

Ebola FOA FAQ's

All of the FAQ's listed below apply to the NIEHS WTP Ebola Biosafety and Infectious Disease Response Training (RFA-ES-15-018) Funding Opportunity Announcement (FOA). These FAQ's are divided into four areas: Program/Technical; Budget; General; Review.

Updated: October 1, 2015

Program/Technical

Question 1: Activity Code: UH4 Hazmat Training at DOE Nuclear Weapons Complex. Is this correct for the Ebola FOA?

Answer 1: The UH4 mechanism is being used for the Ebola FOA as this is a single program component activity code for WTP. This Ebola FOA has nothing to do with current DOE UH4 cooperative agreement. As you can see from the FOA, It states... * Note: This activity code is being used to support Ebola Biosafety and Infectious Disease Response Training.

Question 2: What are some important dates and links for this funding announcement (RFA-ES-15-018)?

Answer 2: Please refer to the table below for:

Important Web URLs	Important Dates
<ul style="list-style-type: none">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.cfmThe needs assessment and gap analysis is available at: https://tools.niehs.nih.gov/wetp/public/hasl_get_blob.cfm?ID=10521	<ul style="list-style-type: none">September 18, 2015: The informational meeting and briefing session was held from 1:00pm – 3:00pm EST and webcasted. You may view the webinar agenda, slides and video online at: https://www.niehs.nih.gov/careers/hazmat/funding/current_funding_opps/index.cfmSeptember 21, 2015: Letters of intent were dueOctober 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.

Question 3: Given the short turnaround time after the briefing meeting till the submission date, what is the best way to ask questions regarding the Ebola Biosafety and Infectious Disease Response Training funding opportunity announcement (FOA)?

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Answer 3: We encourage applicants to contact us to arrange a telephone conversation or send your questions via email to wetp@niehs.nih.gov as they arise so that we may be able to address your concerns as promptly as possible.

Target Population

Question 4: Does the stakeholder community targeted in this FOA include lay community members or specifically first responders and like groups? What is the best way to identify target audience?

Answer 4: This FOA intends to advance safety and health training for workers using a whole-community approach and identify any occupational group that may be at high risk of coming in contact with persons potentially infected with Ebola virus and other emerging infectious diseases, through potentially contaminated materials (biological, chemical or radiological) or infected individuals. Applicants will need to identify target worker populations; environments or tasks that potentially increase exposure to infectious pathogens or contaminated materials (biological, chemical or radiological). The OSHA Ebola personal protective equipment (PPE) matrix (<https://www.osha.gov/Publications/OSHA3761.pdf>) has identified and stratified target populations according to occupational exposures in both health care and non-healthcare scenarios. The NIEHS WTP Ebola Biosafety and Infectious Disease Response Training Initiative is focused on reaching at-risk populations which may or may not have been identified through this matrix. Applicants are highly encouraged to include collaborators from infectious control, occupational medicine, industrial hygiene and other worker safety fields who may facilitate the identification of target populations applicable to your institution or geographical region.

Question 5: What workers can be trained?

Answer 5: In general there is a broad potential audience. Workers that can be trained include anyone who, directly or indirectly, may be at risk for of coming in contact with persons potentially infected with Ebola Virus Disease or other infectious diseases through potentially contaminated materials or potentially infected individuals. Workers at risk may include:

- Air transport (such as cabin crew, airline crew, border protection officers, transportation security screeners, and other air transport workers).
- Medical treatment (such as physicians, allied health care professionals, nurses, midwives, emergency medical technicians, paramedics, humanitarian aid workers, emergency medical service workers, healthcare attendants, clinical and research laboratory workers, other allied health care professionals, morticians, coroners, medical examiners, and forensic scientists).
- Environmental services in hospital and non-hospital settings (such as janitors, housekeepers, sanitizing personnel, maintenance workers, dietary aide workers).

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- Waste handling (such as solid and household waste handlers, Department of Transportation (DOT) permitted waste disposal and collection workers).
- Cleanup (decontamination and disinfection workers).

Note: You must have access to the proposed at-risk workers and not rely on open enrollment in order for them to attend, so relationships are key. The OSHA PPE matrix (<https://www.osha.gov/Publications/OSHA3761.pdf>) provides a good road map to target populations as referenced above.

Question 6: Within the scope of the target population, can first responder students, for example Emergency Medical Technician (EMT) students, who are in the healthcare delivery process but not actually out in the field, be trained under the Ebola Biosafety and Infectious Disease Response Training funding opportunity announcement (FOA)?

Answer 6: Students are definitely important aspects of the future workforce and can certainly be included for any awareness level instruction under the WTP Ebola Biosafety and Infectious Disease Response training FOA. However, taking into consideration decay of knowledge and lack of sustainability, operations-level training may be more challenging for students. As such, we do not encourage operation-level training for students at this time, unless they are working directly in the field and justified to be potentially at-risk populations or settings.

Question 7: Within the scope of the target population, is there any restriction against military types, military groups to receive training under this funding opportunity announcement (FOA)?

Answer 7: Target populations could include military groups. As long as the applicant can demonstrate access to these military groups and justify potential risk then they may be included. It should be dually noted that foreign components in any capacity is not allowed and applicants should be aware that international training for domestic workers would not be allowable. Other federal agencies will focus on deployment-related training.

Question 8: If we are targeting out-of-state trainees that will be taking the training at our in-state location with all of our trainers and partners, is our application responsive?

Answer 8: Our NIEHS WTP Awardees are usually multiple state programs as we are also requiring them to be in the Ebola FOA; however, if you are targeting trainees from other states and you can show that your training program has access to those trainees, you must provide a strong justification with letters of support from organizations or employers outside of your home state to support this claim in order for us to consider this application to be responsive. Otherwise, you would need to conduct training in multiple states in order to be responsive.

Question 9: With respect to the scope of target populations, are federal employees excluded from training? There are federal law enforcement training centers in our region and we are

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exploring if their learners could take advantage of education and training materials under the Ebola Biosafety and Infectious Disease Response Training Response funding opportunity announcement?

Answer 9: As with any other target population, applicants will need to address concerns about functional response roles, potential for exposure and training needs and so forth. Federal employees can be considered. Applicants will need to address how they currently fit into the local incident command, what training their own agencies would provide them and how this FOA expands the opportunity for innovative training. Most importantly, you would need to demonstrate a partnership agreement and access to the targeted population.

Areas of Training and Models

Question 10: Will a short informational session (30 minute briefing) with video put out as broadly as possible to entice people into taking longer curricula be acceptable?

Answer 10: We strongly prefer hands on training and the use of existing training resources and materials as provided by federal partners. It is not the best use of our funds to develop training videos.

Question 11: Are the Train-the-Trainer Model and the NIEHS WTP Direct Training Model intended to be two separate and distinct formats that can be utilized to deliver training, or are they used in conjunction with each other?

Answer 11: Yes. The Train-the-Trainer Model and NIEHS WTP Direct Training Models are two separate formats for training.

Question 12: Under the elements of the Direct Training Model, one outlines 24-40 hours of operations level learning activities. Is this specified range of hours a requirement for all training proposals, or is that only if you choose to develop and deliver the Direct Training Model?

Answer 12: This range is recommended for your use as well as the curricula that have already been developed on our Ebola Resources page at <http://tools.niehs.nih.gov/wetp/index.cfm?id=2542>.

Question 13: Would it be acceptable to propose to develop an awareness level online learning program (2-8 hours in length), and offer this as a prerequisite to an in-person awareness/operations level Train-the-Trainer course offering as defined under the Train-the-Trainer (TTT) Model section?

Answer 13: In general terms, we strongly prefer hands on training and the use of existing training resources and materials as provided by federal partners as we currently have an awareness level training already developed on our Ebola Resources page at

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<http://tools.niehs.nih.gov/wetp/index.cfm?id=2542>. While online learning is a valuable tool, the intent of this FOA is to focus on engaging students in a classroom setting.

Question 14: Does this Request for Applications (RFA) intend for greater focus on course development or more dissemination of training?

Answer 14: The awarded programs will focus on dissemination of environmental infection control and hazard recognition training within a broad-set of occupational and community settings, including healthcare and non-healthcare job sectors. To help relieve the burden of training, NIEHS Worker Training Program and federal partners will provide guidance materials, as developed or suggested under the cooperative agreements by federal partners, such as targeted fact sheets, videos, podcasts, resource documents, awareness training PowerPoints and so forth, and assist awardees to develop an evidence-based curricula that can be easily disseminated. The intent of this RFA is to support awardees in focusing on innovative strategies and target populations and developing evidence-based curricula based off of existing guidance. The intent is not to develop new training material when material already exists that addresses a training need.

Question 15: Does the submitted application need to include full curriculum details in its entirety?

Answer 15: Applicants, independently or as part of partnered relationships, should develop safety and health training curriculum for workers who are at high risk of coming in contact with persons potentially infected with Ebola virus and other emerging infectious diseases through potentially contaminated materials (biological, chemical or radiological) or infected individuals. Applicants should include a diagram of the proposed organizational structure that will be involved in development or dissemination of training. This diagram should demonstrate how the interactions with potential training partners and coalitions will achieve the goals of the developing curriculum as applicable to the target population. Applicants should also describe in outline form the applicable standards, curricula components, modules, learning objectives and performance measures that are being proposed. The outline for each curriculum must not exceed two (2) pages in length. Copies of the actual curricula are not required for the application. However, it will be critical to show applicable resources, standards that will be integrated, outcome of training, and access to suggested population, proposed innovation and added value from training to support development and dissemination of a compelling training curriculum.

Question 16: Can we use the funding to translate awareness and operations courses into Spanish?

Answer 16: The Centers for Disease Control and Prevention (CDC) and other federal partners have developed materials in Spanish for a broad array of infectious diseases, including Ebola Virus Disease. Those materials and others currently in development should be utilized as much as possible. It would be appropriate to coordinate activities with other applicants who need Spanish language materials. If translation is extremely integral to reaching your

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identified target population, a strong and compelling justification for developing and translating the training material must be included in your application.

Question 17: Is it a permissible expense to provide release time for awareness, operations or Train-the-Trainer curricula?

Answer 17: No, we do not cover release time. It is reasonable to provide incentives to support the training; however, it must be fully justified in your budget.

Question 18: We have community health centers interested in two (2) hour lunch-and-learns. Is that permitted?

Answer 18: It may be okay if they've already had infectious disease control training and this is enhancing their base training. You should provide a strong rationale in your application as to how effective, beneficial, and appropriate the lunch-and-learn would be for the targeted audience.

Question 19: Is this program looking to test new or different methods of education within the Ebola Biosafety initiative which may provide data or evidence-base alluding to best education techniques and practices? Is this a purely a training and dissemination initiative or can we add research components to enhance data behind best education techniques?

Answer 19: The NIEHS Worker Training Program (WTP) is not a research program. Research about the training and education process is certainly done in other branches and NIH institutes. NIEHS WTP has looked at different education and training approaches that have evolved over time. Our e-learning program has changed how we, WTP, do education. Hands-on and virtual training both have evolved over time. While we believe and have supported projects focused on learning about best education approaches in the past, in this funding opportunity announcement (FOA), we embrace that aspect through our evaluation component. Demia Wright, Public Health Educator, demonstrated different program effectiveness measures and education training data that may be integrated as a research component. This FOA in particular aims to build capacity for a cadre of trainers and advance workplace protection by disseminating awareness, operations, direct or train-the-trainer models for infection control, occupational medicine, biohazardous protection, hazard recognition and so forth, as described in Part 2, Program Description, within the announcement.

Evaluation

Question 20: With regards to program evaluation, is there any way to know the expectations or robust elements for a responsive program evaluation?

Answer 20: The NIEHS Worker Training Program is developing an Ebola Biosafety Training program logic model which will be an outcome approach that describes the program's anticipated outcomes or impact over time (i.e., from short-term to intermediate to long-term

outcomes). These types of logic models, which outline the approach and expectations behind a program's intended results, are most useful in designing effective evaluation and reporting strategies. More information was shared during the funding opportunity announcement (FOA) briefing informational meeting on September 18, 2015 from 1:00 – 3:00pm EST. We encourage you to watch the archived video at:

https://www.niehs.nih.gov/careers/hazmat/funding/current_funding_opps/index.cfm

Collaborations

Question 21: Should we consider synergistic collaborations with other healthcare or training facilities?

Answer 21: Yes. As part of this Request for Applications (RFA), the NIEHS Worker Training Program has a special focus to increase national capacity for trainers, broaden infection control and prevention infrastructure. We welcome new or existing multi-state, national or regional collaborations to develop and disseminate training programs that will prevent occupational exposure to Ebola Virus Disease (EVD) and emerging infectious diseases for a broad range of job categories. These collaborations may include coordination of biosafety training outside of the laboratory setting, partnerships with ASPR and CDC frontline healthcare facilities, Ebola assessment hospitals, Ebola treatment and coordination centers or additional training coalitions to help achieve sustained infectious disease and biosafety training efforts.

Question 22: Will NIEHS accept complimentary approaches, independently or with collaborations, in order to help increase the indirect cost rate of 8%?

Answer 22: As stated in the Request for Applications (RFA), "Allowable indirect costs for this program are limited to 8% of a modified indirect cost bases which excludes amounts over the first \$25,000 for each consortia agreement, equipment costs, and tuition and related trainee fees." NIEHS Worker Training Program is cognizant of the need to generate program income or cost-sharing models. Applicants are encouraged to consider methods to sustain the program, develop inter-organizational collaborations and combine coordinated plans to generate program income to assist in supporting efforts under the Ebola Biosafety and Infectious Disease Response Training component. For clarification, as per National Institute of Health (NIH) Grants Policy Statement, program income is gross income earned by a grantee, a consortium participant, or a contractor under a grant that was directly generated by the grant-supported activity or earned as a result of the award. Program income includes, but is not limited to, income from fees for services performed, tuition, the use or rental of real or personal property acquired under the grant, license fees and royalties on patents and copyrights. However, it is important to note: Only the rate specified in the RFA will be considered and any applications that come in with a rate higher than 8% will be considered non-responsive.

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Question 23: ASPR and other HHS agencies have also recently released funding opportunity announcements that will cover various geographical areas for Ebola training. If we apply to both grants, will this be considered duplicative efforts?

Answer 23: It depends. ASPR and other HHS agencies have focused on hospital preparedness efforts and awarded designated Ebola hospitals, treatment and coordination centers which encompass mostly patient care, healthcare workers and direct care-related training. When submitting an application for the WTP Ebola Biosafety and Infectious Disease Response Training funding opportunity announcement, it will be the applicants' responsibility to ensure there is no duplicative of work, target populations or tasks. The NIEHS WTP and federal partners are also committed to meeting prior to making awards to ensure there is no duplication of efforts.

Question 24: Is the purpose of this RFA to supplement regional Ebola centers?

Answer 24: The intent of the NIEHS Worker Training Program Ebola Biosafety and Infectious Disease Response Training funding opportunity announcement is to work collaboratively in a broader community context, outside of the regional centers' focus. We encourage applicants to reach out to local Ebola centers, discuss current training initiatives and identify additional training needs or target populations. NIEHS WTP and federal partners are committed to meeting prior to making awards to ensure there is no duplication of efforts.

Question 25: Should applicants team up with local Ebola assessment, treatment or coordinator centers or will that be considered duplication of efforts?

Answer 25: Our intent is to advance a collaborative vision of a strong, vigilant infection control and prevention health system within the occupational setting. Sustained, coordinated and complementary efforts by health coalitions will enable a system that is ready and able to identify hazards, mitigate and remediate hazardous risks while controlling and responding to endemic diseases more effectively. We encourage applicants to reach out to local Ebola centers and training organizations to discuss current efforts to identify and define additional training needs or populations that have not been addressed. NIEHS WTP and federal partners are committed to meeting prior to making awards to ensure there is no duplication of efforts.

Question 26: What kind of expertise should be included in the core development, training teams or key personnel?

Answer 26: Through the NIEHS Worker Training Program Ebola Biosafety and Infectious Disease Response Training funding opportunity announcement, we are looking to build national capacity for instructors, infection control and prevention for Ebola and emerging infectious diseases, and biosafety training programs outside of the laboratory setting that collectively increase hazard recognition skills for a broad range of populations and

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occupational settings. Anyone of the following should submit a letter of support or be listed as key personnel in support of the application:

- Have an existing track record or may be a new critical need to support biosafety and infection control fundamentals, high-impact training interventions for occupational health and safety;
- Develop and advance training programs for hazard recognition, risk assessment, application of controls and worker protection such as engineering and administrative controls, selection and use of personal protective equipment (PPE), training on donning and doffing of PPE, isolation and containment protocols, and disinfection and disposal protocols and so forth.

Question 27: Can you expand on the extent of the collaborations that can occur within the Ebola Biosafety and Infectious Disease Response Training funding opportunity announcement? Can multiple roles by one individual be considered responsive on multiple applications?

Answer 27: We understand that one consortium member may be involved with various consortiums and research projects. Whether taking on the role of a consultant on a competing grant, serving as a Principal Investigator on a primary grant or engaging in collaborations with other organizations, we recommend the applicant submitting each grant may benefit from providing explicit details about the role and demonstrate there is no overlap, no conflict of interest or duplication of efforts by the consortium member. Addressing each role affirmatively to limit assumptions may help peer reviewers understand your justification for multiple roles, synergy or innovative exchange.

Question 28: Can you comment on the area each applicant should include, should an applicant define a region, state, and so forth?

Answer 28: Applicants must demonstrate new or existing national, regional or multi-state geographical partnerships that can provide the essential training, tools and infrastructure needed to strengthen risk assessment and prevention mechanisms for enhanced biosafety in various occupational settings for workers at risk for increased exposure to infectious individuals or contaminated material. This may include, but is not limited to, multiple geographical areas in different states, a particular population within every state or even targeted populations within multiple regions. This FOA encourages programs to reach vulnerable constituents beyond a single locality and support capacity building efforts.

Emerging Infectious Diseases

Question 29: When referring to “other emerging infectious disease” or pathogens, is there any one in particular that should be considered?

Answer 29: We encourage applicants to focus on environments or tasks that increase exposure to high risk pathogens as described by the Centers for Disease Control and Prevention (CDC)

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and National Institute of Allergy and Infectious Diseases (NIAID) Category A, B or C Priority Pathogens/Agents. These three categories of pathogens are based on how easily they can be spread and the severity of illness or death they cause. Focus of other emerging infectious diseases includes, but is not limited to, the categorized pathogens, such as the Ebola virus, that can be easily transmitted person-to-person and result in high or high-to-moderate mortality and morbidity rates or cause public panic and social disruption requiring special action for public health preparedness. Training curriculum may build on the NIEHS WTP hazmat model and train at-risk populations on hazard recognition, risk reduction, infection prevention and biosafety skills in the occupational setting, keeping the aforementioned category descriptions and pathogen lists in mind. A description of the CDC Category A, B and C Priority Pathogens can be found here:

<http://www.bt.cdc.gov/bioterrorism/overview.asp>. A list of the NIAID Priority Agents can be found here:

<http://www.niaid.nih.gov/topics/biodefenserelated/biodefense/pages/cata.aspx>. These priority pathogens are periodically reviewed by authoring agencies are under continual revision with federal partners.

Question 30: Can you provide clarification on the focus of training program regarding Ebola versus other infectious diseases?

Answer 30: In terms of scope, we have attempted to think about the immediate, acute, time to respond to Ebola training needs. Many of the principles around training, protection and response are analogous to other infectious disease situations. This FOA focuses on the longer term response to facilitate capacity building within the country, within a number of institutions and worker populations. Lessons learned from the Ebola epidemic are applicable to emerging infectious diseases and encourage an all-hazards, whole-of-community approach to advancing infection control and biosafety outside of the laboratory setting.

Question 31: Would NIEHS consider funding a local or statewide program to train workers at-risk for exposure to emerging infectious disease, including Ebola Virus Disease, under this FOA?

Answer 31: Applicants must demonstrate new or existing national, regional or multi-state geographical partnerships. These partnerships must provide the essential training, tools and infrastructure needed to strengthen risk assessment and prevention mechanisms for enhanced biosafety in various occupational settings for workers at risk. For a well-rounded training approach, the NIEHS WTP encourages cooperation, collaborations, partnerships, and affiliate engagement to build training coalitions and relationships with referral and treatment centers. If the applicant identifies target audiences that are in a local capacity, you will need to justify why multi-state, regional or national partnerships would not be beneficial.

Budget

Question 32: Are awardees allowed to pay travel costs associated with the Applicant Informational Meeting on September 18, 2015 in NC from awarded funds, or is it an organizational cost?

Answer 32: NIEHS grant funds may NOT be used to attend the application information meeting that will be held September 18, 2015 in NC. It is important to be aware that "awards" include grants and other agreements in the form of money or property in lieu of money, by the Federal Government to an eligible recipient. The term does not include: technical assistance, which provides services instead of money; other assistance in the form of loans, loan guarantees, interest subsidies, or insurance; direct payments of any kind to individuals; and, contracts which are required to be entered into and administered under procurement laws and regulations. Costs associated with attending informational meetings are considered 'costs of doing business' and are unallowable under a grant.

Question 33: Are awardees allowed to pay for travel costs associated with the Applicant Information Meeting on September 18, 2015 in NC with program income?

Answer 33: Program income CANNOT be used. Program income means gross income received by the awardee or sub awardee directly generated by a grant supported activity, or earned only as a result of the grant agreement during the grant period. Program income is to be used to support the on-going program. Preparing for and submitting an application is not part of the program. HHS Grants Net indicates: "Regardless of the alternative(s) applied, program income may be used only for eligible costs, in accordance with the governing statute, any program regulations, the applicable cost principles, and the terms and conditions of the award."

Question 34: What is the total funding level for the NIEHS WTP Ebola Biosafety and Infectious Disease Training FOA?

Answer 34: NIEHS intends to commit \$3 million in FY 2016 for a total of \$9 million over a period of three (3) years to fund an estimate of 5 to 8 awards. The maximum project period is three (3) years.

Question 35: When submitting the budget in assist, do applicants need to submit three budget periods or one budget period?

Answer 35: Applicants will need to submit for three budget periods.

Question 36: When could funding begin? June of 2016?

Answer 36: Due to the emergency nature of this initiative, secondary review for this FOA has been expedited to undergo electronic early council concurrence in March 2016. If early concurrence with council is achieved as scheduled, awards may be made as early as April 1st, 2016.

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Question 37: Will NIEHS fund additional Ebola training after this award period of over? What is the vision after the three year period?

Answer 37: At this time, there are no additional funds that are available to us. There is always a possibility that NIEHS may receive additional funding in the future in this area.

Question 38: Can you clarify the allowable costs for expenses incurred by the participants? Specially, is food an allowable cost?

Answer 38: It would depend on the program. Typically, food is not an allowable cost, but if justified, it can be an exception.

Question 39: Pg I-111 states "A complete consortium budget form should be completed by each consortium org." Can you confirm the prime grantee's budget would be included in the R&R budget form & doesn't need to be separately detailed in a Sub award budget attachment?

Answer 39: During the webinar, Pam Clark, from Grants Management, demonstrated where the budget and sub awards should be reflected. In the sub award section there is a section for sub awards and is where the sub award budgets should be reflected. It should reflect one total for the sub awards and each sub award would require an attachment. The prime awardee would display their budget categorically.

Question 40: If you have a consortium that involves three or more satellite divisions, how should multiple investigators be listed?

Answer 40: Within the consortium or sub award budget, you may certainly have multiple PI's. The 424 application process will not allow a sub award within a sub award. In the event you have multiple organizations and want multiple PI's, we recommend identifying one primary institution with one principle investigator followed by additional organizations and PI's listed as part of the sub awardees.

Question 41: Are we allowed to include stipends or reimbursement for training course participants in our budget?

Answer 41: That would be looked on a case-by-case basis. In previous program or projects the NIEHS WTP has initiated, stipends were not allowed. However, again, if well justified, consideration may be given.

Question 42: Our program will require utilization of a motor vehicle for the delivery of our operational training in the "workplace" of our targeted populations. This vehicle will be used to transport the various training supplies and equipment to conduct appropriate training. It will also be used to demonstrate the proper organization and storage of emergency preparedness supplies. Is the purchase of a vehicle an allowable cost under this cooperative agreement? Can you provide the NIH policy that allows for the purchase or

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rental of motor vehicles to be used for conducting the research project as general purpose equipment?

Answer 42: The purchase of or rental of a vehicle that will be used for the sole purpose of supporting your training program is an "Allowable Cost". It would be considered an "Equipment" item and should be designated in the appropriate category on the SF 424 R&R. Please keep in mind that a sufficient justification along with documentation of the cost of the vehicle should also be included in your application.

NIH Policy states: "General purpose equipment means equipment which is not limited to research, medical, scientific or other technical activities. Examples include office equipment and furnishings, modular offices, telephone networks, information technology equipment and systems, air conditioning equipment, reproduction and printing equipment, and motor vehicles."

General

Question 43: Within the Ebola biosafety and infectious disease response training RFA, it states on page 4 that proposals may be submitted through grants.gov and tracked using ERA comments or may be submitted using assist system, but on page 23 it says organizations must submit applications to grants.gov. Which statement is correct?

Answer 43: Both statements are correct. Depending on how you pull together your application, the NIH spent a lot of time and effort developing the ASSIST mechanism to help you understand and fit your applications together and a highly encouraged submission process. Guidance with grants.gov is limited, so you might have to spend a little bit more time. On the NIH website, they have videos that talk about how you're able to pull together your applications, biosketches and additional guidance information. We suggest you use these videos, but it's completely up to you as to which mechanism you decide to use. The important part is to make sure you submit it and you get a confirmation that it has been submitted. The assist system will provide a screen image of the application along with confirmatory statement. NIH website can take up to two days to reflect submission confirmation.

Question 44: For letters of support, what type of support is required for this FOA?

Answer 44: Letters of support should demonstrate collaborative commitment with partnerships and support for the biosafety training program. They should demonstrate assurances of access to proposed populations for training and identify the target population requiring training.

Question 45: The RFA states: *...eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.* We will identify these two individuals but do we also need to have two eRA accounts?

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Answer 45: The institution must have one account. The signing official and the PI have accounts under the institutional account.

Question 46: The FOA instructions basically ask for the same information in Related Other Information - Program Summary/Abstract and Program Narrative subsections as in Research Plan— Specific Aims and Research Strategy. Please clarify the differences between these two sections.

Answer 46: The Program Summary/Abstract and Program Narrative is a standard section of the NIH applications. The Abstract is a short summary of the project, generally a paragraph or two in length. The Project Narrative is generally 2-3 sentences. These sections are truncated descriptions of the Specific Aims and Research Strategy and are available to the public. The Research Plan includes a more complete description of the project and is not available to the public.

Question 47: For the ASSIST Application, does the 30-page limit include subsections Program Summary/Abstract and Program Narrative in Related Other Project Information Section?

Answer 47: The 30 page limit pertains to the Research Strategy and does not include the Program Summary/Abstract, Program Narrative, or Specific Aims.

Question 48: Is the cover letter attachment required under R&R Cover Page? The SF 424 (R&R) Guide encourages the submission of the cover letter but its purpose does not seem applicable to this FOA.

Answer 48: A cover letter is required.

Question 49: Under tab—Related Other Project Information, are the following attachments required: Organizational Structure? Curricula Outlines?

Answer 49: Yes. Organizational Structure: Applicants should include a diagram of the organizational structure and describe the interaction and inclusion of subject matter and training experts. This diagram should demonstrate how the interactions between potential training partners and coalitions will achieve the goals of the curriculum as applicable to the target population. The diagram should be uploaded as a pdf file titled "Ebola Biosafety Training Organizational Structure."

Curricula Outlines: Describe in outline form the applicable standards, curricula components, modules, learning objectives and performance measures. The outline for each curriculum must not exceed two pages in length and should be included here only. Do not include copies of the actual curricula. The diagram should be uploaded as a pdf file titled "Curricula Outlines."

Question 50: Are there other types of information that can be included in the appendix, e.g., example of program evaluation forms, results of employer surveys, etc.?

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Answer 50: Copies of survey instruments, evaluation forms, handouts, training material are reasonable items to include as Appendices. Data or results from these forms should be summarized in the Research Plan and not placed in the Appendix. Keep in mind that reviewers often skip Appendices if they are numerous and/or large. Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide. As part of other attachments, the application should include an organizational structure and curricula outline.

Question 51: What is the font and spacing limitations for the grant?

Answer 51: As per SF-424 instructions at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf, please see page I-22 for Font, Size and Spacing for your grant submission. It states...Prepare the application using Arial, Helvetica, Palatino Linotype, or Georgia typeface in black font color. Font size in each final PDF document must be at least 11 points (or larger). Since some PDF converters may reduce font sizes, it is important to confirm that type density in each final PDF document, including both characters and spaces, is no more than 15 characters + spaces per linear inch and no more than six lines per vertical inch. Final PDF documents should be formatted to be no larger than standard paper size (8 1/2" x 11). The final PDF document should have at least one – half inch margins (top, bottom, left, and right) for all pages.

Question 52: Does the limitation of submissions, for example, number of applications per institution, apply for sub awardees or just the primary?

Answer 52: The actual funding opportunity announcement says that only one application can be submitted per institution. If you have consortium members on several projects, you can use a sub awardee under multiple applications however, you must adhere to one application for institution as defined in the FOA.

Question 53: Where can we find more information about Ebola Training Resources?

Answer 53: More information can be obtained from the NIEHS Worker Training Program Website for Ebola/Infectious Disease: <http://tools.niehs.nih.gov/wetp/index.cfm?id=2542>

Question 54: Are foreign organizations or a foreign component in a domestic application allowed to apply?

Answer 54: No. Foreign institutions not based in the United States (U.S.) or non-domestic (non-U.S.) entities are not eligible to apply. In addition, non-domestic (non-U.S.) components of U.S. organizations are also not eligible to apply. Foreign components are not allowed in any aspect of this funding opportunity announcement.

Question 55: Is there a role for consideration of, for example, ethical and legal duty to treat privacy issues, workplace safety issues, standard of care in crisis situations and liability issues?

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Answer 55: Each organization will have their own guidance and regulations as standard operating procedures (SOPs). We would expect these SOPs to be incorporated in the training that is done at the local facility. NIEHS WTP's role is to help organizations adhere to their local policies with respect to training, ethical, legal, privacy and liability issues. It will be imperative that the trainer, whether it's the organization's trainer or one of our grantee trainers, understands all considerations and is very familiar with the administrative controls, ethical requirements, HIPAA compliance and standards of care at the local level and should be addressed or justified appropriately within the RFA.

Question 56: Given that this is a training-related grant, due to special instructions for the SF424 in section 8, do NRSA sections apply? If yes, are we to submit the PHS398 training budget for any reimbursement for trainees to attend, training in the technical approach or do attendees need to be students.

Answer 56: No, NRSA sections do not apply.

Question 57: Is this FOA a part of the Global Health Security Agenda (GHSA) initiative organized by the White House and www.globalhealth.gov?

Answer 57: This funding opportunity announcement is independent of the GHSA initiative.

Advisory Board Members

Question 58: The research plan section asks applicants to describe administrative structure including the role of the advisory board. Should we list the names of the advisory board members?

Answer 58: Evidence of sufficient program advisors with demonstrated expertise is required in this Request for Application (RFA). Applicants will be required to describe the role of the advisory board, and show plans for how they will be used to assure the quality of the training program. The description should include frequency of meetings and how they will be expected to advise the principal investigator or program director. We encourage you to clearly describe the desired expertise to be represented by the board. Also describe how they will evaluate training activities with respect to worker feedback mechanisms, review of course critiques and other appropriate evaluations or quality assurance procedures. To avoid conflicts of interest, during the application review period, applicants are encouraged not to invite or contact specific advisory board members until after awards are made. Names of potential advisory board members should be kept confidential. Instead focus on defining the role, expertise, and expected level of interaction and feedback of the advisory board.

Question 59: The FOA states under the role of the Advisory Board:

“Show plans for how they will be used to assure the quality of the training program including frequency of meetings and how they will advise the PD/PI. This should include a description of the expertise of the membership of the external board, detailed plans on

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when the board will meet, how the board will evaluate training activities, and what formal procedures the board will follow to provide advice to the PD/PI. The advice should include at a minimum incorporation of worker feedback mechanisms; review of course critiques and Board of Advisors evaluations and other appropriate evaluations and quality assurance procedures. New Advisory Board members should not be contacted before application or named in the application.”

We have an existing Advisory Board with 2014 letters of commitment for 2015-2020. Can we submit these 2014 letters since their time period of commitment overlaps the three year period of this FOA?

Answer 59: Applicants should ask the present Advisory Board members to submit new letters in which they state they agree to be a board member of this new project. The reason you should do this is so reviewers will know that the current members have committed to another project (grant application). Please do not submit names or letters of new potential board members. You may list what expertise a new board member would need for this new grant application, but not their names and/or letters

Review

Question 60: How do I know NIH has received my application?

Answer 60: Principal Investigators should check their eCommons Account for their applications. This is the last step in the submission process. If you do not see your application within 2 days of submitting through Grants.gov, NIH has not received it. For assistance in the submission process, please contact the eRA Help Desk (see <http://grants.nih.gov/grants/ElectronicReceipt/support.htm>). Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Question 61: Can changes be made to my application after it has been submitted? Can I submit additional or corrected material?

Answer 61: Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date. The applications are assumed to be complete when submitted. No changes are allowed to the applications, and supplemental material is limited to updates in the status of publications or grant funding. An exception is for system-generated problems with legibility. If unforeseen circumstances should lead to a change in key personnel, please contact Scientific Review Officer, Dr. Janice B. Allen, allen9@niehs.nih.gov.

Question 62: Who will review the grant applications? Is there an NIH standing study section?

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Answer 62: An ad hoc committee of reviewers (Special Emphasis Panel) will be recruited to assess the merit of the NIEHS WTP Ebola Biosafety and Infectious Disease Response applications. There is no standing study section for this review. The committee members will have expertise in appropriate areas reflecting the themes of the proposed projects, including adult education and training; industrial hygiene, infectious disease, infection control, occupational medicine and worker safety training experience.

Question 63: What is the timeline and how will I know the review stage my application is in?

Answer 63: Note that the Scientific Merit Review meeting is scheduled for February 2016 and the Advisory Council Review is scheduled in May 2016 (March 2016 Early Concurrence) as per information contained in the Ebola FOA. Principal Investigators should check their eCommons account for communications regarding the review. Much of the review process is electronic, and as the applications proceed through it, information is automatically posted in eCommons.

Question 64: When will I know the results from the review committee?

Answer 64: Scores are posted in eCommons within three business days of the review meeting. A written report of the reviewers' comments (Summary Statement) is generally available in eCommons within 30 days after the meeting.

Question 65: I'm wondering about where to include the list of personnel. The RFA asks that the Administration, Staff, Advisory Board section include "list technical support staff members". What is considered a technical support staff member? Do we need to include in the narrative a listing of all staff? If not, where do we list all staff? Does that go in the 398 All Personnel Form and get attached in ASSIST? Does it go in the budget justification?

Answer 65: Technical Support Staff are any individuals that provide technical support to your grant. They could include consultants, advisory board members, and so forth. We suggest you put the key staff in the narrative as indicated. In addition, key personnel, collaborators, and consultants should submit letters of support. According to Scientific Review, if you don't want them identified as key personnel, the only place they can think to put them is under the budget justification. Previous FOA applications coming in through the ASSIST system have added them after all the budget summaries either in the overall component or the sub components.

Question 66: The most current biographical sketch form is "Approved Through 8/31/2015". Is it allowable to use this version for the Ebola Competitive FOA which is due October 21, 2015?

Answer 66: As you may be aware the Office of Management and Budget (OMB) has to approve new forms for NIH to use. Sometimes the new forms are not approved before the old forms expire. You may use the current forms that are approved through 8/31/15 until the new

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forms are available. OMB generally let applicants know at least 60 days in advance when new forms will become available and have to be used, however, changes may take place at any time and at the discretion of OMB.

All revised forms and instructions are available on the SF 424 (R&R) Forms and Applications page and adjustments have been made to improve their usability. Please use the most updated version that is posted and available online for the general Biographical Sketch Format Page prior to submitting your application by visiting:
<http://grants.nih.gov/grants/funding/424/index.htm#biosketch>

Question 67: Has the review panel been selected and can you ensure that they all have a full understanding and appreciation for the value of peer training in the 2006 NIEHS minimum safety and training criteria?

Answer 67: The letters of intent are used in the initial phase of reviewer recruitment. Once applications are submitted, the scientific review branch and officer will ascertain the expertise that is needed to address the research proposals and projects. Expert peers from occupational medicine, industrial hygiene, infectious disease, infection control, occupational health and safety, and other applicable fields may be designated to form the special emphasis panel for this FOA.

Question 68: Will applicants have access to the peer review meeting roster prior to the meeting?

Answer 68: Yes. Thirty (30) days prior to the meeting, applicants will have a chance to review the unofficial special emphasis panel meeting roster. While it will not be the official roster as that is only available on the day of the meeting, the unofficial roster will give you an indication of the expertise that has been recruited on this panel. If applicants have an objection to the recruited panelists, they are welcome to email Dr. Janice Allen, allen9@niehs.nih.gov to further inquire and allow scientific review branch to handle as required.

Question 69: How can we view the unofficial meeting roster for the special emphasis panel?

Answer 69: Please visit the NIEHS Rosters public domain website by clicking on the link below. Select the year of your meeting and search for "Ebola Biosafety and Infectious Disease Response Training": <https://public.era.nih.gov/pubroster/jsp/proster1.jsp?ABBR=ZES1&CID=100558>

We encourage you to contact us to arrange a telephone conversation or send your questions via email to wetp@niehs.nih.gov as they arise so that we may be able to address your concerns promptly.