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Strengthening Grants Management in LMICs: The Role of Mentorship & Staying Updated with NIH Policies

Kenya Medical Research Institute
University of California, San Francisco

Presenters



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Kenya Medical Research Institute (KEMRI)



In Search of Better Health

- State Corporation established in Kenya in 1979
- Currently ranks as one of the leading Centres of excellence in health research both in Africa as well as globally

MISSION

To improve human health and quality of life through research, capacity building, innovation and service delivery

VISION

To be a leading centre of excellence in research for human health

www.kemri.go.ke



In Search of Better Health

KEMRI's FUNDING

EXTERNAL FUNDING TREND FROM JULY 2019 TO JUNE 2024



70% External Grant Funding and 30% GOK

- **>75%** of GOK funding is towards human resource capacity
- Key funders include: US DOD, NIH, CDC, BMG, GSK, UNITAID, Fred Hutchinson Cancer Center, EDCTP, Wellcome Trust, National Institute for Health and Care Research (NIHR)

University of California San Francisco (UCSF)

Advancing Health Worldwide

- 1 of 10 campuses within the University of California system
- Founded in 1874
- Focuses exclusively on the health sciences
- Enrolls approximately 3,200 graduate and professional students and no undergraduate students



UCSF's Funding (FY2023)

“These public research funds lay a foundation for a healthier future for everyone.”

CATHERINE LUCEY, MD —

- US \$1.8B in research funding
- US \$91M in international research
- 380 UCSF faculty conducting projects in more than 62 countries
- \$789M in NIH funding
 - 1st among public universities
 - 2nd overall among all public and private universities
 - Top public recipient of NIH funding for 17 consecutive years

Agenda

The Role of
Mentorship
KEMRI
& UCSF

Before mentorship

Collaboration with UCSF

Learning experiences

Post mentorship

Envisioning the Future

Staying
Updated
with NIH
Policies

Significant policy items

Impacts on LMICs





The Role of Mentorship



In Search of Better Health



University of California
San Francisco

advancing health worldwide





Challenges

Systemic issues that touched on policies, people, processes, systems, and training

Highly decentralized Organogram

Inadequate/lack of policies and manuals

Lack of an automated system to process payments

Threshold for approval of documents/payments

A weak/nonexistent pre-award section

Delays in contract and sub-contract signing

PIs lack of knowledge of institute financial and procurement regulations

Poor communication between PIs and research administrators

Slow procurement of goods

Lack of a justifiable indirect cost rate



NIH G11 Grant - UCSF Collaboration with KEMRI



Conduct a needs assessment at KEMRI identifying and measuring the area of greatest institutional risk and research infrastructure gaps



Provide a comprehensive, vigorous, and innovative training program on the grant life cycle – a total of 8 people trained (3 for 8 weeks in 2017 and 5 for 5 weeks in 2018)



Transform the existing Grantsmanship department into an established Office of Sponsored Research (OSR) providing high quality pre- and post-award support to researchers while balancing institutional and sponsor compliance requirements



Develop a long-term sustainability roadmap that will direct and support the OSR activities after the completion of this project - the planning process determines the optimal organization structure, role, and resources required to implement and maintain this new state



Develop a monitoring and evaluation (M&E) plan using a logic model listing short and long- term goals as the basis for this activity



NIH G11 Grant – Needs Assessment

- 2-part assessment process targeting the KEMRI research populations addressing
 - Institutional risk
 - Research infrastructure gaps
 - Challenges in the areas of Pre-Award support and Post-Award/Finance support
- Provided a set of recommendations addressing
 - Policy gaps/revisions
 - Process, system, and organizational changes
 - Training
 - “Quick wins”
- Outlined possible options to transform the Office of Grantsmanship



NIH G11 Grant – Training

- Baseline overview training at KEMRI on pre-award research administration, financial management, and faculty training
- Leadership workshop at UCSF focused on program management issues
- UCSF hosted an 8-week training program which included both general knowledge as well as targeted training in the individual trainee's areas of responsibilities
- Research administrative staff workshop at KEMRI in the full life-cycle process



NIH G11 Grant – Reorganization

- Needs assessment presented 4 options:
 - 1) Close Collaboration between the Office of Grantsmanship (OG) and Finance
 - 2) Create a single Office of Sponsored Research (OSR) that maintains separate functions for OG and Finance
 - 3) Merge functions of OG and Finance into one Consolidated Unit
 - 4) Carry out a multi-year transition that carries out Option 1 through Option 3 while KEMRI invests in supporting staff development, system implementations, and policies and process changes



NIH G11 Grant – Monitoring & Evaluation

- Framework and key indicators were based on key areas recommended in the needs assessment report
 - Establishment or revising of KEMRI policies and procedures
 - Process, system, and organizational changes
 - Evaluating and defining roles and responsibilities
 - Improvements in communication impacting research
 - Training in key research administration areas that involve scientists and staff



NIH G11 Grant – Sustainability

- Long-term sustainability roadmap directs and supports the OSR activities after the completion of the G11 project
- Based on the needs assessment report and adjusted for
 - Implementation of new systems
 - Development/revision of policies
- Determines the roles and resources required to implement and maintain this new state



Learning Experiences from UCSF

Clearly defined sections with roles and responsibilities spelled out

Effective pre-award section that relieves the PI of the administrative burden

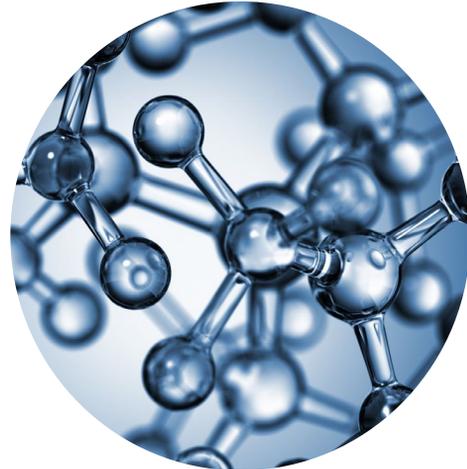
Effective post-award section with staff assigned to PIs who help the PI on their grant from inception to closeout

Just In Time phase where an application is likely to be funded, the PI applies for ethical approvals and Conflict of Interest

Close collaboration and teamwork between the central office, Office of Sponsored Research, the department the PI is domiciled in, and the PI to ensure a seamless flow of project activities

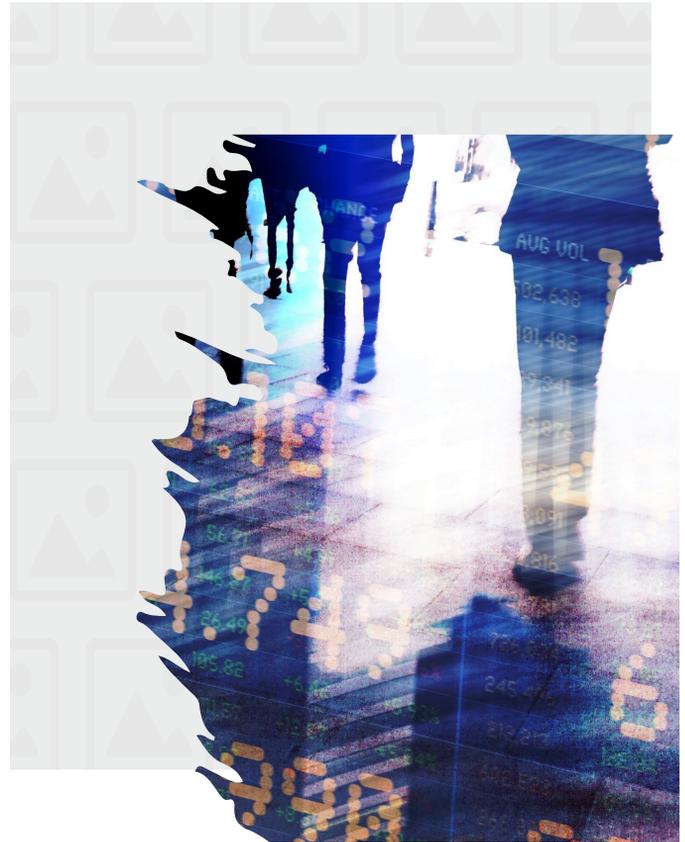
Software for pre- and post-award in place that provides end to end information on a grant

Email prompt reminders for deadlines in regard to invoicing, submission of technical/financial reports, project end date, etc.



Post Mentorship: Roadmap To Improvement Of Grants Management

- A roadmap for improvement of the grants management function was tied to the KEMRI strategic plan 2018-2023 that had 5 strategic themes of which two directly affected grants management





Post Mentorship: Roadmap To Improvement of Grants Management

- Strategic theme 2: Corporate Governance - To strengthen corporate governance by transforming and reengineering business processes to achieve efficiency and effectiveness in health research and service delivery
- Strategic theme 3: Research Infrastructure – Automation of key institute processes to increase financial compliance and streamline award management

Envisioning The Future One-Stop-Shop Model

Benefits: Increased efficiency, enhanced compliance, greater accountability



PRE-AWARD
DESK



POST-AWARD
DESK



COMPLIANCE
AND LEGAL
DESK



FINANCIAL
MANAGEMENT
DESK



MONITORING
AND
EVALUATION
(M&E) DESK



CAPACITY
BUILDING AND
TRAINING
DESK



PARTNERSHIP
AND
COLLABORATION
DESK



Envisioning The Future



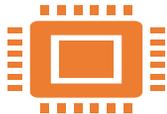
Fostering more collaborations



Compliance



Improved procurement processes



Efficiency - Approval workflows



“The journey of a thousand miles begins with a single step” – Chinese proverb



Staying Updated with NIH Policies

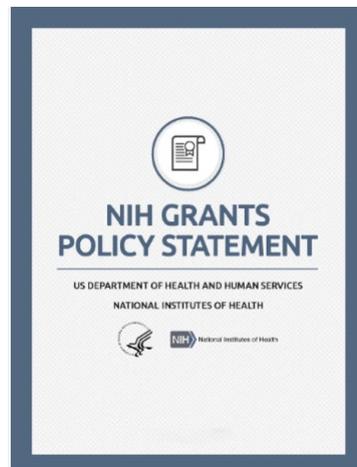
Focus on NIH GPS April 2024 Updates
and Implications for LMICs

Introduction to NIH Grants Policy Statement (NIHGPS)

Definition: The NIH Grants Policy Statement outlines terms and conditions for NIH grant awards.

Latest Update: Revised in April 2024, applicable from October 1, 2023.

Purpose: Ensures compliance with NIH policies and federal regulations.



Collaboration

NOT-OD-23-182

Effective January 2, 2024

Mandates that prime recipients ensure compliance from their subrecipients regarding specific NIH guidelines

The formal written agreement between the prime recipient and each subrecipient must be signed by both parties

Financial Reporting Changes

Revised 8.1 “Changes in Project and Budget”

Clarifies that recipients must notify NIH of significant developments impacting award-supported activities as soon as they become known





Data Management and Sharing Policies

Revised 8.2.3.1 "Policy for Data Management and Sharing (DMS Policy)"

Incorporates current NIH DMS policy

Effective October 1, 2024

Requires all grant applications to include a DMS plan

Requires all RPPR to include status of data sharing, repositories, and unique identifiers for data that have been shared

Updates to the processes for submitting requests to revise a DMS Plan through the Just in Time (JIT) Module, the Prior Approval Module, and the RPPR Module in eRA Commons

Single Institutional Review Board (sIRB)

Revised 4.1.15.10 "NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research"

Clarifies expectation that U.S.-based sites are to rely on a U.S. sIRB for multi-site research





Impact on LMICs - Increased Administrative burden

- Stricter compliance requires higher administrative capacity
- LMIC institutions may face challenges managing limited resources
- Opportunity to strengthen administrative functions to manage NIH grants



Conclusion

NIH GPS updates provide opportunities but also challenges for LMICs

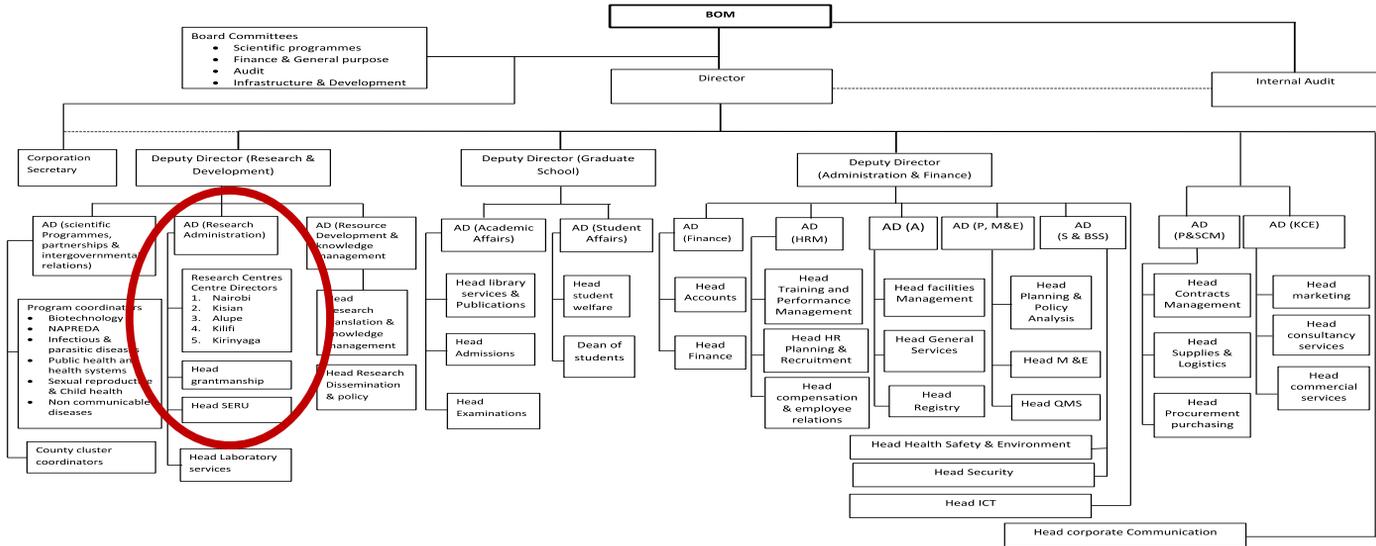
Institutions must enhance their capacity to meet NIH compliance standards



Appendix - Resources

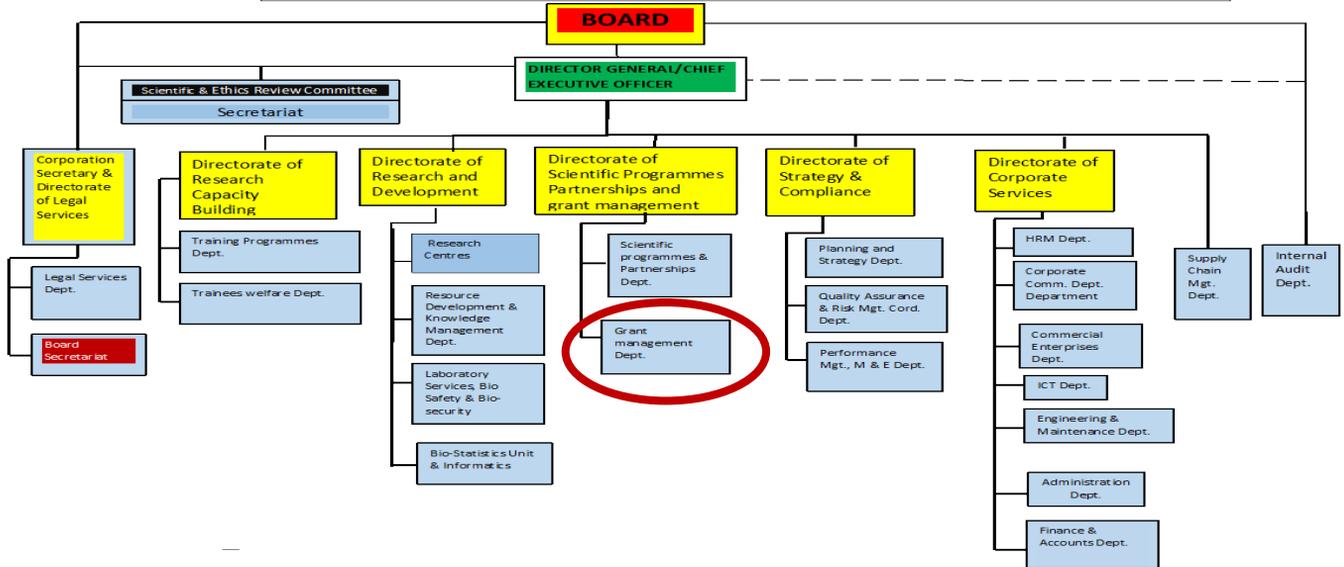
Before Mentorship: KEMRI Organogram 2018

KEMRI REVISED ORGANIZATIONAL STRUCTURE 2018



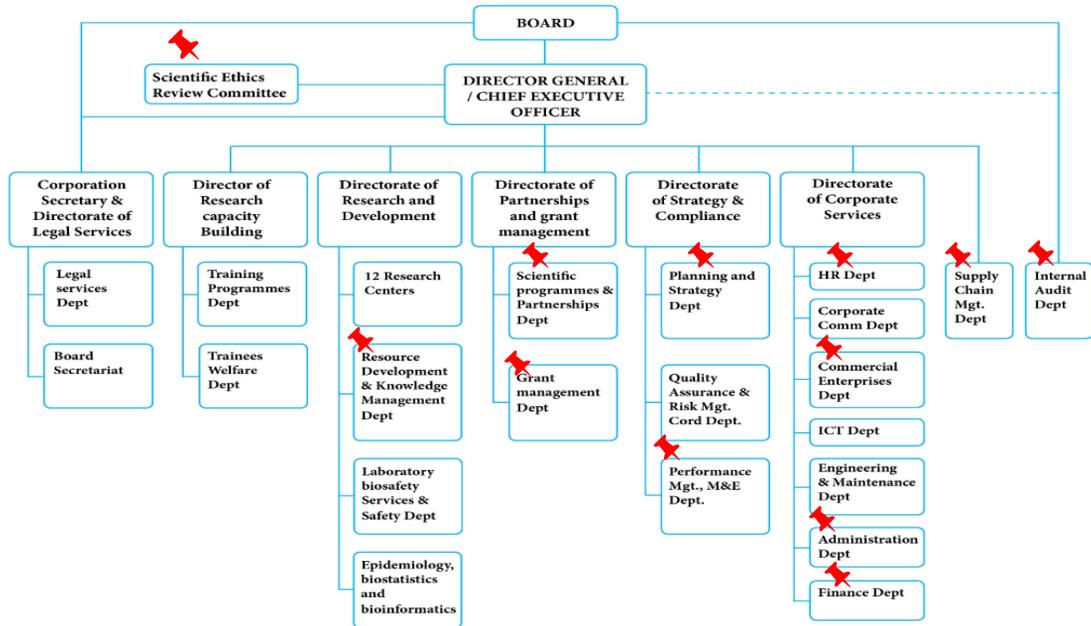
After Mentorship: New Structure

KEMRI ORGANIZATION STRUCTURE



RESEARCH MANAGEMENT & ADMINISTRATION LANDSCAPE IN KEMRI

Research administrators in KEMRI encompass various staff involved directly in the management of Research and grants



Key Updates in the April 2024 NIHGPS (1/5)

| Section | Title | Comments |
|--------------|--|---|
| All sections | GPS throughout | Replaced "prime recipient" with "pass-through recipient" for consistency with Uniform Guidance 2 CFR 200.332 . |
| All sections | GPS throughout | Replaced use of terminology from FOA (Funding Opportunity Announcement) to NOFO (Notice of Funding Opportunity) for consistency with Uniform Guidance 2 CFR 200.204 and NOT-OD-23-109 (Updates to Funding Opportunity Terminology). |
| All sections | GPS throughout | Replaced use of term "commercial organization" with "for-profit" organization for consistency with Uniform Guidance terminology in 2 CFR Part 200 . |
| 1.2 | Glossary | Added entries for: <i>Animal Welfare Assurance</i> , <i>For-profit Organization</i> , <i>Notice of Funding Opportunity</i> . |
| 2.3.5.1 | Other Funding-Related Notices | Created a new section describing Notice of Intent to Publish (NOITP) and Request for Information (RFI). |
| 2.3.7.5 | New Investigators and Early Stage Investigators | Clarified the definition of Early Stage Investigator in line with NOT-OD-19-072 (Updates to NIH Policy on ESI Application Status). |
| 2.3.7.7 | Post-Submission Grant Application Materials | Added language to state that NIH will accept preliminary data as post-submission material under some circumstances in line with NOT-OD-23-106 (Revising the NIH/AHRQ/NIOSH Post-Submission Material Policy). |
| 2.3.7.10 | NIH Data Management and Sharing and Genomic Data Sharing | Revised heading from "NIH Genomic Data Sharing" to "NIH Data Management and Sharing and Genomic Data Sharing" and updated with high-level statement of DMS plan requirement for applications. |
| 2.3.9 | 2.3.9 Application Receipt Information and Deadlines | Added clarifying statement that electronic submission is generally required. |
| 2.3.9.1 | Electronic Submission Requirements | Revised heading from "Paper Applications" to "Electronic Submission Requirements" and stated requirements for required electronic submission of NIH applications. |

Key Updates in the April 2024 NIHGPS (2/5)

| | | |
|-----------|---|---|
| 2.3.9.2 | On-time Application Submission | Revised heading from “Electronically Submitted Applications” to “On-time Application Submission” and stated requirements for on-time application submission. |
| 2.3.9.2.1 | Late Applications | Added subsection heading “Late Applications” for clarity. |
| 2.3.9.3 | Continuous Submission for Appointed Members of NIH Federal Advisory Committees | Revised heading from “Modified Submission Policy for Appointed Members of NIH Review and Advisory Group and Reviewers with Recent Substantial Service” to “Continuous Submission for Appointed Members of NIH Federal Advisory Committees” and added language to clarify continuous submission requirements and criteria per updates provided in NOT-OD-20-060 (Update of NIH Continuous Submission Policy: Change in Submission Deadlines and End of Recent Substantial Service Option). |
| 2.3.9.6 | Natural Disasters and Other Emergencies | Added new section and content based on multiple reminder notices on NIH Extramural Response to Natural Disasters and Other Emergencies . |
| 2.5.1 | Just-in-Time Procedures | Added language from Other Support instructions that each PD/PI or other senior/key personnel must electronically sign their respective Other Support form prior to submission to certify that the statements are true, complete, and accurate. |
| 2.5.1 | Just-in-Time Procedures | Revised guidance, per NOT-OD-20-033 (NIH and AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for Research Training Grant, Fellowship, and Career Development Award Applications), to clarify the My Bibliography is collected via the Interim/Final Research Performance Progress Report. |
| 2.5.1 | Just-in-Time Procedures | Updated instructions for SBIR STTR Foreign Disclosure Form, per NOT-OD-23-139 (Implementation of the NIH SBIR and STTR Foreign Disclosure Pre-award and Post-Award Requirements). |
| 2.5.2 | 2.5.2 Submitting Revised Project Summary/Abstracts, Specific Aims, and/or Public Health Relevance Statement | Removed PDF file as an acceptable document format to send revised Project Summary/Abstracts, Specific Aims, and/or Public Health Relevance Statement. |
| 4.1.1 | Animal Welfare Requirements | Clarified foreign institution requirements under the Public Health Service Policy on Humane Care and Use of Laboratory Animals. |
| 4.1.1 | Animal Welfare Requirements | Clarified neither activities nor costs for activities for live vertebrate animals may be charged to NIH grants if there is not a valid Animal Welfare Assurance and IACUC approval of the activity. |
| 4.1.1.1 | Animal Welfare Assurance Requirements | Clarified neither activities nor costs for activities for live vertebrate animals may be charged to NIH grants without a valid Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW). |
| 4.1.1.2 | Verification of IACUC Approval | Clarified to require applicant verify there is congruence between the application and the Institutional Animal Care and Use Committee (IACUC)-approved protocol when it provides the IACUC approval date. |

Key Updates in the April 2024 NIHGPS (3/5)

| | | |
|-----------|--|---|
| 4.1.1.4 | Foreign Recipients and Foreign Performance Sites | Clarified foreign recipients that will perform live, vertebrate animal activity onsite must provide OLAW with an Animal Welfare Assurance for Foreign Institutions. |
| 4.1.1.4 | Foreign Recipients and Foreign Performance Sites | Clarified requirements and replaced "foreign organization's IACUC" with "foreign organization's animal welfare committee or oversight body". |
| 4.1.2 | Civil Rights Protections | Updated language to incorporate NOT-OD-23-047 (Updates to the Non-Discrimination Legal Requirements for NIH Recipients). |
| 4.1.3.3 | Good Cause Extension (GCE) Request Process | New section added based on NOT-OD-23-080 (Clinical Trials Results Information Submission: Good Cause Extension Request Process and Criteria Document Posted on ClinicalTrials.gov) and documents cited in that notice. |
| 4.1.10 | Financial Conflict of Interest | Edited to align with recent updates to Section 15.2 regarding the content of subrecipient agreements. |
| 4.1.15.2 | Certification of IRB Approval | Added language stating that NIH-funded sites in the United States cannot accept or rely on a non-US IRB and therefore, NIH will not accept an approval from a non-US IRB. |
| 4.1.15.10 | NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research | Added language clarifying that NIH expects sites located in the US to rely on a US Single Institutional Review Board for Multi-Site Research (sIRB). |
| 4.1.27 | Research Misconduct | Updated the end date for filing the Annual Report on Possible Research Misconduct from March 1 to April 30. |
| 8.1 | Changes in Project and Budget | Updated to state recipients are required to notify NIH of developments that have a significant impact on the award-supported activities as soon as they become known. |
| 8.2.3.1 | Policy for Data Management and Sharing (DMS Policy) | Revised section to incorporate current NIH DMS policy. |
| 8.2.3.1.1 | Genomic Data Sharing (GDS) Policy | Moved GDS to subsection of DMS (new section 8.2.3.1.1) from prior section (8.2.3.5). |
| 8.2.4 | Inventions and Patents | Revised government support clause to require grant number, including the two-letter institute code and six-digit serial number, and specify NIH as the Federal agency. |
| 8.4.1.5.2 | Financial Expenditure Reports | Updated section to replace OFM with the FFR Reconciliation and Financial Closeout Support Center (FFR-C) within OPERA as the entity which now receives and reviews expenditure data. |
| 8.4.1.5.3 | Revised Financial Reports and Expenditures | In line with NOT-OD-23-102 (Guidance for the Repayment of Grant Funds), added language clarifying that recipients must submit a revised FFR when a refund of \$20,000 or greater is due back to NIH, and that refunds under \$20,000 should be sent directly to PMS with instruction to post the funds to Miscellaneous Receipts. |

Key Updates in the April 2024 NIHGPS (4/5)

| | | |
|------------|--|---|
| 8.6.1 | Final Federal Financial Report | In line with NOT-OD-23-102 (Guidance for the Repayment of Grant Funds), added language clarifying that recipients must submit a revised FFR when a refund of \$20,000 or greater is due back to NIH, and that refunds under \$20,000 should be sent directly to PMS with instruction to post the funds to Miscellaneous Receipts. |
| 11.2.2.3 | Degree Requirements | Revised predoctoral training to include basic biomedical or clinical sciences, in behavioral or social sciences, or in health services research. |
| 11.2.9.2 | Stipends | Added statement to clarify that while stipends are not provided as a condition of employment, NIH policy is not intended to discourage or otherwise prevent recipient institutions from hiring NRSA trainees and fellows as employees or providing them with benefits consistent with what the institution provides others at similar career stages per NOT-OD-23-111 (Reminder – NIH Policies for NRSA Stipends, Compensation and Other Income) |
| 11.2.12 | Changes in the Project | In line with NOT-OD-23-094 (NIH Redesign of the xTrain Module in eRA Commons), added language clarifying the responsibilities of the two sponsoring organizations when a fellowship is transferred. |
| 11.3.2.5.1 | Predocctoral Training | Added language that defines dual degree program and clarifies eligibility for the predoctoral training program. |
| 11.3.3.3 | Special Program Considerations | Removed "educationally" from "educationally disadvantaged backgrounds". |
| 11.3.3.3 | Special Program Considerations | Removed "retention" from NIH's requirements for diversity recruitment. |
| 11.3.13.1 | Statement of Appointment (Form PHS 2271) | Per NOT-OD-23-094 (NIH Redesign of the xTrain Module in eRA Commons), added requirement that trainees sign reappointments and amendments, just as they are required to sign the initial appointments. |
| 14.10.1 | Allowable Costs | Corrected language to state that when meals are justified by the applicant as an integral and necessary part of a conference (i.e., a working meal where business is transacted), grant funds may be used for such meals, provided that meal costs are not duplicated in participants' per diem or subsistence allowances. |
| 14.10.2 | Unallowable Costs | Removed meals as an unallowable cost. |
| 15.2 | Administrative and Other Requirements | Added language that NIH will not support any consortium agreement that does not meet minimum requirements and NIH reserves the right to request copies of the written agreement as stated in NOT-OD-23-182 (NIH Final Updated Policy Guidance for Subaward/Consortium Written Agreements). Added statement that NIH expects recipients to ask potential subrecipients, at the application stage, to submit language in their letters of support indicating their awareness of these requirements and the subrecipient's willingness to abide by all requirements should an award be issued. |
| 15.2.1 | Written Agreement | As outlined in NOT-OD-23-182 (NIH Final Updated Policy Guidance for Subaward/Consortium Written Agreements), added requirements that the formal written agreement between the recipient and each consortium participant/subrecipient is signed and agreed to by both parties, a subaward cannot be issued if a subrecipient is unwilling to sign the written agreement outlining the requirements in this section, and foreign subrecipients must |
| | | provide the primary recipient access to copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report no less than once per year, in alignment with the timing requirements for Research Performance Progress Report submission. |