviews and is relevant to all deadlines related to submitting final proposal document. This requires advance planning/coordination of schedules. *Note*: the methodologist is often working on multiple proposals with the same deadline.	
8 to 10 weeks prior to sponsor deadline	Meet with Pre-Award Specialist and Associate Dean for Research to: • provide detailed overview of planned project • review sponsor guidelines, review budgetary needs (e.g., faculty effort during AY and summer, funds for graduate students, potential HR issues, allocation of credit, etc.) • discuss internal (Cayuse) and external (e.g., NIH ASSIST) submission process • discuss plans for external reviews prior to submission • create detailed timeline together, etc. • discuss current submission process/details (OneDrive folder, file naming conventions)
Key issues to discuss with chairs while planning and before chairs review the Cayuse include the possible allocation of departmental research space for the proposed project, GA tuition and stipends (e.g., consistent with departmental norms, department able to provide needed resources), and faculty effort/course releases. PIs should encourage all UNCG team members to have such discussions with their chairs. **{If departments cannot provide all needed space,** please see this policy. If you wish to request HHS Research Space for the proposed project, please complete this form.}	

Minimum of 6 weeks prior to sponsor deadline[1] *Soon after this meeting, the PI will receive a customized budget template that the PreAward Specialist has started that will include current faculty salary, the correct F&A rate,*	Attend preliminary budget meeting. PI must review UNCG budget template first to familiarize themselves with what is expected and be ready to answer the following: • Who is on your team (investigators/key personnel) • How much effort does each person need to do the planned work; when (summer, AY; same or varied across grant years); will course releases be requested (please review the following policies prior to this meeting: effort on grants LINK, course release LINK)

and potentially other items discussed at the preliminary meeting. Then the PI (or their designee) will work on fleshing out the rest of the budget and will share that and their draft justification back with the PreAward Specialist for review and feedback. This often requires multiple edited versions. The final versions are due 10 business days prior to the deadline.	• Will there be staff, GRAs, post docs? Will staff/postdoc(s) be new or existing positions? • Travel? Where for what? • Publication fees • Participant incentives—amount and number • Materials, supplies, equipment? • If there are to be subawards, the contact information for institutions' grant specialists is needed. *The institutional representatives must communicate with one another about deadlines and needed documents.* • Consultants • Are there additional budgetary needs that do not seem to fit in the noted categories? **Do PIs/Investigators need to talk with department chairs again based on new details that have emerged?**
5 to 6 weeks prior to sponsor deadline (depends on their needed turnaround time; be sure you have confirmed this with them in advance)	<u>Optional enhancement, but highly recommended</u>: Send draft to Scientific Reviewer of Your Choosing (you select the reviewer and make review arrangements with them; contact the OOR Assistant Dean for Research Finance & Operations to discuss payment arrangements paying between $300$500 depending on their expertise & experience.) HHS OOR will pay the reviewer.
4 weeks prior to sponsor deadline	All research team members should: (1) complete the research based COI for this specific project, (2) check to ensure that their annual disclosure is up-to date <u>via Cayuse</u> and (3) check that their COI training is up to date which can be checked via the <u>CITI website</u>.
{<u>If there are subawards,</u> our **Pre-Award Specialist will work with the collaborating institution's grants manager to obtain needed documents around this time. She will send needed documents/templates and negotiate a deadline with them so investigators on both ends can focus on the science.** All such documentation (e.g., their LOI, scope of work, biosketches, facilities, equipment if applicable, completed: subrecipient form, budget form, performance site form, personnel form) is needed for Cayuse routing and/or the external submission.}	

3 to 4 weeks prior to sponsor deadline[2]	Optional enhancement, but highly recommended: Make arrangements with OOR Assistant Dean for Research Finance & Operations for review by our recommended technical editor; forward draft to Assistant Dean to share with reviewer. HHS OOR will pay for this.
2 weeks (10 business days)[3] prior to sponsor deadline	PI submits all proposal documents/attachments to Pre-Award Specialist for checking and uploading (e.g., specific aims, research strategy, references, biosketches, facilities, equipment, budget, budget justification, etc.) by saving them in the OneDrive folder that was created for the proposal by HHS OOR.

HHS OOR will create a folder for the proposal and share it with the PI via OneDrive. The folder will be named OOR PI Last Name (e.g., OOR_Leerkes) so you know it is the shared folder with us (OOR) and we know it our shared folder with you specifically (PI Name) as on our end it is embedded under a broader Proposals folder. Then, within your PI folder, we will create a subfolder for any grant you are working on named by sponsor name or abbreviation/mechanism_month and year of due date; (e.g., NIH R01_2_24; RWJF_6_24). The PI will save the above documents in this folder. Only final polished/submission-ready documents should be saved here. Please save the .docx versions of most documents, but not the specific aims or research strategy, so the Pre-Award Specialist can make minor adjustments if needed before converting to pdf. For the specific aims and research strategy please save the pdf to the folder so your intended formatting is preserved. If changes are

needed for these documents you will be asked to make them to ensure format (bullets, page breaks, location of figures and tables etc) is exactly as wanted). The PI should have their own folder for preliminary drafts and other materials; they should also maintain the final versions in their own folder. Our folder is intended to support the submission process; it is not for long-term storage for PIs. Many submission portals necessitate brief names. Please see Appendix A for guidance re naming documents.

6 to 10 business days prior to sponsor deadline	Pre-Award Specialist will route Cayuse to department chairs, center directors, units for review and approval. PIs and all investigators complete research-based COI disclosures (and annual conflict disclosure if outstanding and conflict of interest training if expired); the proposal may not be forwarded to OSP for final review submission if disclosures are incomplete. {PI completes human subjects section for NIH in ASSIST}
7 business days before sponsor deadline	If critical edits to primary proposal documents are needed (e.g., NIH specific aims page and research strategy) they will be accepted; if this happens, must notify Pre-Award Specialist via email that these documents were updated from above in OneDrive folder. This is a courtesy, and we request it be used sparingly as it creates time pressures.
Minimum of 5 business days before the deadline (e.g. if due at end of day Friday, must be in hand by noon Monday)	All final documents loaded in Cayuse (and ASSIST or other submission portal) and routed to Compliance/OSP.

Until Submission is Confirmed	PIS must be ready to edit documents/address questions based on OSP review prior to submission; make sure you are accessible. There must be good communication (email preferred) with Pre-Award Specialist about which documents have changed so the correct ones are loaded and ultimately submitted.

{The listed action in braces {} is only applicable for certain projects; check with Pre-Award Specialist}

[1]Additional time will be needed under some circumstances such as if you plan to have multiple subcontracts or if you plan to exceed the NIH $500,000 annual cap.

[2]Exact timing depends on volume of PIs requesting this review and the reviewer's availability.

[3]Business days refer to standard Monday through Friday work week (approximately 8 am to 5 pm) and exclude University Holidays (New Year's Day, Martin Luther King Day, Spring Holiday, Memorial Day, Independence Day, Labor Day, Thanksgiving Holiday, Winter Holiday)

Note: **Grant applications to foundation and/or industry sponsors require permission from OSP. Individuals seeking funds from foundations, even for a regularly occurring, open call, must complete this form.**

Appendix A: About Your Proposal OneDrive Folder

The HHS Office of Research will create and share a folder for your grant submission materials in OneDrive. The purpose of doing so is to: (1) prevent needing to search through emails for needed documents, (2) avoid confusion about current drafts, and (3) ensure multiple individuals in HHS OOR have access to the needed documents in the event Pre-Award Specialist is unavailable at a critical juncture or multiple individuals are assisting with submissions due to high volume.

Items that should be saved in the folder:

This folder is intended to support the grant submission process. It should not be the primary working folder for a grant that might be shared with multiple other people and include many other documents, nor should it be viewed as long term storage of submission materials for the investigative team. This folder should only include documents that are required by UNCG and the sponsor for internal routing and external submission. Further, the folder should only include final/penultimate drafts (i.e., the research teams final draft prior to possible revisions requested by internal reviewers/approvers).

Proposed naming conventions: Files that you save in this OneDrive folder do not need to include PI/study name, the mechanism or the date, as they are saved in an outer folder that includes this information. Further, long names of this type are not accepted by many submission portals and it just creates work for HHS OOR/OSP to change them. Rather, filenames should be short and mirror the wording used by the sponsor as noted below. " indicates the document name noted in the left column should serve as the filename.

For NIH proposals:

Document Name	Filename

Budget	"
Budget Justification	"
Project Summary/Abstract	Summary
Project Narrative/Public Health Relevance	Narrative
Facilities & Other Resources	Facilities
Biosketch	Biosketch_last name of investigator, consultant, etc
Specific Aims	"
Research Strategy	"
References Cited	"
Letter(s) of Support	Letter of Support_last name of supporter or agency name/acronym
Data Management and Sharing Plan	"
Data Monitoring and Safety Plan	"
Multiple PI Plan?	"

Note: NIH has a 50 character limit for names of attachments uploaded in ASSIST. PIs are responsible for the Human Subjects Section which includes attachments (e.g., Inclusion across the lifespan). Make sure you name those with this limit in mind. If you exceed the limit, you can still upload the attachment, but when we do the validation check, it will appear as an error and will need to be corrected. Please help us avoid this.

Other common filetypes:

Document	Filename
Letter of Intent	"

Scope/Statement of Work	Scope of work
Project Summary	"
Project Description	"