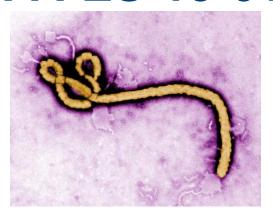
FOA Applicant Information Briefing WTP EBOLA Biosafety & Infectious Disease Response Training (UH4) RFA-ES-15-018



September 18, 2015
Keystone Conference Room 1003AB
National Institute of Environmental Health Sciences

National Institutes of Health • U.S. Department of Health and Human Services

Introduction & Welcome

Joseph T. Hughes Jr.

Director

Worker Training Program

Division of Extramural Research & Training

Briefing Meeting Guidelines

- (*) Agenda
- ② Questions & Answers

Link to RFA:

http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-15-018.html

Link to FAQ:

http://www.niehs.nih.gov/careers/hazmat/funding/current_funding_opp s/ebola_foa_faq_20150904_508.pdf

AGENDA

• 1:00 pm	Introduction and Welcome	Chip Hughes
• 1:05 pm	Ebola Biosafety and Infectious Disease Response Training FOA Program Components	
	WTP Overview	Chip Hughes
	Ebola Background & Partnerships	Chip Hughes
	- Gap Analysis	Chip Hughes
	Anticipated Awards	Chip Hughes
	Worker Training Core Values	Sharon Beard
	- Program Goals	Jim Remington
	 Areas of Training & Performance Objectives 	Jim Remington
	- Target Populations	Jim Remington
	- Ebola Resources	Nina Jaitly
	- Evaluation	Demia Wright
	 Responsive Applications, Tips & Quality Assurance 	Kathy Ahlmark
• 1:45 pm	Questions & Answers – Program Technical	NIEHS Staff
• 2:00 pm	FOA Review Process & Considerations	Janice Allen
• 2:20 pm	FOA Fiscal & Administrative issues	Pam Clark
• 2:40 pm	Questions & Answers	NIEHS Staff
• 2:55 pm	Closing Comments & Adjourn	Chip Hughes



Mission and Vision Statements



Mission: To discover how the environment affects people in order to promote healthier lives. Vision: To prevent disease and improve human health by using environmental sciences to understand human biology and human disease.

WTP Overview Ebola Background & Partnerships

Joseph T. Hughes Jr.

Director

Worker Training Program

Division of Extramural Research & Training



WTP Overview

Background: Working through cooperative agreement grants with 20 non-profit consortia representing over 100 training organizations including unions, universities, and community colleges, the NIEHS WTP focuses on workers who deal with hazardous materials, including biohazards, and emergency response.

WTP Community: This includes healthcare and hospital workers at all levels, emergency responders, hazardous material truck drivers and transportation workers, hazardous and solid waste disposal workers, heavy equipment operators, and site decontamination workers.



Experience: The NIEHS WTP program has over 25 years of experience providing worker health and safety training related to potential exposures to biological hazards and safety as they perform their job duties.

WTP Overview

Training: Many of the training courses provided by NIEHS WTP awardees are based off of OSHA's standards that commonly apply to emergency response and recovery workers, including:

- ☐ Bloodborne Pathogens standard (29 CFR 1910.1030)
- □ OSHA's Respiratory Protection standard (29 CFR 1910.134)
- OSHA's PPE standard (29 CFR 1910.132)
- □ Section 5(a)(1) of the Occupational Safety and Health (OSH) Act of 1970 (General Duty Clause)
- □ OSHA Best Practices for Hospital-Based First Receivers of Victims From Mass Casualty Incidents Involving the Release of Hazardous Substances.



Biological Safety Training: Involved in providing occupational biological safety training to workers during:

- ✓ H5N1 outbreak
- ✓ Anthrax attacks (2001)
- ✓ H1N1 Avian Influenza (2009)
- ✓ mold remediation from Hurricanes
 Katrina and Sandy (2005 & 2012)
- ✓ Ebola preparedness (2013)

Partnerships



 Office of the Assistant Secretary for Preparedness and Response (ASPR)



 Centers for Disease Control and Prevention (CDC)



 U.S. Department of Health and Human Services (DHHS)



 Occupational Safety and Health Administration (OSHA)



 National Institute of Occupational Safety and Health (NIOSH)

Background & Partnerships

August 2015: Funding Announcement

Released \$9M)

NIEHS
reprogrammed
existing extramural
funds for domestic
Ebola
preparedness to
7K workers across
18 states

November 2014: ASPR, CDC, NIH, IOM, NRC Ebola Response Workshop

August 2015: Needs Assessment Released

Ebola
Biosafety
Initiative

Early 2015:
NIEHS received
\$10M to develop
biosafety training
for US based
workers; WTP
charged to lead
efforts

Spring /Summer

2015:
Training &
Performance
Objectives and
Ebola Resources Summer 2015:

Literature
Review (Ebola
Training
Courses), Gap
Analysis from
stakeholder
surveys

Summer 2015: WTP consulted public and private sector worker representatives, thought leaders and stakeholders

May 2014: Supplement Awards (\$650K) & Grantee Workshop

- Literature search of PubMed and Web of Science for health and safety, training and disease
- Of 71 courses
 - 52 awareness
 - 9 operations
 - 6 comprehensive
 - 1 clinical care
 - **–** 3 TTT
- Most common form of delivery:

Awareness: Web

– Operations: Classroom

	Average Duration	Shortest	Longest
Awareness	3.28 hours	15 minutes	40 hours (Web series)
Operations	15.9 hours	4 hours	32 hours
Comprehensive	28 hours	24 hours	40 hours
Train-the-Trainer	8 hours	8 hours	16 hours
Clinical Care	5.5 hours	NA	NA

The most common form of delivery was web-based for awareness-level courses, and classroom and hands-on for operations-level courses. Most courses are no longer being offered.

	Most Common Mode of Delivery		
Awareness	Web-based (31)	Classroom (15)	Hands-on (8)
Operations	Hands-on (9)	Classroom (9)	Lab-based (1)
Comprehensive	Hands-on (all)	Classroom (all)	

- CDC Guidance:
 - PPE Equipment To be Used by Healthcare Workers During Management of Patients with Ebola in U.S. Hospitals
 - Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus
 - Interim Guidance for U.S. Residence Decontamination for Ebola and Removal of Contaminated Waste

OSHA Standards:

- General Duty Clause (Section 5(a)(1)
- Bloodborne Pathogens (1910.1030) standard
- Hazard Communication (29 CFR 1910.1200) standard
- PPE (29 CFR 1910.132) standard
- Respiratory Protection (1910.132) standard
- HAZWOPER (1910.120) standard for infectious material

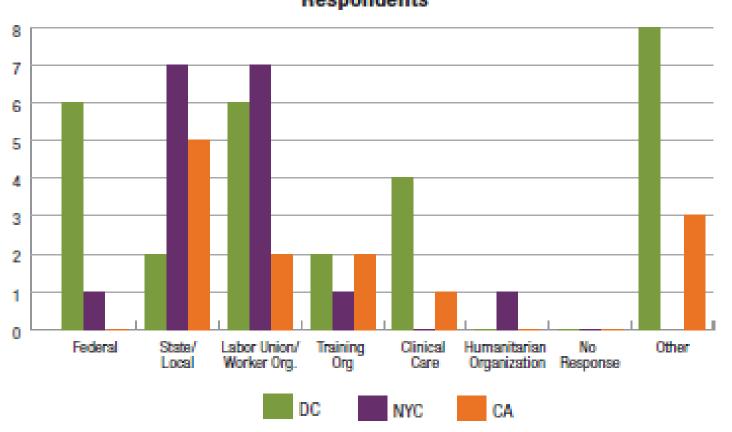
- Stakeholder Input Key Themes:
 - Despite recent infectious disease outbreaks of national significance, there is not a training atmosphere that endures past the incident.
 - Guidance issued by federal health and safety authorities continues to be disease-specific rather than on generalized hazard assessment, generalized infection control preparedness measures and worker safety and health
 - Guidance issued is confusing or not practical for many end users outside of the healthcare profession
 - More emphasis needs to be placed on general worksite preapredness
 - Hospitals focus on infection control and not worker health and safety

- Stakeholder Input Key Themes:
 - There needs to be more integration of important hospital departments to better address protection of workers and patients
 - Programs that had cooperative input from labor and management were felt to be most successful
 - Participants agreed that training should be competency-based but could not agree on which competencies to include in training
 - Waste management and training for waste handlers is very important
 - Engineering and administrative solutions are necessary to reduce risk of human contamination

Stakeholder Surveys:

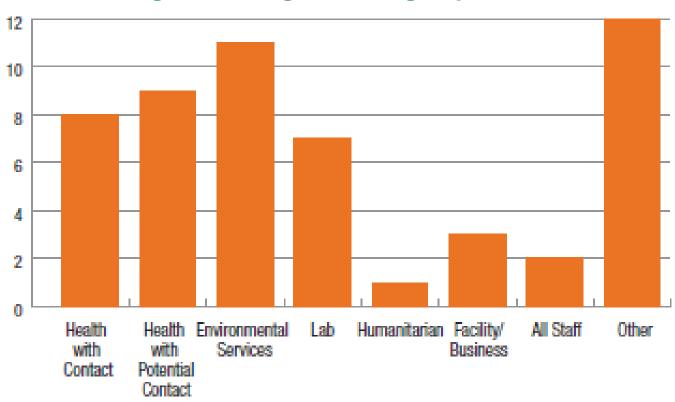
Figure 1: Organizations Represented by Questionnaire Respondents

Respondents



Stakeholder Surveys:

Figure 2: Target Training Populations

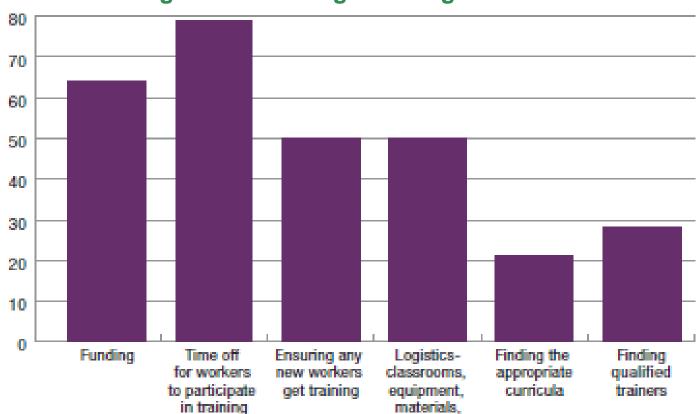


- Stakeholder Surveys:
 - The most trainings (12) reported were created for "other" workers, including:
 - Airport/aircraft cleaners
 - Airport workers
 - Compliance officers
 - Environmental remediation workers
 - Epidemiologists
 - Maintenance staff
 - Other staff potentially involved in response
 - Public health responders
 - Urban mass transit workers
 - Volunteers



Stakeholder Surveys:

Figure 3: Training Challenges Identified



- Overall Gap Analysis Themes:
 - There is no current mechanism to integrate public health, medical, occupational and worker safety activities in a comprehensive and all-encompassing approach that incorporates:
 - Perspective of key stakeholders
 - Delivers concise, easy to understand, risk-based protective guidance
 - Informs the full spectrum of workers

- Overall Gap Analysis Themes:
 - 2. Sustaining a high level of readiness is difficult due to a number of factors including:
 - Complacency
 - Inadequate funding
 - Loss of interest as the outbreak resolves
 - Pathogen-specific training
 - Emphasis on technical aspects of PPE, which are not employed in daily use or ongoing training, make it difficult to maintain high level of competency

Anticipated Awards

- NIH intends to commit:
 - -\$3 million in FY 2016 per year
 - Total of \$9 million over a period of 3 years
 - Estimated 5-8 awards

Worker Training Program Core Values

Sharon D. Beard

Industrial Hygienist/Program Administrator

Worker Education and Training Branch

Division of Extramural Research & Training

Training and Educating for Workforce Health & Safety

- Development and use of the <u>Minimum Criteria for Health and</u> <u>Safety Training</u>
- NIEHS Technical Workshops
- Gold Standard of Training
- Peer Worker Trainers
- Real Life Training Scenarios
- New Areas of Training Hazmat Disaster, Nanomaterials, Green Jobs, Ebola, etc.

- Cooperative Agreements and Consortium Approach to Training
- Formalized training curriculum and tools (Hurricane, Earthquake, Oil Spills)
- National Clearinghouse for Worker Safety & Health Training
- Interagency Working Groups and Local Partnership



Why Cooperative Agreements?

- national coordination, and to avoid duplication of efforts and overlap in program development and delivery;
- facilitate the ongoing exchange of relevant scientific and technical information;
- ensure regulatory compliance with applicable federal worker health and safety requirements and national consistency in the delivery of training curricula; and
- the need to have a timely and appropriate response to events of national significance.





Photo: US Army

Core Goals of Training

- Domestic non-profit organizations and higher learning institutions
- Demonstrated expertise and experience in worker training & education
- Demonstrated ability to reach and involve target worker populations that is national or regional in scope
- Establishment of innovative program evaluation protocols to demonstrate training effectiveness and impact
- Target HAZWOPER populations covered by 29 CFR 1910.120 of OSHA

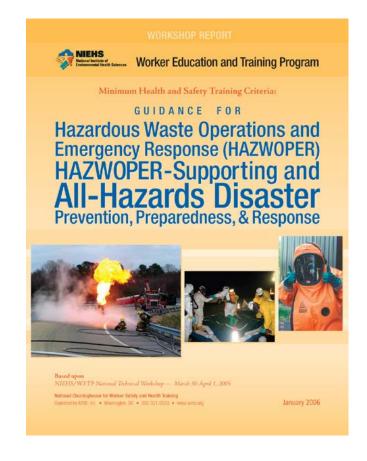
- Diffusion of NIEHS WTP awardee model programs and best practices with innovative program evaluation protocols
- Creation of national safety and health training benchmarks and guidance
- Integration of safety and health training with work practices, skills development & workplace OSH programs
- Development of worker-centered education & training delivery to support lifelong learning, workplace protections, ease of accessibility & new opportunities for hazardous waste workers & emergency responders

NIEHS Minimum Health and Safety Training Criteria

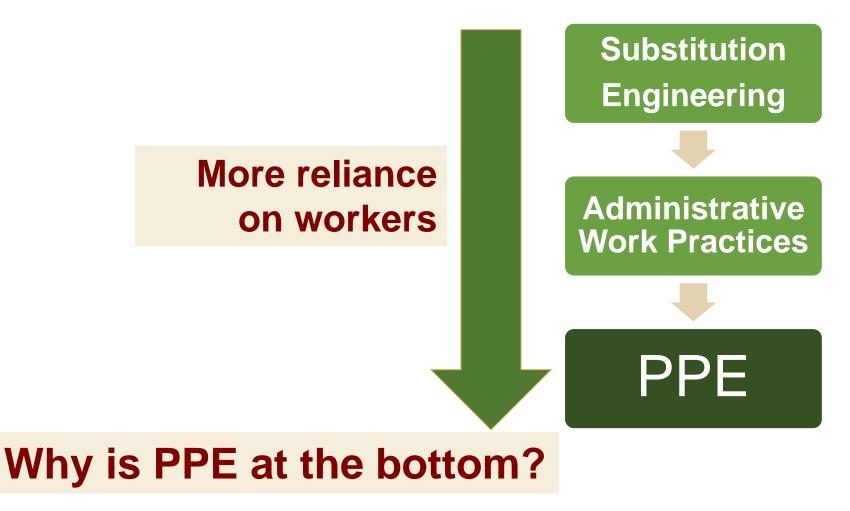
Guidance for Hazardous Waste
Operations and Emergency Response,
HAZWOPER- Supporting, and AllHazards Disaster Prevention,
Preparedness and Response
Released January 2006

Major changes Include:

- Advanced training technologies application and integration;
- Requirements for additional training programs to support HAZWOPER work; and
- Post-9/11 all-hazards preparedness training.



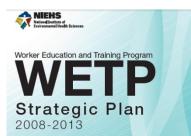
The Hierarchy of Control Measures



National Institutes of Health U.S. Department of Health and Human Services

NIEHS WTP Strategic Plan Priorities

 Continually seek and encourage opportunities to collaborate with organizations (at all levels) that share the common goal of protecting and their communities.



- Advocate for the health and safety of emergency responders and skilled support personnel through actively participating in all phases of the national response to disasters.
- Oversee and manage the expansion of a national network of trainers with diverse specific skills grounded on a common training doctrine. These trainers will become a national resource for providing health and safety education and will prepare responders to perform their duties in a hazardous environment.
- Leverage and actively integrate technology and innovation to improve the delivery of education and training to workers performing duties in a hazardous environment.
- Plan can be found at: https://tools.niehs.nih.gov/wetp/public/hasl_get_blob.cfm?id=6430



National Clearinghouse for Worker Safety and Health Training

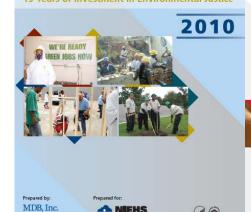
MANY RESOURCES!

- NIEHS Minimum Criteria (Appendix E of 1910.120)
- Contact information for non-profit training providers
- Curricula Catalog for hundreds of courses
- Weekly E-Newsbrief
- Calendar of Important Conferences and Events
- Special Reports and Additional Resources
- Links to OSHA and those other agencies
- **30•** Ebola Training Resources





15 Years of Investment in Environmental Justice





AUGUST 2015

Ebola Biosafety and Infectious Disease Response Training
Needs Assessment and Gap Analysis for the NIEHS Worker Training Program





Important things to remember...

Please read the FOA's and talk to NIEHS staff

Use the WTP web site:

http://www.niehs.nih.gov/careers/hazmat/index.cfm

Use the web version of the FOA and the ASSIST

Instructions. Go with FOA first if they differ!!!!

Send questions to NIEHS Staff contacts or

wetp@niehs.nih.gov

Frequently asked questions (FAQ's) will be posted on the Worker Training web-site



Program Goals

Jim Remington

Program Analyst

Worker Training Program

Division of Extramural Research & Training

Overall Goals

Goals: The major objective of this cooperative agreement is to prevent work-related harm by assisting in the training of workers in how best to protect themselves and their communities from exposure to hazardous materials, waste and chemical emergency response.



Need: Nationally coordinated training program and partnerships to promote occupational biosafety training outside of the laboratory setting.

- The Ebola Biosafety and Infectious Disease Response Training FOA: Identify and have access to target worker populations with the potential for biohazard exposure
- Capacity to provide relevant training in a manner that is understood
- Evaluate effectiveness and continued quality improvement

Program Concepts

All hazards approach

Whole of community

Build off and reinforce day-to-day infection control training and Standards

Build educational capacity for biosafety training to impart skill sets that contribute to:

- occupational risk assessment (risk stratification)
- critically judge potential impact of outcomes
- understand exposure control
- biological and environmental controls to prevent injury and disease

Train the Trainer model (local resources for local workers)

- Training information
- Training skills

Training Levels Goal

- Awareness-level
 - Awareness-level training is intended to promote workers' understanding and knowledge of relevant potential exposures, precautions, safety standards and guidance.
- Operations-level
 - Operations-level training is intended to promote workers' understanding and demonstrate the capacity for effectively executing standards of proficiency, by practice, for applicable activities related to potential occupational exposure to Ebola or other emerging infectious diseases and hazardous scenarios.

Training Delivery Models

- Train-the-Trainer
- Develop a cadre of instructors nationwide with:
 - critical training skills to identify and determine training needs,
 - design participant-oriented learning materials and exercises ,
 - apply adult learning concepts,
 - assist learners in evaluating their own learning and incorporate an evaluation process
 - understand factors related to educational motivation, passion, conditioning and
 - facilitate a training program with stimulating exercise activities as applicable to biosafety training and infection control in the occupational setting for targeted populations.

Training Models

Direct Training

 Organization's Instructors provide training to designated healthcare and non-healthcare audiences utilizing site specific information with regards to protocols, supplies, and job tasks

Training Resources

- The NIEHS WTP has developed a series of PowerPoint slides for awareness- operations-level training that could serve as a starting point for developing customized trainings that meet the needs of various worker groups.
- These Ebola Awareness and Operations Level training slides can be found on the NIEHS WTP Ebola site: http://tools.niehs.nih.gov/wetp/index.cfm?id=2542

Training Content

Performance Objectives

- Awareness and site specific operational training
- Potentially Infectious Material
- Chemical Material
- Physical Environment (Safety Risk Management)
- Exposure Risk Assessment
- Means of Transmission
- Engineering Controls
- Administrative and Work Practice Controls
- Personal Protective Equipment
- Respiratory Protection
- Decontamination and Waste Management
- Hazard Communication
- Compliance with Guidelines, Standards, and Regulations
- Occupational Health- Post Exposure Protocols, Medical Surveillance, Vaccination, Respirator Clearance
- Emergency and Incident Response (Emergency Response and Exercise Drills)

- Site specific operational training
- Potentially Infectious Material
- Chemical Material
- Physical Environment (Safety Risk Management)
- Exposure Risk Assessment
- Means of Transmission
- Engineering Controls
- Administrative and Work Practice Controls
- Personal Protective Equipment
- Respiratory Protection
- Decontamination and Waste Management
- Hazard Communication
- Compliance with Guidelines, Standards, and Regulations
- Occupational Health- Post Exposure Protocols, Medical Surveillance, Vaccination, Respirator Clearance
- Emergency and Incident Response (Emergency Response and Exercise Drills)

Performance Objectives

- These knowledge topics and performance objectives can be found on the Safety and Health Resources Page:
 - Link: http://tools.niehs.nih.gov/wetp/index.cfm?id=2542

Awareness Level:

https://tools.niehs.nih.gov/wetp/public/hasl_get_blob.cfm?ID= 10562

Operations Level:

https://tools.niehs.nih.gov/wetp/public/hasl_get_blob.cfm?ID= 10563

Target Population

High Risk Populations

Air transport

- Cabin/airline crew members
- Border protection/compliance officers
- Transportation security screeners
- Other air transport workers

Medical Treatment

- Physicians
- Allied health care professionals
- Nurses
- Midwives
- Emergency medical technicians/Paramedics
- Humanitarian aid workers
- Emergency/first responders
- Morticians/Coroners/Medical examiners
- Forensic Scientists
- Veterinarians
- Clinical/resaerch laboratory workers

Environmental Services

- Janitors
- Housekeepers
- Sanitizing personnel
- Maintenance workers
- Dietary aide workers

Waste Handling

- Solid and household waste handlers
- DoT permitted waste disposal/collection
- Disinfection and decontamination teams

Ebola & Infection Control Resources

Nina Jaitly

WTP Contractor
Public Health Physician

Worker Training Program

Division of Extramural Research & Training

Safety and Health Resources for Ebola

- http://tools.niehs.nih.gov/wetp/index.cfm?id=2542
 - Worker Training Program Resources
 - Ebola Awareness Orientation: Health & Safety Essentials
 - Ebola Operations Level Training
 - Worker Training Program Awardee Resources
 - Other Guidance and Training
 - Federal & State resources
 - Other organization
 - PPF
 - Cleanup of Contaminated Objects
 - Transport of Contaminated Objects
 - Workplace and Job Specific Guidance
 - Other Infectious Diseases

WTP Resources

- NIEHS Worker Training Homepage
 - http://www.niehs.nih.gov/careers/hazmat/index.cfm
- NIEHS WTP National Clearinghouse Page
 - http://tools.niehs.nih.gov/WTP/
- NIEHS WTP Current Funding Opportunities Page
 - http://www.niehs.nih.gov/careers/hazmat/funding/current_funding_ opps/index.cfm
 - Ebola Resources –
 http://tools.niehs.nih.gov/wetp/index.cfm?id=2542

Quality Control and Evaluation Plan

Demia Wright

Public Health Educator

Worker Training Program

Division of Extramural Research & Training

Basis for Evaluation in the Worker Training Program



NIEHS WTP Minimum Criteria



Overall program logic model



Evaluation Best Practices for Health and Safety Training Report



Kirkpatrick Model for Training Evaluation

Goal of Evaluation in this Program

Program effectiveness

 Health and safety of workers in biohazard and infectious disease occupational settings

Accountability

• Responsiveness & reporting out

Key Evaluation Concepts

Trainings completed and hours provided

Relevance/satisfaction feedback on the training from workers

Learning/knowledge and skill acquisition from training

Worker use of training leading to capacity, protection, and empowerment

Safety culture and safety climate in the worker environment

Integration and coordination around worker training in occupational settings with the potential for exposure to Ebola and other biosafety hazards

Tools and Resources Available

General Evaluation Resources

- NIEHS Minimum Criteria http://tools.niehs.nih.gov/wetp/index.cfm?id=142
- NIEHS Resource Guide for Evaluating Worker Training http://tools.niehs.nih.gov/wetp/index.cfm?id=92
- NIEHS PEPH Metrics Manual (Ch. 5)
 http://www.niehs.nih.gov/research/supported/dert/programs/peph/metrics/index.cfm
- WTP Evaluation Summary Report http://tools.niehs.nih.gov/wetp/events.cfm?id=2521
- Kirkpatrick Model for Training Evaluation http://www.kirkpatrickpartners.com/OurPhilosophy/TheKirkpatrickModel/tabid/302/Default.aspx

Ebola Biosafety and Infectious Disease Recommended Performance Objectives

- Awareness
- Operations

Logic Models

- WTP logic model http://tools.niehs.nih.gov/wetp/1/12FallMeeting/wetp_logic_model.pdf
- WK Kellogg Logic Model Development Guide https://wkkf.issuelab.org/resource/logic-model-development-guide.html

Future Resources with Program Initiation

Program logic model

Evaluation guidance document

Sample data collection instrument

Guidelines and Instructions

Kathy Ahlmark

Program Analyst

Worker Training Program

Division of Extramural Research & Training



Tips for a Successful Application

- Make it easy for the reviewers, follow the instructions in the FOA
- Application should be well organized, clearly written, and complete in all details
- Closely follow the Guidelines
- Follow all SF-424 instructions for font and spacing limitations

General Information

Important Web URLs

The FOA for NIEHS WTP Ebola Biosafety and Infectious Disease Response Training is available at: http://www.niehs.nih.gov/careers/hazmat/funding/current_funding_opps/index.cfm

The needs assessment and gap analysis is available at: https://tools.niehs.nih.gov/wetp/public/hasl_get_blob.cfm?l
D=10521

General Information

 Use the NIEHS Worker Training Program Safety and Health Resources for Ebola/Infectious Disease Response Workers: http://tools.niehs.nih.gov/wetp/index.cfm?id=2542

 Review the NIEHS Worker Training Program Minimum Criteria Document under 'Key Documents": https://tools.niehs.nih.gov/wetp/

Keep Track of Deadlines

September 21, 2015: Letters of intent are due

 October 21, 2015: Applications are due by 5:00 pm local time of the applicant organization.

It is recommended that you upload your application at least two weeks in advance to ensure your application has no errors and is completely uploaded before October 21, 2015 at 5 pm

Make the Reviewers Job Easy!

- Be Clear
- Be Complete but Concise
- Be Organized
- Be on time Application due
 October 21,2015, by 5:00 PM
 local time of applicant organization

Questions & Answers of Program/Technical Issues

Grant Application Process and Peer Review

Janice B. Allen, Ph.D.

Alfonso R. Latoni, Ph.D., Chief

Scientific Review Branch

Division of Extramural Research and Training

National Institute of Environmental Health Sciences

Allen9@niehs.nih.gov (919) 541-7556)

alfonso.latoni@nih.gov (919-541-7571)

Letters of Intent

- Letter of Intent (LOI) due September 21, 2015
- Email to Allen9@niehs.nih.gov
- Include Principal Investigator (PI) full name, institutional address, telephone number, email address; key personnel; and participating organizations
- Brief description (abstract) of the project (optional)

Application Process

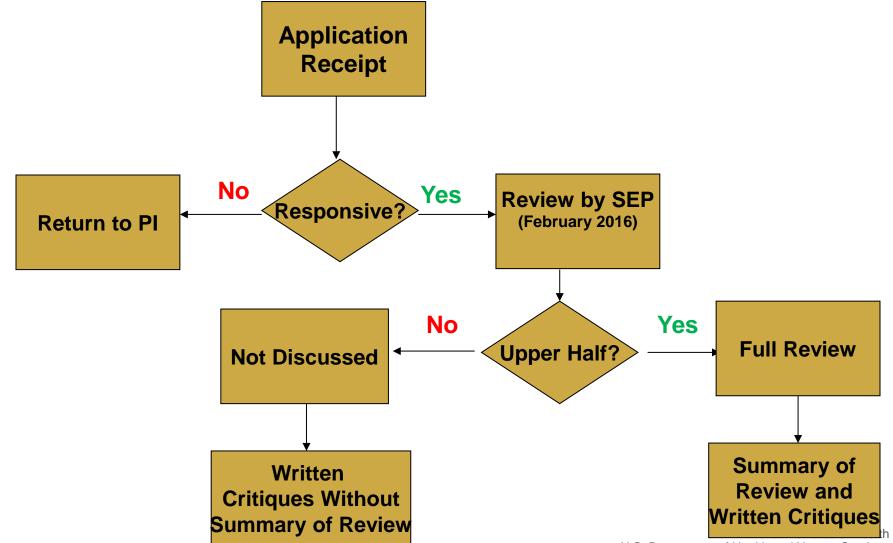
- Applicant organizations should register in NIH Commons and Grants.gov
- Pls should register in https://commons.era.nih.gov/commons/
- Receipt Date, 5:00 pm local time, October 21, 2015 (firm!)
- Electronic submission through ASSIST is the only acceptable submission process
- The ASSIST system has been well tested; however, immediately contact the Helpdesk should any problems arise
- The ASSIST is built with flexibility for different FOA requirements, so not all errors will be prevented
- Start early!

CRITICAL MESSAGE...

Periodically check your eRA Commons Account: If you do not see the grant application image in eRA Commons, the NIH does not see it either. You must follow up on the process and use eRA Commons to check. We need to know you have submitted an application in order to assign and review.

Start early and submit early!

Peer Review Process – First Level



Special Emphasis Panels (SEPs)

- Composed of peers with proven expertise that is closely relevant to the grant applications and the FOA
- Review meetings are closed/confidential and reviewers are required to disclose potential conflicts of interest
- Grant applications that go to full review will be given an Overall Impact Priority Score between 1 (best possible score) and 9 (worst possible score
- The Summary Statement will be available in you eRA Commons; discussed grant applications will include a Resume and Summary of Discussion

Peer Review Scoring

- The NIH scoring system focuses on the impact of the proposed project on the field, and what it will accomplish if successful
- Scores 1 through 9, reported as average X10, between 10 and 90
 - HIGH Impact: 1 3
 - MODERATE Impact: 4 6
 - LOW Impact: 7 9
- Described in detail at http://grants.nih.gov/grants/peer_review_process.htm

Review Criteria

- Reviewers will evaluate the scientific and technical merit of the grant applications based on the specific review criteria described in the FOA
- Reviewers will specifically assess Significance, Investigators, Innovation, Approach, and Environment.
- Individual (the above five) criterion scores are reported in the Summary Statement. Also, between 1 and 9.
- Budgets will be reviewed for their appropriateness to the scope of the work and the level of effort for key personnel, but not scored.

Additional Points to Consider

- Protection of human subjects in research, and inclusions, are reviewed and could affect the Overall Impact Priority Score if not adequately addressed in the grant application
- Human subject research generally does not occur in training, but if it is proposed, protections must be addressed

Grant Applications That Review Poorly:

- Lack clarity. Reviewers are unable to determine what you are planning to do.
- Lack sufficient detail. Specificity generates confidence.
- Are poorly prepared. Typos, misspelled words, small font size, and poor grammar irritate reviewers.
- Are poorly thought out. Reviewers can tell a first draft when they see one.

Grant Applications That Review Well:

- Specifically address all the essential components of the FOA. Tell the reviewers what they need to know.
- Are clearly written, well organized, and prepared according to instructions. Again, don't make the reviewers work too hard. Ask colleagues to read prior to submission
- Demonstrate rather than assure. A "trust me" attitude is a "kiss of death."

Peer Review Process - Second Level

- A Funding Plan is prepared by Program Officers/Administrators
- Submitted to the NIEHS National Advisory Council for recommendations
- Council meets May 2016
- Funding decisions communicated to PIs

Contact for Review-Related questions:

Janice B. Allen, Ph.D.

Scientific Review Officer

Scientific Review Branch

National Institute of Environmental Health Sciences

(919) 541-7556

Allen9@niehs.nih.gov

FOA Applicant Information Briefing for

Worker Training Program (WTP) Ebola Biosafety and Infectious Disease Response Training (UH4)

RFA-ES-15-018

Budget Information

- NIEHS GRANTS MANAGEMENT
 - George Tucker
 - Pamela Clark

Electronic Budget

 Webinar for Applicants: Initial Look at the Electronic Submission Process

http://grants.nih.gov/grants/webinar docs/webinar 20121213.htm

- SF424 (R&R) Detailed Budget forms differ from Paper PHS 398
 Budget Forms in both have the same substance in look/feel.
 Some items in different places
 - Some items not collected as specific line items
- Budget data <u>collected</u> at component and subaward levels only
 - Component and subaward budget data used to autocalculate "Cumulative" (Composite) budget

Budget Preparation

- Form Pages, Approvals, Other Support, Notices
- Forms (http://grants.nih.gov/grants/forms.htm)
 - SF424 R&R (Research & Related) electronic submission
- Approvals
 - IRB Approval (Human Subjects)
 - Begin process at time of application, but final approval will be requested for Just In Time*
- Other Support
 - "0%", "Varies", "As Needed", etc., are not acceptable
 - Total time commitment cannot exceed 12 calendar months

^{*}Just in Time: Request for information required prior to award.

Budget Preparation

- Provide detailed categorical budgets
- Each Project
- Each Subaward/Consortium (<u>Note: SF424 will</u> not allow Subawards on Subawards)

Escalation

Budgets submitted in subsequent years may request an escalation on recurring direct costs. (Note: Currently NIH does not provide an escalation in subsequent years)

Must be justified:

- Is the amount of escalation requested supported by institutional policies?
- Is the amount clearly stated?

Travel to Annual Meetings

Budget: Funds for travel by appropriate staff (i.e., PI, Business Official, Project Leaders /Administrators, etc.) to attend the WTP annual meeting shall be included in the Parent budgets and subsequent subawardee budgets for each year.

Budget Preparation

- Parent Grant Direct Costs
 - Consideration of *equipment* in the out-years will be based upon justification and availability of funds
- Subawards/Consortium
 - must follow same guidelines as parent; <u>budget pages required and should</u> <u>follow associated project</u>
 - Subawards/consortium direct costs are included in the parent grant
 Subtotal Direct Costs, which may be subject to budget caps
 - F&A of subawards/consortium is included in Total direct Costs of parent grant, but will not count against budget cap
- Budget Justifications (Be detailed and specific)
 - Are all costs itemized?
 - Are all additions and changes in subsequent/future years fully justified and identified clearly; specifically changes in personnel effort?

R&R Budget Sections A & B

Personnel separated into 2 sections:

- A. Senior/Key Person
 - First field must be completed, even if person on a component given role of "Project Leader" and not PD/PI

B. Other Personnel

 Postdocs, Grad Students, Undergrads: Only number of personnel required (not specific names)

*Include only personnel employed by (e.g., receiving salary from) your organization.

R&R Budget Section C, D & E

C. Equipment Description	Equipment is defined as an item of property has an acquisition cost of \$5,000 or more are expected service life of more than one year.	nd				
List items and dollar amount for ea	ch item exceeding \$5,000	Funds Requested (\$)				
Additional Equipment:	Add Attachment Delete Attac	hment View Attachment				
	Total funds requested for all equipment listed in the attached file					
	Total Equipment					
D. Travel		Funds Requested (\$)				
1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions) Identify the total funds requested.						
2. Foreign Travel Costs	Not Allowed					
	Total Travel Cost					
E. Participant/Trainee Support (Funds Requested (\$)					
1. Tuition/Fees/Health Insurance	Unless specifically stated in an announcement, NIH					
2. Stipends	and other PHS agencies, Applicants should leave Section E. blank. (Tuition remission for graduate students					
3. Travel	should continue to be included in Section F. Other Direct					
4. Subsistence	Costs when applicable).					
5. Other						
Number of Participants/Traine	es Total Participant/Trainee Support Costs					

Close Form RESEARCH & RELATED BUDGET - SECTION F-K, BUDGET PERIOD 1 Next Period * ORGANIZATIONAL DUNS: * Budget Type: Project Subaward/Consortium Enter name of Organization: End Date: Start Date: Budget Period 1 F. Other Direct Costs Funds Requested (\$) 1. Materials and Supplies 2. Publication Costs 3. Consultant Services 4. ADP/Computer Services 5. Subawards/Consortium/Contractual Costs 6. Equipment or Facility Rental/User Fees 7. Alterations and Renovations 9. 10. **Total Other Direct Costs** G. Direct Costs Funds Requested (\$) Total Direct Costs (A thru F) H. Indirect Costs Indirect Cost Indirect Cost Rate (%) Indirect Cost Type Base (\$) * Funds Requested (\$) **Total Indirect Costs** Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number) I. Total Direct and Indirect Costs Funds Requested (\$) Total Direct and Indirect Institutional Costs (G + H) J. Fee Funds Requested (\$)

Add Attachment

R&R Budget Sections F - K

Subaward/Consortium/Contractual Cost not prepopulated. Include both Total Direct and Indirect cost

K. * Budget Justification

(Only attach one file.)

R&R Budget Sections F-K

Tuition remission

Include in Item F, Other Direct Costs (boxes 8, 9 or 10)

Supplies

- Not a major line item on 424 budgets
- Included as line F.1 (Other Direct Costs: Materials and Supplies)

Alteration and Renovations

- Not a major line item on 424 budgets
- Included as line F.7 (Other Direct Costs: Alterations and Renovations)

Cumulative budget is automatically calculated based on budget period data provided.

RESEARCH & RELATED BUDGET - Cumulative Budget

VIC	ed.	Totals (\$)		(\$)
Se	ction A, Senior/Key Person	ſ		
Se	ction B, Other Personnel			
То	tal Number Other Personnel			
То	tal Salary, Wages and Fring	je Benefits (A+B)		
Se	ction C, Equipment			
Se	ction D, Travel			
1.	Domestic			
2.	Foreign			
Se	ction E, Participant/Trainee	Support Costs		
1.	Tuition/Fees/Health Insurance	œ		
2.	Stipends			
3.	Travel			
4.	Subsistence			
5.	Other			
6.	Number of Participants/Train	1ees		
Se	ction F, Other Direct Costs			
1.	Materials and Supplies			
2.	Publication Costs			
3.	Consultant Services			
4.	ADP/Computer Services			
5.	Subawards/Consortium/Con	tractual Costs		
6.	Equipment or Facility Rental	Wser Fees		
7.	Alterations and Renovations	i e		
8.	Other 1			
9.	Other 2			
10.	Other 3			
Se	ction G, Direct Costs (A thr	u F)		
Section H, Indirect Costs				
Section I, Total Direct and Indirect Costs (G + H)				
Se	ction J, Fee			



R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

ASSIST provides the ability to add up to 30 subaward budgets per component using the SF 424 RR budget form. ASSIST will automatically include the subawards with the application so there is no need to attach them as separate files.

- If submitting an application with >30 subaward budgets, budgets 31 and above should be converted to PDF and included as part of the Budget Justification of the parent budget in Section K of the R&R Budget form.
- The sum of all subaward budgets (e.g., those attached separately on this form and those provided as part of the budget justification), must be included in Line F.5 Subawards/Consortiums/Contractual Costs of the parent budget.
- When submitting award budgets that are not active for all periods of the project, fill out the subaward R&R Budget form and include on the number of period for which the subaward is active. The budget period start/end dates reflected in each period of the subaward should match the project budget period start/end dates that correspond to the active periods.
- Example: Parent Project budget/performance period is 01/01/2016-12/31/2018
 - Consortium #1 is only performing in Year 3 therefore, their budget period would be 01/01/2018-12/31/2018.
 - Consortium #2 is performing in all three years, therefore, they should have budget pages for all budget periods. 01/01/2016 12/31/2018.

OMB Number: 4040-0001 Expiration Date: 6/30/2016

R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

Instructions: On this form, you will attach the R&R Subaward Budget files for your grant application. Complete the subawardee budget(s) in accordance with the R&R budget instructions. Please remember that any files you attach must be a PDF document.

Click here to extract the R&R Subaward Budget Attachment

Important: Please attach your subawardee budget file(s) with the file name of the subawardee organization. Each file name must be unique.

1) Please attach Attachment 1	Add Attachment	Delete Attachment	View Attachment
2) Please attach Attachment 2	Add Attachment	Delete Attachment	View Attachment
3) Please attach Attachment 3	Add Attachment	Delete Attachment	View Attachment
4) Please attach Attachment 4	Add Attachment	Delete Attachment	View Attachment
5) Please attach Attachment 5	Add Attachment	Delete Attachment	View Attachment
6) Please attach Attachment 6	Add Attachment	Delete Attachment	View Attachment
7) Please attach Attachment 7	Add Attachment	Delete Attachment	View Attachment
8) Please attach Attachment 8	Add Attachment	Delete Attachment	View Attachment
9) Please attach Attachment 9	Add Attachment	Delete Attachment	View Attachment
10) Please attach Attachment 10	Add Attachment	Delete Attachment	View Attachment
11) Please attach Attachment 11	Add Attachment	Delete Attachment	View Attachment
12) Please attach Attachment 12	Add Attachment	Delete Attachment	View Attachment
13) Please attach Attachment 13	Add Attachment	Delete Attachment	View Attachment
14) Please attach Attachment 14	Add Attachment	Delete Attachment	View Attachment
15) Please attach Attachment 15	Add Attachment	Delete Attachment	View Attachment
16) Please attach Attachment 16	Add Attachment	Delete Attachment	View Attachment
17) Please attach Attachment 17	Add Attachment	Delete Attachment	View Attachment
18) Please attach Attachment 18	Add Attachment	Delete Attachment	View Attachment
19) Please attach Attachment 19	Add Attachment	Delete Attachment	View Attachment
20) Please attach Attachment 20	Add Attachment	Delete Attachment	View Attachment
21) Please attach Attachment 21	Add Attachment	Delete Attachment	View Attachment
22) Please attach Attachment 22	Add Attachment	Delete Attachment	View Attachment
23) Please attach Attachment 23	Add Attachment	Delete Attachment	View Attachment
24) Please attach Attachment 24	Add Attachment	Delete Attachment	View Attachment
25) Please attach Attachment 25	Add Attachment	Delete Attachment	View Attachment
26) Please attach Attachment 26	Add Attachment	Delete Attachment	View Attachment
27) Please attach Attachment 27	Add Attachment	Delete Attachment	View Attachment
28) Please attach Attachment 28	Add Attachment	Delete Attachment	View Attachment
29) Please attach Attachment 29	Add Attachment	Delete Attachment	View Attachment
30) Please attach Attachment 30	Add Attachment	Delete Attachment	View Attachment

Resources

- SF424 (R&R) Application and Electronic Submission Information" webpage:
 - http://grants.nih.gov/grants/funding/424/index.htm
- Applying Electronically:
 - http://grants.nih.gov/grants/ElectronicReceipt/com_index.htm
- Need help with ASSIST?
 - http://grants.nih.gov/grants/ElectronicReceipt/faq_full.htm#about

eRA Commons - https://commons.era.nih.gov/commons/index.jsp

Registered PD/PIs can check assignment/contact information, review outcome, and other important information.

eRA Commons Help Desk:

Hours: Mon-Fri, 7AM-8PM EDT/EST Web: https://www.era.nih.gov/need-help Toll-free: 866-504-9552. Phone: 301-402-7469. TTY: 301-451-5939.

Questions & Answers of Review/Fiscal Issues



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