**Introduction to NIH**

Joan M. Lakoski, PhD • Robert J. Milner, PhD

## Why should I write a grant?

1. To gain funding for research & career development; add to CV, enhance job-seeking . . .
2. **Grant writing improves your science**

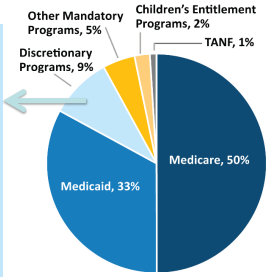
- translates vague ideas into concrete plans
- identifies problems, challenges (& alternatives)
- enables feedback

## A successful proposal is an effective act of communication

## The National Institutes of Health is an Agency under the Department of Health & Human Services (HHS)

**National Institutes of Health (NIH)**
Food & Drug Administration (FDA)
Centers for Disease Control (CDC)
Indian Health Service (IHS)
Substance Use and Mental Health Services Administration (SAMHSA)
Agency for Healthcare Research & Quality (AHRQ)

**Discretionary Programs ($144B)**

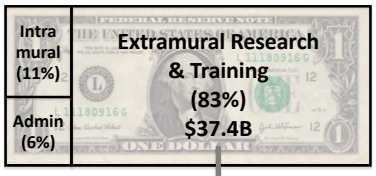



**FY2024 HHS Budget* ($1.84T)**

*https://www.hhs.gov/sites/default/files/fy-2024-budget-in-brief.pdf (archived)

## NIH supports intramural research in its own labs and extramural research & education through grants

**FY24 Budget = $47.1 billion**




- ~50,000 grants
- 300,000 researchers
- 2,500 institutions

**NIH Director**

**Jay Bhattacharya, MD, PhD**
Stanford University
Health Economist

https://healthpolicy.fsi.stanford.edu/news/bhattacharya-awarded-robert-j-zimmer-medal-intellectual-freedom

## NIH consists of 27 Institutes & Centers (I/Cs)

**21 National Institutes** each focused on an area of biomedical research:

- National Cancer Institute (NCI)
- National Institute of Neurological Disease & Stroke (NINDS), etc
- National Library of Medicine (NLM)

**6 Centers** providing support for research:

- National Center for Advancing Translational Sciences (NCATS), etc
- **Center for Scientific Review (CSR)**

***Your research must fit within the scope of an NIH Institute***

## Each NIH Institute supports research & education in a specific area of biomedical research

**Institute Director**
— senior scientist/administrator

**Intramural Research Programs**
— at the Bethesda campus & other federal sites

**Extramural Research Programs**
— external support through grants

**Institute Advisory Council**
— oversight body for the Institute
— senior scientists, lay persons, government reps
— provides strategic oversight
— *final approval on grant funding*

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## Extramural research, training, and education are supported by multiple grant mechanisms

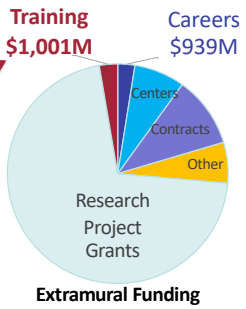
Research Project Grants
- R-series: R01, R03, R21

Research Centers

**Research Training**
- **F-series: F30, F31**, F32
- T-series: T32

Research Careers
- K-series: K01, K08, K23 K99/R00

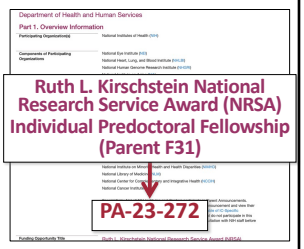
Contracts




**Extramural Funding $37.4B**

## Funding awards at NIH are described in a Notice of Funding Opportunity (NOFO)

**Program Announcement (PA)**
- Description of Award
- Eligibility
- Application Requirements
- Review Criteria
- Contact Information




https://grants.nih.gov/grants/guide/pa-files/PA-23-272.html

***New Fellowship Program Announcements will be issued for deadlines after May 25, 2025***

## Ruth L. Kirschstein National Research Service Award (NRSA) supports pre- and post-doctoral training

FY24 budget: $1,001 million (2.2%)
— to support ~17,400 trainees

**Institutional Awards** (80%)
(FY24: $800 million; ~13,700 trainees)

**T32:** pre- & postdoc training grants

**Individual Awards** (20%)
(FY24: $200 million; ~4,000 awards)

**F30: MD/PhD NRSA**

**F31: predoctoral NRSA**

F32: postdoctoral NRSA

F99/K00: predoctoral to postdoctoral

## Predoctoral Fellowships (F30, F31) provide support for promising doctoral candidates

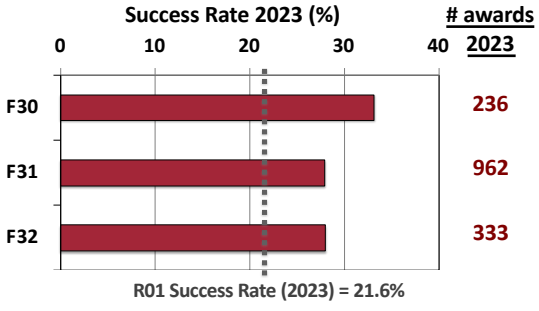
Support for research training leading to a PhD or equivalent research degree

**F30:** support for dual doctorate (MD/PhD) or equivalent students

Financial support:
- stipend (at NIH scale)
- tuition & fees (up to 60% cost)
- institutional allowance ($4,550)
- up to 5 years of support
- **childcare costs: up to $3,000/year***

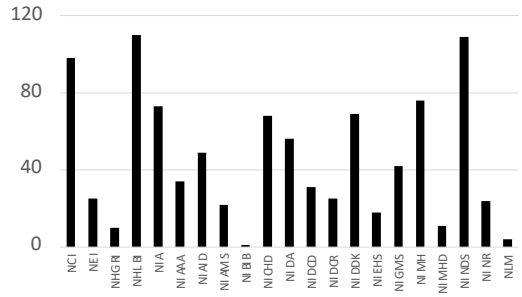
*see: NOT-OD-24-116
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-116.html

## Success rates for fellowship awards are higher than success rates for R01 awards




Success Rate = # grants funded / # submitted

## Numbers of grants funded differ between Institutes — F31 grants 2023

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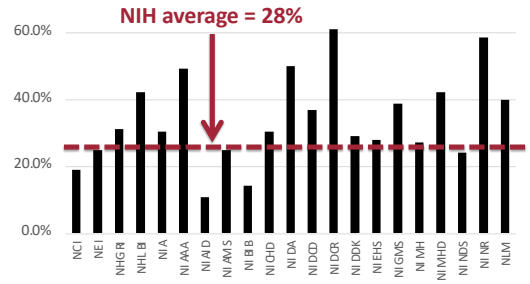
## Success rates differ between NIH Institutes — F31 grants 2023




## Extramural research is funded through specific Institutes

***Where does my research fit at NIH?***

| | | | | | |
|---|---|---|---|---|---|
| FIC | NCATS | NCCIH | NCI | NEI | NHGRI |
| NHLBI | NIA | NIAAA | NIAID | NIAMS | NIBIB |
| NICHD | NIDA | NIDCD | NIDCR | NIDDK | NIEHS |
| NIGMS | NIMH | NIMHD | NINDS | NINR | NLM |

What area of human health will benefit from my research?

Discuss with your supervisor
— *which institute supports their research?*

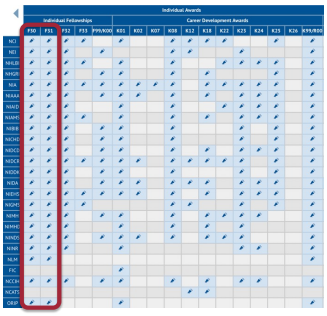
https://grants.nih.gov/funding/find-a-fit-for-your-research-nih-institutes-centers-offices

## Be aware that not all Institutes support all funding mechanisms

**Fellowship & Career Development Awards**

**Institutes**

**F30, F31**



https://researchtraining.nih.gov/institute

## NIH funds Direct Costs to the Investigator & Indirect Costs to the Institution

**Direct Costs (DC)**
—> **Investigator**

**100%**

funding for a specific research project: salaries, supplies, equipment, travel, etc

**Indirect Costs (IDC)**
—> **Institution**

**30–70%**

funding for support of research: light, heat, maintenance, facilities

**Indirect Costs (IDC)**, also called Facilities & Administration (F&A), is a % of direct costs, normally* set for each institution through audit & negotiation

**Direct Costs + Indirect Costs = Total Costs**

**on February 7, 2025, NIH issued a notice limited IDC to 15%*
*— this ruling is currently being challenged in court*

## Extramural Research in each NIH Institute is organized into Programs

Each **Program** covers an area of research or training & is directed by a **Program Official (PO)***

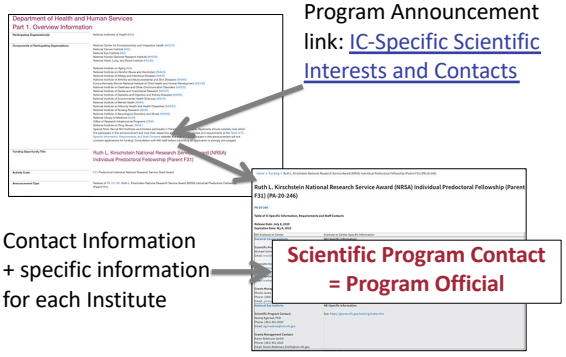
**Program Officials** administer funded grants in their area & provide support for applicants

There are Program Officials for training and career development programs
— each Institute has a Program Official assigned to Fellowship applications

***Cultivating the interest and support of Program Officials is essential!***

*https://grants.nih.gov/help/ic-staff-roles#program-officials

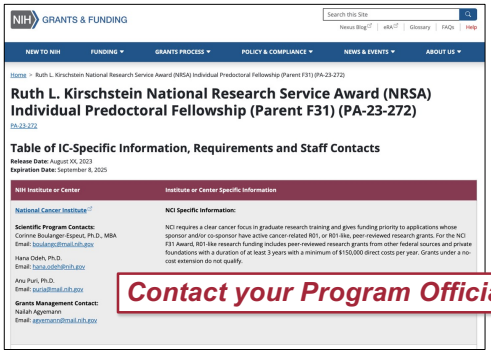
## Program Officials are listed for each award mechanism




Program Announcement link: IC-Specific Scientific Interests and Contacts

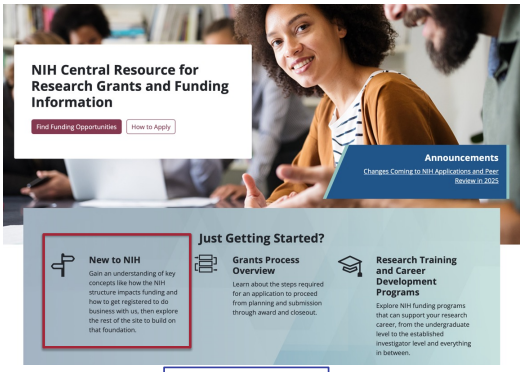
Contact Information + specific information for each Institute

## Fellowship Contacts at NIH



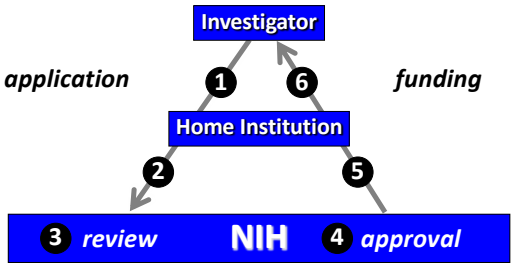

F31 Table of Institute and Center Contacts:
https://grants.nih.gov/grants/guide/contacts/parent-F31.html

## Visit the NIH website to learn more about NIH




https://grants.nih.gov

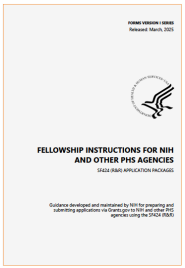
## The Grant Triangle defines the relationship between you, your institution, and NIH




*6 steps between application & funding*

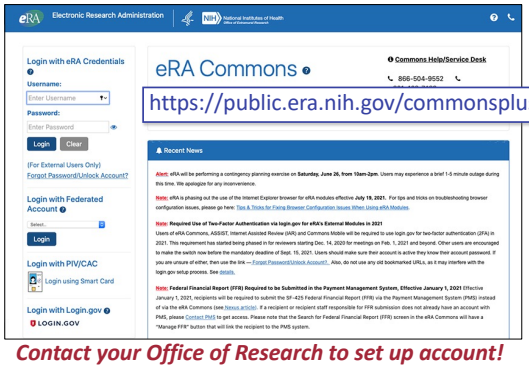
## Step 1. An application is initiated & prepared by an investigator

- prepared in response to a NIH program announcement (PA) following NIH instructions
- NIH provides instructions for each type of Award
  — Fellowship Awards
- **use Forms I**




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

## You must have an eRA Commons account to submit applications to NIH



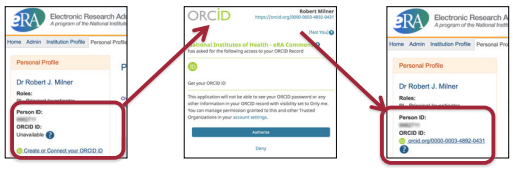

*Contact your Office of Research to set up account!*

## You must have an ORCID identifier linked to your eRA Commons Personal Profile

**ORCID** — Open Researcher and Contributor Identifier

- unique, persistent identifier that tracks your contributions over time

*go to eRA commons* *link to orcid.org* *add ORCID iD*



***Applications will NOT be accepted unless an ORCID iD is linked to the PI's eRA Commons Profile!***

*see:* NIH Notice NOT-OD-19-109

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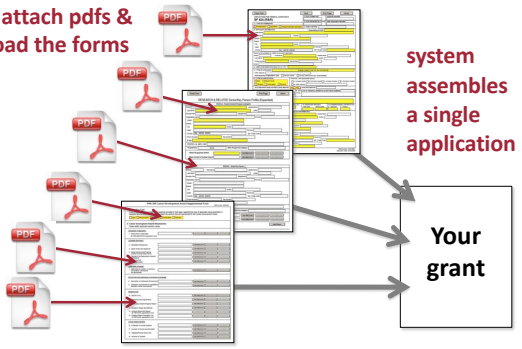
## The application consists of electronic forms + attachments (pdf)

Format for attachments is defined:

- single-spaced
- specific fonts & sizes
- single column
- minimum margins

***Applications that do not conform may be returned without review!***

## The electronic submission system assembles the separate pdfs & forms into a single application




## Step 2. The application is submitted to NIH through your home institution

Home Institution → (2) → NIH

- only institutions accredited by NIH are allowed to submit applications
- institutions must submit assurances & certifications that the funding will be spent appropriately
- institutions review applications prior to submission to ensure compliance with policies

***Your Institution's Research Office will have a deadline for their review — make sure you comply***

## Step 3. At NIH the application is assigned to a study section for review

NIH (3) *review*

- all applications are submitted to the NIH Center for Scientific Review (CSR)
- CSR Referral Officers assign each application to
  - — a Study Section for review
  - — NIH Institute(s) that will fund the proposal
- assignments are made by review of the abstract & keywords but can be targeted
  - — *Assignment Request Form*

***Discuss assignment with your Program Official***

## Most grant reviews at NIH are managed by the Center for Scientific Review (CSR)

Independent unit within NIH separate from Institutes

Receives & assigns applications:

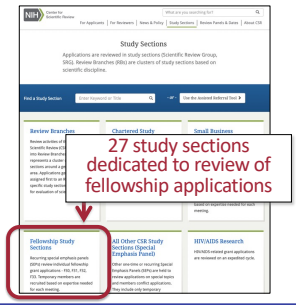
- to Study Sections for review
- to Institutes for funding

Administers review panels (Study Sections)

## NIH Study Sections and membership rosters are listed on the NIH website

Standing membership and rosters for last three meetings

Roster also listed on the summary statement



https://public.csr.nih.gov/StudySections

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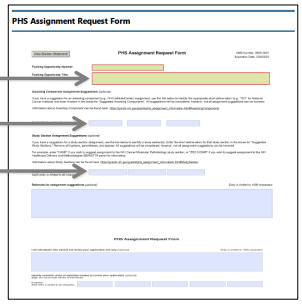
## Use the Assignment Request Form to request assignment to a NIH Institute and/or Review Panel

Program Announcement

Request NIH Institute

Request review panel




## NIH Study Sections usually meet for 1–2 days, 3 times per year

**Members:**

- working scientists (~15-30)
- one member serves as Chair

**Scientific Review Officer (SRO):**

- NIH staff person
- assigns grants to reviewers, collates reviews etc

## Each proposal is typically reviewed by 3 reviewers

The **review criteria** are defined for each application type

Each assigned reviewer provides written critiques submitted before the meeting

Each proposal gets an **Impact Priority** score:

- scale: 10 (exceptional) to 90 (worst)
- bottom 50% of applications may be *unscored*

## There are currently* five review criteria for fellowship proposals

**Candidate**

**Sponsor** (mentor)

**Research Training Plan**

**Training Potential**

**Environment & Institutional Commitment**

The Program Announcement describes each criterion in more detail

***The criteria will change for applications submitted after May 25, 2025***

## The fellowship application & review process will be revised for applications submitted after May 25 2025

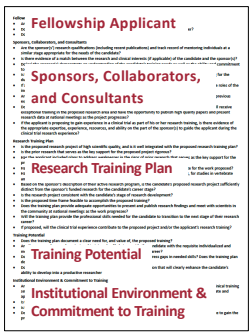
The goal of the changes is to improve the chances that the most promising fellowship candidates will be consistently identified by scientific review panels. The changes will:

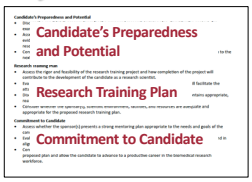
1. **Focus reviewer attention on three key assessments:** the fellowship candidate's preparedness and potential, research training plan, and commitment to the candidate
2. **Ensure a broad range of candidates and research training contexts can be recognized as meritorious** by clarifying and simplifying the language in the application and review criteria
3. **Reduce bias in review by emphasizing the commitment to the candidate** without undue consideration of sponsor and institutional reputation

https://grants.nih.gov/policy/peer/revisions-nih-fellowship-application-review-process.htm

## The review criteria will be simplified — five criteria are reduced to three

**OLD** → **NEW**




Fewer but more specific questions for reviewers

https://grants.nih.gov/policy/peer/revisions-nih-fellowship-application-review-process.htm

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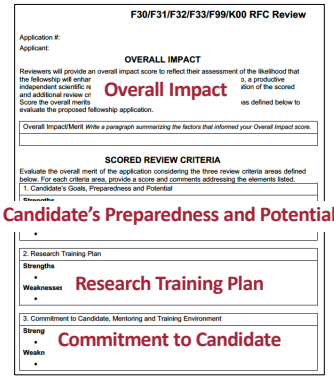
## NIH uses a template for reviewer comments & scores


F30/F31/F32/F33/F99/K00 RFC Review

Application #:
Applicant:

OVERALL IMPACT

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the fellowship will enhar … a productive independent scientific ra … ision of the scored and additional review cr … Score the overall merits … as defined below to evaluate the proposed fellowship application.

Overall Impact

Overall Impact/Merit *Write a paragraph summarizing the factors that informed your Overall Impact score.*

SCORED REVIEW CRITERIA

Evaluate the overall merit of the application considering the three review criteria areas defined below. For each criteria area, provide a score and comments addressing the elements listed.

1. Candidate's Goals, Preparedness and Potential

Candidate's Preparedness and Potential

2. Research Training Plan

Strengths
•
Weaknesses
•

Research Training Plan

3. Commitment to Candidate, Mentoring and Training Environment

Streng …
•
Weakn …
•

Commitment to Candidate

## Each assigned reviewer recommends an impact score on a range of 1 (exceptional) to 9 (poor)

| Overall Impact or Criterion Strength | Score | Descriptor |
|---|---|---|
| High | 1 | Exceptional |
| | 2 | Outstanding |
| | 3 | Excellent |
| Medium | 4 | Very Good |
| | 5 | Good |
| | 6 | Satisfactory |
| Low | 7 | Fair |
| | 8 | Marginal |
| | 9 | Poor |

Strengths

Weaknesses

http://grants.nih.gov/grants/peer/guidelines_general/scoring_system_and_procedure.pdf

## Other criteria are reviewed for adequacy

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Biohazards
- Select Agents
- Instruction in **Responsible Conduct in Research** (RCR)
- Budget and Period of Support
- Data Management Sharing Plan

## A typical sequence of review . . .

1. process moderated by Chair
2. reviewers indicate preliminary enthusiasm
3. primary & secondary reviewers present
4. tertiary reviewer comments
5. open discussion among panel
6. reviewers recommend final scores
7. all panel members score application
8. SRO writes summary of discussion

## What happens next . . .

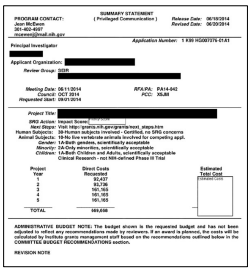
**Impact Priority Score** is posted to eRA Commons (within 3 business days after meeting)

Written reviews (**Summary Statements** or "pink sheets") are collated by SRO & distributed to applicant via the eRA Commons (within 30 days)

Scores and reviews are sent to the NIH Institute for final review & funding approval

## Read the Summary Statement carefully

- Impact Score and Percentile
- Brief summary of the discussion Criterion scores from the reviewers
- Bulleted critiques (strengths and weaknesses) from the reviewers
- Budget recommendations
- Any administrative comments
- Reviewer Roster


SUMMARY STATEMENT

*Discuss with your mentors and Program Officer*

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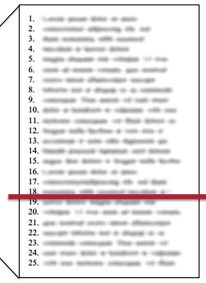
## Step 4. The Institute Advisory Council approves funding

**NIH 4 *approval***

Reviewed applications ranked by **Impact Priority Score** or **Percentile**



**Available Funding**

***PAYLINE***

## Step 5. The Program sends funding for the grant to the home institution

**NIH** → **5** → **Home Institution**

**Notice of Award (NoA):**

- legal document authorizing funding to your home institution
- states budget for the current year & any subsequent years
- terms & conditions of the Award
- posted on eRA Commons & sent to your Grants office

***Money goes to the Institution, NOT to you!***

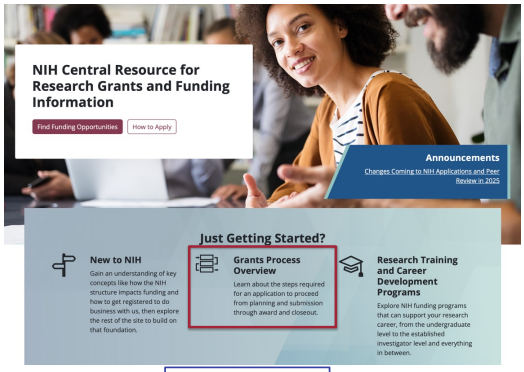
## Step 6. The home institution administers the grant for the investigator

**Home Institution** → **6** → **Investigator**

Institution sets up accounts according to the grant budget to pay salary, purchase supplies & equipment, etc.

***You can now focus on research!***

## NIH website has information on grants process




https://grants.nih.gov

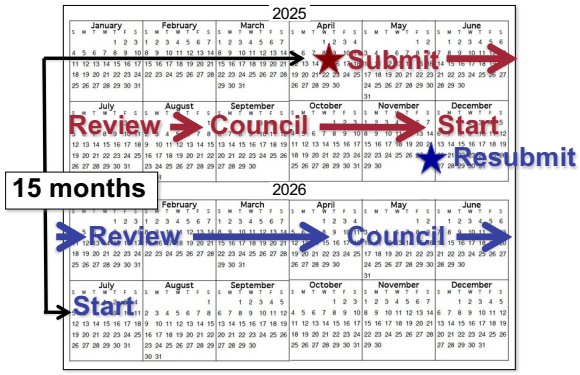
## There are three deadlines per year for submission of Fellowships

| Receipt | Review | Council | Start |
|---|---|---|---|
| April 8 | June-July | Sept-Oct | December |
| Aug 8 | Oct-Nov | Jan-Feb | April |
| Dec 8 | Jan-Feb | May-June | July |

Applications must be received electronically on or before the receipt date.

Your Grants Office has an earlier submission deadline.

## Plan ahead for resubmission!

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