GRANT GUIDE: NIH

Fundamentals of applying for National Institutes of Health research grants

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▪ required   ○ if applicable   ● recommended

1. Introduction: Why & How Use this Guide?

This guide was written with two **types of applicants** in mind:

1. Junior faculty who need to get a sense of what it takes to *develop a compelling and comprehensive ('full') grant proposal*. Especially when it is their first application or they have failed to compete successfully in the past, it helps to take a step back and consider all the pieces. A grant application is not simply a collection of documents. It is a vision that must be expressed clearly and concisely every step of the way. Moreover, this vision needs to harbor something new and exciting. A competitive grant proposal takes time to crystalize.

2. Senior faculty or successful past applicants who need an *update or quick refresher*. Instructions and requirements change constantly, and this guide discusses the latest. It also includes processes specific to Georgia State University, which apply to everyone.

This guide was developed by experienced and successful grant applicants and grant reviewers. It includes tips and notes of caution ('grantsmanship') you may not be aware of or learn easily otherwise.

This guide was developed in close consultation with the official NIH application instructions, but avoids repeating those instructions. The goal is to give an overview of the process and soft information to help applicants get organized.

Disclaimer: This guide does not at any time in any way replace the official NIH guidelines and policies. In case of doubt, call your local (university) grants officers or NIH program officials.

How to Use: Read this guide start to finish, chronologically, the first time. Thereafter, the table of contents can be used to work on specific, isolated questions and application pieces one-off.

Figure 1 (page 6) summarizes the *proposal submission steps everyone needs to take*.

Editorial:

*   Hyperlinks to websites are shown as blue underlined text, which signals an *active* link. If you notice a problem or need help, contact your local grants & contracts officer (see section 2.5).

*   Because the actual address of websites can be quite long, {small underlined dotted text} is used to help locate a webpage in writing. It will show the various steps to take, if any, to get to a particular page {main page / next step / subsequent step / target page}.

*   Cross-references to guide sections and to the official NIH grant application guidelines (in Chapter 4) are highlighted in yellow. The latter denote the relevant Chapter and Chapter section.

    This symbol denotes GSU-specific rules and recommendations throughout this guide.

2. Resources at Georgia State University (GSU) and the Andrew Young School of Policy Studies (AYSPS)

2.1 University Research Services Administration - URSA:

URSA {ursa.research.gsu.edu} is GSU's resource for grants and contracts activities, compliance and safety, and research administration. In addition to offering post-award help, the office and website provides many good and necessary resources to get oriented, started, and submit a proposal for sponsored research. *Developing and writing a grant proposal remains the responsibility of the applicant and his/her department and school.*

The *Office of Sponsored Proposals and Awards* (OSPA, see 2.2) is part of URSA.

Important URSA sites include:
- Human Subjects and Institutional Review (IRB)
- Institutional Animal Care and Use Committee (IACUC)
- Responsible conduct in research and associated (CITI) training
- Help with finding funding opportunities using PIVOT and other avenues.

Directly relevant to the **application process**:

- Research Portal {URSA/Proposals & Awards}: *The portal is used to request key personnel submission registrations and to electronically route proposals to OSPA. As of November 2016, all proposals are routed electronically* (see 2.4).

  ☞ PORTAL Login requires a campus ID and password.

  🕑 Use to request **FastLane** and **eRA Commons Registrations**
     (see also 4.8 | KEY SYSTEMS AND REGISTRATIONS)
  🕑 Use to **route proposals to OSPA** (see also 2.2 and 2.4)

- Conflicts of Interest (COI) and Significant Financial Interest (SFI) disclosures {URSA/ Additional Resources/ Conflicts of Interest}: Investigators must complete training on COI and complete a Financial Disclosure form each year. Additionally, SFI is required for each individual proposal. *An investigator is anyone who is responsible for the design, conduct, and performance or reporting of a sponsored project at GSU, regardless of title or position. Make sure training and disclosures of all investigators are up-to-date early on during proposal development.* If not, a proposal cannot be submitted.

2.2. Office of Sponsored Proposals and Awards - OSPA:

OSPA {URSA/ Contacts/ OSPA Structure and Contacts}, as part of URSA, is dedicated to proposal review and submission.

OSPA is organized according to sponsor type and has dedicated teams for various grant programs and institutions, including NIH. A staff directory is available and staff welcome questions, visits and planning meetings with anyone learning to understand the application and award process, or needing a refresher.

Applicants should be in communication with OSPA throughout the application process, especially at the beginning and end. They should notify OSPA when they consider a submission in response to a particular funding opportunity. *A short planning meeting with OSPA is strongly recommended*. A proposal can be routed to OSPA for review (see 2.4 – GSU PROPOSAL ROUTING) 1 – 2 weeks prior to submission deadline when a draft budget and project summary are ready, and have been reviewed and approved by the applicant department.

All sponsored project proposals are submitted by OSPA. Note that OSPA will not submit without the explicit confirmation from the Principal Investigator (PI) that the proposal is ready and final. In order to submit, *the PI must grant OSPA access to the proposal in some submission portals, such as NSF's FastLane* (see 4.8 – SUBMISSION, REVIEW & TIMELINES).

Important **Proposal Development** resources include:

- Writing tips, help and resources at GSU and NIH {URSA/ Proposal & Awards/ Get Started with Proposal/ Proposal Writing Resources}. Sites do not necessarily offer new information, but may link to existing NIH. *Study the overviews regularly to see what is new and may help.*

  - Budget Development {URSA/ Proposal & Awards/ Develop Proposal Budget}: The budget is an important part of any sponsored proposal and *OSPA strongly recommends its **templates** (excel spreadsheets) to accurately develop and calculate budget items*.

- The budget development site also provides details on **allowable / unallowable costs, direct** and **indirect Costs (F&A rates), fringe benefits, cost sharing** and the **budget justification** (see also 4.11 | BUDGET JUSTIFICATION).

- An online training module {URSA/ Proposal & Awards/ Develop Proposal Budget/ How to Build a Proposal Budget Training} explains how to build a proposal budget.

- The Institutional Fact Page lists key information to enter, such as the organizational DUNS number, about the *applicant organization, which is Georgia State University Research Foundation (GSURF), not GSU* {URSA/ Proposals & Awards/ Get Started with Proposal/ Fact Page and Key Institutional Documents/ Institutional Fact Page}.

- The GSU Fact Book {oie.gsu.edu} contains information on admissions, enrollment, degree programs, finances, faculty and staff, and physical facilities to be included in grants and reports.

2.3. CAYUSE – Proposals submitted through grants.gov:

CAYUSE {URSA/ Proposals & Awards/ Get Started with Proposal/ Using CAYUSE424 for Preparing Proposals} is a 'system-to-system' software application GSU and other universities use for the *creation, review, approval and submission of grant proposals submitted through Grants.gov.* Grants.gov is a federal funding site and submission portal (see also 4.8 | KEY SYSTEMS AND REGISTRATIONS). CAYUSE *offers a live overview of potential errors and sponsor-system warnings before submission, which is important and helpful.* It avoids last minute submission problems and potentially missed deadlines.

   ☞ `CAYUSE Login requires a campus ID and ID password.`

Although there are several ways to submit proposals to NIH, OSPA strongly recommends using CAYUSE (see 4.7 – APPLICATION FORMS, INSTRUCTIONS AND FORMAT PAGES). It provides a live summary of potential application errors and sponsor warnings, which is helpful and important to avoid submission delays.

When using CAYUSE, check your Professional Profile under the {People} tab so you are properly registered with CAYUSE and visible to others. Access for Others or to certain types of information is controlled through Permissions that can be accessed by clicking the Key Symbol in the upper right corner of the main screen. Permissions can be set by whomever initiates the proposal in CAYUSE, such as the PI or local pre-award support (see 2.5 – PRE-AWARD SUPPORT).

2.4 GSU Proposal Routing:

- As of November 2016, all sponsored proposals are routed for approval through the **Research Portal** (see 2.1 - URSA). Your local research administrator or pre-award support team (see 2.5) will initiate the routing and develop the proper approval workflow to include all investigators and their chairs and deans.

Following department routing and approval, all sponsored proposals must be reviewed by OSPA (see 2.2). *It checks the financial and administrative aspects of the proposal, not the scientific content. OSPA requests at least 5 **business** days to review proposal documentation. This does not include the departmental/college routing.* Proposals with special features such as cost sharing, numerous subcontracts or consultants, and conditions that necessitate legal review, require additional lead-time.

OSPA recommends submitting at least one day ahead of the deadline.

2.5 Pre-Award Support at AYSPS:

Grants & Contracts Officers:

Cynthia Maria Atkins Woods, MBA	**Denise Jenkins**
Grants & Contracts Officer, III	*College Financial Officer*
Andrew Young School of Policy Studies	Andrew Young School of Policy Studies
14 Marietta Street, NW Suite 625	14 Marietta Street, NW Suite 616
Atlanta, GA 30303	Atlanta, GA 30303
Office: 404-413-0012	Office: 404-413-0006
Fax: 404-413-0004	Fax: 404-413-0004
catkinswoods@gsu.edu	djenkins@gsu.edu

2.6 Steps for ANY Sponsored Proposal:

Please refer to Figure 1 on the next page for an overview of steps.

The first step in the grant application process is to notify your local pre-award support in the department, school or college (see 2.5). Let *them* know you are considering an application, and let them tell *you* what's new and next. Seasoned applicants should do this too as it helps the department be prepared and stay up to date as well as be a helping hand and your advocate.

The second step is to notify OSPA (see 2.2), which your local pre-award support may do for you. *A short planning meeting with OSPA is strongly recommended.*

Step three is to check and secure your registrations and disclosures (see 2.1).

Step four is to develop and write an NIH grant proposal using CAYUSE (see sections 4.7 – 4.11). *Pay close attention to the funding opportunity announcement (see 4.5), which supersedes any general proposal development requirements and instructions.*

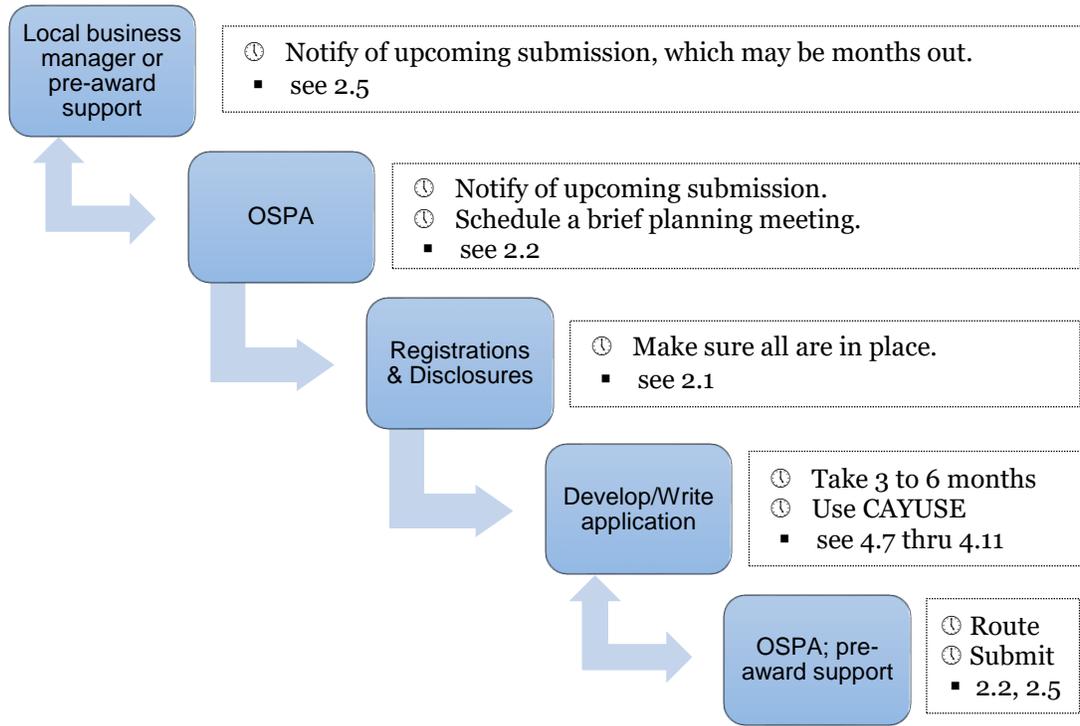The last step is proposal submission by OSPA.

Figure 1: Sponsored proposal submission steps at GSU

3. Standard NIH Application Documents & Information (to be provided by the applicant)

Name:	Type:
☐ Cover Sheet (SF424 R&R Form)	Information
☐ Project/Performance Site(s) Locations	Information
☐ Project Summary/Abstract	Document, limit: 30 lines
☐ Project Narrative	Document, limit: 3 lines
☐ Specific Aims	Document, limit: 1 page
☐ Research Strategy	Document, limit: 6 to 12 pages
☐ Bibliography & References Cited	Document
☐ Budget	Information
☐ Budget Justification	Document
☐ Senior/Key Person Profiles	Information
☐ Biosketches	Documents, limit: 5 pages each
☐ Letters of Support	Documents
☐ Facilities & Other Resources	Document
☐ Equipment	Document
☐ Cover Letter	Document
☐ Assignment Form, *recommended*	Information
☐ Protections of Human Subjects, *if necessary*	Document
☐ Inclusion of Women & Minorities, *if necessary*	Document
☐ Inclusion of Children, *if necessary*	Document
☐ Target Enrollment Table, *if necessary*	Document
☐ Data Safety Monitoring Plan, *if necessary*	Document
☐ Appendices, *if any*	Document(s), limit: 10
☐ Other Attachments, *if necessary*	Document
☐ Introduction, *if resubmission or required*	Document

Note: An application package will require additional administrative information not listed here that is derived or entered relatively easily by the applicant (e.g., project title) or the applicant organization. The checklist above contains the pieces that are specific and unique to the proposed project and the applicant will have to develop and provide.

4. Applying to NIH

4.1 About

The National Institutes of Health (NIH) is part of the U.S. Department of Health and Human Services (DHHS), and the largest public funder of biomedical research in the world. It invests more than $32 billion annually to '*enhance life, and reduce illness and disability*' (see below 4.3 – MISSION).

4.2 Structure

NIH is made up of 27 different Institutes and Centers (ICs), such as the National Institute on Aging (NIA), the National Cancer Institute (NCI), the National Library of Medicine (NLM) and the Fogarty International Center (FIC), which focuses on Global Health. Each has a specific research agenda, often focusing on particular diseases or body systems. All but three of the ICs receive their funding directly from Congress.

NIH has an internal ("intramural") research arm that employs and train researchers to advance science. Grants and Funding for investigators outside NIH are handled by the external arm, the Office of Extramural Research (OER).

4.3 Mission

NIH has a mandate to *promote public health and welfare*. It supports basic research, but puts an emphasis on *health-related applications and medical sciences*. To better understand and speak to NIH's mission, consider reading the NIH strategic (2016-2020) plan.

Each IC has its own mission. Applicants are advised to study the different missions carefully to determine where their work or proposed research fits well/best. Unless stated otherwise in a funding opportunity announcement (FOA, see section 4.5), funding may be requested from more than one IC. For instance, an application focusing on depression in older adults may request support from NIA and NIMH (the National Institute on Aging; Mental Health). – See also COVER LETTER (4.11).

In addition, applicants should pay close attention to the specific mission and requirements of the funding announcement they respond to even if it is a general ('parent') announcement (see 4.5). The application guide (see 4.7) stipulates general recommendations and requirements.

Applicants are strongly advised to contact a Program Officer before developing and writing a full proposal to make sure the work is of interest and a good fit to the IC and NIH in general. Be prepared to have a summary of the proposed work or specific aims page ready (see 4.10).

4.4   Website(s) & Mailing Lists:

Grants & Funding information has its own menu on the main website www.nih.gov. It lists the types of grants, due dates, policies and compliance, forms, and an overview of How to Apply to NIH and other Public Health Service (PHS) agencies. Although much will be covered in this guide, applicants are advised to spend time with the sites, especially the latter (How-To-Apply). It is an ongoing resource for new and recurring applicants.

The **weekly e-mail listserv** (NIH TOC) releases new funding opportunity announcements and notices published in the *NIH Guide for Grants and Contracts*, the official publication for NIH grant policies, guidelines and funding opportunities. It is published daily, and a table of contents (TOC) is issued weekly.

Funding opportunities (active, expired) can be searched using the **NIH Guide to Grants and Contracts** feature {NIH/ Grant & Funding/ Funding}. Note: Many granting organizations are included in this search, not just NIH.

A great way to stay informed of funding opportunities in general is to subscribe to the listserv of Grants.gov, which posts information on many grant programs (see also 4.7 – APPLICATION INSTRUCTIONS & FORMS and 4.8 | KEY SYSTEMS AND REGISTRATIONS). *Note that grants.gov will provide updates on funding opportunities, but not NIH policies and procedures.*

4.5   Types of Funding Opportunity Announcements (FOA)

- *Parent Announcements* (PAs): Ongoing, broad announcements for submitting investigator-initiated ('unsolicited') applications for a particular grant type (see 4.6) that use the standard receipt (due) dates. Typically, many ICs participate.

- *Program Announcements* (PAR/PAS): Issued by one or more IC to highlight areas of scientific interest; encourages applications for a new or ongoing program.
    - PAR: special receipt, referral, and/or review considerations;
    - PAS: special set-aside funds.

- *Requests for Proposals* (RFP): announcements by one or more IC to highlight well-defined areas of scientific interest to accomplish specific program objectives. When applying, it is critical your science/proposal fits the scope of the RFA. The amount of set-aside funds is indicated as well the anticipated number of awards. These proposal usually have one single due date.

Each announcement conveys key pieces of information about the funding program, its requirements and budget. *Study this annotated FOA to learn more. Every time you apply, study the announcement carefully before developing a proposal to make sure you can accommodate (all) needs and interests.*

Some FOA modify the general instructions of the application guides (see 4.7 – APPLICATION INSTRUCTIONS & FORMS). *In such cases, the FOA instructions must be followed.*

4.6 Types of Proposals/Grants:

NIH uses 'activity codes' (e.g., R01, R21, R34) to differentiate between different research-related proposals and support. ICs vary in the way they use the activity codes and not all ICs accept applications for all types of grant programs or they apply specialized eligibility criteria. *Look closely at the FOA to determine which ICs participate and eligibility specifics*.

- Research Grants (R-series)
- Career Development Awards (K-series)
- Research Training and Fellowships (T & F series)
- Program Project/Center grants (P series)
- Resource Grants (various series)
- others....

This guide focuses on the most common type of grant proposal at NIH, the Research Grants (R-series). However, many of the stipulations outlined here apply to the other programs and discrepancies or additional instructions are outlined clearly online using the HTML version of the official, general NIH application guide (see next page: **Forms**).

4.7 Application Forms, Instructions & Format Pages:

There are three avenues to submit an application to NIH, all of which are electronic and will solicit the *same content* (i.e., information, documents). They are merely different submission options. All require a funding opportunity announcement number (see 4.5) to initiate an application.

Although each of the options is shown here, GSU favors one (see below).

I.   **ASSIST** {https://public.era.nih.gov/assist}: The '*Application Submission System & Interface for Submission Tracking'* (ASSIST) system is NIH's own web portal for the preparation and submission of grant applications to NIH and other Public Health Service (PHS) agencies. Information is directly entered into ASSIST or uploaded as PDF attachments.

II.   **Grants.gov** {www.grants.gov}: Grants.gov is a government portal used by many federal grant-making agencies, not just NIH, and their applicants to find and apply for federal grants. Applying through *Grants.gov allows the applicant to download the application package to his/her computer and work on it offline.* The package can be found online {grants.gov/ Applicants/ Apply for Grants} or is retrieved easily by clicking the {Apply Using Downloadable Forms} button in the funding opportunity announcement.

III. **CAYUSE**: CAYUSE is a third-party, electronic proposal development and submission platform that GSU uses for grant proposals submitted through Grants.gov. It is a system-to-system solution that *offers a live overview of potential errors and sponsor-system warnings before submission, which help to avoids last minute submission problems and potentially missed deadlines*. See sections 2.3 (CAYUSE) and 4.8 (| KEY SYSTEMS AND REGISTRATIONS) for more details on using CAYUSE.

OSPA (see 2.2) *strongly recommends all grants.gov applications be submitted through CAYUSE, including NIH.* It provides a real-time summary of potential application errors and sponsor warnings.

- **Forms**:

    NIH posts the appropriate and necessary application forms, called ***Standard Form 424 (Research & Related)*** or ***SF424 (R&R)*** with each funding opportunity announcement. If you are submitting an unsolicited application (see 4.5), check the latest parent announcement for the appropriate forms and instructions.

    The HTML (Internet) version of the NIH application guide shows each form per application section along with instructions and tips {grants.nih.gov/ About Grants/ How To Apply}. Forms are also found in a Table {grants.nih.gov/ About Grants/ Forms Library} which provides little to no explanation, however.

    Forms and instructions are updated regularly, be sure to use the latest (Forms Version D, or FORMS-D as of 5/25/2016).

- **Instructions**:

    General ("G") instructions on how to apply and complete forms are found in the SF424 R&R application guide, which may be viewed online (HTML) on the NIH website {grants.nih.gov / About Grants/ How To Apply} or downloaded as PDF by scrolling down to **Form Instructions (Version D**). It is a comprehensive, general guide containing instructions for research, training, fellowship, career development, and multi-project applications. Filtered guides specific to each type of grant are posted on the same website.

    Reference will be made later (sections 4.10; 4.11) to the application guide and where to find information using the official application guide sections denoted as [G.xxx – section name].

    Check *specific instructions* in the funding opportunity announcement you are responding to, especially for solicited program announcements and requests for proposals (see 4.6 – TYPES OF GRANTS).

- **Format Pages**:

    Some document should not be created from scratch by the applicant, but must use a template called format pages. Files must be converted to PDF before they can be uploaded and included in the application package. Biosketches, for instance, are submitted using a format page.

    Format pages are updated regularly, be sure to check and use the latest.

4.8   Submission, review & timelines:

- **Key systems and registrations:** Organizations and investigators need to be registered in several systems in order to apply for NIH funding using one of the submission options (see 4.7). Registrations may take 4 - 6 weeks to complete, *ascertain early they are in place or initiated*. Contact URSA/ OSPA (2.1, 2.2) for the organizational registrations:

  1) **Grants.gov/CAYUSE**: Grants.gov is a government portal used by many federal grant-making agencies, not just NIH, and their applicants to find and apply for federal grants. The applicant organization (i.e., GSU) must have an active registration in order to submit proposals through Grants.gov. The organizational registration is OSPA's responsibility.

     OSPA strongly recommends grants.gov submissions be prepared using CAYUSE (see 2.3). Initiating an application in CAYUSE will render it visible and accessible to OSPA. However, if the PI works with a local, departmental grants officer not affiliated with OSPA, that staff member should be given access using the CAYUSE permissions function.

     ☞ CAYUSE requires a campus ID and ID password.

  2) **eRA Commons** is NIH's online proposal and award management system that allows applicants, grantees and federal staff to securely share, manage and process grant-related information. *It is used for a number of pre-award tasks, such as tracking the status of an application submission. It is not used to actually submit a proposal to NIH.* Some of the individuals named on a grant application (e.g., principal investigator) must be registered in eRA Commons and their credentials must be included in the application package in order to submit. Check the NIH eRA Commons User Registration website to find out who should register.

     Principal Investigators (PIs) must be registered with eRA Commons. The registration can be requested electronically using the **Research Portal** (see 2.1 – URSA). PIs can do this themselves or their pre-award support (see 2.5) can. Registration yields an eRA Commons ID and password.

     ☞ eRA Commons requires an eRA Commons ID and password.

- **Due dates** vary between funding announcements, but many use standard or *standing* receipt dates. On the specified date, applications are due by 5:00 PM local time of the applicant organization. A separate policy applies to due dates on Holidays and Weekends.

  Many NIH programs accept submissions 3 times per year, but some opportunities are only open once a year. *Study the funding announcement carefully to time your application appropriately.* Renewal/resubmission/revision applications may have different due dates than new applications. AIDS and AIDS-related applications have their own due dates.

- **Peer Review**: The first level of review is done by a Scientific Review Group (SRG) composed primarily of non-federal scientists (e.g., university faculty) who have expertise in relevant scientific disciplines and current research areas. The second level of review is performed by Advisory Councils or Boards at the ICs. The second level determines whether an application is funded; the first advises on the scientific merit of applications. Only if an application is considered to have scientific merit and passes the first level of review is it considered for second level review and funding. All other applications are not considered for funding.

- **Scoring**: Although an application must have scientific merit to be considered for funding, not all good applications get funded. Funding chances depend on the score an application receives during scientific review by the SRG. *The lower the score, the better*. Although all applications get reviewed and scored, only the top 40 to 50% are discussed by the SRG in a closed-door panel meeting. The rest is not considered for panel discussion or "not Discussed (ND)". An overview of reviewer comments detailing the strengths and weaknesses of the application is provided in summary statements (also called *summary sheets*) that are shared with applicants about a month after SRG panel meeting. Reviewer guides and Critique templates can be viewed online to get a sense of what reviewers look for.

- **Review criteria - general**:

    1) *Significance*: Does the project address an important problem or a critical barrier to progress in the field?

    2) *Investigator(s)*: Are the Program Director/Principal Investigator (PD/PI), collaborators, and other researchers well suited for the project?

    3) *Innovation*: Does the application challenge and seek to shift current research or clinical practice paradigms by using novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?

    4) *Approach*: Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?

    5) *Environment*: Will the (scientific) environment in which the work will be done contribute to the probability of success?

    6) *Overall Impact*: How likely is the project to have a sustained, powerful utility or influence on the research field(s) involved given the above criteria.

    Additional review considerations include the PROTECTIONS OF HUMAN SUBJECTS; INCLUSION OF WOMEN, MINORITIES, AND CHILDREN; USE OF VERTEBRATE ANIMALS; and Biohazards (see 4.11).

    For Resubmissions, the committee evaluates if the application responds to comments (concerns) from the previous review and proper adjustment were made. For Renewals, the committee will consider the progress made in the last funding period. For Revisions, the committee considers if the proposed expansion of the scope of the project is appropriate.

- **Review criteria – specific**: carefully read the funding opportunity announcement (see 4.5) to address and accommodate any other important review and funding considerations in your proposal. Use language specific to the announcement if appropriate to align your proposal

with the Institute's or NIH's specific area(s) of interest. Also check and accommodate budget requirements and limitations.

- **Timeline**: After submitting, it takes about 2 to 4 months for an application to be reviewed by individual reviewers and the SRG panel, and 5 to 8 months for the Council to meet and make a funding decision. The earliest project start date is 9 months after submission, provided funding is awarded. Check the Due Dates website for an overview of review and award cycles for specific grant types. *It is imperative applicants are prepared to receive an award.* A major requirement for award is IRB and/or IACUC approval (see 4.11 | HUMAN SUBJECTS; VERTE-BRATE ANIMALS/ ENDANGERED SPECIES).

4.9   Proposal Development– general recommendations:

- **Contact program officer(s) - POs**: *Contacting NIH program personnel prior to proposal preparation and submission is strongly encouraged.* They can comment on your idea and its fit with the program you are considering. You can also ask questions about the composition of the review panel, common flaws in proposals submitted to this program and things to emphasize to make the proposal stand out.

  If the PO welcomes an application, or approves other important decisions, state so in a cover and identify the relevant officer by name and affiliation (see also 4.11 | COVER LETTER).

- **Do your homework**:

  o *Read the FOA carefully:* Program solicitations may deviate from the general instructions and requirements listed in the official application guides. If so, the FOA must be followed. Be sure to check and read the latest announcement carefully. In case of doubt/conflict, contact the program officer(s).

  o *Be responsive to general and specific interests, priorities, and missions.* Read the FOA carefully, study the program and division missions, and have an understanding of the NIH strategic plan (see 4.3 - MISSION). It is updated every 4 years.

  o *Follow the application instructions exactly:* The official application guide (see 4.7 – INSTRUCTIONS & FORMS) discusses the content (forms, information) that must be provided but also specifies how to format documents. Format requirements include, but are not limited to:

    + *typefaces*, which include recommended text fonts (e.g., Arial) and size (10 or 11 larger depending on the font). *Avoid small or crammed text as it may frustrate reviewers*;

    + *margins*: at least one-half inch in all directions;

    + *line spacing*: no more than 6 lines of text in a vertical inch;

    + *text color*: must be black but some exceptions are allowed.

- **Do not waste reviewers' time** – *Write iteratively and crisply*: Reviewers are not paid for their time, it is considered an honor and service to review. This means they review applications on top of everything else they have going, often late at night, on weekends, and during (family) trips. Make sure your application reads easily and well. Conversely, if you are sloppy in your reasoning and formatting (typos…), reviewers may quickly loose interest. They will finish the review, but not be motivated, which may lower their opinion of your work and the team. Give reviewers reason to keep going, stay interested and focused. Take the time to develop and *revise the application multiple times*.

- **Give yourself plenty of time** (3 to 6 months): A good application has interesting and important goals, a strategy and plan that make sense, and a team that can do the job well. In a good, satisfactory application, everything adds up. It does not have to be perfect, but the proposal cannot have major flaws or oversights in its goals, approach or team. This takes time to crystalize and often many revisions.

- **Have someone else read and critique key parts of the application**.

4.10 Grant Application – Key, Competitive Parts:

The main, competitive pieces of an NIH application are the SPECIFIC AIMS and RESEARCH STRATEGY. These two documents drive reviewer scores, which does not mean the other pieces are not important. Everything should add up, but the AIMS and STRATEGY are what drives scores and panel (SRG) discussion. If the project goals are not exciting and/or the research plan is unrealistic or not solid, enthusiasm for the application drops quickly. Conversely, if these pieces are good, other weaker aspects of the application may be given the benefit of the doubt or only be noted as a minor concerns in reviewer critiques and discussions.

- **SPECIFIC AIMS** [G.400 - PHS 398 Research Plan Form / Item 2]: This page should concisely state the goals of the proposed 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.

   Before listing the specific aims, briefly outline the problem and needs gap, why we should care, what you propose to do to make things better and how that will help or advance matters. *Make sure you are proposing something new, not just important*.

   Continue listing succinctly the specific aims of the proposed work, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

   Spell out milestones (benchmarks for success) and deliverables for each aim.

     Limited to 1 page
     Attach PDF to PHS 398 Research Plan Form, Field 2.

- **RESEARCH STRATEGY** [G.400 - PHS 398 Research Plan Form / Item 3]: This section should include sufficient information for evaluation of the project independent of any other document or resource. Do not circumvent page limits by referring to external sources (e.g., websites) or other parts of the application. Be specific, informative, and avoid redundancies.

  The RESEARCH STRATEGY is organized in a specific order and each section should start with the appropriate section heading:

  1) *Significance*: Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. Describe the scientific premise (the evidence base) for the project, including the strengths and weaknesses of published research or preliminary data crucial to your application. Explain how your project will improve scientific knowledge, technical capability, and/or clinical practice.

  2) *Innovation*: Explain how the proposed work challenges and seeks to shift current research or clinical practice paradigms. Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and the advantage over existing methodologies, instrumentation, or interventions. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

  3) *Approach*: Describe the overall strategy, methodology, and analyses used to accomplish the project's specific aims. Describe the proposed experimental design and methods and how they will achieve robust and unbiased results. Include how data will be collected, analyzed, and interpreted as well as any resource sharing plans if appropriate.

     In the Approach section, it is recommended to identify which members of the team do what. This can be done in an introductory paragraph and for individual tasks or activities. In the latter case, point out *Who-does-What-for-How-long-When*, but briefly (1 or 2 sentences).

     Approach and write the Approach section as a recipe*: "In order to achieve X* [Aim], *we will do ABC* [tasks, steps, activities with a person/team and timeline attached]. Use consistent headings, subheadings, and tabs, spacing and formatting to delineate the different parts and activities of the proposed work.

     Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.

     If the project involves studies of human subjects, be sure to discuss the recruitment and makeup of samples including in/exclusion criteria. Describe detailed procedures and justifications in the sections on PROTECTIONS OF HUMAN SUBJECTS and the INCLUSION OF WOMEN, MINORITIES and CHILDREN (see 4.11).

Repeat SPECIFIC AIMS in the RESEARCH STRATEGY so the document stands on its own as instructed. However, make sure the documents are aligned: If you change an aim in one, be sure to update it in the other.

If an application has multiple Specific Aims, address *Significance*, *Innovation* and *Approach* for each Specific Aim individually, or for all Aims collectively.

New applications should include information on **Preliminary Studies**, highlighting the data and experience of the PI/team. This helps establish the likelihood of success of the proposed project.

    Limited to 5 to 12 pages depending on the type of grant (see page limits).
    Attach PDF to PHS 398 Research Plan Form, Field 3.

The next piece is not considered competitive but is crucial nonetheless:

▪ **KEY PERSONNEL & BIOSKETCHES** [G.240 - R&R Senior/Key Person Profile (Expanded) Form]: Once your aims and research strategy are clear, the question is who does the job. The team (Investigators) is an integral part of any application. It is one of the merit review criteria (see 4.8).

As discussed, it is helpful if the *Approach section* (RESEARCH STRATEGY) specifies who does what as the aims and project unfolds. It helps reviewers develop a sense of comfort and confidence in the project as they read, and it avoids them piecing together who does what based on biosketches (discussed below) that are provided separately. However, in the *Approach section*, be specific to the proposed project. Use BIOSKETCHES to establish someone's overall experience and track record.

    o *senior/key personnel* are defined as *'individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested'*. Consultants should be included if they meet this definition. The Principal Investigator (PI)/Project Director (PD), for instance, is key personnel.

       Senior/Key Person profiles are entered in the R&R Senior/Key Person Profile (Expanded) Form, starting with the Project Director/Principal Investigator (PD/PI).

    Although not required, the instructions state the remaining senior/key person profiles should be entered in alphabetical order. *Note that these profiles and associated biosketches will appear in the application in the order provided by the applicant. Therefore, you may want to start with the most important or unique collaborators first so reviewers see them right away.*

    A BIOSKETCH is required for all senior/key persons and *Other Significant Contributors (OSCs). OSCs are individuals who contribute to the development or execution of the project, but do not commit any specified measurable effort.*

Definitions of Personnel and other concepts are found in Part III, Section 3 of the Supplemental Grant Application Instructions.

o *BIOGRAPHICAL SKETCHES*: Biosketches or "Bios" offer a resumé of an investigator's education, employment history, and research, funding and publication track record. *If they are considered key personnel, consultants also may have to provide a biosketch*.

Biosketches start (section A) with a *Personal Statement that explains why this person is suitable for the specific role(s) they play on the proposed project*. *Be sure to include publications or research products that highlight experience and qualifications*. Contributions to Science (section C) may include contributions not related to the proposed project. Avoid redundancies with section A and limit contributions to one half page, including citations.

Follow all instructions, and give yourself plenty of time to prepare your own and request the bio of others. Even if people have one available, the Personal Statement must describe the project and person's role correctly and pointedly. If no bio is available, plan 3 to 4 weeks to obtain a good, final one from everybody.

 📖 Limited to 5 pages, per bio
 📖 Dedicated Format Page (see 4.7).

 🖑 Attach PDF to R&R Senior/Key Person Profile for each key individual.

4.11 Grant Application – Other Important Pieces:

▪ **PROJECT SUMMARY/ABSTRACT** [G.220 - R&R Other Project Information Form / Item 7]: Although not a competitive section, the ABSTRACT is where many reviewers and program officers start. If it is good, the reader gets excited to learn more.

A good abstract includes statements that summarize the *background* (what is the problem or missing today), *significance* (why is that important), your project (*solution*) with a description of broad, long-term objectives and relevance to the mission of the agency. The research design and methods for achieving stated goals should be described briefly.

The Abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application.

 📖 Limited to 30 lines.
 🖑 Attach PDF to the R&R Other Project Information Form, Field 7.

- **BUDGET** [<mark>G.300 - R&R Budget Form</mark>]: An NIH proposal must include a budget for each year of support requested. The budget section is filled out electronically per project period (year).

> *See your pre-award supports (section 2.5) to plan and kick start the budget*. Use OSPA's **budget templates** *(spreadsheets)* to develop and calculate the budget {URSA/ Proposal & Awards/ Develop Proposal Budget/ Budget Templates and Justification}.
>
> *CAYUSE/Grants.gov applications (see <mark>2.3</mark>; <mark>4.8</mark>) will enter their budget in CAYUSE spreadsheets that match the NIH budget pages.*

Main expense categories are *Personnel* (salaries/benefits, section A and B), *Equipment* (C), *Travel* (D), *Participant/Trainee support costs* (E), *Other Direct Costs* (Materials & Supplies; Publication costs; Consultant services; Computer services; Subawards; Rental/ User fees; Alterations & Renovation; and Other), and *Indirect Costs* (H).

The indirect cost rate is known as Facilities & Administrative Costs (F&A) and is established by your organization (GSU).

Equipment is not to be confused with computers and other electronic items. It is an item over $5,000 that is not available on campus or otherwise, and must be acquired. Less expensive and more common equipment items, such as computers needed for the execution of the project, are budgeted under *Materials and Supplies* (section F1. Other Direct Costs). Laptops or computers for personnel is typically not supported.

The cost and effort of *Personnel* can be derived quite easily once your AIMS and APPROACH are clear. If you know '*Who-does-What-for-How-Long-When*' (see <mark>4.10</mark> | RESEARCH STRATEGY/*Approach*), it follows you know who is involved at roughly what effort (i.e., how many hours and thus weeks or months do you need a person in any given year?). If you know their salary, the necessary budget request can be derived.

Although the budget is not a competitive piece of the application, reviewers are asked to rate it as appropriate (or not), and may suggest adjustments.

- ☞ Budget information is entered directly into the R & R BUDGET form for each project period separately.

- **BUDGET JUSTIFICATION** [<mark>G.300 - R&R Budget Form</mark>]: Although firm requirements or format pages are not provided, it helps to spell out all expense categories (A through I) per budget period and provide a brief explanation for each budget item. Why is travel $xx, xxx? Why consultants $xx,xxx? If done well, it instantly satisfies the "justification" requirement and shows that you know what you are doing.

- 📖 Only 1 file may be attached.
- ☞ Attach PDF to Research & Related BUDGET form, Field K.

- **LETTERS OF SUPPORT** [G.400 - PHS 398 Research Plan Form / Item 13]: Consortium and other important collaborating partners as well as key personnel and other significant contributors (OSCs) all should provide a letter of support. Letters should stipulate expectations, arrangements, and fees – if any.

  Consider drafting letters to save others time, but avoid letters looking and sounding the same. It suggests your partners/team were/are not involved, and potentially, are not committed to the project. This looks bad.

  Have letters printed on official letterhead if applicable and saved as PDF.

  - 📖 Merge and attach letters as 1 PDF file.
  - 🎩 Attach PDF to the PHS 398 Research Plan Form, Field 13.

- **COVER SHEET** [G.200 - SF 424 (R&R) Form]: Contains a number of boxes, some of which may be prepopulated based on information already entered. Information such as the title and duration of the project are entered here, but also congressional district of the applicant and other administrative information.

  GSU Administrative information, such as its DUNS number and institutional representatives and contacts, can be found online {URSA/Proposals & Awards/ Get Started with a Proposal / Fact Page and Key Institutional Documents / Institutional Fact Page}, or ask your pre-award support team (see 2.5).

  - 🎩 Information is entered in SF424 (R & R) Form. Note that the form nor filename mention 'cover sheet or page'. ☹

- **PROJECT/PERFORMANCE SITE LOCATION(S)** [G.230 - Project/Performance Site Location(s) Form]: This form lists where work will be performed (a primary location, and others if necessary).

  GSERF is the applicant organization, and GSU is the primary performance site. Be sure to use the correct DUNS number (see 2.2 – OSPA | INSTITUTIONAL FACT PAGE.

  If a site is involved in human subjects' research, the applicant organization is responsible for ensuring that the site operates under appropriate federal assurances and complies with federal regulations and human subjects research policies (see 4.11 | HUMAN SUBJECTS).

  - 🎩 Enter information in the Project/Performance sites location(s) Form.

- **FACILITIES & OTHER RESOURCES** [G.220 - R&R Other Project Information Form / Item 10]: Describe how the environment in which the work will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual support). Discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements. Be sure to list resources that are essential to the proposed work, for instance, lab space or interview and test rooms.

  If there are multiple performance sites, describe available resources for each site.

  - ⌐ Attach PDF to the R&R Other Project Information Form, Field 10.

- **EQUIPMENT** [G.220 - R&R Other Project Information Form]: List major equipment item already available to the project including location and capabilities. For instance, MRI scanners or intricate lab equipment.

  - ⌐ Attach PDF to the R&R Other Project Information Form, Field 11.

- **BIBLIOGRAPHY & REFERENCES CITED** [G.220 - R&R Other Project Information Form /Item 9]: Provide a bibliography of any references cited. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations.

  Consider using a citation manager program such as EndNote that manages citations and updates a bibliography as you write.

  - ⌐ Attach PDF to the R&R Other Project Information Form, Field 9.

- **PROJECT NARRATIVE** [G.220 - R&R Other Project Information Form / Item 8]: Using no more than two or three sentences, describe the relevance of this research/work to public health.

  - ⌐ Attach PDF to the R&R Other Project Information Form, Field 8.

- **PROTECTIONS OF HUMAN SUBJECTS** [G.400 - PHS 398 Research Plan Form / Item 5]: This document *must be included if human subjects are involved* [*Are Human Subjects Involved*?] If the answer is "No" but your research involves human specimens and/or data from subjects, you must provide a justification for your claim.

More information on exemptions and human subject research scenarios and protections are found in the Supplemental Grant Application Instructions, **Part II**. Details on *what to include in the* PROTECTIONS OF HUMAN SUBJECTS *section* are found in **section 4.1** of these instructions.

Note that Human Subjects are distinct from Research Participants. The distinction has budgetary implications. Contact OSPA for more information.

Whereas the latter usually *get* something from the investigators (e.g., training, information), the former tend to *give* something (answers, data). Study protocol review by an institutional review board (IRB) ensures that whatever subjects give is safe, justified, and reasonable while the process of asking subjects to participate is ethical, and the decision to participate, voluntary.

If IRB approval has been obtained, enter the date of approval on the COVER SHEET form. If approval has not been obtained, indicate "Pending". However, should the proposal be recommended for award, the organization must provide IRB approval or exemption documentation before an award can be made. *Also, awards cannot be processed by GSU or applicants given access to their funds until all compliance pieces are in place.*

If "Pending" is selected, OSPA recommends investigators start laying the groundwork for an IRB protocol and review soon after submitting their proposal, especially when multiple institutions or sites are involved. That way the team can start the project soon after an award is made.

Be sure to provide sufficient information in the RESEARCH STRATEGY (see 4.10 – KEY APPLICATION PIECES) who is in/excluded and other details relevant to determining the quality and rigor of the proposed work. Do not use the Human Subjects section to circumvent the page limits of the RESEARCH STRATEGY.

Reviewers do assess the Protections and if not adequate, they may note this in their critique and bring it up in panel discussions.

⌐ Attach PDF to the PHS 398 Research Plan Form, Item 5.

- **DATA SAFETY and MONITORING PLAN** [G.400 - PHS 398 Research Plan Form / Item 6]: If the project includes a clinical trial, and you answered 'Yes' to the question on the Cover Page Supplement Form, a Data Safety Monitoring Plan (DSMP) must be included.

  A clinical trial is characterized by a) prospective assignment of human subjects; b) One or more intervention, and; c) Identification of one or more health-related biomedical or behavioral outcomes (see **Definitions** / **Part III** of the Supplemental Instructions).

Create a document entitled 'Data and Safety Monitoring Plan' and include information that describes, amongst others, the overall framework for safety monitoring and what information will be monitored as well as the frequency of monitoring, including plans for interim analysis and stopping rules. See **section 4.1.5** of the <u>Supplemental Instructions</u>.

    🖰   Attach PDF to the <u>PHS 398 Research Plan Form</u>, Field 6.

- **<u>INCLUSION OF WOMEN & MINORITIES, and OF CHILDREN</u>** [<mark><u>G.400 - PHS 398 Research Plan Form / Items 7, 8</u></mark>]: NIH policy requires that clinical research includes women, minorities and children unless it can be justified scientifically they should not be included.

  Reviewers evaluate whether the argument(s) provided by the applicant to include or exclude women, minorities and children make sense and if not, they may note this in their critique.

  A child is defined as an individual under 18 years of age.

  See **sections 4.2** and **4.4** as well as **5.6** and **5.8** of the <u>Supplemental Instructions</u> to draft these documents.

      🖰   Attach a PDF of each inclusion document to the <u>PHS 398 Research Plan Form</u>, Items 7 and 8, respectively.

- **<u>INCLUSION ENROLLMENT REPORT</u>** [<mark><u>G.500 - PHS Inclusion Enrollment Report</u></mark>]: All applications involving clinical research must submit an Inclusion Enrollment Report. This form is used to report both planned and cumulative (or actual) enrollment, and describes the sex/gender, race, and ethnicity of the study participants.

  See sections **4.3** and **5.7** of the <u>Supplemental Instructions</u>.

      🖰   Enter information in <u>PHS Inclusion Enrollment Report</u>.

- **<u>VERTEBRATE ANIMALS</u>** [<mark><u>G.400 - PHS 398 Research Plan Form / Item 9</u></mark>]: Projects must comply with the Animal Welfare Act, and be approved by the organization's Institutional Animal Care and Use Committee (IACUC) prior to award.

  If IACUC approval has been obtained, enter the date of approval on the COVER SHEET form. If approval has not been obtained, indicate "Pending". However, if the proposal is recommended for award, the organization must provide IACUC approval before an award can be made.

Provide sufficient information in the RESEARCH STRATEGY/*APPROACH* (see 4.10 – KEY APPLICATION PIECES) why animals are used and provide a concise, complete description of the animals and proposed procedures.

☞ Attach PDF to the [PHS 398 Research Plan Form](#), Item 9.

- **COVER LETTER** [G.200 - SF 424 (R&R) Form / Item 21]: Previously, the cover letter attachment was used to communicate assignment and review requests to the Division of Receipt and Referral (DRR) and to scientific review officers (SROs). This information must now be provided in the *PHS Assignment Request Form* (below). Both documents are for internal use only and will not be shared with reviewers.

  Refer to the instructions for items that are permitted, as well as for specific situations in which a cover letter must be included. Briefly, cover letters are used for late applications, changed/corrected applications, for subaward budget components that are not active all budget periods; any required agency approval documentation; when intending to submit a video as part of the application; for work that will generate large-scale human or non-human genomic data.

  ☞ Attach PDF to the [SF424 (R&R) Cover Page Form](#), Item 21.

- **ASSIGNMENT REQUEST FORM** [G.600 – PHS Assignment Request Form]: This form is optional but may be used to convey information about your preference(s) for assignment and review of your application to DRR and SROs, such as the awarding component (e.g., NCI, NIA, NIMH, etc.), study section assignment, reviewers who should not review your proposal, and areas of scientific expertise.

  ☞ Enter information in directly into the [PHS Assignment Request Form](#).

- **OTHER ATTACHMENTS**: [G.220 - R&R Other Project Information Form / Item 12]: Attach a file or files only to provide any other project information not provided already or in accordance with the announcement and/or agency-specific instructions.

  ☞ Merge files if necessary and attach 1 PDF to [R&R Other Project Information Form](#), Field 12.

- **APPENDICES** [G.400 - PHS 398 Research Plan Form / Item 16]: Include no more than 10 appendices, such as surveys and other data collection instruments. Patents may be included if directly relevant to the project. Publications may be included in special circumstances. *Do not use appendices to circumvent the page limits of the RESEARCH STRATEGY.*

  ☞ Merge files if necessary and attach PDF to [PHS 398 Research Plan Form](#), Field 16.

- **INTRODUCTION** [G.400 - PHS 398 Research Plan Form / Item 1]: *New (first time) applications should **not** include an Introduction unless specified in the FOA.* An unfunded application that was modified after initial review and is resubmitted for new consideration (Resubmissions), as well as funded but revised projects (Revisions), should include an introduction that 1) summarizes substantial additions, deletions, and changes to the application, and 2) responds to the issues and criticism raised in the summary statements (see 4.8 | **Scoring**). Introductions must fit on one page unless specified otherwise.

  ☜ Attach PDF to the PHS 398 Research Plan Form, Field 1.

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