### SMHS Office of Research Workforce Development Preparation of an NIH Training Grant Application For Investigators and Administrative Assistants

### **OVERVIEW**

The Office of Research Workforce Development (ORWD) led by Dr. Alison Hall provides resources and guidance to SMHS faculty who are preparing NIH R25 research education and NIH T32 training grants or similar proposals. This office maintains a relational training database that is used to track alumni and develop the NRSA training tables required for these submissions. Dr. Hall, who has extensive experience leading and serving as study section reviewer for NIH training applications will provide additional strategic assistance as desired. In addition, the ORWD has accumulated sample applications, template language for required sections, and effective illustrations which can be provided upon request.

The purpose of this guide is to orient and assist the PI who is considering a training application about the resources we might provide. This guide provides resources important for writing the proposal, but please always refer to the most recent instructions in the FOA that supersede any instructions here.

### CONTACTS

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### STRATEGIC MEETING OF PIS WITH ORWD

While different in structure and intent, research education (R25) and training (T32) grants generally provide essential support for a *research education or training program* that can pay trainees (salary or stipend) and provide support for the program (research supplies or workshops or tuition), but offer limited or no financial support to research preceptors or program leaders. Unlike R01 research grants, these grants incur 8% indirect cost recovery. They are all about outstanding programs to prepare the future biomedical workforce. They are also long applications (25 page narrative, **Arial 11, narrow margins**) with up to 8 required data tables that require institutional information. We are ready to help.

In a typical example, a T32 program might support 4 trainees for two years each, and include 16 faculty preceptors (3-4 times as many as trainees) who have research funding largely from the target NIH Institute, in a unique, focused program (eg. Cancer, HIV, summer research, etc...). Generally, there is a common course, workshop, retreat and/or curriculum, along with elective opportunities that sets the program apart from other available training.

Please meet with ORWD early to discuss your ideas so we might help you identify PIs of similar grants, and speak with faculty members who lead training efforts on campus (e.g. Graduate Program Directors or the IBS Director) to discuss how the proposed program might utilize existing resources and integrate with current programs.

It is also essential that the PD/PI identify appropriate administrative assistance to run the program. Who will assemble the application? Who will insure the program activities occur and trainees attend? Who will manage finances? This is typically in the PI home department. The administrator will likely work closely with the PD/PI and ORWD during preparation of the application.

### KNOW YOUR NIH FUNDING MECHANISM

- Different NIH institutes participate in various funding opportunities, including the "parent" <u>T32 FOA.</u>
- Research education programs can vary in intent from institute to institute, and you should read the R25 FOA and associated Notices.
- Refer to the SF424 Guidelines
- NIH T32 Due Dates: Standard 5/25, 9/25, 1/25. Please check the FOA for any institute-specific deadlines.
- Look up other funded awards in NIH RePORTER
- Speak to your program officer about your ideas.

# TIMELINE FOR PROPOSAL DEVELOPMENT

Activity Timeline	months before submission						
	6	5	4	3	2	1	Submit!
Conceptualize the training program							
Read FOA and Institute-specific guidelines							
Identify GW PI/PDs							
Discuss with NIH Program Officer							
Identify preceptors and examine draft Data Tables							
Obtain biosketches – if sent, agrees to be a mentor							
Identify courses and degree programs							
Identify RCR instruction							
Draft proposal narrative 25 pages				-			
Review Data Tables; alert ORWD with changes							
Develop Budget and Budget Justification							
Obtain Letters of Support							
Organize resources pages							
Write and review abstract							
Review final application							
Submit to OSP 5-10 days before NIH deadline							

# **FACULTY PRECEPTORS**

Draft a list of faculty trainers who might serve as key personnel/ preceptors. Things to consider: NIH research funding or equivalent, extensive training history, contributions to program (e.g. teach a course), experience mentoring, especially URM, undergraduate PhD or

MD focus of your application. Make sure that the trainers represent the variety of departments that would be useful for the topic of the training grant. Plan for 3-4 times the number of trainers as # of slots you are hoping to fund. If you provide the draft list of trainers, we can provide you with information about **funding** and **training history** that you will use to finalize your list. The PI should meet with potential preceptors to learn their interest in this particular training program.

Interested faculty must provide their updated NIH biosketches that include training experience. Receipt of the biosketch is confirmation that the faculty will participate. Biosketches will be checked and edited to include teaching and mentoring. RWD will also edit for Current/Completed grants.

### NRSA TRAINING GRANT TABLES-drafts from ORWD.

The tables you need will vary depending on the type of submission (renewal, new proposal, predoctoral only, postdoctoral only, combined, etc.). To determine which tables you need, review the <u>NIH Data Tables Instructions</u> and <u>NIH Application Guide</u> from the FOA.

The Office of Research Workforce Development will develop NRSA tables for your application using the training database. The database is updated several times a year with federal grants (NIH RePORTER and Federal RePORTER), foundation grants (OVPR), graduate student records (IBS office), postdoctoral scientists (HR), publications (PubMed), and faculty-submitted training records. It is important that the PI review these tables in advance of the deadline so they can be updated.

The PI will summarize the data tables in the Research Training Program Plan, using at least one paragraph for every table. The rationale for each table is included below, and the PI should address these points for the required tables.

### Table 1. Census of Participating Departments and Interdepartmental Programs

Table 1 indicates the total number of faculty members and trainees in each department, the number of trainees currently supported by any HHS training award, and the number of faculty and eligible trainees in each department that are associated with the proposal being submitted. "Eligible" trainees are U.S. citizens or permanent residents. This table shows whether the program has enough trainers and trainees to support the program and whether it has enough representation from relevant scientific disciplines. *Example:* "Of the 50 students affiliated with participating departments, 22% are in participating faculty labs and 75% are training grant eligible. Despite this, only a small number of these trainees (5%) receive NIH training grant support. Clearly there is a need to expand the number of training opportunities for GW trainees interested in translational research."

### Table 2. Participating Faculty Members

This table displays the participating faculty by rank, research interest, and department. This table displays the experience of participating faculty in training predoctorates and post-doctorates. It summarizes general information about participating faculty. Describe the rationale behind the selection of participating faculty, and address the distribution of faculty academic rank, departments, and research areas.

**Example**: "The faculty mentors have been selected due to their expertise in selecting candidate trainees with the potential for success in research, and their ability to train their students for independent and productive research careers.

# Table 3. Federal Institutional Research Training Grants and Related Support Available to Participating Faculty Members

This table shows current <u>institutional</u> research training support and any overlap in participating faculty members. This table is used to assess the institutional environment and determine the number of awarded training positions. Describe whether that support

is restricted to certain groups of trainees (e.g. early-stage graduate students, medical students, etc.). Explain instances where there is overlap of participating faculty. **Example:** "At GW there is 1 active NIH predoctoral training grant with 5 training slots (4 predoctoral and 1 postdoctoral). Among the 20 preceptors in this proposal, 5 are associated with the other active training grant."

### Table 4. Research Support of Participating Faculty Members

This table shows the funding support that will be available to support trainees, and it displays the ability of each trainer to support students. It is also evidence of the strength of the university's research environment. Summarize the total and average grant support. If any faculty are included who do not have grant support, explain why they are included and how trainees in their labs would be supported.

**Example**: "The preceptors associated with this training program are competitive in obtaining research support, as shown by the large number of active faculty grants. This will ensure trainee research support and that the trainees are exposed to faculty strategies to effectively fund their research."

# Table 5A and 5B. Publications of Those in Training

This table lists the past <u>ten years</u> of trainees for each mentor. For each trainee, it lists their training period and all publications that resulted from their training with the mentor. This table indicates the strength of each faculty member in fostering trainee productivity through publishing. It is also an indicator of research quality. Summarize the average number of papers published by trainees, the number of first author publications, and the number of trainees who did not publish.

**Example:** "Data Table 5A shows the remarkable listing of trainee publications. On average, trainees in this program published two papers in journals such as..."

Table 6A and 6B. Applicants, Entrants, and their Characteristics for the Past Five YearsThis table summarizes the past five years of applicants and entrants to the program.This table indicates the strength of the program in recruiting trainees, including programselectivity and competitiveness. It is used in determining the number of awarded trainingpositions. Analyze the number of potential trainees, the qualifications, characteristics,and eligibility of applicants (U.S. citizens and permanent residents), and recent trends inenrollment.

**Example:** "The percentage of training grant eligible applicants accepted into our predoctoral programs has steadily increased from 75% in 2015 to 85% in 2018."

# Table 7. Appointments to the Training Grant for Each Year of the Current Project Period (Renewal/Revision Applications only).

This table summarizes the appointments to the training grant. This allows for the evaluation of the awarded training program. Summarize appointments to the grant. Explain any trainees that ended the program early or any positions that went unfilled. *Example:* "Sixteen trainees were appointed to the grant between 2015 and 2019, with a completion rate of 90%."

# Table 8A, 8B, and 8C. Program Outcomes

This table lists the past fifteen years of trainees for renewals and the past five years of eligible trainees for new applications. For each trainee, the table summarizes funding support, subsequent positions, and subsequent awarded grants. This table displays how effective the program is in achieving training objectives and fostering research careers. Summarize how well the program has been in helping trainees obtain research careers and subsequent grant support. Describe how trainees' subsequent positions benefit the greater biomedical research field.

**Example**: "This table clearly shows the ability of these mentors to recruit and train a highly successful pool of trainees, with 85% going on to careers in research and 20% receiving subsequent NIH funding."

COMPONENTS OF THE PROPOSAL	Length		
Project Summary/Abstract	30 lines		
Project Narrative	2-3 Sentences		
Introduction to Application (resubmission and revision only)	1-3 pages		
Program Plan, including:	25 pages		
A. <b>Background</b> (~2-3 pages): history and needs for program			
B. Program Plan			
a. Program Administration (~2 pages): program director(s),			
coordinator, internal or external advisory committees			
b. Program Faculty (~5 pages): describe each faculty member			
c. Proposed Training (~6 pages): describe structured training			
program			
d. Training Program Evaluation (~2 pages): plans to review			
program, how program leads to program goals			
e. Trainee Candidates (~2 pages): describe pool of candidates			
f. Institutional Environment and Commitment to Training (~1-2			
pages): GW support and commitment			
g. Qualifications of Trainee Candidates and Admissions and			
<b>Completion Records</b> (~4 pages): ability to recruit and retain			
strong candidates			
C. Recruitment Plan to Enhance Diversity (~2-3pages)			
Plan for Instruction in the Responsible Conduct of Research (RCR)	3 pages		
Multiple PD/PI Leadership plan, as applicable	1 paragraph		
Methods for Enhancing Reproducibility			
Progress Report (for renewals)			
Participating Faculty Biosketches	5 pages per person		
Letters of Support	1-2 pages each		
Bibliography & References cited			
Facilities & Other Resources			
Equipment			
Human Subjects, as applicable	1 paragraph		
Data Safety Monitoring Plan, as applicable			
Vertebrate Animals, as applicable	1 paragraph		
Select Agent Research, as applicable	1 paragraph		
Consortium/Contractual Arrangements, as applicable			
Budget Justification	1 page		
Data Tables			

We provide some selected instructions, tips, and review criteria below, but these do not substitute for the NIH instructions. ALWAYS read the instructions! At this writing July 2020, we are in Fellowship Instructions for NIH and other PHS Agencies, Forms F, here https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/fellowship-forms-f.pdf Project Summary/Abstract (30 lines)

Include the objectives, rationale, design, and key activities of the training program. Describe the trainee appointments, including duration, number and level of trainees and expected trainee outcomes.

- Project Narrative (2-3 sentences)
   Describe the relevance of this training program to public health.
   Example: "The cancer training program will provide enhanced training and education to biomedical scientists that will result in increased understanding of cancer and will lead to potential cancer therapies for United States citizens."
- □ Introduction to Application (Resubmission and Revision only)

# Resubmissions: 3 pages, NIH Resubmission Applications

### Program Plan (25 pages total)

1. Background (2-3 pages)

Describe the rationale behind the training program, background of the program, and why the program is needed now. Explain how the program relates to existing training activities at GW. Why is it important that this program happens at GW (research strengths, culture, facilities, location, etc.)? How does this proposal capitalize on GW investments? **Examples**:

"This program capitalizes on recent GW investments in cancer research, including..." "The demand for advances in cancer biology has never been higher. To meet this demand, a new cohort of interdisciplinary, translational cancer scientists is essential..." "GW is ideally positioned to foster the necessary interdisciplinary training at both pre- and postdoctoral levels via the proposed Program Title". Summarize Data Tables 1-3

# 2. Program Administration (2 pages)

**Program Director:** Describe the director's qualifications, relevant scientific background, current research, experience in research training, and percent effort in this program. If multiple PD/PIs are proposed, explain how this will benefit the program and trainees and outline roles and responsibilities (also multi-PI plan needed).

Administrators: Describe administration of the program, including responsibilities of involved personnel and how the director will incorporate feedback on the program. Describe the executive committee or internal advisory board, if included.

# NIH Review Criteria:

- Does the PD/PI have the scientific background, expertise, and administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program?
- Does the PD/PI plan to commit sufficient effort to ensure the program's success?

# 3. Program Faculty (5 pages)

Include a section for each faculty member, in a table or in short paragraphs. The faculty: trainee ratio should be about 4:1 or 3:1. Refer to Data Table 2 to describe each faculty member's relevant research and each mentor's success in training individuals at the level requested by the program (e.g. predoctoral, postdoctoral). Describe any past collaborations between faculty (joint mentorship, joint publications, etc.). Use Table 4 to describe faculty training history, trainee publishing success, and the ability of faculty to support trainee research. For faculty that do not have training experience, describe plans to make sure they become effective mentors. Describe the process by which faculty mentors will be added or removed and how they will be evaluated for participation.

# Summarize Data Tables 2-4

# NIH Review Criteria:

- Are sufficient numbers of experienced preceptors/mentors with appropriate expertise and funding available to support the number and level of trainees (including short-term trainees, if applicable) proposed in the application?
- Do the preceptors/mentors have strong records as researchers, including recent publications and successful competition for research support in areas directly related to the proposed research training program?
- Do the preceptors/mentors have strong records of training individuals at the level of trainees (including short-term trainees, if applicable) proposed in the program? Are appropriate plans in place to ensure that preceptors lacking sufficient research training experience are likely to provide strong and successful mentoring?

# 4. Proposed Training (6 pages)

Describe the structured training program trainees will participate in and how it will prepare them for a career in biomedical research. What are the objectives of the program, and how will the program design lead to effective training? Why is it important that this program happens **at GW** (research strengths, culture, facilities, location, etc.)? The training program must supersede a graduate degree program.

- Indicate: number of trainees and duration of training, background needed by trainees, plans to customize the program for trainees with different backgrounds, degree distribution (e.g., M.D. vs. Ph.D. for postdocs), course work (identify instructors, synopsis), research opportunities, activities to enhance research and professional skills (Individual Development Plans, oral and written presentation, grant/fellowship writing, and laboratory and project management for postdocs), plans to match trainees and mentors, trainee evaluation, meetings with mentors (describe content and frequency).
- Indicate how departments are coordinated and how this will enhance training
- How does this program differ from others in the DMV area?
- Provide a sample program for an individual trainee. Include the curriculum, research experiences, qualifying examinations, seminars, journal clubs, etc.
- Think about what is innovative? Basic/clinical/community? Disparities? Technologies?
- Describe what is common for all trainees-a course, a retreat, etc. that makes it a program beyond just working in one lab.

# NIH Review Criteria:

- Are the objectives, design and direction of the proposed research training program likely to ensure effective training?
- Do the courses, where relevant, and research experiences provide opportunities for trainees to acquire state-of-the-art scientific knowledge, methods, and tools that are relevant to the goals of the training program?
- Is the proposed training program likely to ensure trainees will be well prepared for research-intensive and research-related careers?

# 5. Training Program Evaluation (2 pages)

Indicate what you expect each trainee to start with, what your interventions (program) will do to them, and what outcome you expect from each trainee (publications, fellowship applications, completed degree, research career etc.). Show clear relationship between

grant objectives and outcomes. Describe how you will get trainee feedback and how metrics like trainee career development, publications, degree completion, and post-training job positions are tied to program goals. How will you track your trainees? For what? Try a logic model.

Show how training leads to competency attainment. For many training grants, competencies will resemble the <u>National Postdoc Association competencies</u>:

- Discipline-specific conceptual knowledge
- Research skill development
- Communication skills
- Professionalism
- Leadership and management skills
- Responsible conduct of research

# NIH Review Criteria:

• Does the program propose a rigorous evaluation plan to assess the quality and effectiveness of the training? Are effective mechanisms in place for obtaining feedback from current and former trainees?

**Logic Model Example** (from Linda S. Behar-Horenstein "Guidance for Writing T32 Curriculum and Evaluation Components":

# 6. Trainee Candidates (2 pages)

Describe the size and qualifications of the trainee candidate pool, including information on prior research training.

Be specific in describing:

- Recruitment plans, including application and selection process, eligibility, letters or transcripts. Retention plans
- Criteria for trainees to be reappointed to the program.

# Summarize Data Table 6

# NIH Review Criteria:

- Is a recruitment plan proposed with strategies likely to attract well-qualified trainees for the training program?
- Is there a competitive applicant pool of sufficient size and quality, at each of the proposed levels (predoctoral, postdoctoral and/or short-term), to ensure a successful training program?
- Are there well-defined and justified selection and re-appointment criteria as well as retention strategies?
- 7. Institutional Environment and Commitment to Training (1-2 pages) SEE TEMPLATE This is a signed letter on GW letterhead from the Dean that describes GW's support and commitment to establishing and growing the program. It describes shared facilities, space, equipment, funds for course development, time for faculty mentors, or support for other trainees in the program. It includes how this program differs from existing externally funded GW training programs.

# NIH Review Criteria:

• Is the level of institutional commitment to the training program, including administrative and research training support, sufficient to ensure the success of the program?

 Qualifications of Trainee Candidates and Admissions and Completion Record (4 pages) Describe the program's ability to recruit and retain trainees. Describe the selectivity of admissions and success in recruiting individuals from groups underrepresented in biomedical research. Justify the number of positions requested Summarize Data Tables 5, 7-8

# NIH Review Criteria:

- Has the training program ensured that trainees are productive (or, for new applications, other past students/postdoctorates in similar training) in terms of research accomplishments, publication of research conducted during the training period, and subsequent training appointments and fellowship or career development awards?
- How successful are the trainees (or, for new applications, other past students/postdoctorates in similar training) in achieving productive scientific careers as evidenced by successful competition for research science positions in industry, academia, government or other research venues; grants; receipt of honors; highimpact publications; promotion to scientific leadership positions; and/or other such measures of success?
- To what extent do trainees' subsequent positions in industrial, academic, government, non-profit, or other sectors benefit from their NRSA-supported research training and directly benefit the broader biomedical research enterprise?

# 9. Recruitment Plan to Enhance Diversity (~2-3 pages) SEE TEMPLATE

Describe how you will recruit trainees from groups underrepresented in the biomedical sciences. See <u>NOT-OD-031</u> for NIH Interest in Diversity. Describe past recruitment of diverse trainees and strategies to enhance recruitment of diverse trainees. Include recruitment, pipeline programs and success, faculty leadership/role models, For renewals, provide details on past experiences recruiting diverse trainees, including successful and unsuccessful strategies.

- PI/faculty efforts- visits to minority-serving institutions, recruitment at national meetings
- Formal partnerships with minority institutions

# NIH Review Criteria:

• Peer reviewers will separately evaluate the recruitment plan to enhance diversity after the overall score has been determined. Reviewers will examine the strategies to be used in the recruitment of individuals from underrepresented groups. The plan will be rated as acceptable or unacceptable.

Plan for Instruction in the Responsible Conduct of Research (3 pages) SEE TEMPLATE
 See <u>Supplemental Instructions</u>, Part III, Section 1.16: Policy on Instruction in the Responsible
 <u>Conduct of Research</u>:

- **Describe the format** (e.g. coursework, discussion groups, face-to-face interaction). Online-only instruction is not acceptable.
- **Summarize the subject matter** (e.g. conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics)
- Describe faculty participation and roles of mentors in instruction

- Describe duration of instruction (total contact hours- minimum of 8 hours)
- Describe frequency of instruction (at least once in each career stage or once every four years)
- Describe how participation in RCR instruction will be monitored.

### □ Multiple PD/PI Leadership Plan (1 paragraph)

As applicable, how will multiple PIs benefit the program and trainees? Describe the organization of the leadership team, including communication and decision-making plans procedures for conflict resolution.

**Example**: Both PIs, Drs. X and Y, will provide oversight, coordination and execution of the project. The two PIs will meet in the spring to review application procedures and plans for the summer with the Internal Advisory Board, and together every two weeks to accept candidates to the program. They will hold weekly conferences during the summer to discuss program direction, progress, troubleshooting and coordination. The PIs will meet with the External Advisory Committee and review participant feedback at the end of each summer. Both PIs will ensure that institutional compliance and data collection are met. Dr. X will serve as contact PI and will be responsible for communication with NIH and submission of annual progress reports.

- □ Methods for Enhancing Reproducibility SEE TEMPLATE
- Progress Report (for renewals)
- Participating Faculty Biosketches

Follow <u>instructions for biographical sketches</u>. Biosketches should include past training information. Biosketches will be sent to RWD for review and then sent to Julia Bellafiore (jbellafiore@gwu.edu) for upload.

□ Letters of Support

Include letters from consultants, if applicable, external advisory committee members, and the Dean and/or Dean for Research describing institutional commitment. The office of Research Workforce Development will share example letters upon request.

- Bibliography & References cited
- □ Facilities & Other Resources SEE TEMPLATE
- Equipment SEE TEMPLATE
- Data Tables (above)
- □ Human Subjects-Complete only if human subjects are involved in trainee research.
- Data Safety Monitoring Plan-Complete only if trainee research includes clinical trials.
- Vertebrate Animals-Complete only if trainee research uses vertebrate animals. You will be asked for this in the JIT request.
- Select Agent Research- Complete only if trainee research uses select agents identified by HHS or the USDA.
- Consortium/Contractual Arrangements-Complete only if the budget includes consortiums/contracts.
- □ Budget (1 page) SEE SAMPLE BUDGET

Refer to the NIH for current NSRA stipend amounts. Fiscal year 2020 amounts are listed in <u>NOT-OD-20-070</u>. Provide stipend and institutional trainee expenses. Indirect costs at 8%. Other Attachments.

If you will include an Advisory Committee, provide a plan for appointment of the committee for monitoring program progress. Provide composition, roles, responsibilities, expertise of committee members, and frequency of meetings. Describe how the committee will evaluate the program.

RESOURCES <u>University of Alabama Grants Library</u>: Sample F, K, and T proposals

T32 scholar studies: Linda S. Behar-Horenstein & Alena Prikhidko (2017) Exploring mentoring in the context of team science, Mentoring & Tutoring: Partnership in Learning, 25:4, 430-454

Updated August 2020