Course Description

The course covers the objectives and process to create specific aims and proposal development for PhD students. Participants will write a research proposal in the format of a fellowship, including a Specific Aims page (one page) and Research Plan (6 pages) for use in discussions with mentors for the grant-style candidacy examination. The course will address issues of rigor and reproducibility including sample size to be considered in proposed studies. Additional sections on candidate background, bio-sketch, sponsor statement, and training plan that are necessary for NIH fellowship applications will also be examined.

Course Director:

Alison K. Hall, Ph.D.
Associate Dean for Research Workforce Development | Professor of Neurology
The George Washington University | School of Medicine and Health Sciences
Ross Hall, Room 709G | 2300 I Street, NW | Washington DC 20052
202-994-0200 | akhall@gwu.edu

Workload: This 2-credit class will meet for 2 hours each week, Mondays 10-12. Outside reading, assignments, and other preparation is expected to take up, on average, 3 hours per week, for a total of 5 hours per week. Students will be graded on a Credit/No Credit basis, with passing grade = 70%

Prerequisite(s): None. This class is designed for IBS PhD students preparing a grant-style qualifier proposal. PhD students or postdocs in other programs who anticipate a fellowship application are welcome to take the class, with course director approval.

Required Texts:
- University of Alabama Birmingham Grant Library
- SMHS Research/ Research Workforce website, and the NIH fellowship section
- The instructions for NIH fellowships, with the "nitty gritty" are at https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/fellowship-forms-e.pdf. It has a dandy "bookmark" upper right, to get through the 135 p document. Fellowship Supplemental form (eg everything you care about) starts p 58- (intro, background and goals, research training plan, sponsors, inst commitment etc).
- Additional articles and videos as indicated in the weekly schedule

Optional Texts
Robertson JD et al (2018). The grant application writers workbook (the NIH version)
Hollenbeck 2014. A practical guide to writing a Ruth L. Kirschstein NRSA Grant (available online at Science Direct

Learning Outcomes

By the end of the course, the learner will be able to:

1. Demonstrate the proposal writing, and revision skills needed to successfully complete an NRSA-style PhD qualifier proposal
2. Create a focused specific aims page, develop a research strategy that incorporates well-formulated hypotheses, rationales, specific objectives and long-range research goals
3. Organize additional candidate and training sections needed for an NIH fellowship application
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| 1 Monday Jan 11 | **In class lecture: Overview: Qualifier or Fellowship?**  
This course is designed to prepare doctoral students to write a grant-style PhD qualifier proposal comprised of a 1 page specific aims page and a 6 page research strategy section. The PhD qualifier is related to a full fellowship application as it includes these sections as well as additional components that will be addressed in some class sessions. Many participants will revise the successful qualifier and associated documents into an NIH fellowship (or other foundation) application.  
Most assignments will be drafted as homework, discussed in class in discussions with your peers, and after revision, turned into Blackboard for a grade. This will require you to share a draft with your assigned partner, and conversely, to provide helpful edits in Word track changes and in conversation. This activity is important to develop everyone’s critical skills, and discussion often improves the proposal. Even after a section is “completed,” you should expect to refine your drafts several times as your ideas solidify.  
This course requires considerable time to read resources and importantly, to draft proposal sections outside of class. Scientific writing, and particularly grant proposal writing, involves a focused style of writing in which you persuade a reader about the rationale and importance of your proposal. Persuasive writing is an important goal of the class.  
We use the current NIH F31 fellowship funding opportunity for informational purposes. When you are actually ready to apply for a fellowship, please refer to the most recent announcement and instructions!  
All assignments require:  
- A direct tone and active verbs  
- Limited use of "I."  
- Arial 11 font, single spaced throughout  
- 0.5 margins (“narrow”) consistent with NIH requirements.  
- Use of topic sentences that express the main idea of the paragraph  
The class is organized so that students draft specific aims, discuss them with their mentors, and be prepared to submit aims to their qualifier committee by May 1, although students can begin earlier. For IBS students, submission of the specific aims “starts a clock” to complete a qualifier examination before the Fall semester begins.  
**Homework:**  
1. Review the section of the IBS Handbook on GW PhD qualifier expectations and instructions.  
3. Read the Review Criteria for an NIH F31 fellowship in the announcement.  
2. Compare two example F31 applications, [F31 Schwartz](https://grants.nih.gov/grants/guide/pa-files/PA-20-246.html) in NIAID and [F31 Hauser](https://grants.nih.gov/grants/guide/pa-files/PA-20-246.html) from the University of Alabama Birmingham CTSI [Grants Library](https://grants.nih.gov/grants/newsearch/grants_search.html) for discussion in the next class. You are sent to these repositories so you might find helpful examples—look through others!  
2. Complete your Proposal Worksheet to discuss in next class  
**Turn In to Blackboard: Nothing today** | Nothing due |


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<tr>
<td>Jan 18</td>
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<td>MLK holiday</td>
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<tr>
<th>2</th>
<th>Jan 25</th>
<th><strong>To start class today:</strong></th>
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<td>• Each participant will introduce themselves, their mentor, and the proposed title and project, using the Proposal Worksheet.</td>
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<td>• Address questions about NRSA review criteria and IBS review criteria</td>
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**In class lecture: Hypothesis to Specific Aims**

You have an idea about an area of research, and maybe even a hypothesis. Think about your planned experiments by drafting objectives, or specific aims, and prepare a full page that describes how and why you will tackle those experimental questions.

The specific aims page is the hardest part of the grant proposal, and likely to be revised many times. There is no reason to develop details of your research approach if the specific aims are weak, so dive in now, and expect to make changes. In general, we anticipate you will have two specific aims in a qualifier or fellowship, to avoid the common mistake of being over-ambitious.

The best aims are designed not to “prove” a point, or ask “does A cause B” but an aim where the result does not depend on one outcome, and where different outcomes are of interest.

- Define the role of X in Y mediated perturbation of function
- Elucidate the role of X signaling on function in disorder
- Evaluate tissue as reservoir for virus
- Determine response of tissue during infection
- Define RNA features that lead to process
- Determine mechanism by which X and Y differ in effects on activity

Specific Aims and effective proposals use action verbs, and specific aims emphasize complexity in Bloom’s Taxonomy verb list. Work to use action words, and avoid words that lead reviewers astray (see below).

Your next homework is to draft specific aims page (not just the two grant statements), using a standard structure:

- First line "hook"
- Paragraph what is known
- Paragraph the gap you will address/ your approach
- Paragraph why address this question now
- your hypothesis
- your two aim statements with short paragraph description of approach
- paragraph the impact of your study

All in a document not longer than one page.

Begin by stating the major objectives of your research, and think about the topic sentence, or "hook" for the reader. Include the objectives of your research project, what you want to accomplish. The project aims should be driven by the hypothesis you set out to test. Make sure they are highly focused. Describe briefly each of the aims you will use to test your hypothesis.

Ideally, the aims should be related, but not dependent, upon each other. Be sure all objectives relate directly to the hypothesis you are setting out to test. If you have
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|      | more than one hypothesis, state specific aims for each one. Keep in mind your research methods will relate directly to the aims you have described. Choose objectives that can be easily assessed by readers.  

**Homework:**  
1. From your two scientific questions, develop your full Draft Specific Aims page using the [Tips-for-Writing-Specific-Aims.docx](#)  
2. Review Measurable verbs, Bloom’s Taxonomy verb list, How to Use Active Verbs, Active Verbs for Goal and Objective Statements, and Words to avoid NIH grant central  

**Additional Resources:**  
Science Buddies: A Strong Hypothesis  
You Tube Research Questions (7 min)  
Grant Writing-Survival-Skills-2013-10-17.pdf  
NIHResearchProposals OUTLINE Example(1).pdf  

| 3 Feb 1 | **To start class today:**  
- discuss your draft specific aims page  
- use Specific Aims Instructions and Rubric in peer discussion  

**In class lecture: Aims and Significance**  
Plan to revise your specific aims page with peer input, and discuss your specific aims with your research mentor after this class. Use what you have learned to revise the Specific Aims page for the next class (and feel free to update and modify the aims as you develop your proposal).  

Next you must describe why your study is important to do. While NIH R01s require sections of both “significance” and “innovation” that are crucial for strong applications, fellowship applications are much shorter and don’t require the innovation component. However, it is useful to consider how to address these components in your research strategy with a paragraph each.  

How do I write significance?  
Is there a model figure that can convey your ideas?  
How will you do an adequate literature review for your application?  

**Homework:**  
1. Read NIAID Write your Research Plan [here](#), including significance and check points  
2. Revise your specific aims page  
3. Write your significance paragraph  
4. draft a figure or working model that conveys your study  

| 4 Feb 8 | **Due in Blackboard today:**  
Revised Specific Aims page  
Significance half page  

**In class lecture:** Rigor Reproducibility and Transparency  

Due in Bb today: revised specific aims page;
Strong experimental design, methodology and analysis and interpretation are at cornerstones of outstanding biomedical research, but formal education in these topics is often not emphasized by laboratory leaders or journal publishers. Recent reports highlighted that a number of pre-clinical studies essential for clinical trials in humans could not be reproduced. These reports have identified the need for increased rigor and reproducibility in biomedical science.

There are 4 elements of rigor that should be addressed in several areas of the application, with examples.

- Rigor of the prior research
- Rigor of the proposed research
- Biological variables
- Authentication

How will you address experimental design, rigor and reproducibility, methodology, and variables in your proposal? What does scientific premise mean in your application? Can you predict and justify the sample size you need to test in your studies? What statistical tests will you do, and how do you describe in your proposal? Is it important to consult with a biostatistician?

The NIH has also produced several training modules and specific research resources that can serve as the basis for discussion.

You might be interested in this free, 6 week online course from iBiology on "Let's Experiment: A guide for scientists working at the bench," that covers research skills, critical thinking, and responsible conduct. The syllabus is attached. I cannot tell if it's "too low" or "too high" but it's marketed for UG-postdocs. I'll tell the first years, too... Course Syllabus.docx

The link for the course is inside the syllabus...

### Homework:

1. Review examples of scientific rigor [here](#), then draft one paragraph for how you address rigor and reproducibility in your proposal.
2. Read Rigor, Reproducibility and Transparency FAQs. Watch one NIH module and report on how this is addressed at GW, for example [Module 4: Sample Size](#), Outliers & Exclusion
3. Complete your model/concept figure

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<tr>
<td>Feb 15 No class</td>
<td>President’s Day</td>
<td>Significance paragraph</td>
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<tr>
<td>5 Feb 22</td>
<td>Discuss in class today: Your model/concept figure Your Rigor, Reproducibility and Transparency paragraph</td>
<td>Discuss in class today: Model figure, rigor paragraph</td>
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In class lecture: the NIH fellowship biosketch

The NIH biosketch is designed to highlight for reviewers your background and accomplishments that prepare you to lead the application. A biosketch is tailored to each specific application. The biosketch tells your story--this is one place that the first person "I" is good!

Your curriculum vitae is not your NIH biosketch, but is a good starting point. Some folks use [SciENcv](#) to manage the biosketch. You will also need your NIH
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|      | **eRA commons user name, ORCID ID and a MyNCBI My Bibliography for your biosketch.**  

The biosketch includes 4 general sections: Personal statement (paragraph), Positions and Honors (list), Contributions to Science, Grades/Support.  

**Personal statement**, about 300 words, half a page single spaced. Indicate the proposal goal, your relevant experiences, motivation and leadership qualifications. If you had difficulties, mention them here.  


**Contributions to science (up to 5)**. Topic sentence, background of problem, findings, influence, role in work, up to 4 citations. Often reflect a period of research (undergrad, postbac, grad school).  

**Grades/research support**. List titles and grades for every class, undergraduate and graduate. You can shorten course titles.  

The NIH now requires all researchers with an F,K, or T grant to list their ORCID ID and associate it with your eRA commons personal profile.  

If you are planning on submitting an NIH fellowship, please request an eRA commons account from GW, using this form [eRA Commons Registration Form.pdf](#).  

**Homework**  
1. Review the NIH Biosketch [page](#) for instructions and examples  
2. Draft your biosketch for discussion next class  
3. Register for an ORCID ID, and MyNCBI bibliography  

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**6 March 1**  

**To start class today:** Discuss your fellowship biosketch, using [Biosketch Rubric](#)  

**In class lecture: How to organize your research strategy**  
If you haven't already, you should discuss your aims and outline with your research mentor.  

This section is similar, but distinct from the Research Strategy in an R01 independent investigator grant that focuses entirely on the quality of the science and design of the project. For your qualifier (and in a fellowship application), reviewers know you are in training. We want to understand how the quality of the science, the significance of the project, and logic of the experimental design contribute to the overall training potential of your application. Organize the Research Strategy section around your specific aims. If you have preliminary data, or can cite some from your lab, this can show feasibility.  

**Significance 0.5 p (you have written a draft)**  
- Describe the importance of the problem or critical barrier to progress in the field that the proposed project addresses.  
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.  
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed.  
- Use a model concept figure/working model  

**Approach (the rest of the 6 pages)**  
- Often begins with brief context, may have preliminary data in this section  

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|      | • Organize the rest by aim: Restate your aim, then build rationale, approach, anticipated results, alternatives for each  
|      | • Describe how any results in literature lead to your hypothesis (think about premise)  
|      | • Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project.  
|      | • Include how the data will be collected, analyzed, and interpreted; sample size, power, significance of outcomes  
|      | • Describe expected results  
|      | • Always have a paragraph on potential problems and alternative approaches  
|      | **Aim 1: Test XYZ**  
|      | Relevant background to this aim (1/4 page)  
|      | Preliminary data to support this aim (up to 1/3 page)  
|      | Hypothesis to test in this aim (sentence)  
|      | Experimental Design to test this hypothesis (4-6 paragraphs of studies, perhaps with diagram)  
|      | Limits and Alternatives (paragraph)  
|      | Then do it again for Aim 2.  
|      | **Homework:**  
|      | 1. Revise/update NIH biosketch and submit for grading  
|      | 2. Draft the first half of your Research Strategy (through Aim 1) for discussion in class  
|      | [https://grants.nih.gov/podcasts/All_About_Grants/episodes/Grant_Writing_April_2010.mp3](https://grants.nih.gov/podcasts/All_About_Grants/episodes/Grant_Writing_April_2010.mp3)  
|      | NIH Tips for Applicants  
|      | [https://www.youtube.com/watch?v=9cNRMsCGfHo&hl=en_US&version=3](https://www.youtube.com/watch?v=9cNRMsCGfHo&hl=en_US&version=3)  
| 7--March 8 | Discuss in class: Your draft research strategy through Aim 1 using Research Strategy Rubric  
|      | **Homework:** revise research strategy for Aim 1. Begin to write Aim 2 with same principles for discussion in class March 23  
| March 15 | Spring break March 15-March 20  
| No class | Nothing due  
| 8--March 22 | **To start the class: Discuss in class:**  
|      | Discuss Aim 2 research strategy  
|      | **In class lecture: the individual development plan**  
|      | An important component of a training application is addressing your own strengths and weaknesses in relation to your goals. You should have initiated an individual development plan in the first year for Career Day. Now is the time to update/revise that IDP with an eye to what you need to learn in the next couple of years to achieve your career goals.  
|      | Discuss in class Aim 2 research strategy
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<td>In theory, you will have completed all didactic coursework for your PhD at the end of the second year. Are there any additional skills you need for your research goals (eg regulatory affairs, clinical trials, etc)? Some of these electives are taught in health sciences. Are there national workshops that would benefit your study (eg Cold Spring Harbor courses)? Are there skills workshops you need (eg Python camp)? Gelman Library has these.</td>
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<td>Which national meetings include researchers in your field? Are you a member? Where will you present your research posters? Are these meetings appropriate for your career networking? How will you gain skills in critical analysis of data with your research group? When are lab meetings/group meetings/research day at the university, retreats, external experts in monthly seminars? Now is the time to take advantage of these. You might take a look at the GW career services page on self-assessments; they list a number of options (MBTI is &quot;sixteen personalities&quot;). It's also on a free site, but leaves some the interpretation of test results to you.</td>
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<td><strong>Homework:</strong></td>
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<td>1. Complete your individual development plan at <a href="#">MyIDP</a> with goals for next year.</td>
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<td>2. Discuss with mentor: your specific aims page, your research strategy (6 pages, including significance, working model figure, aim 1, aim 2; bibliography).</td>
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<td><strong>To start the class:</strong></td>
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| • Discuss your IDP and your SMART goals  
• resources for career development at GW and national professional organizations | Discuss in Class: the IDP |  |
<p>| <strong>In class lecture: Applicants Background and Goals for Fellowship Training (6p)</strong> |  |  |
| What strengths and weaknesses for your research project do you have right now? What do you need to learn to do the research? What do you need to learn for your career goals? Who will teach you those things, and how? Do you have a timeline for your research career development? A section of the F31 fellowship application asks that you describe (in 6 pages total) Doctoral Dissertation and Research Experience. Training Goals and Objectives Activities Planned Under this Award |  |  |
| I suggest you organize your training goals (longer section) and activities (shorter section, with timeline) around the <a href="#">National Postdoc Association</a> research core competencies in discipline-specific knowledge research skill development communication skills professionalism leadership and management responsible conduct of research This section will briefly review what you have accomplished, and still have to learn, and how you will learn it. Who will teach you? how? when? This section must be pretty specific. |  |  |</p>
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|      | Why is GW the best place to do this research? Are there available experts on your thesis committee? Core research facilities? A fellowship application also requires letters of recommendation (3 not including your mentor(s), and sometimes letters of collaboration. Who will those come from? what will they say about you?  
**Homework:**  
1. Draft your 6 page candidate background and goals, including grades for discussion next week.  
2. List your recommenders and what different aspects they can say about you. Consider drafting your own letters so each may reflect key strengths  
**Additional Resources**  
Read Chapter 3 Hollenbach Who-Are-You--The-Fel_2014_A-Practical-Guide-to-Writing-a-Ruth-L-.pdf |            |
| 10--April 5 | **To start class**  
Discuss Application background and goals  
**In class lecture: Institutional templates**  
Several sections of a fellowship application describe relatively typical institutional practices, including the Budget, Institutional Environment and Commitment to Training, Responsible Conduct of Research, and Diversity Eligibility.  
Applicants are strongly encouraged to review the template and personalize or update for the individual. These will be discussed.  
**Homework:**  
1. Update relevant templates for your application |            |
| 11--April 12 | **Due in Blackboard today:**  
final specific aims page (1 page)  
final research strategy (6 pages)  
**In class lecture: Sponsor(s) statement**  
- Your goals should match your mentor's plan, and it's useful to draft your Sponsor(s) statement for discussion. The Sponsor and co-sponsor statement (6 pages total) contains  
  - Research support available (in a table)  
  - 5 previous fellows/trainees (in a table)-especially examples at your career stage  
  - Training Plan, Environment and Research Facilities (closest to your goals and activities)  
  - Number of Fellows/trainees to be supervised during the fellowship  
  - Applicants qualifications and potential for a research career  
- This section is generally written by your mentor and should be individualized for you. You should draft some of this to discuss with your mentor. In an ideal world, you will work in to your research strategy the training activities mentioned here and in your statement.  
**Resources:**  
Read Hollenbach Chapter 4: Who's the Boss-Sponsor, Collaborators, and Consultants  
**Homework:**  
1.Update your draft Applicant background and goals | Due in Blackboard final specific aims page; and final research strategy (6 pages) |
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<th>Week</th>
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| 2. | Access NIH Reporter and look up your sponsor’s grants for the table  
2. Draft your sponsor’s statement | Due in Blackboard: Applicant background and goals; Environment and institutional commitment to training |
| 12 April 19 | **Discuss In class:** your Sponsor and Co-Sponsor Statements (6 pages)  
- Research Support Available  
- Sponsor/co-sponsor’s Previous Fellows/Trainees  
- Training Plan, Environment and Research Facilities  
- Number of Fellows/Trainees to be Supervised During the Fellowship Applicants Qualifications and Potential for a Research Career  
your Institutional Commitment template updates |  

**In class lecture: NIH review process**

This course has guided the preparation of the Specific Aims page and the Research Strategy sections required for the GW grant-style qualifier that most students complete at the end of year two.

Following successful defense of the qualifier, a doctoral student may wish to prepare an NIH F31 NRSA predoctoral fellowship application, that requires many of the documents prepared in the class (Specific aims page, research strategy, NIH fellowship biosketch, candidate background and goals, institutional commitment and environment, sponsors statement, etc). Later, if you wish to pursue a fellowship application, please see materials online at smhs research and see your department administrator and Dr. Hall for additional guidance.

Next steps for a fellowship application:

- identify and contact NIH program officer
- prepare full F31 application and submit through Cayuse eRA commons

What happens to your application in review? Your application will be assigned to a review group often called a study section, comprised of ~25 experts from around the nation. Participants in the last review may be listed in the CSR member roster. Your application will be assigned to a primary, secondary and tertiary reviewer for thorough reading and review bullet points (see summary statement). On the day of review, the primary reviewer will present an initial overall score (1-9) and strengths and weaknesses, the secondary add any additional points, and the tertiary make comments. After discussion and update on recommended score, all members of the study section will vote on your application. That impact score is often averaged with previous sessions of the study section to give you a percentile (depends on the study section), and you will recieve those scores (days) and summary statements (weeks) after the review session. Depending on the outcome, you may have to resubmit, with responses to their comments in an Introduction section followed by a full application including any revisions.

**Additional resources**


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<tr>
<th>13 April 26</th>
<th>All wrapped up: Understanding the qualifier timetable and the fellowship timetable and next steps</th>
<th>Turn in Sponsor and Co-Sponsor statements</th>
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<td>See SMHS Research website Checklist and resources <a href="#">here</a></td>
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- we expect that everyone should be able to submit their specific aims and start the qualifier clock by the deadline of June 1. Preliminary data is not required for the
qualifier, so you should be able to make adequate progress even without regular access to the lab.

- The qualifying exam is an important exercise designed to provide academic oversight in support of your progress through the PhD and eventual entry into the field as an independent investigator. The committee composition should facilitate this goal. Your qualifying committee should consist of your mentor, your co-mentor (where applicable), plus 3 members, at least 2 of whom must be IBS trainers. A committee chair should be selected from among the 3 members. Committees must be approved by the Graduate Program Directors of your program. The IBS will host a meeting in May for all qualifying committee members to review expectations and address any questions.
- Once you have determined your committee members and the date you intend to submit your specific aims, please submit your Qualifier Examination Form to gwibs@gwu.edu. The form can be found on the IBS website. For initial submission, please fill out the yellow fields in the attached sample. You should update the IBS each time you complete one of the milestones in the process, and we will update your form, culminating in the final sign-off from the committee after your defense.

Qualifying exam packet.pdf
Sample Qual Exam Form.pdf

Assignments and Grades

Assignments

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<tr>
<td>NIH Biosketch 5 pages</td>
<td>10</td>
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<tr>
<td>Specific Aims 1 page</td>
<td>20</td>
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<tr>
<td>Research Strategy 6 pages</td>
<td>30</td>
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<tr>
<td>Candidate Background and Training Plan 6 pages</td>
<td>10</td>
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<tr>
<td>Template Revisions; Advisors and Letters</td>
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<td>Participation &amp; Additional Assignments</td>
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University Policies

University Policy on Religious Holidays
1. Students should notify faculty during the first week of the semester of their intention to be absent from class on their day(s) of religious observance.
2. Faculty should extend to these students the courtesy of absence without penalty on such occasions, including permission to make up examinations.
3. Faculty who intend to observe a religious holiday should arrange at the beginning of the semester to reschedule missed classes or to make other provisions for their course-related activities

Support for Students Outside the Classroom
Disability Support Services (DSS)
Any student who may need an accommodation based on the potential impact of a disability should contact the Disability Support Services office at 202-994-8250 in the Rome Hall, Suite 102, to establish
eligibility and to coordinate reasonable accommodations. For additional information please refer to: gwired.gwu.edu/dss/

**Mental Health Services 202-994-5300**
The University's Mental Health Services offers 24/7 assistance and referral to address students' personal, social, career, and study skills problems. Services for students include: crisis and emergency mental health consultations confidential assessment, counseling services (individual and small group), and referrals. counselingcenter.gwu.edu/

**Academic Integrity Code**
Academic dishonesty is defined as cheating of any kind, including misrepresenting one's own work, taking credit for the work of others without crediting them and without appropriate authorization, and the fabrication of information. For the remainder of the code, see: studentconduct.gwu.edu/code-academic-integrity