NIH Fellowship Info Session 1

June 9th, 2021

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Stefanie Makinson, PhD (Grant & Research Development Associate)
NIH Fellowship Info Session 1 Agenda

- Sign-in
- Course goals
- What is a Fellowship Award?
- What are the components of a Fellowship Award?
- What goes into each component?
- NIH Biosketch
- Contacting the NIH Scientific Review Officer
- eraCommons and ORCID
- Timeline
Course Goals

• To familiarize the applicant with the NRSA fellowship award (Session 1)

• To learn about the resources available that may help you in developing a proposal (Session 1)

• To understand how to write a competitive grant application (Session 2)
What is a NRSA Fellowship Award?

Overall goal
To help ensure that a diverse pool of highly trained scientists are available in adequate numbers and in appropriate research areas to address the Nation's biomedical, behavioral, and clinical research needs.

Purpose
To provide support to promising predoctoral & postdoctoral applicants who have the potential to become productive and successful independent research investigators.
What are the components of a Fellowship Award?

1. NIH Instructions (SF424 Application Guide)

2. Funding Opportunity Announcements (FOA)
   - Publicly accessible document where a federal agency makes it known that there are funds available for those wishing to compete for that funding
     - Parent Announcements (PA)
       - Areas of increased research priority
       - Special types:
         - PAR: PA with special request, receipt or referral considerations
         - PAS: PA with special funds set aside
     - Request for Applications (RFA)
       - Narrow, defined research focus

# NIH Parent Announcements (PA)

<table>
<thead>
<tr>
<th>Form Number</th>
<th>Activity Code(s)</th>
<th>Title</th>
<th>Announcement Number</th>
<th>Issuing Organization</th>
<th>Release Date</th>
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<th>Expiration Date</th>
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<tbody>
<tr>
<td>FORMS-F</td>
<td>F30</td>
<td>Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowship for Students at Institutions Without NIH-Funded Institutional Predoctoral Dual-Degree Training Programs (Parent F30)</td>
<td>PA-21-050</td>
<td>NIH</td>
<td>10/26/2020</td>
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<td>FORMS-F</td>
<td>F31</td>
<td>Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity)</td>
<td>PA-21-052</td>
<td>NIH</td>
<td>10/28/2020</td>
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There are also F99/K00 for predoc to postdoc transition: Neuroscience, NIDCR, & Kidney, Urology or Hematology (KUH). See [https://researchtraining.nih.gov/programs/fellowships](https://researchtraining.nih.gov/programs/fellowships) for more info.

MD/PhD: Apply to F30, if NIH institute participates
Reading a FOA

• Is your institute participating?
• Title of the funding opportunity
• Are there important notices?
• Due date
• Background of the funding opportunity
• Eligibility (school and applicant)
• Instructions to be used in addition to the SF424 guide
• Review criteria
• Scientific contact information

Department of Health and Human Services
Part 1. Overview Information

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<tr>
<th>Participating Organization(s)</th>
<th>National Institutes of Health (NIH)</th>
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| Components of Participating Organizations | National Center for Complementary and Integrative Health (NCCIH)  
National Cancer Institute (NCI)  
National Eye Institute (NEI)  
National Human Genome Research Institute (NHGRI)  
National Heart, Lung, and Blood Institute (NHLBI)  
National Institute on Aging (NIA)  
National Institute on Alcohol Abuse and Alcoholism (NIAAA)  
National Institute of Allergy and Infectious Diseases (NIAID)  
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)  
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)  
National Institute on Deafness and Other Communication Disorders (NICDC)  
National Institute of Dental and Craniofacial Research (NIDCR)  
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)  
National Institute of Environmental Health Sciences (NIEHS)  
National Institute of Mental Health (NIMH)  
National Institute on Minority Health and Health Disparities (NIMHD)  
National Institute of Nursing Research (NINR)  
National Institute of Neurological Disorders and Stroke (NINDS)  
National Library of Medicine (NLM)  
Division of Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs (ORIP)  
National Institute on Drug Abuse (NIDA) |

Special Note: Not all NIH Institutes and Centers participate in Parent Announcements. Applicants should carefully note which ICs participate in this announcement and view their respective areas of research interest and requirements in the Notice of IC-Specific Information, Requirements and Staff Contacts website. ICs that do not participate in this announcement will not consider applications for funding. Consultation with NIH staff before submitting an application is strongly encouraged.

Funding Opportunity Title
Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship (Parent F31)

Activity Code
F31 Predoctoral Individual National Research Service Grant Award

Announcement Type
Reissue of PA-19-671

Related Notices
• December 06, 2018 - Notice of Special Interest (NIH) Ruth L. Kirschstein National Research Service Award (NRSA) Fellowship Awards to Support Training in Research Related to Down Syndrome as Part of the NCLCIDE Project. See Notice NOT-OD-20-009.

Funding Opportunity Announcement (FOA) Number
PA-19-195

Companion Funding Opportunity
None

What are the components of a Fellowship Award?

1. NIH Instructions (SF424 Application Guide)
2. Funding Opportunity Announcements (FOA)

What are the components of a Fellowship Award?

NIH Fellowship Award Checklist

VP&S Office for Research Grant Starter Kit

https://research.ps.columbia.edu/content/grant-starter-kit
Grant Starter Kit

- Writing and preparing your application
  - VP&S Fellowship Award Application Guide
  - R01 Writing Guide
  - Link to NIH instructions
- Link to NIH Fellowship award success rates
- Templates & examples

https://research.ps.columbia.edu/content/grant-starter-kit
What are the components of a Fellowship Award?
Docent

Required.

• Address to the Division of Receipt and Referral

• Essential information:
  • Application title
  • Title of FOA (PA or RFA)
  • If you plan on submitting a video
  • If your study will generate large-scale human or non-human genomic data
  • List of references (name, department affiliation, and institution)
  • See complete list.

Cover Letter

January 29, 2020

Center for Scientific Review
Division of Receipt and Referral (DRR)
National Institute of Health
8701 Rockledge Drive MSC 7716
Bethesda, Maryland 20892-7716

INSTRUCTIONS: Remember to remove all gray highlight! Fill in the grey areas with the appropriate information. Also, fill out your title and department in the header and include your contact information in the footer. NIH Instructions may be found here: https://grants.nih.gov/grants/guide/applications-guide.html#appdev

Subject: Name of Funding Opportunity (PA or RFA)

Dear Administrator:

I am pleased to submit this application to the NIH. Please find attached an application titled, “proposel title,” for review under the Name of Funding Opportunity (PA or RFA). I have spoken with the Scientific/Research Contact at the NIH Institute and believe has determined that the research in my proposal is consistent with the Institute’s scope.

Below is a list of my referees:

(1) Name: Departmental affiliation, Institution
(2) Name: Departmental affiliation, Institution
(3) Name: Departmental affiliation, Institution

If applicable, the cover letter should also include:

• Explain why your application is a late submission.
• Note your eligibility for continuous submission of applications.
• Explain that the application is a part of a set of collaborative applications.
• Explain any subscale budget components that are not active for all periods of the proposed grant.
• State that you have submitted any required agency approval documentation for the type of application you’re submitting, e.g., NIH approval for submitting applications seeking $500,000 or more or for seeking a conference grant or cooperative agreement.
• Information about a video as part of the application.
• Statement regarding NIH Genomic Data Sharing Policy if the proposed studies generate large-scale human or non-human genomic data

Sincerely,

[Insert signature]

First and Last Name, Degree

Address, Building and Room 8, New York, NY 10032  UNI@emc.colostate.edu  Telephone: 252.XXX.XXXX
Project Summary/Abstract

➢ Required. 30 lines total.

• Publicly viewable on NIH Reporter

• State the application’s broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency). Describe the research design and methods for achieving the stated goals. Be sure that the project summary reflects the key focus of the proposed project so that the application can be appropriately categorized.

• In addition to summarizing the research project to be conducted under the fellowship award, describe the fellowship training plan and the environment in which the research training will take place.

https://projectreporter.nih.gov/reporter.cfm
Project Narrative

➢ Required. 3 sentences of text.

• Publicly available on NIH Reporter.

• Describe the relevance of this research to public health. For example, NIH applicants can describe how, in the short or long term, the research would contribute to fundamental knowledge about the nature and behavior of living systems and/or the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. If the application is funded, this public health relevance statement will be combined with the project summary and will become public information.

• Often called the lay abstract. Pretend you’re writing for congress or someone that isn’t in science.

Public Health Relevance Statement:

PUBLIC HEALTH RELEVANCE: Amyotrophic lateral sclerosis (ALS) is a debilitating and fatal neurodegenerative disease with no known cure and despite great efforts by the research community, little about ALS pathogenesis is understood. While recent studies have reported spinal circuitry abnormalities in both human ALS patients and in mouse models, the pathways responsible for this dysfunction have yet to be elucidated. Using an established stem cell derived model of ALS, this project aims to identify the synaptic mechanisms that underlie spinal circuitry aberrations, a vital step towards understanding ALS pathophysiology and for future discovery of mechanism-based therapies.
Bibliography & References Cited

➢ Required. No page limit.

• Should include references from throughout the application (Applicant’s background, specific aims, research strategy etc.)

• Format Instructions:
  • No specific format is required
  • You can use “et al.” in place of listing authors
  • Comply with public access policy and include PMC reference numbers when citing papers that you author or that arise from NIH-funded research

• Web of Science: literature search tool to look at papers that reference other papers
  • https://library.cumc.columbia.edu/web-science

https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm#citations

https://ori.hhs.gov/infographics
Facilities & Other Resources

➢ **Required. No page limit.**

➢ **Scorable criteria:** Institutional Environmental & Commitment Training

**What to include:**

- **Scientific Environment**
  - Lab space (including biohazard resources), computing, animal, clinical, office, core facilities

- **Institutional Environment**
  - Resources/descriptions of the university, school, department, center(s), institute(s), infrastructure specifically for graduate students (Knowledge Center, Vagelos Education Center, etc.)

- **Training and Career Development**
  - Program descriptions, seminars, journal clubs, course descriptions, student groups etc.

- If there are multiple sites, describe all sites.

- Be careful to not include hyperlinks or URLs unless FOA says to...

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The VP&S Grant Starter Kit and the Facilities & Resources Bank has templated language that you can include:

**Potential career development and training resources**

- University offices and spaces
- Individual Development Plan (IDP)
- Grant and scientific writing
- RCR at Columbia
- Courses pertaining to rigor

https://research.ps.columbia.edu/content/facilities-other-resources
Equipment

➢ Required if using major equipment. No page limit.
➢ **Scorable criteria**: Institutional Environmental & Commitment Training

What to include:

- List all major equipment ($5,000 or more) available for the project
- If appropriate, identify the equipment’s location.
- Include individual lab equipment, departmental equipment, equipment in core facilities etc.
Introduction (only for resubmission applications)

- Required for resubmission or if FOA says so. Not allowed for new or renewal applications.
- 1 page document.
  - Responds to the issues raised in the summary statement.
  - Summarizes the substantial additions, deletions, and changes to the application. Individual changes do not need to be highlighted or delineated via color, bold, or italics.
Applicant’s background and goals for training

- **Required. 6 pages maximum.**
- **Scored criteria**: Fellowship Applicant and Training Potential
  - Three sections
    - A. Doctoral Dissertation and Research Experience
    - B. Training Goals and Objectives
    - C. Activities Planned Under this award

*More on this next week!*
Required. 1 page maximum.

Scored criteria: Research Training Plan

- State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will have on the research field(s) involved.
- List succinctly the specific objectives of the research proposed (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology).

More on this next week!
**Research Strategy**

➢ Required. 6 pages maximum.

➢ **Scored criteria:** Research Training Plan

• Two sections:
  1. Significance
  2. Approach

More on this next week!

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**RESEARCH STRATEGY**

1. **Significance**

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2. **Approach**

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Required. 1 page maximum.

**Scored criteria:** Research Training Plan/Training Potential

- Describe the collaborative process between you and your sponsor/co-sponsor(s) in the development, review, and editing of this Research Training Plan. Also discuss your respective roles in accomplishing the proposed research.
- Often 0.25 – 0.75 of a page
Selection of Sponsor and Institution

➢ Required. 1 page maximum.

➢ Scored criteria:
  ➢ Sponsors, collaborators, and consultants
  ➢ Training Potential
  ➢ Institutional Environment and Commitment to Training

• Describe the rationale/justification for the selection of both the sponsor and the institution.

• Explain why the sponsor, co-sponsor (if any), and institution were selected to accomplish the research training goals. If the proposed research training is to take place at a site other than the applicant organization, provide an explanation here.

• See instructions if you propose to train at a foreign institution.
Progress Report Publication List

- Only for renewal applications.
  - Renewal applications are very rare for fellowship awards.
Responsible Conduct of Research

- Required attachment. 1 page maximum.
  - Include: prior training in RCR, plans to participate in RCR during the award
  - Address five components: (1) Format; (2) Subject Matter; (3) Faculty Participation; (4) Duration of Instruction; (5) Frequency of Instruction
  - NIH wants to see a refresher every 4 years

Potential courses/training:
- GSAS Responsible Conduct of Research and Related Policy Issues (G4010)
- SPS Research Ethics (Permission of the instructor required)
- MSPH Research Ethics & Responsible Conduct of Research (P9630)
- Online Rascal Course
- Departmental, small group conversations etc.
- One-on-one conversations with mentor(s)


https://ori.hhs.gov/infographics
Sponsor and co-Sponsor Statements

➢ Required. 6 pages total allowed. Upload as a single PDF.

➢ Scorable criteria:
  ➢ Sponsors, Collaborators, and Consultants
  ➢ Training Potential

• Need a statement from each sponsor/co-sponsor

• Organize with the following topics (see instructions for details)
  A. Research Support Available
  B. Sponsor’s/Co-Sponsor’s Previous Fellows/Trainees
  C. Training Plan, Environment, Research Facilities
  D. Number of Fellows/Trainees to be Supervised During the Fellowship
  E. Applicant’s Qualifications and Potential for a Research Career
  F. If applicable, clinical trial information
Reviewer Comments on the Sponsor, Collaborators, Consultants section

- The Sponsor’s relative inexperience in mentoring students is mitigated by the co-sponsor’s experience.
- Has not mentored a graduate student through to completion; however, the inclusion of Dr. X as Co-Sponsor alleviates some of this concern.
- The sponsor’s commitment to publishing exclusively in high impact journals may be a barrier to trainees getting publications out in a timely manner to fuel their careers appropriately.

Sponsor/co-Sponsor Statements should be *tailored* to the applicant.
- Provide overview of applicants previous training and future training to show how they are aligned with applicant’s long-term goals.
- Convey that they really know the person.
- You may be asked to draft some content for your sponsor.
Letters of Support

➢ Optional. 6 pages total allowed. Upload as a single PDF.

➢ Scorabble criteria:

➢ Sponsors, Collaborators, and Consultants

• Include a letter from any collaborators, consultants, or advisors that are expected to contribute to the scientific development or execution of the applicant's planned project and research training.

• The letters should describe the role and contribution.

• Include letters from core facilities, those providing samples/reagents/data etc.

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Sponsors, Collaborators, and Consultants

- Include a letter from any collaborators, consultants, or advisors that are expected to contribute to the scientific development or execution of the applicant's planned project and research training.
- The letters should describe the role and contribution.
- Include letters from core facilities, those providing samples/reagents/data etc.

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Letters of Support

John Smith, PhD
Technical Director
Cryo-Electron Microscopy Center
Columbia University

January 31, 2020

Dear [Applicant],

I am happy to provide you with this letter of support for your grant proposal to study [insert language regarding the scientific focus of the application].

The Columbia Cryo-Electron Microscopy Center was established as a university-wide resource to enable investigators in all fields to incorporate structural biology into their research. Our facility provides technical advice for sample preparation, assists users with loading and operations of our microscopes, and monitors the data collection process. We train all new users on the proper operation of our facility equipment, and have a large amount of experience in helping researchers who are new to the field.

As technical director, I manage four full-time staff members who assist with the operation of our equipment, including: 3 Cryo-Tecnos for high-resolution imaging, a Tecnai cryo-TEM, and an F20 and Tecnai T12 Spirit microscope for sample screening. The facility is therefore fully equipped to provide the training and data acquisition support needed for your project. Also, all personnel will be available to answer questions and assist you with troubleshooting experiments.

As we discussed, your proposal to determine [insert alternative language that describes the purpose of your work] is fully in line with the mission and resources of the cryo-EM center. I would also like to add that we have been collaborating with Dr. [Name of Sponsor] as well as other members of her laboratory for over five years and are looking forward to working with you. I wish you the best of luck in your application!

All the best,

[Signature of the core director]

John Smith, PhD
Institutional Environment and Commitment to Training

- **Required. 2 pages maximum.**

- **Scorable criteria:** Institutional Environmental & Commitment Training
  - Include a description of the well-established research program related to your area of interest.
  - Describe opportunities for intellectual interactions with other individuals in training and other investigators, including courses, journal clubs, seminars, and presentations.
  - Indicate the facilities and resources that will be available for both research and career enhancement activities.
    - Provide an overview and you can refer to the Facilities and Other Resources attachment for details. *The difference from the Facilities and Other Resources attachment is that this attachment should prove to reviewers that Columbia is an outstanding environment to receive training so tweak the language to emphasize that.*
  - **Educational Information:** Describe the doctoral program that you are enrolled in. Includes program structure, required milestones, course info etc. There is template text for each program. Talk to the director of your graduate program.
    - Get from Program Directors. Some reviewers like to see it signed on letterhead. Keep to 1 page.
Description of Candidate’s Contribution to Program Goals

➢ Required if you are applying to a diversity FOA

• Letter on institutional letterhead signed and dated by OGA or your program director

• Explains how the candidate's participation will further the goals of the fellowship program to promote diversity in health-related research. See NOT-OD-20-031 for how NIH defines diversity

• There is suggested language for this letter in the Grant Starter Kit
Vertebrate Animals

- Needed if you are proposing experiments with vertebrate animals (i.e., mice, rats, NHP, xenopus etc.).
- Reviewed as additional criteria, which means that it is considered as part of the overall impact score but doesn’t get an individualized score.

1. Description of Procedures
   - Concise description of the experiments proposed in the Research Strategy that involve vertebrate animals (overview with relevant details in Research Strategy, coherent and brief description here)
     - Examples: behavioral tests, blood collection, surgical procedures, tumor induction, post-irradiation procedures etc.
     - Identify species, strains, ages, sex, and total numbers of animals by species
     - Please note that power analysis and biological variables must be addressed in the research strategy
     - Include all performance site locations (could be many buildings at Columbia or, if applicable, several institutions)

2. Justifications
   - Choice of species
   - Explain why the research goals cannot by accomplished by using an alternative model (e.g. computational, human, invertebrate, in vitro)

3. Minimization of Pain and Distress
   - Describe interventions: analgesia, anesthesia, sedation, palliative care, and humane endpoints that will be used to minimize discomfort, distress, pain and injury

4. Euthanasia (only include if the method is not consistent with AVMA Guidelines for the Euthanasia of Animals)

https://olaw.nih.gov/guidance/vertebrate-animal-section.htm
Optional. No page limit.

Reviewed as an additional consideration. Not considered in the overall impact score.

Three scenarios where you would need this attachment:

1. Excluded select agents
   - Identify the strain(s) to be used that are on the excluded list
     (https://www.selectagents.gov/SelectAgentsandToxinsExclusions.html).

2. Applying for a select agent to be excluded
   - If you have applied or intended to apply to HHS for an exclusion, indicate the status of the request.

3. Applicants proposing to use select agents
   1. Identify the select agent(s) to be used (i.e. Ebola virus, SARS, Goat pox etc). List:
      https://www.selectagents.gov/SelectAgentsandToxinsList.html
   2. Provide the registration status of all entities where select agents will be used.
   3. Provide a description of all facilities where the select agent will be used: monitor possession; plans for biosafety/containment
Resource Sharing Plan

➢ Recommended, required if #2 or #3 apply. No page limit.

➢ Reviewed as an additional consideration. Not considered in the overall impact score.

What to include:

1. Data Sharing Plan
   • Can use general language in the Grant Starter Kit and provided by Columbia Tech Ventures
   • Include a plan for sharing unique reagents (i.e. generated iPSCs, non-commercial plasmids etc.)
   • Some institutes (i.e. NIMH) have their own requirements for what to share (NOT-MH-19-033)

2. Genomic Data Sharing Plan
   • Examples: WES, WGS, RNA-seq, scRNA-seq, GWAS, arrays
   • Recommended to deposit in a public repository (i.e., GEO, dbGAP etc.)
   • WES and WGS need a timeline

3. Sharing Model Organisms Plan
   • Include who made the model and how it may be obtained (i.e. at JAX or Charles River, MTA via Columbia etc.)
Authentication of Key Resources

➢ Optional. No page limit.

➢ Reviewed as an additional consideration. Not considered in the overall impact score.

Key resources that require validation are likely to:

• Differ from lab to lab, or over time

• Vary in qualities or qualifications that could influence the research data

Examples

• Cell lines (i.e., STR profiling or mycoplasma testing)

• Chemicals that are key to the research and are not standard (i.e. liquid or gas chrom/mass spec)

• Genetically modified animals or cells: describe methods to confirm genome modification (i.e., PCR amplification)
Authentication of Key Resources cont.

Tips:
• You may cite procedures that are published and there is consensus for the standard
• Only describe methods and do not show data

Do not include plans for:
• Data sets, databases, machinery or electronics
• New key biological or chemical resources. This should go in the Research Strategy.
• Standard laboratory reagents

➢ For examples, check out the Grant Starter Kit, Columbia’s ReaDI program, and Office of Research Compliance’s NIH Rigor and Reproducibility Webinar (https://research.columbia.edu/reproducibility-resources-and-guidelines-topic)

Human Tissue Questions on the Cover Page From

➢ Required for everyone. Tell you grants manager because they will have to input this information in the application system.

3. Does the proposed project involve human embryonic stem cells?
   • YES, list the 4-digit registration number of the specific cell line(s) from the NIH HESC Registry
   • NO

4. Does the proposed project involve human fetal tissue from elective abortions?
   • YES,
     o provide the “HFT Compliance Assurance”, which is a letter, signed by the PD/PI, assuring the HFT donating organization or clinic adheres to the requirements of the informed consent process and documenting that HFT was not obtained or acquired for valuable consideration.
     o Provide the HFT Sample IRB Consent Form (blank sample)
   • NO
Human Subjects research

➢ Questions required for everyone.

Does any of the proposed research in the application involve human specimens and/or data?

Human Subjects research

➢ Required for everyone.

Does any of the proposed research in the application involve human specimens and/or data?

- NO

Are human subjects involved?

- NO

Skip the rest of the information form and the Human Subjects and Clinical Trials Form

---

Scenario A: Not human subjects research

Scenario B: Does not count as human subjects research

Scenario C: Human subjects research

Human Subjects research

- Required for everyone.

Does any of the proposed research in the application involve human specimens and/or data?

- YES
- NO

**Scenario A: Not human subjects research**

Justification for why application does not involve human subjects research

What to include:
- Information on who is providing the data/biological specimen and their role in the proposed research;
- A description of the identifiers that will be associated with the human specimens and data;
- A list of who has access to subjects' identities; and
- Information about the manner in which the privacy of research participants and confidentiality of data will be projected

**Scenario B: Not considered human subjects research**


Human Subjects research

➢ Required for everyone.

Does any of the proposed research in the application involve human specimens and/or data?

Scenario B: Does not count as human subjects research

Not human subjects research

Justification for why application does not involve human subjects research

Scenario A: Not human subjects research

Are human subjects involved?

YES

NO

Scenario C: Human subjects research

Include a study record and fill out Sections 1-3 of the Human Subjects and Clinical Trials Form (additional form(s)). Pay attention to instructions for exempt vs. non-exempt work.

Answer “YES” to:

Is there is an exemption?

YES

NO

Skip the rest of the information form and the Human Subjects and Clinical Trials Form

Delayed Onset and Delayed Start Studies

• If you anticipate that your study involves human subjects within the period of the award, but the specific plans cannot be described, then you will need to include a delayed onset study.
  o Title
  o justification attachment

• If you can describe your study plans but the start of the study will not coincide with the start of the award, then your study has a delayed start and you will have to fill out a study record
Three different scenarios for study record

- **Scenario 1**
  - Exempt Human Subjects Research – i.e., Exemption 4
  - Note: Follow SF424 instructions for each exemption

- **Scenario 2**
  - Human Subjects Research but not a Clinical Trial (CT)
    - Complete Sections 1-3

- **Scenario 3**
  - Meets the definition of a Clinical Trial (CT)
    - a) Conducting independent CT: Fill out Sections 1-4, and 5 if FOA says to
    - b) Gaining experience in a CT: Fill out Sections 1-3, and 4-5 if the FOA says to

Exempt Human Subjects Research

Meets the definition of human subjects research.
Exempt studies involve human subjects research: research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private information is used/studied/analyzed/generated.

Meets the criteria of one or more of the following exemptions:

- **Exemption 1:** conducted in an educational setting using normal educational practices.*
  *Cannot include any other procedures, such as collection of clinical data or biospecimens.

- **Exemption 2:** uses educational tests, surveys, interviews, or observations of public behavior.*
  *Limited IRB review may be required.

- **Exemption 3:** benign behavioral interventions in adults.*
  *Limited IRB review may be required.

- **Exemption 4:** secondary research using identifiable information or biospecimens if publicly available, or recorded such that subjects cannot be re-identified.*
  *See 46.104(d)(3)(ii), (iii), and (iv) for all criteria.

**Exemption 5:** public service program research or demonstration projects.

**Exemption 6:** taste and food quality evaluations.

**Exemption 7:** storage or maintenance of identifiable information or biospecimens for secondary research use. Broad consent and limited IRB review are required.

**Exemption 8:** secondary research using identifiable information or biospecimens. Broad consent and limited IRB review are required.

**Consider**

**NIH Requirements:**
- Human Subjects education.
- Inclusion tracking for all except exemption 4.

**45 CFR 46 Requirements:**
- Limited IRB review for exemptions 7 & 8, and some study designs under 2 & 3.
- Broad consent for exemptions 7 & 8.

- Cannot involve prisoners, unless research includes a broader population that happens to include prisoners.
- Cannot involve children in:
  - Exemption 2 research if data is recorded with identifiers, for survey or interview procedures, or for observations of public behavior if investigators participate in the activity being observed.
  - Exemption 3 research.

Discuss your research with the IRB.

Study Record

- Need a Study Record for each proposed study involving human subjects
  - Most fellowship applicants only need to complete questions 1 - 3
  - Example info to fill out in the form: study title, clinical trial eligibility, eligibility criteria, age limits
  - Will also need to include attachments (see next slide)

1.4. * Clinical Trial Questionnaire

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

1.4.a. Does the study involve human participants?
1.4.b. Are the participants prospectively assigned to an intervention?
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

Download form here: https://research.ps.columbia.edu/content/nih-human-subjects
Study Record attachments

- If proposing research with human subjects or experience in a clinical trial, fill out Sections 1 – 3 of the study record PDF.
- Sections 2 – 3 have some fill in the blank questions and some attachments (below) to fill out:

<table>
<thead>
<tr>
<th>Attachments to include in the Study Record PDF</th>
<th>Scenario 1 (Exemption 4)</th>
<th>Scenario 2 (HS research, no CT)</th>
<th>Scenario 3 (meets definition of a CT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.3a Inclusion Across the Lifespan</td>
<td>Optional</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>2.4 Inclusion of Women and Minorities</td>
<td>Optional</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>2.5 Recruitment and Retention Plan</td>
<td>Optional</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>2.7 Study Timeline</td>
<td>Optional</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>2.9 Inclusion and Enrollment Report</td>
<td>Optional</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>3.1 Protection of Human Subjects</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>3.2 Single IRB Plan (if yes to sIRB)</td>
<td>Not applicable</td>
<td>Not required at submission if NIH; AHRQ = required</td>
<td>Not required at submission if NIH; AHRQ = required</td>
</tr>
<tr>
<td>3.3 Data Safety and Monitoring Plan</td>
<td>Optional</td>
<td>Optional</td>
<td>Required</td>
</tr>
<tr>
<td>3.5 Overall Structure of Study Team</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>4.3 Statistical Design and Power</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Required for R. Not relevant for fellowship*</td>
</tr>
<tr>
<td>4.5 FDA-regulated intervention justification (if yes to Question 4.5)</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Required for R. Not relevant for fellowship*</td>
</tr>
<tr>
<td>4.7 Dissemination Plan</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Required for R. Not relevant for fellowship*</td>
</tr>
<tr>
<td>5. Other Clinical Trial-related attachments</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Check FOA</td>
</tr>
</tbody>
</table>

*If FOA allows, may propose gaining experience in CT, but not leading one (as such no need to complete).
Tips for filling out the Study Record

- Follow the SF424 Instructions as well as those listed in the FOA to fill out attachments
- Grant Starter Kit has templates and redacted examples
- Use attachments in sponsors’/mentors’ grants as a starting point
- Only IRB can determine the type of human subjects research you are conducting
  - NIH does not require IRB approval at the time of submission but will need an IRB protocol number before study section meets
  - Discuss your research with the IRB if you need clarification on how to categorize your work

Columbia IRB Consultation Service:
https://research.columbia.edu/irb-protocol-and-consent-form-resources/#/cu_accordion_item-8082

Fellowship applicants do not complete questions 4 through 5
Fellowship Budget

- Stipend ($25,836)
- Tuition and Fees
  - 60% of tuition and fees up to $16,000 ($21,000 for dual degree students)
- Institutional Allowance ($4,200)

* $2,000 annual bonus for NIH Fellowship recipients
Foreign Justification

➢ **Optional. No page limit.**

Only include if a component of the project is outside of the US. Such as:

- Foreign collaborator/ mentor/ advisor
  - Referees do not count unless for some reason they are written into your proposal (not recommended)
- Resource (data set, mouse, reagent, cell line etc.) from a collaborator outside the US
- Some of the work will be done outside the US
- Fellowship training will occur outside the US
- Discuss with and obtain approval from NIH before submission.

https://geology.com/world/map/map-of-the-united-states-of-america.gif
Applications for concurrent support

➢ Only required if you have applied or will apply for other support that would run concurrently with this application.
➢ Considered an “other attachment”
➢ 1 page

• Provide a description of the concurrent support. Include type, dates, source(s), and amount in the attachment.
Appendix

- **Optional. Limit of 10 PDFs per application.**

Only include allowable content in the appendix:

- Blank data collection forms, blank survey forms and blank questionnaire forms (or screenshots)
- Sample lists of interview questions
  - For clarification, these blank forms and lists are not and do not include items such as: data, data compilations, lists of variables or acronyms, data analyses, publications, manuals, instructions, descriptions or drawings/figures/diagrams of data collection methods or machines/devices
- Blank informed consent/assent forms
- Other items if they are specified in the FOA as allowable Appendix materials

**Reference Letters**

**Selecting a Referee**

- Three reference letters are required (no more than five)
- The letters should be from individuals not directly involved in the application, but who are familiar with the applicant’s qualifications, training, and interests.
  - e.g., rotation PIs, PIs from undergrad or postbac training, maybe committee members (course directors aren’t the best)
- The sponsor/co-sponsor(s) of the application cannot be counted toward the three required references.
- Make sure you include a list of referees (including name, departmental affiliation, and institution) in the cover letter of the application so that the NIH staff will be aware of planned reference letter submissions.

**Instructions to Provide to Referees**

- Instruction sheet (see right and link to download below).
- Give them your eRA username and the number of the FOA (PA number) to which you are applying.
- Letters must be submitted directly to the eRA Commons.

**Instructions for Fellowship Applicant Referees**

Name of Fellow (First & Last Name as shown in the eRA Commons):

Fellow’s eRA Commons Username: __________________________

FOA Number: __________________________

The fellowship applicant is applying for an individual fellowship award. The purpose of this award is to provide support to promising applicants with the potential to become productive, independent investigators in scientific health-related research fields relevant to the missions of participating NIH Institutes and Centers, and AHRQ. Please put the name of the fellowship applicant at the top of the letter. Also, be sure to include your name and title in the letter.

In two pages or less (PDF format), describe the qualities and potential of the fellowship applicant for the research training for which support is being requested (predoctoral, postdoctoral, or senior fellow). This should include your evaluation with special reference to:
- Research ability and potential to become an independent researcher
- Adequacy of scientific and technical background
- Written and verbal communication abilities including ability to organize scientific data
- Quality of research endeavors or publications to date, if applicable
- Perseverance in pursuing goals
- Evidence of originality
- Need for further research experience and training
- Familiarity with research literature

Referees may provide any additional, related comments that they believe will help reviewers evaluate the merit of the fellow’s application.

**Submitting Reference Letters**


Watch a demo on Submitting Reference Letters through eRA Commons.

Reference Letters are due by the application receipt deadline date, but may be submitted any time after the FOA opens. Reference Letters can be submitted before the grant application submission, and will be held and later linked to the appropriate application once they are received at NIH.

You will be requested to enter the following information online at the time of submission:

**Reference Information:**
- Referee First Name (Required)
- Referee Last Name (Required)
- Referee MI Name (Not Required)
- Referee e-mail (Required)
- Referee Institution/Affiliation (Required)
- Referee Department (Required)

**Fellowship Application Information:**
- PD/F1 (Fellowship applicant) Commons User ID (Required)
- PD/F1’s Last Name, as it appears on the PD/F1’s Commons account (Required) (will be validated to ensure they match)
- Funding Opportunity Announcement (FOA) Number (Required and must match the number of the FOA under which the application is being submitted)
- Reference Letter Confirmation Number (Required only if resubmitting a letter, not required otherwise)

After you have submitted your Letter of Reference, both you and the applicant will receive a confirmation of receipt by e-mail. Your e-mail confirmation will include a Reference Letter Confirmation Number. The Confirmation Number will be required when resubmitting reference letters. Please print the confirmation e-mail for your records.

NIH Biosketch

- CV in NIH format
- Form F (Approved through 02/28/2023)
- Use the Fellowship form!

A. Personal Statement

B. Positions, Scientific Appointments, and Honors

C. Contributions to Science

D. Scholastic Performance

Create your biosketch here!

https://grants.nih.gov/grants/forms/biosketch.htm
NIH Biosketch

A. Personal Statement

i. Structure:

• Current position
• Long-term goal
• Scientific qualifications that make you suited to carry out this research
• Sponsors and training plan

ii. Other things you can mention:

• Factors that affected past productivity (family care, illness, disability etc.)
• Published or created research product in another name
• Explanation for poor grade performance in undergrad
• Alternative careers before this one

iii. No figures, tables, or graphics

iv. Can list up to four research products after the statement that are not mentioned elsewhere in Biosketch

I first became interested in human health and disease in high school when I was awarded an NIH Diversity Supplement to work as a research technician for two summers in Dr. Indira Creative’s lab at the University of Hawaii. I continued to pursue this interest as an undergraduate at Purdue University, where I conducted research with Dr. Daniel Richardson on the mechanisms of action of a new class of small molecules for cancer treatment. This resulted in a co-authorship publication, as well as an invitation to present a poster at the annual Oncological meeting in Denver, Colorado. By the end of my undergraduate career, I knew that I wanted to pursue a long-term career in research. For my graduate training at UC San Diego, I have moved into the fields of genetics and biochemistry by studying the signaling and motility mechanisms of cancer cells, under the mentorship of Dr. Nani Green. Dr. Green is an internationally recognized leader in the field of cancer genetics and has an extensive record for training predoctoral and postdoctoral fellows. Along with giving me new conceptual and technical training, the proposed training plan outlines a comprehensive set of career development activities and workshops. I will have opportunities to engage in public speaking, conduct literature analysis, consider biomedical ethics, and learn about varied career options. For my initial project, I am currently developing a novel protocol for the identification of transcription complexes involved in cancer signaling pathways, which I hope to submit as a first author publication in the next four months. As a native Hawaiian, I am the first in my family to graduate from college, and I am excited to continue making great strides with my education. Overall, I believe that my current research setting in conjunction with my proposed training plan will provide a solid foundation for my long-term goal to become an academic researcher.


https://grants.nih.gov/grants/forms/biosketch.htm
B. Positions, Scientific Appointments, and Honors

i. List in reverse chronological order

ii. Include scholarships, traineeships, fellowships, and development awards, as applicable.

B. Positions, Scientific Appointments, and Honors

Positions and Scientific Appointments

2019 – 2020  Robertson Fellowship for Outstanding Graduate Students, Genetics Department, UC San Diego
2018 – Present Graduate Research Assistant, UC San Diego
2016 – 2018  Lab Technician, University of Hawaii
2014 – Present Member, Association for Women in Science
2014 – Present Member, Sigma Xi
2014 – 2016  Diversity Supplement, National Institutes of Health

Honors

2020  Virtual Poster Presenter, Genetics and Molecular Biology Meeting
2019  Poster Presenter, Advances in Cancer Research and Therapy Meeting
2018  Paula F. Lauenberg award for best senior project in the Biology Department, Purdue University
2014 – 2018 Scholarship, National Merit Scholarship Program
2014  Scholarship, Daughters of Hawaii Society
NIH Biosketch

C. Contributions to Science

i. Up to five contributions to science, including:
   • the historical background that frames the scientific problem;
   • the central finding(s);
   • the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and
   • your specific role in the described work.

ii. Up to four research products per contribution

iii. Research products = published papers, published abstracts, patents

iv. Include MyBibliography link at end

https://grants.nih.gov/grants/forms/biosketch.htm
NIH Biosketch

D. Scholastic Performance

i. Complete “Scholastic Performance”
   i. List by institution and year all undergraduate and graduate courses with grades.
   ii. Explain grading systems that differ from 1-100, A-F, or a 0-4.0 scale. Also include the levels required for a passing grade.

ii. Use the format to the right

Address any weaknesses in the personal statement of your Biosketch.
Contacting the NIH Scientific Program Officer

- Find out who the NIH Scientific Program Officer is for the institute to which you are applying
- Why contact them?
  - Important to establish NIH contacts
  - Whether the mechanism is appropriate and if your research aligns with the institute’s mission
  - If you’re eligible for the mechanism
- Email first, do not call!
- Attach a NIH Biosketch and Specific Aims page
- They may need to be nudged in a 1-2 weeks. Follow-up via email.
- You should email all the applicable NIH Institutes.
Sample email:

Dear Dr. [SPO],

I hope this email finds you well. I am a [graduate student, doctoral candidate etc.] in the [DEPARTMENT/PROGRAM] at Columbia University interested in submitting a F3X application for the April/August/December 8th deadline. The focus of my application is XXX and I will be performing this work under the mentorship of Dr. [SPONSOR].

Would you please help me determine how strong of a candidate I am as well as the appropriateness of my research proposal for [NIH INSTITUTE]? I have attached my NIH Biosketch as well as a draft Specific Aims page for your review.

I would be more than happy to set-up a time to discuss my application with you at your earliest convenience. I look forward to your response.

Sincerely,

[Your full name, title, etc.]
When in Doubt, Reach Out
by NIH Staff

The NIH Grants & Funding website has a wealth of information to help applicants and grant recipients navigate application submission and grant administration requirements. When you can’t find what you need online, don’t hesitate to reach out to NIH staff. Often, the best folks to talk to will be in one of the NIH institutes or Centers. Our Contacting Staff at the NIH Institutes and Centers page can help you understand the roles of NIH staff and help you contact the right person at each phase of the application and award process.

Having trouble navigating our eRA systems? Check out our general Help page for eRA Service Desk and other general support contacts.

Communicating with NIH staff is not only okay, it is encouraged. When in doubt, reach out – we’re here to help.
Welcome to the Commons

System Notification Message

All systems are currently available.

Note: Effective March 22, 2018. If you are registering a new entity in SAM.gov, you must provide an original, signed notarized letter stating that you are the authorized Entity Administrator before your registration will be activated. Read FAQs to learn more about this process change.

Scheduled Commons Maintenance: For maintenance information, see the eRA Scheduled Maintenance Calendar.

Support Related Resources

- Electronic Submission: Learn about the most frequent application errors at Avoiding Common Errors.
- Electronic Application Submission: To learn about completing and submitting an electronic application and access helpful resources, visit the Applying Electronically website.
- eRA Home Page: To find Commons FAQs, User Guides, training materials, and step-by-step instructions for performing tasks in Commons, visit the eRA website.

Commons Related Resources

- Reference Letters: To submit a reference letter when requested by an applicant, please follow this link: Submit Reference Letter.

Privacy Act Statement

You are accessing a U.S. Government Information system, which includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network. This information system is provided for U.S. Government-authorized use only. Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties.

By using this information system, you understand and consent to the following:

1. You have no reasonable expectation of privacy regarding any communication or data transmitting or stored on this information system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transmitting or stored on this information system.
2. Any communication or data transmitting or stored on this information system may be disclosed or used for any lawful Government purpose.

This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes all devices/storage media attached to this system. This system is provided for
eraCommons: ORCID needed for Fellowship

The Open Researcher and Contributor ID (ORCID) is used within NIH and Grants.gov to relate publications to grants. You can associate your ORCID from the Commons Personal Profile module.

In eRA commons:

https://era.nih.gov/erahelp/PPF_Help/8_2_orcid.htm%3FTocPath%3D_____13
How to submit

• VP&S Pre-Award Team is available to assist you with your proposal.
  • Please notify us by 6/28/2021 (6 weeks before the deadline).
  • Email: ps-preaward@cumc.columbia.edu
• MD-PhD students should work with Becky Spurr.
  • Email: rms2254@cumc.columbia.edu
• You can also submit through your department’s grant administrator.

https://www.ps.columbia.edu/research/funding/grant-resources/p-s-pre-award-core
<table>
<thead>
<tr>
<th>Weeks until deadline</th>
<th>Task/item</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 - 12</td>
<td>Determine and meet with mentors/sponsors/collaborators; Draft Specific Aims &amp; Biosketch; Contact NIH</td>
</tr>
<tr>
<td>6 - 10</td>
<td>Contact references and collaborators; Start drafting Applicant Section and Research Strategy; notify departmental administrator/VP&amp;S pre-award team about intent to submit</td>
</tr>
<tr>
<td>5 - 8</td>
<td>Work on Applicant Section and Research Strategy</td>
</tr>
<tr>
<td>4</td>
<td>Send draft of Applicant Section and Research Strategy to mentors for review; speak to grant administrator in the Pre-Award Team for to address the budget; start drafting other attachments</td>
</tr>
<tr>
<td>3</td>
<td>Incorporate feedback; remind references to submit; continue drafting other attachments</td>
</tr>
<tr>
<td>2</td>
<td>Start gathering letters, biosketches etc.; finalize attachments and send to the Pre-Award Team; incorporate any additional feedback</td>
</tr>
<tr>
<td>1</td>
<td>All documents should be submitted to the Pre-Award Core/grant administrator. The Pre-Award Team/grant administrator will upload them into the system.</td>
</tr>
<tr>
<td>0</td>
<td>Last day to submit!! No changes after NOON (12p). Deadline by 5p (including reference letters).</td>
</tr>
</tbody>
</table>
### NIH submission, review, and funding dates

<table>
<thead>
<tr>
<th>F Series Fellowship</th>
<th>Cycle I</th>
<th>Cycle II</th>
<th>Cycle III</th>
</tr>
</thead>
<tbody>
<tr>
<td>New &amp; resubmission due date</td>
<td>April 8</td>
<td>August 8</td>
<td>December 8</td>
</tr>
<tr>
<td>Scientific Merit Review (Study Section)</td>
<td>June – July</td>
<td>October – November</td>
<td>February - March</td>
</tr>
<tr>
<td>Summary statement sent to applicant</td>
<td>July – August</td>
<td>November – December</td>
<td>March - April</td>
</tr>
<tr>
<td>Advisory Council Round (Funding decision)</td>
<td>August or October*</td>
<td>January</td>
<td>May</td>
</tr>
<tr>
<td>Earliest Project Start Date</td>
<td>September or December*</td>
<td>April</td>
<td>July</td>
</tr>
</tbody>
</table>

*Council may be held the month before or after so the project start date may adjust accordingly

Next week

- Review Criteria
- Applicant section
- Specific Aims – see homework assignment
- Research Strategy
- Sample application
Homework for Session 2 and OFR Application Review

- Begin to draft your Specific Aims page for your proposal before Session 2.
  - Identify scientific question(s) – big picture goal of what you want to address and arguments for why you think it is important.
  - Determine what experimental approach you need to answer your scientific question.
- Any draft Aims emailed to the instructors by the end of the day on 6/15 will be briefly reviewed prior to the 6/16 session (and written feedback will be provided by 6/18).
- Our office (OFR) is also available to review drafts of a few application components.
  - Specific Aims and Biosketch: Please send final drafts by 6/28/2021
  - Applicant Section: Please send final drafts by 7/19/2021
Questions?

Feel free to contact us:

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212-305-4078

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