Presenters

- David Hollingsworth, Director of Professional Development and Outreach Initiatives, TAMU Sponsored Research Services

- Jim Izat, Senior Research Development Officer, School of Public Health

OMB Guidance:
Federal Funding
Assistance

Timeline Uniform Guidance Updates

- The Office of Management and Budget (OMB) issues guidance regarding government-wide policies for the award and administration of Federal financial assistance, often referred to as the Uniform Grants Guidance. An updated version of this guidance was released in April 2024.

- Effective October 1, 2024:   The beginning of the federal fiscal year is the date when the changes become effective.

- Federal agencies may elect to apply the final guidance to Federal awards issued prior to October 1, 2024, but must be no earlier than June 21, 2024.

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Data and Evaluation Costs

- 200.455 Organization Cost description expanded to state that the costs related to data and evaluation are allowable

- Data costs include the expenditures needed to gather, store, track, manage, analyze, disaggregate, secure, share, publish, or otherwise use data to administer or improve the program, such as data systems, personnel, data dashboards, cybersecurity, and related items.

- Evaluation costs include many types of expenditures such as staff, materials, contractors, subawards, data infrastructure, and other expenses that support the effective use of evaluation throughout the full program life cycle from planning to implementation and closeout.

Increased Thresholds

- **Equipment**: increases from $5,000 to $10,000 the value of equipment that at the end of the grant period "may be retained, sold, or otherwise disposed of with no further responsibility to the Federal agency" (200.313)

- **Unused Supplies**: increases from $5,000 to $10,000 the value of unused supplies that recipients are required to sell at the end of the grant award period (200.314)

- **Audit:** Increases from $750,000 to $1,000,000 at which a recipient is required to conduct a single audit (200.501)

- **Fixed Amount Subaward:** increases from $250,000 to $500,000 the amount of fixed amount subawards that a recipient may provide with prior written approval from the Federal agency (200.333)

Indirect Costs Base – Modified Total Direct Costs

- Current definition: Consisting of all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel and up to the first $25,000 of each subaward and

- Excludes equipment ($5,000 or more), capital expenditures, charges for patient care costs, rental of off site facilities, tuition remission, scholarships and fellowships, participant support costs, and the portion of each subaward in excess of $25,000.

- Subaward threshold increases from $25,000 to the first $50,000

- Equipment – exceeds the lesser of the capitalization level established by the recipient or subrecipient for financial statement purposes, or $10,000

Entities Without a Federally Negotiated Rate Agreement

- **De Minimis Indirect Rate**: increases from 10% to 15% MTDC, the maximum rate that recipients may use for indirect costs without negotiating an alternative rate with the relevant Federal agency. (200.414)

Reducing the Number of Prior Approvals

UG Section 200.407 Prior Written Approval

Removes certain prior approval requirements including, for example certain costs associated with:

- Entertainment;

- Memberships, subscriptions, professional activity costs;

- Participant support costs.

Mandatory Disclosures (200.113)

- **Revision Adds False Claims Act Violations**

- Applicant, recipient, or subrecipient of a Federal award must promptly disclose whenever, in connection with the Federal award It has credible evidence of the commission of a violation of:

- Federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations

- or a violation of the Civil False Claims Act (31 U.S.C. 3729–3733).

- Also required to report matters related to recipient integrity and performance.

NIH GRANTS POLICY STATEMENT

US DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institutes of Health

APRIL 2024

NIH

- **Simplified Review Framework**

- **New NIH "FORMS-I" Grant Application Forms and Instructions**

- **New Review Criteria for Fellowships**

Goals for the Simplified Review Framework

1. Enable peer reviewers to better focus on answering the key questions necessary to assess scientific and technical merit

2. Mitigate the effect of reputational bias

3. Reduce reviewer burden

See the October 2023 Guide Notice, Open Mike and Review Matters Blogs for more information

13

Five Criteria Reorganized Into Three Factors

Current

Significance - scored

Investigator(s) – scored

Innovation – scored

Approach – scored

Environment - scored

Simplified Framework

(all considered in Overall Impact Score)

Factor 1: Importance of the Research
Significance, Innovation
Scored 1-9

Factor 2: Rigor and Feasibility
Approach (*also include Inclusions for HS and CT Study Timeline*)
Scored 1-9

Factor 3: Expertise and Resources
Investigators, Environment
Evaluated as appropriate or additional expertise/resources needed; gaps require explanation
No individual score

Reduced Additional Review Considerations

Most Additional Review Considerations **removed** from first-level peer review with responsibility shifting to awarding institute/center

Current

Additional Review Considerations
(no effect on overall impact score)

- Applications from Foreign Organizations
- Select Agent Research
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support

Simplified Framework

Additional Review Considerations
(no effect on overall impact score)

- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support

Approach to the Simplified Review Framework

1. **Enable reviewers to improve review by:**

   A. Focusing their attention on three main questions via reorganizing the five review criteria

      ➢ **Factor 1: Importance of the Research** - "Should it be done?"

      ➢ **Factor 2: Rigor and Feasibility** - "Can it be done?"

      ➢ **Factor 3: Expertise and Resources** - "Will it be done?"

   B. Simplify and strengthen review criteria by using conceptual definitions rather than lists of questions.

      ➢ Shifting away from extensive sets of complex questions encourages thoughtful integration of concepts rather than "yes-no" thinking.

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Approach to the Simplified Review Framework (Cont'd.)

2. **Modify the criterion definitions for Investigator and Environment in Factor 3 to reduce reputational bias**

> Reviewers assess the *adequacy* of investigator expertise and institutional resources *with respect to the work proposed* as a binary choice: Appropriate or Additional Resources or Expertise Needed

3. **Relieve reviewer burden by not requiring peer review of select "additional considerations".**

> Considerations not directly related to scientific merit shift to NIH staff administrative review.

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NIH Moving to Updated Application Forms

Concurrent with implementation of the simplified review framework, NIH is transitioning to updated application forms (FORMS-I)

- **FORMS-I application forms must be used for applications with due dates on or after January 25, 2025**

- The updated forms and instructions will be available in the Fall of 2024

- See Forms-I Notice ([NOT-OD-24-086](#)) for more information

Timing and Availability of Application Forms and Instructions

- New and reissued funding opportunities may be initially posted without an application forms package

  - Application forms and associated application instructions will be added at least 30 days and, frequently 60 days or more, prior to the first due date

- Applicants can begin drafting their application attachments using funding opportunity and current (FORMS-H) application guide instructions and adjust as needed once FORMS-I instructions are available.

  Application instructions will be posted, once available this fall on: grants.nih.gov/grants/how-to-apply-application-guide.html

What to Expect Over the Next Year

- **Changes to NIH systems**
- **Continued guidance for applicants and reviewers**
- **Updating and publishing funding opportunities**
- **Releasing new application packages**
- **Reviewer training**

NIH Issue Guide Notice on changes to funding opportunities	Updated funding opportunities begin to appear on Grants.Gov and the NIH Guide	New application packages added to opportunities for due dates on or after January 25	New framework applies to application due dates on or after January 25, 2025	Reviewer training begins for the simplified review framework
April	**Summer**	**Beginning in November**	**January 2025**	**Spring 2025**

Revisions to the NIH and AHRQ Fellowship Application and Review Process

- NOT-OD-24-107   Release Date: April 18,2024

- Goal of the changes is to facilitate the mission of fellowship peer review – to identify the most promising candidates and the individualized training opportunities that will assist them along their paths to support the advancement of the biomedical research enterprise.

Review Criteria - Candidate's Preparedness and Potential

- Discuss the candidate's preparedness for the proposed research training plan. Consider the context, for example, the candidate's stage of training and the opportunities available.

- Assess whether the candidate and sponsor statements as well as the referee letters provide convincing evidence that the candidate possesses qualities (such as scientific understanding, creativity, curiosity, resourcefulness, and drive) that will improve the likelihood of a successful research training outcome.

- Consider the candidate's potential to benefit from the fellowship research training plan and to transition to the next career stage in the biomedical research workforce.

Review Criteria - Research Training Plan

- Assess the rigor and feasibility of the research training project and how completion of the project will contribute to the development of the candidate as a research scientist.

- Evaluate the goals of the overall research training plan and the extent to which the plan will facilitate the attainment of the goals.

- Discuss whether the research training plan identifies areas of needed development and contains appropriate, realistic activities and milestones to address those needs.

- Consider whether the sponsor(s), scientific environment, facilities, and resources are adequate and appropriate for the proposed research training plan.

Review Criteria - Commitment to Candidate

- Assess whether the sponsor(s) presents a strong mentoring plan appropriate to the needs and goals of the candidate.

- Evaluate the extent to which the sponsor(s) and organizational commitment is appropriate, sufficient, and in alignment with the candidate's research training plan.

- Consider whether the level of commitment provided will contribute to the successful completion of the proposed plan and allow the candidate to advance to a productive career in the biomedical research workforce.

Changes to the PHS Fellowship Supplemental Form

1. Revisions to the Applicant Section (now "Candidate Section")
   Grades will no longer be required or allowed.
   Candidates will be required to submit four personal statements:
   (1) a statement of professional and fellowship goals,
   (2) fellowship qualifications,
   (3) a self-assessment, and
   (4) scientific perspective.

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National Science Foundation (NSF)
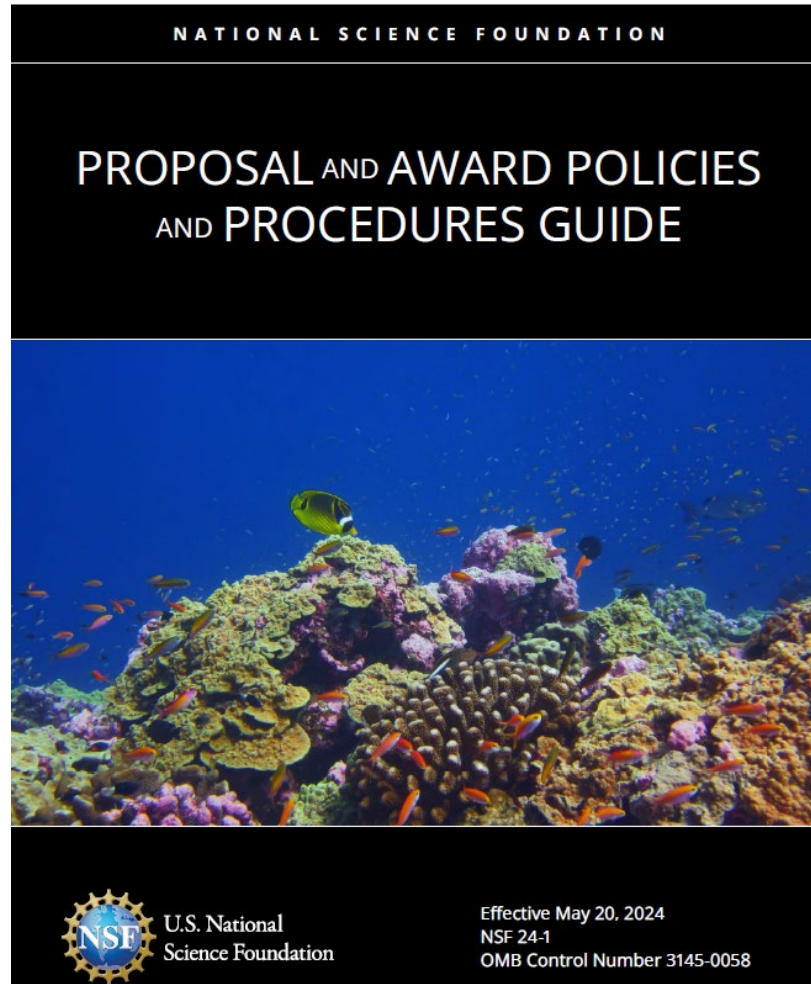
Foreign Organization Justification

- Why support from the foreign counterpart's in-country resources is not feasible;

- Why the foreign organization or foreign individual can carry out the activity more effectively than a U.S. organization or U.S. individual;

- What unique expertise, organizational capability, facilities, data resources, and/or access to a geographic location not generally available to U.S. investigators the foreign organization or foreign individual brings to the project; and

- What significant science and engineering education, training, or research opportunities the foreign organization or foreign individual offers to the U.S.

- Box for "Funding of a Foreign Organization or Foreign Individual" must be checked on the Cover Sheet

Not Eligible to Submit Proposals

Parties to Malign Foreign Talent Recruitment Programs

- Individuals who are a current party to a Malign Foreign Talent Recruitment Program are not eligible to serve as a senior/key person on an NSF proposal or any NSF award made after May 20, 2024.

- Senior/Key Personnel must certify prior to proposal submission and annually for the duration of the award.

- Certifications made in SciENcv on biosketch and current and pending support.

Proposal Preparation

When to Submit Proposals

- Modified to clarify that the 5 p.m. submitter's local time is tied to the organization, and not the location of the PI.

Proposal Font, Spacing, and Margin Requirements

- Modified to allow for submission of proposal documents in landscape format.

Biographical Sketch(es)

- Must be created in SciENcv.

- This section has been revised to remove the 3-page limitation for the biographical sketch. There is no page limitation for this section of the proposal.

- The Synergistic Activities section has been removed from the biographical sketch.

- Disclose contracts associated with participation in programs sponsored by foreign governments including foreign government-sponsored recruitment programs.

Synergistic Activities

- The Synergistic Activities section has been removed from the biographical sketch.

- This information must now be submitted by individuals designated as senior/key persons as part of the senior/key personnel documents in Research.gov. (a separate upload for each person)

- May be up to one page that includes up to five distinct examples that demonstrate the broader impact of the individual's professional and scholarly activities that focus on the integration and transfer of knowledge as well as its creation.

Current and Pending (Other) Support Consulting Activities

Consulting activities must be disclosed under the proposals and active projects section of the form when any of the following scenarios apply:

- Consulting activities will require the senior/key person to perform research as part of the consulting activity;

- Consulting activity does not involve performing research, but is related to the senior/key person's research portfolio and may have the ability to impact funding, alter time or effort commitments, or otherwise impact scientific integrity; or

- Consulting entity has provided a contract that requires the senior/key person to conceal or withhold confidential financial or other ties between the senior/key person and the entity, irrespective of the duration of the engagement.

Current and Pending (Other) Support

In-Kind Contributions

In this section, disclose ALL in-kind contributions with an estimated dollar value of $5000 or more **and** that require a commitment of the individual's time. Provide a brief statement of the overall objectives of the in-kind contribution(s).

An in-kind contribution is a non-cash contribution provided by an external entity that directly supports the individuals' research and development efforts.

An in-kind contribution may include but is not limited to: real property; laboratory space; equipment; data or data sets; supplies; other expendable property; goods and services; employee or student resources.

In-kind contributions with an estimated value of less than $5000 need not be reported.

Mentoring Plan

- Expanded to require a mentoring plan for postdoctoral researchers or <u>graduate students</u> supported on the project.

- There are not separate plans for graduate students and postdoctoral scholars

- Page limitation for the Mentoring Plan remains one page.

- If submitting a collaborative proposal there is only 1 plan per proposal.

- Uploaded in the Supplementary Documents Section

Individual Development Plans for Postdoctoral Scholars or Graduate Students

- Requirement for postdoctoral scholars or graduate students who receive substantial NSF support must have an Individual Development Plan which is required to be updated annually.

- NSF defines "substantial support" as an individual that has received one person month or more during the annual reporting period under the NSF award.

- The plan maps the educational goals, career exploration, and professional development of the individual.

- Certification that each graduate student or postdoctoral scholar has a plan is completed by the PI or Co-PI in Research.gov as part of the annual reporting process.

Seeking and Obtaining Tribal Nation Approval for Proposals that May Impact Tribal Resources or Interests

- Proposals that may impact the resources or interests of a federally recognized American Indian or Alaskan Native Tribal Nation **will not be awarded** without prior written approval from the designated officials of the Tribal Nation.

- Check the box on the Cover Sheet entitled "*Potential Impacts on Tribal Nations.*"

- Include in Supplementary Documents at least one of the following:

- (i) a copy of the written request to the relevant Tribal Nation to carry out any proposed activity/activities

- (ii) written confirmation from the Tribal Nation that review and approval is not required

- (iii) a copy of a document from the relevant Tribal Nation that provides the requisite approval.

Research Opportunity Supplemental Funding Requests for Primarily Undergraduate Institutions (ROA-PUI)

▪ Enables a faculty member (or equivalent), to pursue research as part of a collaborative research team as a visiting scientist at another NSF-supported institution.

▪ Either the visitor's home organization, or the host organization, or both, must be an eligible Primarily Undergraduate Institution (PUI) of higher education.

▪ Is intended to increase or maintain a PUI faculty member's research capability and effectiveness

▪ A formal request for an ROA supplement must be made by the host institution of the NSF-supported PI who wishes to host a faculty member from a PUI institution.

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