**Course Title:** Advanced Studies in Neuroscience or Psychology to write an NRSA F31 Grant Proposal

**Course Number:** 6:830:504

**Course Director:** Mark West

Submit an F31 Fellowship Application to NIH

Investigate NIH Institute and study section

 Is an institute interested in your research training?

 Does that institute fund F31s?

 What study section(s) might review your proposal?

Register in eRA Commons

Register in RAPSS

Class presentation by Zsofia Pal, on negotiating the bureaucracy

Sponsor statement – get a draft by Oct 31 – ask now

Letters of Recommendation – ask now

Go over [PA-20-246](https://grants.nih.gov/grants/guide/pa-files/PA-20-246.html)

Download the Fellowship (F) instructions in the SF424 (R&R) Application Guide

To maintain organization and your sanity, start a folder and continually add sub-folders with descriptive names:

 NRSA app

 SF424 (R&R) Application Guide

 Research training proposal

 Specific Aims

 Rationale

 Preliminary Results

Funding –

 Reviewers want to see evidence that the proposed research training will be supported by adequate funds.

Due the second week:

Identify your project and draft an outline (NOT an abstract). This will progress into a more substantial document. The sooner you write this, the better we can separate what works from what doesn’t.

 A fellowship proposal usually describes research (preliminary studies; proposed research), but keep it grounded and focus on how it enhances your training.

 When potential weaknesses arise as you’re writing, turn them into positives by addressing them, rather than hiding them. Possibly show how your training would be enhanced.

Don’t be “overly ambitious”

 Focus on the main approach(es) in which you’ll be trained, and make the case for why that focus is important…how it will contribute to the field in the future. Proposing too many training areas would raise the concern that none would be thorough.

POINTERS

* Propose attendance at relevant national meetings (one or two per year) enhances training
* A Co-Sponsor enhances training
* RAPSS training (optional)
* NO headers/footers
* Sponsor statement
* Letters
	+ recommendations
	+ training support
* Bibliography
	+ no page limit
	+ cite more, rather than less
* borrow from each other’s documents (OK with all of you?)
* borrow from departmental documents describing:

• our training environment (see my doc on Sakai)

• area requirements

Not-scored criteria (but can reflect on the diligence of your preparation):

 Protections for human subjects

 Inclusion of Women, Minorities, and Children

Responsible conduct of research “adequate and ongoing”

 See Sakai Resources link

Always look for F31 (not F32)

Ignore Institutional Research Training Grant (T32) information.

TIMETABLE

Oct 31 – Nov 15: Sponsor statement

On Monday each week – send me your current versions of any/all documents

Dec 2 – final revisions

Dec 6 - aim for submission

(ORSP must submit for you, well before 5pm Dec 8)

Review criteria in PA-20-246

Read the guidelines for applicants to use

Read the guidelines reviewers will use

**Guidelines for applicants** (copied from a PA):

“Specific Aims: The Fellowship Applicant must describe concisely the Specific Aims, broad, long-term objectives and the goal of the proposed research to test a stated hypothesis. The Specific Aims section is required for all Fellowship applications and is limited to 1 page.

Research Strategy:

This section, including tables, graphs, figures, diagrams, and charts, is limited to 6 pages. See Table of Page Limits. This section should address the Significance of the proposed studies, including the background leading to the present application; and the Approach (including preliminary studies, if any) to provide experimental support of the proposed hypothesis.

Fellowship Applicants must describe a tailored research training plan, including a description of the research strategy (preferably hypothesis-driven) well-suited to the stage of his/her career development to date. Describe the skills and techniques that the candidate will learn during the award period, and discuss the relationship of the proposed research training to the applicant’s career goals. The applicant’s plan should be coordinated with the sponsor’s plan (see below), and should include substantive detail that adds to the information about time allocations requested. The applicant must describe the background leading to the proposed research, the significance of the research, the research approach (design and methods) for achieving the Specific Aims (see above), the rationale, and expected/alternative outcomes of the proposed studies. It is beneficial to include pertinent preliminary data obtained by the applicant in the current or prior laboratory.”

Guidelines reviewers will use:

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the [NIH mission](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11149), all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

For this particular announcement, note the following:

* A fellowship application has a research project that is integrated with the training plan. The review will emphasize the applicant's potential for a productive career, the applicant's need for the proposed training, and the degree to which the research project and training plan, the sponsor(s), and the environment will satisfy those needs.

Overall Impact/Merit

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the fellowship will enhance the applicant's potential for, and commitment to, a productive independent scientific research career in a health-related field, in consideration of the scored and additional review criteria.

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Fellowship Applicant

* Are the applicant's academic record and research experience of high quality?
* Does the applicant have the potential to develop into an independent and productive researcher?
* Does the applicant demonstrate commitment to a research career in the future?

Sponsors, Collaborators, and Consultants

* Are the sponsor(s') research qualifications (including recent publications) and track record of mentoring individuals at a similar stage appropriate for the needs of the applicant?
* Is there evidence of a match between the research and clinical interests (if applicable) of the applicant and the sponsor(s)? Do(es) the sponsor(s) demonstrate an understanding of the applicant's training needs as well as the ability and commitment to assist in meeting these needs?
* Is there evidence of adequate research funds to support the applicant's proposed research project and training for the duration of the research component of the fellowship?
* If a team of sponsors is proposed, is the team structure well justified for the mentored training plan, and are the roles of the individual members appropriate and clearly defined?
* Are the qualifications of any collaborator(s) and/or consultant(s), including their complementary expertise and previous experience in fostering the training of fellows, appropriate for the proposed project?
* If the applicant is proposing to gain experience in a clinical trial as part of his or her research training, is there evidence of the appropriate expertise, experience, resources, and ability on the part of the sponsor(s) to guide the applicant during the clinical trial research experience?

Research Training Plan

* Is the proposed research project of high scientific quality, and is it well integrated with the proposed research training plan?
* Based on the sponsor's description of his/her active research program, is the applicant's proposed research project sufficiently distinct from the sponsor's funded research for the applicant's career stage?
* Is the research project consistent with the applicant's stage of research development?
* Is the proposed time frame feasible to accomplish the proposed training?
* If proposed, will the clinical trial experience contribute to the proposed project and/or the applicant's research training?

Training Potential

* Are the proposed research project and training plan likely to provide the applicant with the requisite individualized and mentored experiences in order to obtain appropriate skills for a research career?
* Does the training plan take advantage of the applicant's strengths and address gaps in needed skills?  Does the training plan document a clear need for, and value of, the proposed training?
* Does the proposed training have the potential to serve as a sound foundation that will clearly enhance the applicant's ability to develop into a productive researcher?

Institutional Environment & Commitment to Training

* Are the research facilities, resources (e.g., equipment, laboratory space, computer time, subject populations, clinical training settings) and training opportunities (e.g. seminars, workshops, professional development opportunities) adequate and appropriate?
* Is the institutional environment for the applicant's scientific development of high quality?
* Is there appropriate institutional commitment to fostering the applicant's mentored training?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the [Guidelines for the Review of Human Subjects](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

Inclusion of Women, Minorities, and Children

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is  justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11174)

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animal Section](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Training in the Responsible Conduct of Research

Responsible conduct of research mus “adequate and ongoing”

 See my Sakai link

All applications for support under this FOA must include a plan to fulfill NIH requirements for Instruction in the Responsible Conduct of Research (RCR).  Taking into account the level of experience of the applicant, including any prior instruction or participation in RCR as appropriate for the applicant's career stage, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) ***Format -*** the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable); 2) ***Subject Matter -*** the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics; 3) ***Faculty Participation -*** the role of the sponsor(s) and other faculty involvement in the fellow's instruction; 4) ***Duration of Instruction -*** the number of contact hours of instruction (at least eight contact hours are required); and 5) ***Frequency of Instruction –*** instruction must occur during each career stage and at least once every four years.  Plans and past record will be rated as **ACCEPTABLE** or **UNACCEPTABLE**, and the summary statement will provide the consensus of the review committee. See also: [NOT-OD-10-019](http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) [Data Sharing Plan](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11151); 2) [Sharing Model Organisms](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and 3) [Genomic Data Sharing Plan](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11153).

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) in accordance with [NIH peer review policy and procedures](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated [review criteria](https://grants.nih.gov/grants/guide/pa-files/PA-18-671.html#_1._Criteria). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

* May undergo a committee process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
* Will receive a written critique.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the appropriate NIH Institute or Center.  The following will be considered in making funding decisions:

* Scientific and technical merit of the proposed project as determined by scientific peer review.
* Availability of funds.
* Relevance of the proposed project to program priorities.