- Thank you for joining the webinar. We will begin shortly.
- Listen to the webinar via your computer speakers or dial in using the telephone number provided on the screen.
- Type any questions into the Q&A box. Questions will be addressed after the presentation.



PAR-18-814 (Independent Clinical Trial Not Allowed) PAR-18-813 (Independent Clinical Trial Required)

Technical Assistance Webinar
June 12, 2018

### Outline of the Webinar

- The BRAIN Initiative
- Program Objective
- Eligibility
- Application Components
- Questions

# Speakers



Moria Bittmann, PhD
Health Program Specialist
Channels, Synapses, and Circuits
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Health Program Specialist
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### The BRAIN Initiative

Moria Bittmann, PhD
Health Program Specialist
Channels, Synapses, and Circuits
NINDS/NIH

### What is The BRAIN Initiative?

- Ten year effort to accelerate development and use of tools to improve our fundamental understanding of how the human brain and nervous system function in health and disease
- Long term goal: A comprehensive understanding of the brain in action, spanning molecules, cells, circuits, systems, and behavior
- Seven high priority research areas were outlined in BRAIN 2025
- New working group will assess BRAIN's progress and identify key opportunities to apply new and emerging tools to revolutionize our understanding of brain circuits

### Seven High Priority Research Areas

Brain Cell Types

1. Discovering diversity: Identify and provide experimental access to the different brain cell types to determine their roles in health and disease.

Tools for Circuit Diagrams

**2. Maps at multiple scales:** Generate circuit diagrams that vary in resolution from synapses to the whole brain.

Tech. to Monitor Neural Activity

**3. The brain in action:** Produce a dynamic picture of the functioning brain by developing and applying improved methods for largescale monitoring of neural activity.

Precise Interventional Tools

**4. Demonstrating causality:** Link brain activity to behavior with precise interventional tools that change neural circuit dynamics.

### **Seven High Priority Research Areas**

Theory and Data Analysis Tools 5. Identifying fundamental principles: Produce conceptual foundations for understanding the biological basis of mental processes through development of new theoretical and data analysis tools.

Advance Human Neuroscience **6. Advancing human neuroscience:** Develop innovative technologies to understand the human brain and treat its disorders; create and support integrated human brain research networks.

Integrate Approaches 7. From BRAIN Initiative to the brain: Integrate new technological and conceptual approaches produced in goals #1-6 to discover how dynamic patterns of neural activity are transformed into cognition, emotion, perception, and action in health & disease.

### Neuroethics

- Identify ethical considerations associated with areas of BRAIN Initiative research
- Identify ethical questions raised by BRAIN Initiative projects that point to a need for neuroethics research
- Conduct empirical research related to brain imaging and modulation, data privacy, or technologies supported by the BRAIN Initiative

See <a href="https://braininitiative.nih.gov/about/neuroethics.htm">https://braininitiative.nih.gov/about/neuroethics.htm</a> for more information about the Neuroethics Division of the BRAIN Multi-Council Working Group. Previous funding opportunities in neuroethics can be seen here: <a href="https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-18-500.html">https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-18-500.html</a>.



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#### The BRAIN Initiative Diversity K99/R00 FOA

- National Eye Institute (<u>NEI</u>)
- National Institute on Aging (NIA)
- National Institute on Alcohol Abuse and Alcoholism (NIAAA)
- National Institute of Biomedical Imaging and Bioengineering (NIBIB)
- Eunice Kennedy Shriver National Institute of Child Health and Human Development (<u>NICHD</u>)
- National Institute on Deafness and Other Communication Disorders (NIDCD)
- National Institute on Drug Abuse (NIDA)
- National Institute of Mental Health (NIMH)
- National Institute of Neurological Disorders and Stroke (NINDS)
- National Center for Complementary and Integrative Health (<u>NCCIH</u>)
- Office of Research on Women's Health (<u>ORWH</u>)

### BRAIN Diversity K99/R00 Objective

• To enhance biomedical research workforce diversity and foster a strong cohort of new, highly skilled and well trained, NIH-supported, independent investigators from diverse backgrounds working in research areas supported by the BRAIN Initiative, as highlighted in BRAIN 2025: A Scientific Vision.

#### Need for the Program

- Promoting diversity in the scientific workforce is critical to the success of the NIH mission and consistent with the mandates of the 21st Century Cures Act.
   See Policy Supporting the Next Generation Researchers Initiative, NOT-OD-17-101
- Large loss of talented researchers during the transition from postdoctoral training to junior faculty positions, particularly those from underrepresented groups:
  - 12% of U.S. neuroscience graduate students and 5% of tenure-stream neuroscience faculty are from diverse groups.
  - Women make up 58% of undergraduate and 53% of postgraduate degrees but only 18% of full professors in biomedical sciences.

2011 Survey Report of Neuroscience Departments and Programs; National Science Foundation, National Center for Science and Engineering Statistics. 2015. *Women, Minorities, and Persons with Disabilities in Science and Engineering: 2015*. Special Report NSF 15-311. Arlington, VA.



#### Postdoctoral fellow

- Less than 5 years experience
- Requires at least 12 months of training



#### **BRAIN** Initiative research

 Must be relevant to the scientific goals of the BRAIN 2025 Report, in areas including but not limited to: engineering, computer science, statistics, mathematics, physics, chemistry, and neuroethics



#### Eligible individuals

- Individuals from underrepresented racial and ethnic groups (NOT-OD-18-129)
- Individuals with disabilities
- Women



U.S. citizen or permanent resident by time of award



U.S. domestic institution

## K99/R00 Dual-Phase Funding

- 1-2 years mentored postdoctoral research training and career development
- Up to 3 years of independent research support in an independent, tenure-track (or equivalent) faculty position

### Transition from K99 to R00

- Except in unusual circumstances, BRAIN will not extend the K99 phase
- Transition is not automatic. You must submit an R00 application (see FOA)
- To activate the R00 phase, you must have been offered and accepted a tenure-track, full-time assistant professor position (or equivalent) by the end of the K99 project period

# Career stage eligibility

Apply during postdoc, transition to faculty

#### **K99 Phase**

- Up to 2 years support in K99 phase
- Salary consistent with institutional salary structure
- Research support up to \$25,000
- Up to \$5,000 for meeting participation

### **R00** Phase

- Up to 3 years of support in R00 phase
- Up to \$249,000 in total costs. Can include salary, research costs (e.g. supplies, travel, equipment), fringe, indirects

### Before You Start

- 1. Define your career and research goals.
- Outline the techniques, skills, knowledge, and relationships necessary to achieve your career goals.
- 3. Perform a skills "gap analysis."
- 4. Define your research plan.
- 5. Build a career development plan that is tailored to your needs.
- 6. Assess guidance and mentorship needed.

# Application Components

### Clinical Trial Not Allowed vs. Required

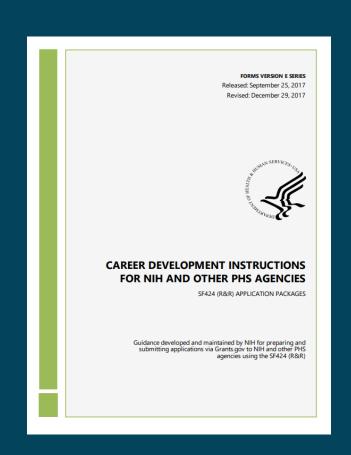
- Use the following four questions to determine the difference between a clinical study and a clinical trial:
  - 1. Does the study involve human participants?
  - 2. Are the participants prospectively assigned to an intervention?
  - 3. Is the study designed to evaluate the effect of the intervention on the participants?
  - 4. Is the effect being evaluated a health-related biomedical or behavioral outcome?
- If the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial
- You should not guess it is important to talk to your mentor and NIH Program Officer

https://grants.nih.gov/ct-decision

### General Guidance

- Read the entire FOA, including the review criteria
- Read the Career Development (K) Instructions of the SF424 Application Guide
- Follow the page limits in the NIH Table of Page Limits
- Get an NIH Commons account at least a month before the application deadline
- Know your organization's Authorized Organizational Representative (AOR) to assist with the application

https://grants.nih.gov/grants/how-to-apply-application-guide.html



### Definitions of Roles

Role	Definition	Senior/key personnel#	Biosketch	Document
PD/PI*	Applicant (you)	<b>√</b>	<b>√</b>	Candidate statement
Sponsor*	Primary mentor	<b>√</b>	<b>√</b>	Plans and Statements of Mentor and Co-Mentor
Co-Sponsor	Secondary mentor	<b>√</b>	<b>√</b>	Plans and Statements of Mentor and Co-Mentor
Referee*	Writes reference letter; not directly involved in project	X	X	Letter of Reference
Collaborator	Plays an active role in the research	Usually not	Not required unless sr./key personnel	Letter of support
Consultants	Provides advice or services	Usually not	Not required unless sr./key personnel	Letter of support
Advisory Committee Members	Provides advice to the PI on research or professional progress	Usually not	Not required unless sr./key personnel	Letter of support

<sup>\*</sup>Required role

<sup>\*</sup>Individuals who contribute in a substantive, meaningful way to the candidate's career development or the career development project

### Reference Letters

- 3 reference letters are required, up to 5 are accepted. If letters are missing, application will not be reviewed.
- Individuals familiar with applicant but not involved in the application
- Notify your referees early and give them plenty of time to submit letters of reference (ensure they have current CV and aims of grant)
- Late letters are not accepted for peer review
- Must include a cover letter that contains a list of referees (including name, departmental affiliation, and institution).

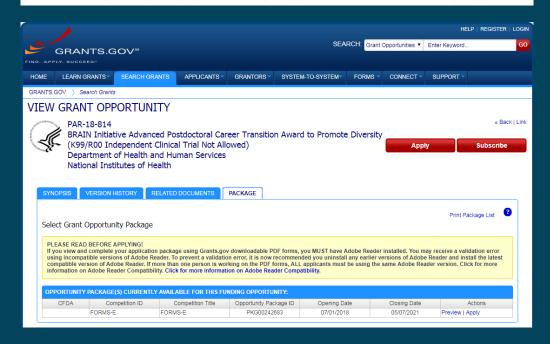
https://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/reference-letters.htm

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

Use the NIH ASSIST system to prepare, submit and track your application online.

#### Apply Online Using ASSIST

- Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application. Check with your institutional officials regarding availability.
- 3. Use Grants.gov Workspace to prepare and submit your application and eRA Commons to track your application.



# Mandatory Forms

- 1. SF424 (R & R)
- PHS 398 Career Development Award Supplemental Form
- 3. PHS 398 Cover Page Supplement
- 4. Research And Related Other Project Information
- 5. Project/Performance Site Location(s)
- Research and Related Senior/Key Person Profile (Expanded)
- 7. Research & Related Budget
- 8. PHS Human Subjects and Clinical Trials Information



# CDA Supplemental Form

# Nancy Desmond, PhD Associate Director Research Training & Career Development Chief Neuroendocrinology & Neuroimmunology Program Division of Neuroscience & Basic Behavioral Science NIMH/NIH

### PHS 398 CDA Supplemental Form

- Candidate Section
- Research Plan Section
- Mentor, Co-Mentor, Consultant, Collaborators Section
- Environment and Institutional Commitment to Candidate Section
- Other Research Plan Sections

The BRAIN Initiative®

Advanced Postdoctoral Career Transition Award to Promote Diversity (K99/R00)

# Candidate Information and Goals for Career Development

- 1. Candidate's Background
- 2. Career Goals and Objectives
  - Include both phases
  - Include a timeline and milestones
  - Be explicit about interest in BRAIN Initiative research area(s)
- 3. Candidate's Plan for Career Development/ Training Activities During Award Period
  - Make clear why additional mentored research training is critical before transitioning to research independence

### Career Development Plan

- Present a specific plan that clearly builds on your existing strengths and weaknesses and explains how each proposed activity is in service of your career goals.
- Demonstrate how you will be fully equipped to transition to independence by the end of the K99 project period.
- Make a strong case for what will be learned by remaining in a postdoctoral position for 1-2 more years.
- Can include both formal courses and research components to build scientific expertise and professional skills. Provide a timeline for the planned activities.
- Provide information on the frequency of meetings with mentors (and how frequently the mentors will meet with each other) and advisory committee (if included). Describe how (and how often) your mentors will evaluate your progress.

### Research Plan Section

- Must span both phases of the K99/R00 award and relate to the BRAIN Initiative for both phases. Usually includes:
  - a specific hypothesis,
  - a list of the specific aims and objectives that will be used to examine the hypothesis,
  - a description of the methods/approaches/techniques to be used in each aim,
  - a discussion of possible problems and how they will be managed, and
  - alternative approaches that might be tried if the initial approaches do not work
- Address: scientific premise, significance, innovation, approach, scientific rigor, biological variables

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# Training in the Responsible Conduct of Research

- 1. Must address all five pieces of information:
  - 1. Format
  - 2. Subject Matter
  - 3. Faculty Participation
  - 4. Duration of Instruction
  - 5. Frequency of Instruction

### Research Plan

- The strongest research plans include a clear rationale with hypothesis-driven aims that are independent of each other.
- Clearly articulate the significance of the research in a way that is understandable to non-experts.
- Fully describe your methods and include a detailed analysis plan including power analyses.
- Include potential pitfalls and alternate approaches.

### Research Plan, continued

- Be clear how the research plan enhances your existing research skills and sets you up for independence.
- Be clear about your role in designing the experiments and collecting preliminary data.
- Be explicit about what aspects of the project you will have "ownership" of and can take with you to an independent position.
- Clearly define K99 and R00 activities. Provide a rationale for the order in which aims will be addressed, and during which phase(s). Provide evidence of long-term viability of the proposed independent phase research plan.

### Other Research Plan Sections

- Vertebrate Animals
- Select Agent
- Resource Sharing
- Authentication of Key Biological and/or Chemical Resources

The BRAIN Initiative®

Advanced Postdoctoral Career Transition Award to Promote Diversity (K99/R00)

# Mentor, Co-Mentor, Consultant, Collaborators Section

- The mentor and each co-mentor must provide a plan/statement (6 pages total)
  - Must explicitly state that the candidate will be allowed to continue to pursue the proposed research project as part of his/her independent research program.
- Letters of Support from Collaborators, Contributors, and Consultants
  - Not the same as letters of reference
  - "Any such person who will contribute to the scientific development or execution of the application's proposed project"
  - Members of an Advisory Committee must provide letters of support

## Mentoring

- Your mentor should demonstrate a strong track record in training and transitioning postdocs to independent careers. Mentors should demonstrate productivity, quality of publications, and adequate funding.
- If applicable, mentoring team should have complementary and relevant expertise. Provide detailed plans for regular interaction with them.
- Letters of support from mentor(s) should be strong and explicitly address the review criteria on which you will be evaluated, including your potential as well as your strengths and areas needing improvement.
- Your mentor should include a comprehensive plan to support your career development and research plans and your efforts to transition to independence.

# Environment and Institutional Commitment to the Candidate

- The institution should provide a document on institutional letterhead from the chair or head of group that describes its commitment to the candidate and the candidate's career development, independent of the receipt of the award
- There should be an explicit commitment to a minimum of 75% protected time, with specific detail of how this was calculated

### **Environment and Commitment**

- Describe how institution will help you to transition to the R00 phase.
- The sponsoring institution must document a strong, well-established research program related to your area of interest
- Describe K99 research facilities and educational opportunities, including collaborating faculty
- Describe any unique features of the scientific environment that benefit the proposed research; e.g., useful collaborative arrangements or subject populations



# Other Application Components

# Lauren Ullrich, PhD Health Program Specialist Office of Programs to Enhance Neuroscience Workforce Diversity (OPEN) NINDS/NIH

### R&R Senior/Key Person Profile

- Applicant
  - Your role is PD/PI
  - Review the Sample Biosketch. http://grants.nih.gov/grants/forms/biosketch.htm
  - Pay attention to the Personal Statement and Contributions to Science sections
- Sponsor/Co-Sponsor
  - Role is "Other Professional"
  - Enter "Sponsor" or "Co- Sponsor" in the Other Project Role Category field.
  - Must include "Current and Pending Support" pages for each mentor and co-mentor(s).

# R&R Other Project Information

- International activities
  - Although foreign institutions are not allowed to apply, foreign components are permitted
- Other Attachments
  - BRAIN Initiative Relevance Description of the relationship of the proposed Research Plan to one or more of the specific goals stated in the <u>BRAIN 2025 Report</u>.
  - Certification Letter Applicants are required to attach a letter on institutional letterhead with institutional official signature certifying eligibility of the candidate for support under this program.

### R&R Budget Form

#### Salary

 For the candidate only, provide the actual base salary, person months, and requested salary and fringe benefits.

#### Other Direct Costs

- In the "Material and Supplies" field, enter only the total research development support being requested for the initial budget period of the K99.
- Enter the indirect cost rate as 8%

### R&R Other Project Information

- Project Summary/Abstract (both phases)
- Project Narrative (both phases)
- Bibliography & References Cited
- Facilities & Other Resources (K99 phase)
- Equipment (K99 phase)

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# PHS Human Subjects and Clinical Trials Information

- New form as of December 2017
- Collects information on human subjects research, clinical research, and/or clinical trials
- All applicants must use the PHS Human Subjects and Clinical Trials Information form regardless of your answer to the question "Are human subjects involved?"
- Follow the instructions carefully

### After You Have a Draft...

- Check what you have written against the Scored Review Criteria
  - Candidate
  - Career Development Plan/Career Goals and Objectives
  - Research Plan
  - Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)
  - Environment & Institutional Commitment to the Candidate
- Slightly different between Clinical Trial Not Allowed and Required

### Post-Submission Materials

- Certain updates are allowed no later than 30 calendar days prior to the peer review meeting
- Send to Scientific Review Officer (SRO) information on:
  - News of an article accepted for publication since submission of the application
  - New sponsor/co-sponsor research funding
  - Change in Sponsor(s) or other Senior/Key Persons
  - New patents
  - Limited other info; for more information: NOT-OD-17-066

### Questions?



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