Issue Date:	May 13, 2021
Deadline for Questions:	May 20, 2021; 1:00 p.m., Washington, DC Time
Closing Date:	June 17, 2021
Closing Time:	1:00 p.m., Washington, DC Time

Subject: Notice of Funding Opportunity (NOFO) Number: 7200AA21RFA00005

Program Title: Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)

Catalog of Federal Domestic Assistance (CFDA) Number: 98.001

Ladies/Gentlemen:

The United States Agency for International Development (USAID) is seeking applications for a cooperative agreement from qualified entities to implement the Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN) program. Eligibility for this award is not restricted.

USAID intends to make an award to the applicant(s) who best meets the objectives of this funding opportunity based on the merit review criteria described in this NOFO subject to a risk assessment. Eligible parties interested in submitting an application are encouraged to read this NOFO thoroughly to understand the type of program sought, application submission requirements and selection process.

To be eligible for award, the applicant must provide all information as required in this NOFO and meet eligibility standards in Section C of this NOFO. This funding opportunity is posted on www.grants.gov, and may be amended. It is the responsibility of the applicant to regularly check the website to ensure they have the latest information pertaining to this notice of funding opportunity and to ensure that the NOFO has been received from the internet in its entirety. USAID bears no responsibility for data errors resulting from transmission or conversion process. If you have difficulty registering on www.grants.gov or accessing the NOFO, please contact the Grants.gov Helpdesk at 1-800-518-4726 or via email at support@grants.gov for technical assistance.

USAID may not award to an applicant unless the applicant has complied with all applicable unique entity identifier and System for Award Management (SAM) requirements detailed in Section D.6.g. The registration process may take many weeks to complete. Therefore, applicants are encouraged to begin registration early in the process.

Please send any questions to the point(s) of contact identified in Section D. The deadline for questions is shown above. Responses to questions received prior to the deadline will be

furnished to all potential applicants through an amendment to this notice posted to www.grants.gov.

Issuance of this notice of funding opportunity does not constitute an award commitment on the part of the Government nor does it commit the Government to pay for any costs incurred in preparation or submission of comments/suggestions or an application. Applications are submitted at the risk of the applicant. All preparation and submission costs are at the applicant's expense.

Thank you for your interest in USAID programs.

Sincerely,

Patricia Elena Bradley (affiliate)
Patricia Bradley
Agreement Officer

Digitally signed by Patricia Elena Bradley (affiliate)
Date: 2021.05.13 10:19:32 -04'00'

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SECTION A: PROGRAM DESCRIPTION

This funding opportunity is authorized under the Foreign Assistance Act (FAA) of 1961, as amended. The resulting award will be subject to 2 CFR 200 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, and USAID's supplement, 2 CFR 700, as well as the additional requirements found in Section F.

DISCOVERY & EXPLORATION OF EMERGING PATHOGENS – VIRAL ZOONOSES (DEEP VZN)

1. Introduction

The emergence of numerous novel zoonotic viruses [1] over the past few decades is a vivid reminder that countries and the global community remain vulnerable to outbreaks caused by diseases for which there are no specific diagnostics, medicines, or vaccines and for which there is no pre-existing immunity in human populations. Many of these diseases are caused by previously unknown viruses that originated in wild animals before spreading to people directly or through livestock. The health and economic impact associated with these events can be significant [2].

Detection and characterization of unknown zoonotic (i.e. animal-origin) viruses before they cause outbreaks, epidemics, or pandemics in human populations enables more efficient and effective preparedness, prevention, and response efforts, saving lives and limiting economic damage. COVID-19's severe impacts (more than 140 million cases and 3.0 million deaths along with major economic disruptions spread over 220 countries and territories in Africa, Asia/Pacific, the Americas, Europe, and the Middle East [3]) demonstrate the perils of not having advance information on possible public health threats that can be used to develop tools to inform monitoring and response. The rapid and extensive spread of the COVID-19 pandemic is also a reminder that a threat anywhere can be a threat everywhere.

USAID has invested more than $1.1 billion in global health security since 2005. An extensive area of work between 2009 and 2020 has been viral discovery and characterization in locations where there is high risk for spillover, amplification, and spread of emerging zoonotic viruses [4]. USAID's on-going multi-sectoral Global Health Security program and its partnerships place the Agency in a unique position to advance efforts related to discovery and characterization of unknown viruses.

Through the new DEEP VZN project, the U.S. Agency for International Development (USAID) seeks to assist a limited number of countries, with a focus on Africa, Asia, and Latin America, to establish capacity to detect, characterize, and disseminate information and findings regarding previously unknown viruses that have originated in wildlife [5]. DEEP VZN will build on more than 15 years of USAID investments in promoting a multisectoral [6] (i.e., "One Health") approach to addressing emerging zoonotic viruses before they pose an overwhelming epidemic or pandemic threat. Specifically, DEEP VZN will assist targeted African, Asian, and Latin American countries in strengthening their capacities to detect and characterize unknown viruses

along chains of transmission where risk profiles favor spillover, amplification, or spread of emerging zoonotic viruses of wildlife origin. Characterization efforts will focus on assessing the zoonotic and pandemic potential of these viruses so that they can be prioritized by other partners for development of tools and countermeasures. The DEEP VZN activities will generate information that can be used by other partners to appropriately address gender in the development of tools and strategies and in the recommendations for any evidence-based viral zoonoses risk mitigation.

2. Overview of USAID's Global Health Security Program

In partnership with other nations, international organizations, and public and private stakeholders, the U.S. government's (USG) Global Health Security (GHS) programming aims to prevent avoidable epidemics, detect threats early, and respond rapidly and effectively to disease outbreaks. In May 2019, the Global Health Security Strategy (GHSS) [7] was approved, outlining the USG's approach to strengthening global health security, including accelerating the capabilities of targeted countries to prevent, detect, and respond to infectious disease outbreaks. The Strategy pursues three interrelated goals: 1) strengthened partner country global health security capacities; 2) increased international support for global health security; and 3) a homeland prepared and resilient against global health threats. Given its foreign affairs mandate, USAID directly contributes to the first two goals. USAID funds and programs focus on: addressing the health security capacity gaps in targeted countries at high risk of infectious disease threats and outbreaks (USAID's major contribution to the Global Health Security Agenda [GHSA]); targeted, applied GHS research; and critical policy and advocacy support for GHS. DEEP VZN will focus on identifying and characterizing novel viral threats which together are critical data needed to address the alarming increase in the frequency and severity of infectious disease outbreaks occurring globally.

3. Evolution of USAID's Global Health Security Investments

For more than 15 years, USAID has been a leader in the global response to the dangers posed by emerging pandemic threats and has invested in GHS activities with the dual goals of minimizing the impact of existing pandemic influenza threats and pre-empting the emergence and spread of novel epidemic/pandemic threats arising from animal populations. The first phase of the USAID's GHS program primarily focused on supporting countries to address these zoonotic threats and understanding overall risk of spillover, amplification, and spread in animal and human populations. The One Health approach for achieving these goals was built around a suite of investments and targeted partnerships designed to give earlier insight into the emergence of new public health threats and enhance country-level capacities across sectors to mitigate their potential impact. With a total investment of over $1.1 billion covering countries in Africa, Asia, Latin America, and the Middle East, USAID's GHS program is the largest and most-extensive One Health program ever implemented. The guiding principles for USAID's GHS program (2009-2020) have been to:

- build on the understanding that the future well-being of humans, animals, and the environment are inextricably linked, a concept known as "One Health";
- promote a cross-sectoral, gender-responsive One Health approach that spans the animal health, public health, environmental, and biodiversity/conservation communities;

- support countries to conduct studies to understand risk of spillover, amplification, and spread of known and unknown emerging zoonotic viruses;
- target promotion of policies and strengthening of skills and capacities critical for both minimizing the risk of new disease emergence and the ability to limit their social, economic, and public health impact; and
- use a risk-based approach to target investments where the likelihood of disease emergence is greatest.

Emerging Pandemic Threats-1 (2009-2014): The first iteration of EPT built off of a previous One Health line of work supported by USAID between 2005 and 2009 which was aimed at addressing the immediate threat posed by highly pathogenic H5N1 avian influenza (AI). The EPT-1 portfolio was focused on building the capacities and evidence base needed to mitigate the impact of novel "high-consequence pathogens" arising from animals. Specifically, the EPT-1 portfolio consisted of four complementary activities, including strategic partnerships with the Food and Agricultural Organization of the United Nations (FAO), World Health Organization (WHO) and World Organization for Animal Health (OIE), and was implemented in more than 20 countries across Africa, Asia, and Latin America:

- PREDICT-1: Focused on building a global early warning system for the emergence of diseases that move between wildlife and people, primarily through detection and discovery of viruses from 28 high-consequence viral families in wildlife species that have frequent contact with humans.
- PREVENT: Aimed at characterizing risks associated with practices and behaviors that facilitate disease transmission between animals and humans and developing strategies for lowering the risk of disease spillover.
- IDENTIFY: A partnership among WHO, FAO, and OIE, focused on strengthening laboratory capacities to safely diagnose and report priority animal and human pathogens.
- RESPOND: Focused on the central role of local universities to train cadres of upcoming professionals and practitioners responsible for supporting, promoting, and implementing the One Health approach.

Key accomplishments:

- Established the "proof of principle" that countries can carry out safe capture and sampling of wildlife followed by conventional PCR testing of blood, urine, feces, or oral/nasal swabs for up to 28 families of zoonotic viruses; sampled more than 56,000 animals and identified 815 novel viruses and 169 known viruses, making it the most comprehensive viral detection and discovery effort at that time; identified which animal species (i.e. rodent, bats, and non-human primates) were most associated with spillover of emerging zoonotic viruses; developed a global "hot spots" map for emergence of viral zoonoses. PREDICT-1 final report: https://ohi.sf.ucdavis.edu/sites/g/files/dgvnsk5251/files/files/page/predict-final-report-lo.pdf.
- Identified that new zoonotic viruses that are capable of infecting diverse host species have higher pandemic potential since these viruses are more likely to amplify by human-to-human transmission with spread on a global scale. https://www.nature.com/articles/srep14830
- Created region-specific lists of high-risk, human and animal diseases, developed/updated standard lab procedures for these diseases, and provided viral identification training for

laboratories in Africa and Asia. https://www.usaid.gov/sites/default/files/documents/1864/IDENTIFY-Compilation-of-Accomplishments__1 -13-2014.docx

- Characterized the nature and frequency of human contact with animals in Africa and Asia. https://www.fhi360.org/projects/prevent-%E2%80%94-emerging-pandemic-threats
- Improved the effectiveness of poultry vaccination in Indonesia (with demonstrated decrease in reported poultry outbreaks and human infections) by identifying which licensed vaccines were efficacious against the specific H5N1 avian influenza virus present in the country. https://ec.europa.eu/food/sites/food/files/animals/docs/ad_cm_ai_nrl-annual-meetings-14_pres-17.pdf
- Established two regional university networks (Central/East Africa and Southeast Asia) and four country university networks (Indonesia, Malaysia, Thailand, Vietnam) to formulate and introduce standardized One Health curricula for pre- and in-service training and serve as a One Health hub across participating universities and countries.

Lessons learned:

- The understanding of risk associated with spillover of emerging zoonotic viruses from animals to people could be further improved by focusing on a smaller subset of viral families and animal species (to allow for larger sample sizes for viral detection), adding surveillance of humans (virology and serology), focusing on common points where animals and humans interact (with behavioral surveillance), and sampling longitudinally in order to gain insight on any seasonality associated with spillover of emerging zoonotic viruses from animals to people.
- Universities play a critical role in creating long-term changes to workforce skills. They work on the cutting edge of their fields to educate students who will comprise tomorrow's workforce. Universities are also testing sites for education, where innovative and trans-disciplinary approaches to training professionals are constantly introduced and refined, including One Health approaches. By investing in universities in developing countries, we can create a long-term in-country capability for improved human resource capacity.
- Focused public sector investments in filling key knowledge gaps related to spillover, amplification, and spread of emerging zoonotic viruses can lead to private sector poultry producers changing their practices (if cost-neutral) based on evidence, thereby increasing the likelihood of sustainability.
- Behavior change communications for AI that were targeted at households increased knowledge, but did not change behaviors possibly because doing so cost more (e.g. buying fencing for household birds, buying feed for caged birds that were previously free-ranging) and/or because the risk of human infection was perceived to be much lower than other common diseases such as malaria or tuberculosis.
- Countries which did not have a strong history of cross-sectoral collaboration on zoonotic diseases, especially those in Africa, would benefit from support to establish or strengthen in-country platforms to coordinate zoonotic disease activities across sectors, especially public health, livestock, and wildlife.

EPT-2 (2014-2020): The second iteration of EPT built on the investments, partnerships, and lessons learned from EPT-1. The focus remained on preventing, detecting, and responding to

emerging viral diseases using a One Health approach, but broadened investments around preparedness. The scope of the program also was expanded to address the threats posed by antimicrobial resistance (AMR), as the inappropriate use of antibiotics in animal husbandry and inappropriate "prescriber-user" practices associated with antibiotic use in clinical care were increasingly understood to be core drivers behind the emergence and global spread of antibiotic-resistant organisms. EPT-2 worked in more than 30 countries across Africa [8], Asia, and the Middle East [9], and was comprised of three activities as well as partnerships with FAO and WHO:

- PREDICT-2: Consolidated the scopes of EPT-1's PREDICT-1 and PREVENT to more-precisely identify and characterize emerging zoonotic viruses in animals and people, as well as behaviors, practices, and conditions associated with viral evolution, spillover, amplification, and spread. The number of targeted viral families was reduced to four [10] and targeted animal-human interfaces reduced to households, markets, and livestock/agricultural production. Longitudinal monitoring at high risk interfaces, human surveillance, animal and human serology, and foci on Ebola in West Africa, Middle East Respiratory Syndrome coronavirus (MERS-CoV) in northeast Africa, and SARS-CoV-2 in Asia were also added.
- Preparedness and Response (P&R): Assisted countries in establishing and strengthening national One Health platforms to develop, formalize, and maintain multisectoral collaboration as well as develop country-specific plans for responding to public health events of unknown etiology.
- One Health Workforce (OHW): Built on the investments of EPT-1's RESPOND by strengthening the capacity of the One Health university networks to address the current workforce needs of ministries in addition to building a pipeline of future One Health workers, expanding the networks to include more countries, and strengthening the operational capacities of the university networks.
- FAO: Focused on risk characterization activities to understand biological drivers of zoonotic virus spillover (including AI and MERS-CoV), amplification, and spread; studied and promoted risk mitigation policies and practices for livestock that reduce the risk of zoonotic virus spillover, amplification, and spread; supported national One Health platforms (in coordination with P&R); strengthened national preparedness within the livestock sector to respond to events of public health concern including epidemiology training for veterinarians; strengthened global livestock surveillance networks; and provided emergency lab, commodity, and other support for outbreaks in livestock.
- WHO: Focused on strengthening influenza surveillance; strengthening national preparedness within the public health sector to respond to events of public health significance; supported One Health national platforms through the development of tools (in coordination with P&R) and invested in a One Health workforce (in coordination with OHW); and provided emergency lab, commodity, and other support for outbreaks in humans.

Key accomplishments:

- Conducted standardized and synchronized monitoring of wildlife, humans, and associated behaviors at specific animal-human interfaces across 28 countries; sampled >100,000 animals and humans and identified an additional 200 novel viruses (including a new Ebola species in Sierra Leone and Guinea and a new coronavirus associated with swine

deaths in China) and 88 known viruses (in addition to those detected under PREDICT-1); and identified an association between RNA virus shedding by wildlife and animal value chains.

PREDICT final report:
https://ohi.vetmed.ucdavis.edu/sites/g/files/dgvnsk5251/files/inline-files/PREDICT%20LEGACY%20-%20FINAL%20FOR%20WEB_0.pdf

PREDICT data:
http://data.predict.global/, https://data.usaid.gov/Global-Health-Security-in-Development-GHSD-/PREDICT-Emerging-Pandemic-Threats-Project-Restrict/cn2r-e2df
https://data.usaid.gov/Global-Health-Security-in-Development-GHSD-/PREDICT-Emerging-Pandemic-Threats-Project/tqea-hwmr

Other PREDICT information:
https://www.nature.com/articles/s41564-018-0227-2
https://www.nature.com/articles/s41586-018-0010-9 ,
https://www.sciencemag.org/news/2019/01/bat-species-may-be-source-ebola-epidemic-killed-more-11000-people-west-africa,
https://ohi.vetmed.ucdavis.edu/programs-projects/predict-project/reports ,
https://static1.squarespace.com/static/5c7d60a711f7845f734d4a73/t/5e95fb725309184f8a1e76b2/15868875%2090640/PREDICT+March+18+Data+Discussion.pdf , https://p2.predict.global/interventions , https://p2.predict.global/insights ,
https://ohi.vetmed.ucdavis.edu/programs-projects/predict-proect/publications

- Developed and made publicly-available a tool for ranking the risk of animal-to-human spillover for newly discovered viruses originating in wildlife. https://www.pnas.org/content/pnas/118/15/e2002324118.full.pdf
- With CDC, co-identified Marburg virus in Sierra Leone, the first-ever detection of the virus in West Africa. https://www.ucdavis.edu/health/news/deadly-marburg-virus-found-sierra-leone-bats/, https://www.nature.com/articles/s41467-020-14327-8
- Collected evidence indicating previously-unrecognized spillover of Ebola viruses in the Democratic Republic of the Congo and Uganda and provided evidence that Ebola/Bombali is zoonotic. https://academic.oup.com/jid/article/218/suppl_5/S277/5039952; https://link.springer.com/epdf/10.1186/s42522-020-00028-1?sharing_token=J6AZyoFlW_WXSCHlhrCB2m_BpE1tBhCbnbw3BuzI2RMvLJRJHNUVHei-FofO0OKe-pIHezGL0eAuEIr6l4pqvwl2HiTJ1uK7ENb4miIpp90R0pBn4tk8Jkh1T3HM1jnl0Qny1-ns6xNrk5LC44OB-iT3a6VVSHNO4DKeZxY8N7A%3D
- Identified a SARS-like coronavirus from bats in China that had spilled over to people https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6178078/
- To overcome low positivity rates for filoviruses among healthy animals, a strategy was developed and deployed in Guinea, Liberia, and Sierra Leone to generate large numbers of samples among the most-likely animal hosts (based on evidence from previous studies) and viral detection was intentionally conducted for filoviruses rather than narrowly for

Ebola/Zaire which was the cause the 2014-2016 human epidemic in West Africa. (See chapter on Ebola Host Project in PREDICT final report.)

- Used PCR and serology to screen animal and human samples from Asia collected under PREDICT (from 2009-2020) for evidence of active or previous infections with SARS-CoV-2 and/or related coronaviruses. Preliminary virological results include detection of two novel SARS-related coronaviruses in specimens from nine animals and non-SARS-related coronaviruses (including two novel viruses) in specimens from 72 additional animals. From 3,329 individuals tested, antibodies to SARS-related coronaviruses were detected in 35 people and antibodies to other non-SARS-related coronaviruses were detected in three people. See https://www.nature.com/articles/s41467-021-21240-1 and https://www.biorxiv.org/content/10.1101/2021.01.26.428212v1.full.pdf.
- Studies from northeast Africa have documented high exposure rates of camels to MERS-CoV viruses with most of the viruses sequenced to date clustering in clade C. This group is distinct from the one that contains the known zoonotic MERS-CoV viruses from the Arabian Peninsula, but there is some experimental evidence by other researchers that some clade C viruses may be zoonotic as well despite the absence of documented human infections in northeast Africa.
  https://www.liebertpub.com/doi/10.1089/vbz.2016.2062?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub++0pubmed&=&,
  https://www.tandfonline.com/doi/full/10.1080/22221751.2018.1560235,
  https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6258726/,
  https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2017.22.11.30487,
  https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6723520/,
  https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7605751/
- Developed and validated a rapid, easy-to-use field diagnostic for identifying H5 and H7 influenza A viruses in birds which allows for faster response to contain these viruses in infected flocks and prevent spread to additional animals or people.
  https://onlinelibrary.wiley.com/doi/pdf/10.1111/irv.12646.
- Developed “Living Safely with Bats” and “Living Safely with Animals” communication tools to convey risk and possible risk-reduction options to communities in West and East African countries. [Note: these two tools have not yet been evaluated for effectiveness in increasing knowledge or changing behaviors.]
  https://p2.predict.global/living-safely-with-bats-book,
  https://documentcloud.adobe.com/link/track?uri=urn%3Aaaid%3Ascds%3AUS%3A5957e613-ecba-4dd4-bc7e-1fa4d60c786b#pageNum=22
- With the Australian Department of Foreign Affairs and Trade and FAO, enhanced farm and market biosecurity, flock health and hatchery management practices contributing to reduced disease and AMR risk in Cambodia, Laos, Myanmar, and Vietnam.
  http://www.fao.org/3/ca5608en/CA5608EN.pdf
  http://www.fao.org/3/ca5515en/ca5515en.pdf
  http://www.fao.org/3/ca5516en/ca5516en.pdf
  http://www.fao.org/3/ca6642en/CA6642EN.pdf
  http://www.fao.org/3/ca7319en/CA7319EN.pdf
  http://www.fao.org/3/ca6114en/CA6114EN.pdf

- Refined the global "hot spots" analyses for emergence of viral zoonoses. https://www.ecohealthalliance.org/wp-content/uploads/2017/10/s41467-017-00923-8.pdf.
- Further refined the understanding of Nipah virus dynamics in bats and implications for spillover to humans. https://www.pnas.org/content/early/2020/10/27/2000429117
- Developed tools, lessons learned, and economic analyses related to One Health programming and provided technical assistance and operational support to 15 One Health platforms in Africa and Asia.
- Developed and implemented a district-level, in-service applied veterinary epidemiology training program (ISAVET) in East, Central, and West African countries to address the dearth of veterinarians with agricultural- and veterinary-specific epidemiologic core competencies. http://www.fao.org/resilience/news-events/detail/en/c/1171750/
- Provided classroom and hands-on training in One Health core competencies to over 13,300 undergraduate students and 33,500 current One Health professionals across Africa and Asia.
- Developed gender-responsive curriculum and training of One Health professionals: Gender One Health and Infectious Disease Training Module. http://afrohun.org/index.php?option=com_content&view=article&id=168&Itemid=1055
- Supported prevention, detection, and response to infectious disease threats through the Global Health Security Agenda. https://www.state.gov/wp-content/uploads/2020/09/GHSA_ProgressImpactFY19_final.pdf

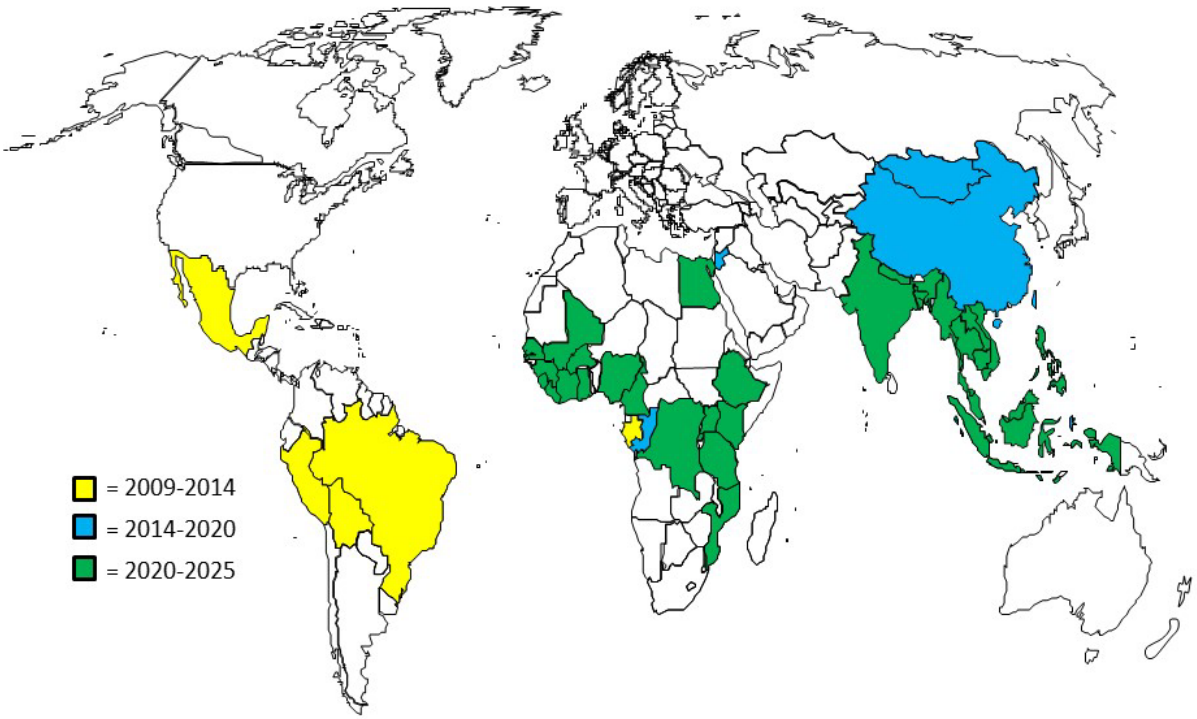
Lessons learned:

- Concurrent, focused, and longitudinal surveillance of wildlife and human populations have provided additional insight on where, when, and how emerging zoonotic viruses (including Ebola) spill over at specific animal-human interfaces; this insight is critical to strengthening the ability of countries to begin developing and testing the effectiveness of interventions to reduce the risk of spillover of these threats from animals to people (although additional information related to spillover risk is needed for viruses such as Ebola, Nipah, animal-origin coronaviruses, and animal-origin influenzas).
- Characterization of novel viruses for zoonotic and pandemic potential remains a lengthy and expensive process which often relies on sharing samples and specialized capacities across multiple countries. Efforts to streamline and consistently support characterization are needed in order to identify which novel viruses are likely to be high-consequence (i.e. zoonotic and epidemic/pandemic potential) before they cause outbreaks.
- In Africa and Asia, the continued spillover, amplification, and spread of emerging zoonotic viruses highlight the large gaps that still exist in biosafety and biosecurity, particularly along animal value chains; the private sector so far has been an underutilized partner for broadly (as opposed to addressing disease by disease) reducing risk along livestock value chains. Reducing the risk of spillover of zoonotic viruses from wildlife to livestock and people (including through animal value chains) is also a gap that needs to be addressed.
- Workforce transformation is a long-term process that requires consultation and collaboration with a diverse set of stakeholders and a better understanding of labor markets' supply and demand curves. In order to better understand and target training opportunities and educational offerings, One Health university networks (OHUNs) must

consult and collaborate with governments, non-governmental organizations (NGOs), donors, and the private sector on their needs and capacities.

- While countries appear to understand the benefits of One Health platforms and have utilized new tools developed with support from EPT-2, the degree to which countries engage with and support their platforms varies, and this has implications for long-term sustainability and the ability to attract donor funding.

GHSA: In 2014, USAID, along with other USG partners, including the National Security Council, Department of State, the U.S. Centers for Disease Control and Prevention (CDC), and the Department of Defense, joined more than 60 countries in implementing the GHSA. At the core of the GHSA is the goal of strengthening capacities for prevention, detection, and response for infectious disease outbreaks using multisectoral collaboration across public health, medicine, agriculture, animal/veterinary health, environment, education/academia, and defense/security agencies. USAID's GHSA activities have been geographically focused in 16 countries in Africa and Asia and used to build workforce capacity and surveillance, laboratory capacity, and preparedness and response systems for addressing prioritized endemic and emerging zoonotic threats. Going forward, USAID's emerging threats and GHSA activities constitute the agency's global health security investments under the GHSS. Countries supported by USAID under EPT-1 and EPT-2/GHSA are shown in the map below. Between 2020 and 2025, USAID will continue its global health security investments with a primary focus on countries in Africa and Asia, although countries in Latin America may be included for viral discovery. DEEP VZN will complement other USAID partnerships that are described below in section 5 ("Collaboration with Other USAID/External Partners").



4. DEEP VZN Goal & Objectives

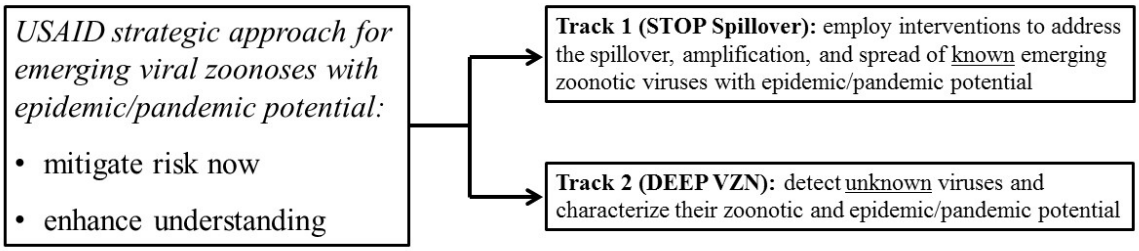
Problem Statement

An analysis of 335 emerging infectious diseases (EID) in humans between 1940 and 2004 revealed a number of important characteristics including: the incidence of EID events is increasing over time; 60% of EIDs are zoonotic and, of those, 72% are from wildlife; the origins of EIDs are correlated with socio-economic, environmental, and ecological factors and are concentrated in tropical and subtropical regions of the world; and global resources to address EIDs are poorly allocated [11]. Zoonotic diseases cause the loss of lives and livelihoods by disrupting local, regional, and global travel and trade, and by threatening the economic and political stability of some of the most vulnerable countries. Among zoonotic diseases, emerging zoonotic viruses are particularly problematic because: these pathogens generally lack specific treatments and vaccines (for animals or people); human populations are more likely to be immunologically naive to novel viral zoonoses giving these pathogens a comparatively-higher likelihood of epidemic/pandemic potential; and these pathogens are often detected during or after amplification or spread in human populations which challenges containment. The on-going COVID-19 pandemic caused by SARS-CoV-2–with more than 3.2 million deaths and an estimated economic loss of at least $28 trillion [12]—has once again highlighted the importance of these three points as well as the significant time lag associated with developing and deploying diagnostics, medicines, vaccines, and risk-reduction interventions after a new zoonotic virus has emerged.

Multiple, previously-unknown zoonotic viruses have emerged and caused outbreaks over the past three decades. Many of these viruses originated in wild animals before spreading to people directly or through livestock such as poultry, swine, horses, and camels. A recent study estimated that there may be an additional 1.67 million undiscovered viruses in mammals and birds, with between 631,000 and 827,000 capable of infecting people [13]. Countries and the international community would be better served, in terms of lives saved and economic damage limited, if they were able to detect and assess the zoonotic and epidemic/pandemic potential of novel zoonotic viruses before they cause widespread outbreaks. However, countries do not routinely invest in monitoring for and characterizing infectious disease threats in advance of their emergence. As a result, **the lack of data on new emerging zoonotic viruses is a serious impediment to countries and the international community being able to prevent and prepare for future threats (sometimes also referred to as "Disease X").** This advance work includes both reducing the likelihood of initial viral spillover from animals to people as well as developing or updating diagnostics and medical countermeasures for new emerging zoonotic viruses.

Building on previous USAID global analyses of risk and investments in countries under EPT-1 and EPT-2/GHSA, the Agency is now employing a dual track strategy to prevent and prepare for future emerging zoonotic viruses with epidemic/pandemic potential (see figure below). **Track one** aims to refine and employ interventions to address the on-going spillover, amplification, and spread of known emerging zoonotic viruses through a recently-awarded project, STOP Spillover. This project will assist countries to: understand the factors that contribute to the risk of spillover of pathogens from wildlife to humans; develop, assess, and implement early risk-

reduction interventions that will reduce the spillover and spread of these threats; and recognize and respond rapidly to zoonotic spillover events [14].



Track two of USAID's strategy for addressing emerging zoonotic viruses includes the new **DEEP VZN** project, which will specifically focus on supporting a multi-country project to detect unknown viruses and characterize their zoonotic and epidemic/pandemic potential and share this information with the greater scientific/One Health community. USAID's support for viral discovery since 2009 and its multi-sectoral GHS Program and partnerships place the Agency in a unique position to meaningfully advance these lines of work.

DEEP VZN Goal: Through in-country institutions, detect and characterize unknown viruses with zoonotic and epidemic/pandemic potential along high-risk chains of transmission to provide data which is publicly shared so that other partners can use them for risk mitigation, policy reform, and development of diagnostics, medicines, and vaccines.

USAID's expectation is that the successful applicant will support host-country institutions and staff in identifying sampling locations (based on risk along chains of transmission), detecting and characterizing unknown viruses, and actively sharing data and analyses with in-country and global stakeholders.

Estimated Budget: total of up to $125 million over five years (2021-2026).

DEEP VZN Strategic Approach: Building upon an institutional legacy in viral zoonoses landscaping and risk analyses, USAID's DEEP VZN Project seeks to strengthen and expand in-country capacities that will considerably advance the detection and characterization processes for unknown viruses with zoonotic and epidemic/pandemic potential. Applicants are expected to reflect this approach by focusing resources on in-country partnerships and sub-awards. DEEP VZN will build on data, tools, and strategies--including those previously developed by PREDICT and FAO with USAID support as well as those supported by other USG agencies and international partners--to strengthen the capacity of a limited number of in-country institutions that will conduct the sampling, detection, and characterization of unknown viruses.

Lessons learned from viral discovery and characterization efforts to date include:

- Previous work has identified chains of transmission, species, and geographic "hot spots" in Africa, Asia, and Latin America and the Middle East where viral detection rates are higher.

- Detecting known and unknown viral threats can safely be accomplished by in-country laboratories and staff.
- While significant, the scale of viral discovery and characterization to date has been relatively small. Improvements in efficiency of sampling, detection, and characterization hold the potential to dramatically increase the scale of data available on unknown viruses and their emergence risk.
- To date, the global community lacks efficient, low-cost, biosafe/biosecure, and standardized methods to reliably characterize newly-identified viruses to determine their zoonotic and epidemic/pandemic potential.
- Focused public and private investments can fill key knowledge gaps to help individuals, communities, governments, and the private sector to reduce risk. However, there is room for improving the speed and extent to which the research findings (specifically detection and characterization of novel viruses) are available to and taken up by those who assess risk, operate surveillance systems and laboratories, mitigate risk, and develop diagnostics, medicines, and vaccines.

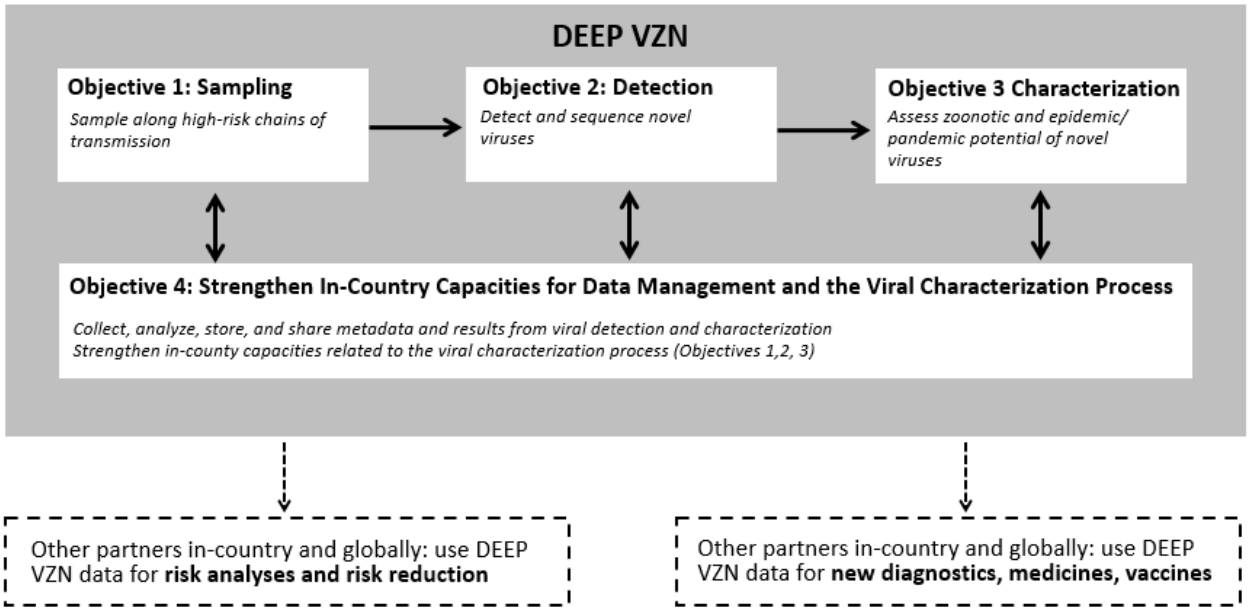
An essential component of DEEP VZN is improving the efficiency of viral detection and characterization in order to identify novel viruses on a much greater scale than previously possible. A key part of this approach will be the use of specific, evidence-based sampling strategies for each country to increase detection rates for unknown viruses in the prioritized families (see below for more information). Such approaches have been successfully employed in China where the geographic distribution of specific host taxa have been important considerations for where to set up sampling in order to detect coronaviruses [15, 16]; in Vietnam where sampling specific interfaces has been shown to impact detection rates for coronaviruses along wildlife value chains [17]; and in East Africa where shedding of coronaviruses by bats occurs at specific times of the year [18].

Through the support provided by DEEP VZN, focus countries will be able to enhance their capacity to detect and assess the zoonotic and epidemic/pandemic potential of previously-unknown viruses. The resulting data will also be used to answer global questions about geographic distribution of novel viruses, which animals can serve as hosts, and nodes along chains of transmission where spillover, amplification, or spread occur. These data potentially can be used by other USAID, USG, and other projects and programs—such as STOP Spillover—to model disease emergence risk, update risk analyses, direct precision surveillance approaches, and implement targeted risk-reduction measures. In addition, information from DEEP VZN could be used by other partners, including donors and the private sector, to develop and pre-position diagnostics, medicines, and vaccines ahead of costly and disruptive epidemics and pandemics. **Because spillover, amplification, and spread of unknown emerging zoonotic viruses potentially affects wildlife, livestock, and human populations, efforts to detect and characterize unknown viral threats under the DEEP VZN project will require in-country (and possibly regional and global) partnerships that are collaborative and multisectoral.**

DEEP VZN will focus on the viral characterization process outlined in the figure below. (More information on the four objectives of DEEP VZN is included further below.) The interlinked objectives cover: collecting samples; detecting, characterizing, and prioritizing new viruses detected; and analyzing and sharing the findings in-country and globally. USAID expects that

DEEP VZN will identify/generate samples for viral detection throughout the life of the project and that viral detection and characterization will take place as soon as possible after collection to ensure that information on viral detection and characterization can be rapidly shared with the country and global scientific/One Health community.

DEEP VZN's Viral Characterization Process



The in-country sampling for unknown viruses under DEEP VZN will serve two very important functions. First, the data generated will be used to identify future infectious disease threats before large outbreaks occur which potentially allows time for other partners to develop or update surveillance postures and risk-reduction measures as well as pre-position diagnostics, medicines, and vaccines (if available). Second, the laboratory techniques for detection of unknown viruses may also be used to assist in the investigation of events of unknown etiology when common pathogens have been ruled out. While some low- and middle-income countries have developed strategies over the past decade to sample for emerging zoonotic viruses, this ability is presently limited in size and scope, not sustainable without external donor funding, and may not be focused along the highest-risk chains of transmission. As a result, these countries have a poorly differentiated understanding of spillover risk, limiting their ability to effectively prevent, detect, and respond to future emergence of viral zoonoses.

Data collection, analysis, storage, and sharing. DEEP VZN is expected to generate actionable data on potential future threats, therefore it is critical that there be a robust data storage and sharing effort so that information on novel viruses will be actively shared with end-users, to include affected communities, policy makers, private sector, and research institutions. Metadata and viral detection and characterization results from DEEP VZN will be stored in-country using existing systems (with augmentation by DEEP VZN, if needed). Since USAID expects that data generated by DEEP VZN will be publicly available—carrying appropriate data utilization rights—through open source platforms for the benefit of global health research and risk analyses,

DEEP VZN will assist in linking in-country data with global systems (e.g. GenBank, GISAID) where appropriate. Knowledge gained by DEEP VZN on novel viruses assessed to be zoonotic and significant epidemic/pandemic threats will be immediately available to the in-country owners of the data and will be expected to be available expeditiously to policy makers, the private sector, and implementing partners so that they are able to take steps to improve surveillance and reduce the risk of viral spillover [see reference 19 for examples of partners that could use this information]. Data and insights developed under DEEP VZN and in partnership with governments may be used to leverage private sector capacities in research and development of diagnostics, medicines, and vaccines. Related to capacity strengthening, DEEP VZN will strengthen select in-country staff and institutions to be able to sample, detect, and characterize unknown viruses as well as analyze, store, and share data with stakeholders in-country and globally. The successful Applicant will be expected to transfer data from DEEP VZN into USAID's Development Data Library (https://data.usaid.gov/). A data management plan is required.

Priority Viruses. To provide some focus for viral detection and characterization, DEEP VZN will concentrate on "known unknown" viruses which are defined here as unknown viruses related to known groups of viruses with members that have demonstrated zoonotic and epidemic/pandemic capacity. (For the rest of this document, "unknown viruses" refers only to "known unknown" viruses.) **Specifically, DEEP VZN will prioritize coronaviruses, filoviruses, and paramyxoviruses of wildlife origin.** (Note: these viruses may be detected in wildlife, livestock, other domestic animals, or humans.) At this time, DEEP VZN will not focus on detection and characterization of previously-unknown groups of viruses (a.k.a. "unknown unknowns"). However, samples collected and archived by DEEP VZN could potentially be tested for unknown unknowns at some later stage or by other partners or institutions.

Criteria used to select these viral families for DEEP VZN include:

- Primarily resident in wildlife hosts;
- Priorities of focus countries and the global research community [20];
- Relatively high detection rates from animal and human samples;
- Likely ability to spill over from animals to people (zoonotic potential);
- Likely human-to-human transmission potential (epidemic/pandemic potential); and
- Associated with significant rates of morbidity and mortality.

Based on these criteria, DEEP VZN will initially focus on coronaviruses, filoviruses, and paramyxoviruses across all focus countries (see below for more information) to help fill in gaps in knowledge concerning: geographic distribution; reservoir and intermediate animal hosts; temporal variations in viral shedding; points of spillover, amplification, and spread; and range of host cell-binding affinities and receptors utilized by new viruses for cell entry. Subject to USAID approval, DEEP VZN could also take a narrower focus on sub-groups within the three viral families (e.g. SARS-like betacoronaviruses and Henipaviruses) at the country or global level using the same samples. The exact list of focus viruses for each country will be determined post-award in consultation with host-country stakeholders and the USAID DEEP VZN project management team. Please note that priority viruses may be added or removed, before or after award, based on the availability of funds and at the discretion of USAID due to changing priorities, policies, or global health events (e.g. emergence of a new Disease X or major shift in

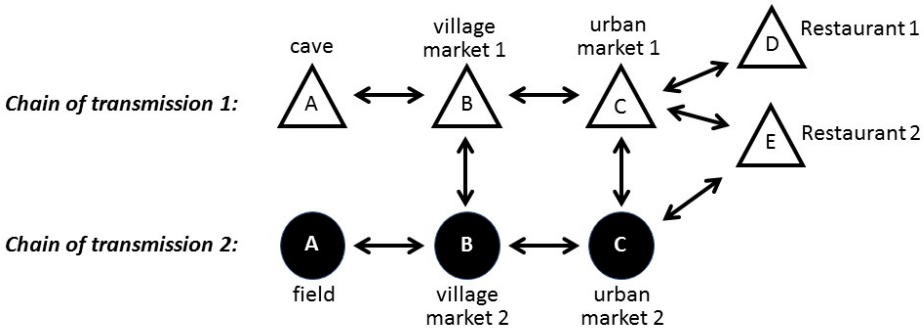
disease epidemiology). **Also note that USAID is not prioritizing influenza viruses for detection and characterization under DEEP VZN because this viral group will be addressed by other USAID projects/partners.**

Priority sampling sites. In order to detect and characterize novel viruses with zoonotic and epidemic/pandemic potential on a greater scale, DEEP VZN will focus its sampling efforts along chains of transmission where there is:

- contact between humans and animal species known or suspected to host zoonotic viruses; and
- direct or indirect evidence for spillover, amplification, and spread of zoonotic viruses.

For the purposes of DEEP VZN, a "chain of transmission" refers to a pathway by which wildlife, livestock, humans, and their viruses move in time and space resulting in opportunities for spillover, amplification, and spread of these viruses. Each chain may have multiple physical locations (e.g. cave, house, market, farm, restaurant) or "nodes" along it, with each node possibly having potential for viral spillover, amplification, and spread. The level of risk associated with a specific chain of transmission or its nodes depends on a number of factors including, but not limited to: type and number of species (animals and people) present; closeness and duration of interactions among species; presence/extent of hygiene, preventative or biosecurity measures; pre-existing immunity among animals and people; and connectivity with other chains of transmission. These chains of transmission may be completely independent of others or overlapping either partially or completely with other chains.

To better illustrate chains of transmission and their nodes, the figure below shows two partially overlapping examples. Transmission chain 1 could be related to bats starting at their origin in a cave (node 1A) and then transiting through a rural market (1B) and an urban market (1C), before ending up in multiple restaurants (1D and 1E). Transmission chain 2 could be related to the sale of rodents starting with the source in a field (node 2A) and moving through a rural market (2B) and an urban market (2C) before arriving at a restaurant (1E). The two chains could potentially mix viruses where there are connections between nodes 1B and 2B, nodes 1C and 2C, and nodes 1E and 2C.



For viral detection and characterization, the nodes along the highest-risk transmission chains could serve as sampling sites. The number of sampling sites per country will be limited and will be aligned with wildlife in natural habitats or along chains of transmission that move these animals or their products (e.g meat, waste) from their points of origin through markets, farms, or restaurants in rural or urban settings where there may be spillover to livestock and people. Sampling at each site is expected to occur longitudinally over the life of DEEP VZN. **While the focus is on viruses of wildlife origin, DEEP VZN will also sample livestock and humans at high-risk nodes along targeted chains of transmission.** It is expected that sampling locations and targets will be driven by the best available existing evidence and risk modeling at country level.

Because DEEP VZN is prioritizing detection and assessment of the zoonotic and epidemic/pandemic potential of novel viruses, Applicants should design their sampling and detection schemes so that they maximize the number of viruses (from the priority viral groups) that are characterized. Strategies/ activities are particularly valued that have paradigm-shifting promise, enabling viral detection and characterization at a scale as yet unrealized. Sampling plans must include the ability to trace "forward" or "backward" along prioritized chains of transmission during successive rounds of sampling in order to collect additional information on species and locations affected.

The exact sampling sites and chains of transmission in each country will be determined post-award in consultation with host-country stakeholders and the USAID DEEP VZN project management team. Please note that sampling sites and chains of transmission may be added or removed after award, based on the availability of funds and at the discretion of USAID due to changing priorities, policies, or global health events.

Focus Countries. Within anticipated resource parameters, DEEP VZN will be implemented in approximately 12 countries that will be determined jointly by the partner and USAID project management team. It is anticipated these countries will be in Africa, Asia, and Latin America in order to improve visibility on unknown viral threats across tropical and sub-tropical regions where risk of emerging zoonotic viruses is highest [11, 21]. As a result, the successful Applicant will be expected to be able to effectively and simultaneously implement activities in all of the regions and countries that are ultimately selected. **USAID expects that the bulk of the sampling, detection, and characterization work outlined below will be conducted by in-country institutions and staff with technical, operational, administrative, and commodity support provided, as needed, from international partners.**

USAID's criteria for selecting specific focus countries for DEEP VZN include:

- risk profiles, including a history of (or potential for) spillovers of emerging zoonotic viruses from animals to people;
- active host-country engagement, including: interest in providing human or financial resources; commitment to using the research results in-country to reduce risk of emerging zoonotic viruses; support for coordination/collaboration within the country and with regional and global partners; complementary in-country initiatives such as risk mitigation efforts related to live animal markets, wildlife trafficking and trade, or conservation;

- history of sharing surveillance and outbreak data within and outside of country in a timely manner and willingness to share research findings and samples with the global community to reduce risk of emerging zoonotic viruses in other countries;
- ability (or potential) to safely conduct viral discovery and characterization in-country at the scale needed;
- rapid start-up potential for DEEP VZN; and
- presence of complementary USAID, U.S. Government, or other investments in GHS (including previous viral discovery).

For the purposes of the NOFO, an illustrative list of initial focus countries for DEEP VZN includes Kenya, Senegal, Thailand, and Vietnam. The full list of countries will be selected post-award by the successful applicant and the USAID project management team and will be phased-in based on an implementation plan agreed to by the same parties. Please note that countries may be added or removed, before or after award, based on the availability of funds and at the discretion of USAID due to changing priorities, policies, or global health events.

The successful Applicant will be expected to execute and manage (possibly multiple) grants or sub-awards under DEEP VZN in each of the approximately 12 focus countries which may be in any or all of the following sub-regions: East Africa; Central Africa; West Africa; South Asia; Southeast Asia; and Latin America.

Local Partnerships and Capacity Strengthening. In keeping with USAID's desire to strengthen in-country capacities, DEEP VZN will work directly with select institutions and staff in the focus countries to design and safely conduct sampling, detection, and characterization of unknown emerging zoonotic viruses and identify their hosts along high-risk chains of transmission. DEEP VZN will be conducted in a way that maximizes detection and characterization of unknown viruses using the resources available while supporting multi-sectoral (i.e. One Health) collaboration and coordination. Achieving the desired results of DEEP VZN will require engagement with relevant stakeholders, including government ministries, national One Health coordination mechanisms, academia, civil society, and the private and NGO sectors, as well as coordination with WHO, FAO and other USAID and USG partners.

DEEP VZN is expected to leave a legacy of strengthened capacity for the participating in-country staff and institutions. The successful Applicant shall ensure that staff trained during DEEP VZN are mostly/all from the host countries and that women and men are equally represented. It is also possible that, as a result of DEEP VZN, multiple countries may strengthen or establish lasting connections (formal or informal) among participating institutions; these regional or global "networks" will not only benefit the project, but may also be used in the future to jointly investigate new outbreaks of unknown etiology and conduct joint research projects. This networking effect was observed in early 2020 among USAID-supported laboratories in several countries as staff reached out to each other to discuss how they could adapt existing viral detection methodologies to identify the newly-emerged SARS-CoV-2 virus. In the various regions, there may be existing relevant laboratory networks which should be leveraged.

It is anticipated that in-country partners for DEEP VZN will have the following characteristics:

- previous experience with viral detection and characterization;

- ability to safely conduct high-quality sampling, viral detection, and viral characterization in-country at the scale required by the project;
- established linkages with host government, private sector, and other multi-sectoral partners;
- demonstrated history of sharing research findings in a transparent and timely manner; and
- ability to receive, track, and report on funding from USAID grants or sub-awards.

Strengthening the capacity of select in-country institutions and staff to implement DEEP VZN will require the successful Applicant to have an understanding of the specific contexts within the focus countries, including unique environmental, cultural, political, economic, and gender considerations. Applicants are expected to be familiar with and use the risk assessments, research findings (including those cited above and below) that were previously-supported by USAID as well as other publicly-available resources to inform strategic planning, baseline analyses, training, and other proposed activities in order to ensure DEEP VZN activities are targeted and not duplicative of these or other efforts. For example, if a country already has a standardized biosafety training course, DEEP VZN should train staff using this protocol rather than using one developed by DEEP VZN.

USAID supported work related to risk understanding and research includes:

- FAO: http://www.fao.org/emergencies/fao-in-action/ectad/en/
  PREDICT (2009-2014): https://ohi.vetmed.ucdavis.edu/programs-projects/predict-project ; PREDICT final report (2014-2020) (https://ohi.vetmed.ucdavis.edu/sites/g/files/dgvnsk5251/files/inline-files/PREDICT%20LEGACY%20-%20FINAL%20FOR%20WEB_0.pdf)
- PREVENT: https://www.fhi360.org/projects/prevent-%E2%80%94-emerging-pandemic-threats
- One Health Workforce: http://afrohun.org/index.php?option=com_content&view=article&id=169&Itemid=1056

Overarching Expected DEEP VZN Results:

- Higher-yield methods and strategies to sample, detect, and characterize unknown viruses and their zoonotic and epidemic/pandemic potential will be developed and deployed and/or existing technologies optimized;
- Capacity of specific in-country institutions and staff to sample. detect, and characterize viruses (to including advanced diagnostics, modeling, bioinformatics, analysis and sharing findings) strengthened;
- Unknown viruses detected and their zoonotic and epidemic/pandemic potential characterized; and
- Data from along high-risk chains of transmission collected, analyzed, shared, risks identified, and analyses translated for end-users to include stakeholders involved in risk mitigation, policy change, and development of diagnostics, medicines, and vaccines.

Objectives and Illustrative Activities. DEEP VZN will work to enhance the capacity of select in-country institutions (and their staff) to detect unknown viruses and characterize their zoonotic and epidemic/pandemic potential. DEEP VZN will employ strategies that will measurably advance the efficiency, improve the efficacy (e.g. differentiate signal from noise), and reduce the cost of efforts across the sampling/detection/characterization continuum (also referred to as the "Viral Characterization Process" in this NOFO).

Objective 1: Conduct Sampling in Focus Countries for Unknown Viruses from the Priority Viral Families

A critical aspect of improving the efficiency of detecting unknown viruses is focusing sampling efforts at locations with the greatest potential for finding viruses in the prioritized viral families. Thus, a risk-based approach is key to ensure that sampling is concentrated at places with likely host species and conditions favorable for viral spillover, amplification, and spread.

The ultimate aim of activities under DEEP VZN's Objective 1 is to efficiently collect high-quality samples (with relevant metadata) that will feed into viral detection (Objective 2) and viral characterization (Objective 3). There is an expectation by USAID that sampling under DEEP VZN will use the same or similar processes across focus countries, but that the actual details of sampling (e.g. when, where, why) will be tailored to the specific risks, capacities, and priorities of each focus country. For example, sampling may be focused along chains of transmission that include natural wildlife habitats as well as other chains of transmission that move these animals or their products (e.g meat, waste) from their points of origin through markets, farms, or restaurants in rural or urban settings where there may be spillover to livestock and people. Final sampling sites, species to be sampled, timing of sampling, etc. will be determined post-award in consultation with the individual focus countries The species to be sampled would likely include wildlife, livestock, and humans.

There is an expectation that samples collected by DEEP VZN will be bio-banked in each country to allow for the possibility of future testing for other viral families, "unknown unknowns", or specific viruses that emerge at some point in the future. As a result, the successful applicant will be required to ensure that focus countries have adequate storage space and that applicable national and international safety and security standards for storage are followed.

While the priority for objective 1 is prospective sampling, DEEP VZN may work with in-country stakeholders to identify a small number of high-quality samples from existing bio-banks that would add value to viral detection and characterization efforts by contributing to filling knowledge gaps being addressed by DEEP VZN. Over the life of DEEP VZN, findings from viral detection (Objective 2) and viral characterization (Objective 3) may be used to refine the original sampling sites and sampling strategy/strategies (Objective 1) to further improve the efficiency of detecting and characterizing unknown viruses. For example, detection of a novel virus at one sampling location may result in additional sampling either "upstream" or "downstream" in the chain of transmission in order to trace it to its origin or destination.

After award, the successful Applicant will support in-country stakeholders to finalize a detailed sampling plan and conduct prospective sample collection along high-risk chains of transmission where there is (1) a higher probability of finding unknown viruses in the prioritized viral families that originated in wildlife and (2) where there are conditions that favor spillover of emerging zoonotic viruses from reservoir wildlife hosts to other wildlife, livestock, or people.

Illustrative Activities for Objective 1 may include, but are not limited to:

- Support strengthening of in-country institutions and staff in focus countries to use available data and predictive models and analytics to inform decisions on how and where to detect unknown viruses along high-risk chains of transmission and points in time (i.e. when viral shedding is highest);
- Support in-country institutions and staff in focus countries to design an innovative and efficient strategy for sampling that will maximize detection and characterization of unknown viruses; to include training, a sampling plan with defined methods, species to be sampled, and sampling sites that are representative of key points of spillover, amplification, and spread where wildlife exist or along wildlife value chains (or points of exposure) in both rural and urban settings;
- Identify and provide any equipment (to include freezers for bio-banking), supplies (e.g PPE), reagents, and support required approvals (e.g. sampling of animals and people, shipping of samples, research permits) needed by the participating in-country partners;
- Provide training on biosafety/biosecurity, safe sampling, and safe handling, transport, and storage of samples;
- Safely sample key species (animals and people) at selected sampling sites in focus countries;
- Collect key metadata associated with sampling sites to include:
    - type of chain of transmission and specific "nodes" where sampling occurred;
    - connection to or position along wildlife value chain and known sources or destinations for wildlife, livestock, or people present at sampling site;
    - organization/lay-out of site;
    - observance of behaviors or practices that could facilitate spillover, amplification, and spread of emerging viruses at the sampling site; and
    - occupation and exposure risk of any humans sampled;
- Safely transport and store prospective samples (and metadata) at participating institutions in focus countries;
- Identify (a limited number of) high-value bio-banked samples (in focus countries and possibly neighboring countries if there is interest), negotiate sample-sharing agreements with the owners of these samples, and (if needed) support shipping costs; and
- For samples from (a limited number of) outbreaks of unknown etiology (in focus countries and possibly neighboring countries if there is interest), negotiate sample-sharing agreements with the owners of these samples, and (if needed) support shipping costs.

Objective 1 expected results:

- In-country institutional and staff capacity to conduct risk modeling to identify and inform sampling efforts strengthened;
- Innovative and efficient strategy for sampling of wildlife, livestock, or people for unknown viruses originating from wildlife at key points for spillover, amplification, and spread developed, approved, and deployed by in-country partners;
- Key species sampled at research sites and additional bio-banked and outbreak samples identified; and
- Prospective samples (and corresponding metadata) safely and appropriately stored.

Objective 2: Strengthen Detection in Focus Countries for Novel Viruses from the Priority Viral Families

Detection of novel viruses is an expensive and time-consuming process. However, experience has shown a substantial return on investment for strengthening capacities to prevent, detect, and contain zoonotic viruses before they cause epidemics and pandemics [22]. Recently, the utility of being able to strategically identify novel viruses during the early stages of an outbreak was demonstrated by Thailand's use of consensus, family-level viral detection protocols to identify and fully sequence SARS-CoV-2 [23] from a sick traveler from Wuhan two days before the causative agent was announced by China. Thailand's rapid identification of this novel virus before there were standard diagnostic tests made it possible for the country to take early action, preventing onward transmission by introducing risk-mitigation measures and enabling targeted screening protocols that rapidly detected additional cases, thereby limiting the health and economic impact in the country.

The ultimate aim of viral detection under DEEP VZN Objective 2 is to screen samples for previously-unknown viruses which can then be characterized under Objective 3. This would primarily focus on prospective samples collected under Objective 1, but could include a limited number of high-value samples from bio-banks in the focus countries. In addition, DEEP VZN may also provide (limited) support to outbreaks of unknown etiology in animals or humans after common pathogens have been ruled out. Key to the success of activities under Objective 2 will be deployment of cost-effective strategies and approaches that substantially advance viral detection at a scale previously unrealized.

USAID expects that most/all novel viruses in the priority families that are detected under Objective 2 will undergo whole genome sequencing and that a high proportion (to be determined) of these novel viruses will be assessed for zoonotic and epidemic/pandemic potential under Objective 3 (viral characterization). Monitoring of viral detection positivity rates based on species, sampling sites, sample types, seasonality, etc. may be used to periodically refine the sampling strategy under Objective 1. There is an expectation by USAID that viral detection under DEEP VZN will use the same or similar processes across focus countries, but that the actual details of detection will be tailored to the specific risks, capacities, and priorities of each focus country.

After award, the successful Applicant will be expected to work with in-country partners to finalize the most-appropriate viral detection strategy/strategies, priority viruses, as well as all other details associated with viral detection. Please note that viral detection strategies, methodologies, and number and type of viruses or viral groups may be added or removed, before or after award, based on the availability of funds and at the discretion of USAID due to changing priorities, policies, or global health events.

Illustrative Activities for Objective 2 may include, but are not limited to:

- Support in-country institutions and staff in focus countries to develop an efficient viral detection strategy to include identification of needed laboratory training and protocols;
- Test, validate and standardize viral detection protocols that will enhance the yield and efficiency of viral discovery (e.g. population-based serological studies intended to inform targeted discovery efforts) compared to current methods;

- Identify and provide any equipment, supplies (e.g PPE), or reagents (e.g. primers and probes and any other specialized reagents/components for viral detection needed by the participating in-country partners;
- Provide training on biosafety/biosecurity and safe handling of samples;
- Support in-country laboratory/laboratories with detecting priority viruses in samples from research sites and (to a lesser extent), outbreaks of unknown etiology, and bio-banks; and
- Assist in-country laboratory/laboratories (or contracting with other organizations/companies to) to conduct whole genome sequencing for all novel viruses detected.

Objective 2 expected results:

- Protocols or techniques to test, validate, and enhance the yield and efficiency of viral detection improved;
- Detection and genomic sequencing of novel viruses from prospective samples (and, if appropriate, outbreaks of unknown etiology and bio-banks) safely conducted; and
- Ability of select in-country laboratories to provide technical assistance and/or detection capabilities for viral discovery in-country and in the region improved.

Objective 3. Strengthen Characterization in Focus Countries of Novel Viruses from the Priority Viral Families

The processes of characterizing viruses to assess their zoonotic and epidemic/pandemic potential are complicated, expensive, and time-consuming. However, this step is crucial to improve understanding of emergence risk profiles, identifying and mapping hotspots of emergence with improved granularity, and prioritizing newly discovered viruses according to their epidemic and pandemic potential. This refined understanding of risk is essential in directing efficient use of resources for precision targeted surveillance, prevention, and preparedness. To date, several methods have been used to characterize novel viruses including: comparing genetic sequences with known viruses; evaluating host plasticity (ability to infect multiple species) [24]; receptor binding or characterization assays; demonstration of previous or active human infections (by serology/virus neutralization and viral detection, respectively); *in vitro* binding or replication studies using human cells; and *in vivo* transmission studies using animal models.

The first three methods above can be safely done in many countries, but the *in vitro* and *in vivo* studies require specialized assays and increased lab biosafety and biosecurity standards which makes them less practical in many low- and middle-income countries. While some regional or global labs can conduct the *in vitro* and in *vivo* studies, approvals for shipping samples outside of the host country may challenge timely characterization. However, approaches that leverage advances in generating pseudotyped viruses from genetic sequences and can be safely handled for receptor binding studies may help overcome these constraints. A limitation of comparing genetic sequences of novel viruses with those that are known and evaluating host plasticity is that it is only possible if there are enough viruses that are similar and if enough information is available on which animals can host a particular virus. For example, host plasticity was unknown for SARS-CoV-2 when the COVID-19 pandemic started, but since then the virus has been shown to naturally infect humans, cats, dogs, ferrets, gorillas, mink, pumas, lions, snow leopards,

and tigers [25], demonstrating its considerable host plasticity which is consistent with it being a zoonotic virus.

The ultimate aim of virus characterization under DEEP VZN Objective 3 is to identify and deploy more-efficient methods to evaluate which of the novel viruses detected under Objective 2 have zoonotic and epidemic/pandemic potential. Under limited circumstances, DEEP VZN may characterize a small number of novel viruses in the prioritized viral families if they were previously detected by the country, but not assessed for zoonotic and epidemic/pandemic potential. **While the characterization strategies may include *in vitro* studies, the project DEEP VZN will not support *in vivo* animal transmission studies or Gain of Function studies because of the safety risk involved.** However, if DEEP VZN identifies novel viruses which are considered high priorities for *in vivo* animal transmission studies, DEEP VZN may assist the country in exploring options for having samples shipped to and work conducted at regional or global BSL-4 laboratories in partnership with the focus country to include facilitating in-country researcher(s) to work on the additional studies at the regional or global laboratories (when feasible).

There is an expectation by USAID that viral characterization under DEEP VZN will use the same or similar processes across focus countries, but that the actual details of characterization will be tailored to the specific risks, capacities, and priorities of each focus country. At a minimum, all novel viruses identified under Objective 2 will undergo phylogenetic analysis and evaluation of host plasticity while some proportion (to be determined) of these novel viruses will be analyzed for evidence of ability to infect and replicate in humans using *in vitro* tests. Based on analyses for zoonotic and epidemic/pandemic potential, viruses will be ranked by DEEP VZN according to risk and this information made available through in-country and international multi-sectoral fora so that other partners can update risk analyses (e.g. priority zoonotic diseases), surveillance, risk-reduction interventions, diagnostics, medicines, and vaccines. Information on viruses with zoonotic and epidemic/pandemic potential may also be used to periodically refine the sampling strategy under Objective 1.

After award, the successful Applicant will be expected to work with in-country partners to finalize the most-appropriate characterization strategy/strategies and methods as well as other details associated with characterization. Please note that strategies or methodologies for viral characterization may be added or removed, before or after award, based on the availability of funds and at the discretion of USAID due to changing priorities, policies, or global health events.

Illustrative activities for Objective 3 include, but are not limited to:

- Support in-country institutions and staff in focus countries to develop a characterization strategy to include methodologies, training needs, and, if applicable, identify a small number of novel viruses in the prioritized viral families that were previously detected by the country, but not assessed for zoonotic and epidemic/pandemic potential;
- Test, validate and standardize protocols that will improve efficiency, speed, and cost profile over currently available viral characterization processes;
- Identify and provide any equipment, supplies (e.g. PPE), reagents (e.g. cell lines and any other specialized reagents/components needed for viral characterization), or Material

Transfer Agreements needed by the participating in-country partners (for example, if additional characterization cannot be safely carried out in-country and samples need to be sent regional or global laboratories);
- Provide training on biosafety/biosecurity, safe handling of samples/viruses, and characterization studies (if deemed to be appropriate in-country);
- Support in-country lab(s) with characterization studies on novel viruses from DEEP VZN or a limited number of prioritized viruses from other studies to assess their zoonotic and epidemic/pandemic potential;
- If newly identified viruses are shown to infect and cause pathology in human cell lines and there is interest by other labs (that have appropriate biosafety certification) to conduct additional studies, facilitate dialogue between the requesting lab(s) and the host country (researchers and government) regarding possible transfer of samples; and
- Support in-country partners in analyzing and interpreting data originating from characterization studies.

Objective 3 expected results:
- Lab and bioinformatics capacity for characterizing unknown viruses in select in-country institutions strengthened;
- Assessment of zoonotic and epidemic/pandemic potential for novel viruses conducted;
- Novel viruses ranked according to zoonotic and epidemic/pandemic potential; and
- Ability of select in-country laboratories to provide technical assistance and/or analyses for zoonotic and epidemic pandemic potential of novel viruses in-country and in the region improved.

Objective 4. Strengthen Focus Country Capacities for Data Management and the Viral Characterization Process

To date, many efforts related to viral detection and characterization have face numerous challenges. These include: limited scale (e.g. number of viruses and number of countries); findings often available only in publications (sometimes years after the work is completed or not in a form that can be used by others to take action); and resulting publications not always including in-country staff as lead authors. As a result, key data (e.g. genomic sequences, metadata, zoonotic and epidemic/pandemic potential) are often not included as part of global data sets in a timely manner or shared within countries. This limits their utility in influencing country and global decision making to support preparedness for disease outbreaks as well as development or updating of risk-mitigation measures, diagnostics, medicines, and vaccines. In addition, previous viral detection and characterization in low- and middle-income countries have not sufficiently emphasized strengthening of in-country staff and institutional research capacity to carry out (and publish) this work as well as support neighboring countries.

In order to highlight the importance of data and capacity strengthening under DEEP VZN, the two elements are included in a cross-cutting objective that is separate from sampling, detection, and characterization. The ultimate aim of strengthening in-country capacities for data management and the viral characterization process under DEEP VZN Objective 4 is to enhance country and regional abilities to conduct viral detection and characterization of unknown viruses in prioritized families and make the data available for use by others as quickly as possible. (Note:

for the purposes of this NOFO, the term “data management” is used broadly to describe an overall process that includes data collection, analysis, sharing, and storage.) DEEP VZN seeks to address not only the “data” gap related to awareness of future public health threats, but also the “research/implementation” gap by supporting in-country staff to disseminate actionable information to stakeholders in a form that is both relevant and timely. The skill sets strengthened for research, data management, and sampling, detection, characterization under DEEP VZN are easily adaptable to other pathogens.

DEEP VZN will work with the focus countries to identify and strengthen their ability to collect, analyze, store, and share findings within the country and with the global community. This includes data, findings, and analyses from Objectives 1, 2, and 3. As a guiding principle, in-country data systems will be used to avoid duplication and information will be shared across sectors to support a One Health approach. It may be desirable to identify key data sets that need to be collected across the DEEP VZN focus countries which may require the project to develop some augmentations to the in-country systems if this data currently is not collected and stored. In addition, linkages to global data sets will be established if they do not already exist. There is an expectation that publications related to DEEP VZN research will include host-country staff as lead authors. DEEP VZN will encourage participating researchers in the focus countries to interact in a virtual network in order to provide technical support. Focus countries may also decide to provide technical support to neighboring countries for testing samples relevant to DEEP VZN, including those from outbreaks of unknown etiology. Other networking opportunities for countries participating in DEEP VZN may be proficiency testing, simulations related to detecting unknown viruses, and joint research projects in coordination with FAO, OIE, WHO, and other organizations involved in setting standards and conducting research. USAID expects Applicants to be cognizant of existing networks to avoid duplication.

There is an expectation by USAID that data use and capacity strengthening under DEEP VZN will use the same or similar processes across focus countries, but that the actual details will be tailored according to the systems, capacities, and priorities of each focus country. USAID is not expecting DEEP VZN to create a new data system for all of the data generated by the project; rather, the project will use existing data systems in-country to increase the likelihood of sustainability and interoperability among sectors. According to USAID standard procedures for awards, the successful Applicant will be responsible for submitting all DEEP VZN data to the Development Data Library. Where possible, country DEEP VZN staff will be host-country nationals from the participating in-country institutions. At a minimum, all focus countries will have regular (at least semi-annually), multi-sectoral meetings with stakeholders in order to discuss DEEP VZN’s progress, findings, and future plans. As analyses of zoonotic and epidemic/pandemic potential of novel viruses become available throughout the project, DEEP VZN will support in-country and international multi-sectoral fora to share data so that other partners can update risk analyses (e.g. priority zoonotic diseases), surveillance, risk reduction interventions, diagnostics, medicines, and vaccines.

After award, the successful applicant will be expected to work with in-country partners to finalize the most-appropriate data management and capacity strengthening strategy/strategies and methods as well as other associated details. Please note that strategies or methodologies for data management and capacity strengthening may be added or removed, before or after award,

based on the availability of funds and at the discretion of USAID due to changing priorities, policies, or global health events.

Illustrative activities for Objective 4 include, but are not limited to:

- Support in-country institutions and staff in focus countries to develop a data management plan to include type of data to be collected, methods for analyzing and sharing, and mechanisms to storing.
- Support strengthening of sampling, viral detection, and characterization capacity for select staff and institutions in focus countries;
- Strengthen the capacity of in-county staff and institutions to publish research findings in peer-reviewed journals;
- Support the development of an inter-country DEEP VZN research network which may also include proficiency testing, simulation exercises, and research support for neighboring countries;
- Identify appropriate in-country mechanisms/processes for storing metadata, viral detection and characterization results (including genetic sequences), and analyses;
- Develop more-efficient processes to reduce the lag between viral detection and characterization and sharing the data with other partners for developing new tools for prevention, detection, and response to outbreaks;
- Identify international data sets and repositories and their mechanisms/processes that could be used for sharing genetic sequence data and other findings/analyses from DEEP VZN viral detection and characterization;
- Actively pursue opportunities to link data generated under DEEP VZN with international repositories and biohubs, leveraging discovery and characterization efforts for maximum utility to international community;
- In partnership with USAID and host governments post-award, explore opportunities with industry to leverage the pipeline of data and analyses generated that may be of utility in medical countermeasure research and development;
- Convene multi-sectoral fora to share virus detection and characterization findings, methodologies and protocols with in-country and international partners to include other DEEP VZN focus countries; and
- Calculate the total cost of the sampling, detection, and characterization under DEEP VZN for each country and share with in-country stakeholders, including government, private sector, and donors.

Objective 4 expected results:

- In-country capacity for viral detection and characterization strengthened;
- Inter-country research and technical networks established;
- Newly validated methodologies and protocols, data and analyses associated with viral detection and characterization shared (in-country and internationally, including through peer-reviewed publications);
- External partners working on prevention, detection, and response to emerging viral zoonoses have timely access to data from DEEP VZN; and
- Cost of in-country viral characterization processes calculated and shared.

5. Collaboration with Other USAID/External Partners

USAID anticipates that the successful DEEP VZN applicant may engage with and leverage USAID's GHS portfolio, the Bureau for Global Health and other USAID bureaus/offices in Washington, and with missions. The partner landscape presented below is intended to illustrate the breadth of collaborative opportunities related to the DEEP VZN mandate. The DEEP VZN implementing partner will be expected to leverage complementary work, where relevant, but Applicants are not asked to identify links with each of these organizations and activities at this time. Examples of potential areas of collaboration include:

- One Health research;
- laboratory strengthening;
- risk reduction;
- safer wildlife value chains;
- data and information management systems;
- bio-banking;
- gender; and
- private sector and community engagement.

The Bureau for Global Health has recently issued six awards:

- Infectious Disease Detection and Surveillance (IDDS), led by ICF International. IDDS focuses on strengthening disease detection networks and surveillance systems. Opportunities for collaboration between DEEP VZN and IDDS may include improving detection of emerging zoonotic viruses.
- Medicines, Technologies, and Pharmaceutical Services (MTaPs), led by Management Sciences for Health (MSH). MTaPs is helping low- and middle-income countries to strengthen their pharmaceutical systems to ensure sustainable access to and appropriate use of safe, effective, quality-assured, and affordable essential medicines, other health technologies and medicines-related pharmaceutical services. DEEP VZN may find areas of collaboration with the MTaPS project in the area of informing its infection prevention and control efforts.
- One Health Workforce-Next Generation (OHW-NG), led by the University of California-Davis. OHW-NG enhances the capacity of university networks and their member institutions in Africa and Southeast Asia to develop and deliver training and programs that build the capacity of national ministries and the private sector to prevent and quickly respond to disease threats across human, animal, and environment sectors. DEEP VZN may find opportunities to collaborate with OHW-NG in conducting research in coordination with the One Health university networks and faculty and student training opportunities.
- STOP Spillover, led by Tufts University. STOP Spillover will assist countries in Africa and Asia to reduce spillover, amplification, and spread of known emerging zoonotic viruses. DEEP VZN may collaborate with STOP Spillover by identifying and prioritizing novel viruses for inclusion in the latter's surveillance and risk-reduction activities.
- Coalition for Epidemic Preparedness Innovations (CEPI). The grant to support CEPI focuses on the organization's overall mission to accelerate the development of vaccines against emerging infectious diseases and enable access to these vaccines during outbreaks. DEEP VZN may find opportunities to collaborate with this project particularly in developing and updating vaccines for emerging zoonotic viruses.

- Transformational Strategies for Farm Output Risk Mitigation (TRANSFORM), led by Cargill [26]. TRANSFORM is supporting development of market-driven solutions to improve biosecurity along animal value chains in order to reduce the spread of emerging zoonotic diseases. DEEP VZN may have opportunities to collaborate with TRANSFORM by identifying and prioritizing novel viruses for inclusion in the latter's surveillance and risk-reduction activities.

USAID also invests in activities implemented by Johns Hopkins Center for Communication Programs (CCP) through the Breakthrough-ACTION project, guiding new learning and driving broader application of proven practices and tools in social and behavior change. DEEP VZN may find opportunities to collaborate with this project particularly in informing risk communications related to reducing risk of viral spillover. USAID Missions may also opt to invest additional funding in DEEP VZN.

DEEP VZN also is expected to coordinate with U.S. Government partner agencies that work on related One Health activities, including the U.S. Centers for Disease Control and Prevention (CDC), the Defense Advanced Research Projects Agency (DARPA), Defense Threat Reduction Agency (DTRA), the U.S. Department of Defense/Global Emerging Infections Surveillance (GEIS), the National Institutes of Health, and the US Department of Agriculture. These agencies have a long history of supporting surveillance, labs, training, and research related to animal and human infectious diseases, including ones that are zoonotic. DEEP VZN activities must clearly complement and not compete with this programming. The IAVI ADVANCE initiative includes a HIV genomic sequencing project which is being leveraged for COVID-19 [27].

International Organizations. The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), which have been key partners under USAID's GHS portfolio, are working to strengthen the public sector's capacity to prepare, prevent, detect and respond to emerging threats including zoonotic diseases and antimicrobial resistance. Work includes strengthening core capacities in surveillance, laboratory methods and analysis, multisectoral coordination, biosecurity and biosafety in labs and farms, infection prevention and control, and outbreak investigation. DEEP VZN should leverage strategies, methods, and tools developed and used by these organizations, avoid duplication and may work with FAO to further develop local research capacity in these areas by providing in-service training opportunities for practical field and laboratory experience. As part of a whole-of-society, all hazards approach, the International Federation of Red Cross Red Crescent Societies (IFRC) is working to strengthen community-level epidemic and pandemic preparedness. DEEP VZN could work with the IFRC and its National Societies to improve community-based monitoring of emerging zoonotic diseases and community preparedness for outbreaks of zoonotic diseases.

Bilateral and Multilateral Community. USAID anticipates that DEEP VZN may find opportunities to collaborate with other bilateral and multilateral partners, e.g. Bill and Melinda Gates Fund Zoonotic Hubs. The Australian Government's Health Security Initiative for the Indo-Pacific region was launched in 2017 to support the prevention and containment of infectious disease threats with the potential to cause social and economic harms on a national, regional or global scale. Through 2019, the Australian Department of Foreign Affairs and Trade (DFAT) contributed AUD$6 million through USAID programs to enhance prevention, detection and

response to emerging infectious disease and AMR threats in the Mekong sub-region in Asia. Additionally, the World Bank has expressed interest in economic analyses of emerging diseases and supporting detection and response for outbreaks.

Other Collaborating Partners. In addition to the organizations listed above, DEEP VZN may collaborate with others engaged in One Health and related work, such as the World Organization for Animal Health (OIE), and regional development banks. These engagements would create opportunities to collaborate on research, risk analyses, and risk reduction.

Monitoring, Evaluation and Learning. DEEP VZN will include a comprehensive monitoring, evaluation and learning (MEL) plan that clearly indicates the results that will be achieved during the life of the activity, relevant targets, sensible performance indicators, and a process for integrating learning into activity implementation. As appropriate, indicators should be culturally- and gender-sensitive and responsive. The MEL plan will also include data sources, methods and frequency of data collection, quality assurance procedures, and a process for how data will be analyzed, disseminated and used to inform activity planning, implementation and improvement. The proposed MEL framework must be aligned with agency priorities, including the U.S. Global Health Security Strategy (https://www.whitehouse.gov/wp-content/uploads/2019/05/GHSS.pdf). An important component of DEEP VZN will be the development of a learning agenda to identify and address specific knowledge gaps related to activity implementation and viral discovery and characterization. The learning agenda should include a set of questions that will be addressed during the activity, a process for addressing each of these questions, and a plan to disseminate (to specific institutions) and use findings to improve activity implementation and improve the efficiency and cost-effectiveness of viral discovery and characterization.

Gender. DEEP VZN will align with Agency-wide commitments mandated by the USAID Gender Equality and Female Empowerment Policy with the intent to support 23 sustainable development outcomes. USAID conducted a contextual gender analysis that considered existing data (from EPT-1, EPT-2, GHSA, others), tools, and remaining gaps in knowledge on spillover risk of emerging zoonotic viruses in high-risk animal or human populations and along high-risk chains of transmission. The analysis revealed that although males and females are similarly susceptible, biologically, to emerging disease threats, the impact of those infections is experienced differently by each group. The variability in gender constraints, such as roles and responsibilities, patterns of decision-making power, and cultural gender-related norms and beliefs affect men's and women's ability to change risky behaviors surrounding emerging disease threats and risk-reduction interventions. DEEP VZN acknowledges the gendered nature of inequitable access to healthcare and differences in risk profiles and cultural norms that place an extra burden on women to collect and prepare food as well as provide care (including caring for sick family members in addition to general care in the household). The underlying disparities in household duties and healthcare access and disadvantaged socioeconomic status can translate into increased risk of disease and the lack of women's participation in health programs, research, outreach and education, One Health training, and animal health resources. Thus, this activity will support gender-responsive and culturally-appropriate research relevant to women, girls, men, and boys related to their exposure to viruses of wildlife origin along high-risk chains of transmission. The research findings will be integrated by other partners into risk mitigation efforts, therefore directly impacting gender and sex-specific risks. It is expected that the DEEP VZN

implementing partner will conduct a thorough assessment of the context (barriers/obstacles, incentives, and any other enabling factors) and gender considerations that need to be addressed and provide a Gender Action Plan/Strategy to ensure that gender-sensitive approaches are integrated into programmatic operations in each country context. Women's empowerment and reducing gender inequality and discrimination should also be monitored as a critical component of the program's performance management plan. The research under DEEP VZN and related training will incorporate mapping gaps in knowledge, on-going analysis, and addressing unintended consequences for women, girls, men, and boys.

Climate Risk Management. Climate risk management (CRM) is required for all USAID-supported activities, with limited exceptions (see ADS 201 Mandatory Reference, https://www.usaid.gov/ads/policy/200/201mal). Climate risk is the potential for negative consequences on activity objectives and/or outcomes due to changing climatic conditions. Climate risks can be manifested through potentially severe adverse consequences for development programs resulting from the interaction of climate-related hazards with the vulnerability of societies and systems. A climate risk may arise when an activity element, target, or beneficiary is exposed to a climate hazard such as higher temperatures, flooding, or drought. USAID will work with the successful applicant to identify climate risks that can affect the successful implementation of this program. The successful applicant will be encouraged to complete the Climate Risk Tool for any activities that meet the moderate to high risk rating. Per instructions in the award documentation, the successful applicant will be expected to ensure that subgrantees and subcontractors have the capability to implement CRM. The successful applicant will, if appropriate, provide orientation to subgrantees and subcontractors on climate risk management. Per Mandatory Reference for ADS Chapter 201 Climate Risk Management for USAID Projects and Activities, the successful applicant may integrate "documentation" of the benefits of taking action to reduce climate change impacts and/or increase adaptive capacity" in their performance monitoring in program elements with moderate or high risk ratings.

Notes:

[1] Includes Hendra (1994), Nipah (1997), H5N1 avian influenza (1997), SARS-CoV-1 (2002), H1N1 influenza (2009), MERS-CoV (2012), H7N9 avian influenza (2013), and SARS-CoV-2 (2019). Cumulative human deaths from these viruses alone have totaled more than 3.2 million as of April 18, 2021. Sources: CDC, WHO.

[2] https://www.sciencedirect.com/science/article/pii/S235277141830034X?via%3Dihub

[3] As of April 18, 2021. Source: https://covid19.who.int/

[4] Throughout this document, "high-risk" is used to refer to locations, populations, and animal-animal or animal-human interfaces where there is an increased probability of spillover, amplification, or spread of emerging zoonotic viruses due to the presence of specific types of viruses, animals, behaviors, and conditions. For the purposes of this document: "spillover" is defined as an event in which an emerging zoonotic virus is transferred from one animal host (livestock or wildlife) to another or to humans; "amplification" is defined as an increase in the

number of copies of a zoonotic virus either within animal or human populations; and "spread" refers to an increase in the geographic distribution of a zoonotic virus.

[5] For the purposes of the DEEP VZN activity, "wildlife" shall include terrestrial species that may act as a host or reservoir for the transmission of zoonotic viruses to humans, and does not include captive zoo animals, fish and aquatic species, insects, plants, or domesticated animals such as dogs or cats. Wildlife species are the sources of many of the highly-lethal emerging zoonotic viruses that repeatedly and sporadically spill over into other wildlife, livestock, and humans and are generally poorly controlled in human populations once spillover occurs.

[6] "Multisectoral" refers to a broad coalition of partners that are needed for addressing emerging zoonotic viruses using an approach (i.e. "One Health") that considers the health of people, animals, and the environment. These partners may include public health, livestock, wildlife, public and private sectors, academia, and NGOs.

[7] https://www.whitehouse.gov/wp-content/uploads/2019/05/GHSS.pdf

[8] As a result of the 2014-2016 Ebola epidemic in West Africa and the launching of the Global Health Security Agenda in 2014, EPT-2 included countries in West Africa.

[9] Egypt and Jordan were included in EPT-2 in order to conduct Middle East Respiratory Syndrome coronavirus (MERS-CoV) surveillance.

[10] Influenzas, coronaviruses, filoviruses, and paramyxoviruses. All of these viral families include multiple members that have caused epidemics and/or pandemics.

[11] Global Trends in Emerging Infectious Diseases, Jones, et al., Nature, 2008, Vol 451: pp 990-994.

[12] https://www.imf.org/en/Publications/WEO/Issues/2020/09/30/world-economic-outlook-october-2020

[13] https://science.sciencemag.org/content/359/6378/872.full

[14] STOP Spillover press release: https://www.usaid.gov/news-information/press-releases/sep-30-2020-usaid-announces-new-100-million-project-threats-emerging-infectious

[15] https://www.biorxiv.org/content/10.1101/2020.05.31.116061v1.full

[16] https://jvi.asm.org/content/jvi/86/7/3995.full.pdf

[17] https://www.biorxiv.org/content/10.1101/2020.06.05.098590v3

[18] https://link.springer.com/article/10.1186/s42522-019-0008-8

[19] To improve surveillance, data will be made available to inform aligned activities (if available in the same country), e.g. FAO, IDDS, STOP Spillover, TRANSFORM, and WHO. For reducing spillover, data will be made available for USAID-supported efforts under STOP Spillover, TRANSFORM, FAO, Breakthrough Action, and Breakthrough Research.

[20] CEPI (https://cepi.net/), U.S. National Institutes of Health (https://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens), WHO Research and Development framework (https://www.who.int/research-observatory/analyses/rd_blueprint/en/).

[21] https://www.ecohealthalliance.org/wp-content/uploads/2017/10/s41467-017-00923-8.pdf

[22] http://documents1.worldbank.org/curated/en/961101524657708673/pdf/122980-REVISED-PUBLIC-World-Bank-One-Health-Framework-2018.pdf

[23] https://www.frontiersin.org/articles/10.3389/fpubh.2020.555013/full?&utm_source=Email_to_authors_&utm_medium=Email&utm_content=T1_11.5e1_author&utm_campaign=Email_publication&field=&journalName=Frontiers_in_Public_Health&id=555013

[24] https://www.nature.com/articles/srep14830

[25] https://www.who.int/emergencies/diseases/novel-coronavirus-2019, https://www.oie.int/en/scientific-expertise/specific-information-and-recommendations/questions-and-answers-on-2019novel-coronavirus/events-in-animals/

[26] https://www.usaid.gov/news-information/press-releases/apr-1-2021-usaid-engages-private-sector-global-health-security-efforts

[27] https://www.iavi.org/our-work/clinical-epidemiology-research/advance

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SECTION B: FEDERAL AWARD INFORMATION

1. Estimate of Funds Available and Number of Awards Contemplated

USAID intends to award one (1) Cooperative Agreement pursuant to this notice of funding opportunity. Subject to funding availability and at the discretion of the Agency, USAID intends to provide up to $125,000,000USD in total USAID funding over a five (5) year period. This Activity will be incrementally funded over the life of the Activity, subject to the availability of funds. However, USAID reserves the right to make more than one award under this NOFO.

2. Start Date and Period of Performance for Federal Awards

The anticipated period of performance is five (5) years. The estimated start date will be upon signature of the award, on or around October 1, 2021.

3. Substantial Involvement

USAID's substantial involvement during the implementation of this Agreement will be limited to the elements listed below:

a. Approval of the Recipient's Annual Implementation Plans:

Implementation plans include, but are not limited to, annual work plans, including planned activities for the following year and any subsequent revisions, international travel plans, planned expenditures, event planning/management, international meeting preparation.

USAID requires the approval of implementation plans annually to ensure alignment with stated goals, milestones and outputs. The implementation plan communicates how and when the recipient will complete project activities and is drafted annually to describe new activities. This plan will be developed in partnership between the recipient and the AOR team. The AOR will ensure that the implementation plans fit within the scope, terms and conditions of the agreement.

b. Approval of Specified Key Personnel:

Designation of key personnel positions, approval of key personnel and any changes for the positions listed below:

- Project Director
- Deputy Project Director/Operational Lead

All individuals proposed as Key Personnel in the Recipient's application are hereby approved. Any future approval of key personnel will be authorized by a separate administrative letter. The Recipient must submit, reasonably in advance, any proposed replacement (including proposed substitutions) along with written justification in sufficient detail to permit evaluation of the impact on the program. No replacement shall be made by the Recipient without the written consent of the Agreement Officer.

c. Agency and Recipient Collaboration or Joint Participation:

- Collaborative involvement in the selection of advisory committee members, if the recipient establishes an advisory committee that provides advice to the recipient. The AOR may participate as a member of this committee. Advisory committees must only deal with programmatic or technical issues and not routine administrative matters.
- Collaborative involvement in the selection of countries, viruses, and interfaces.
- USAID review and approval of monitoring, evaluation, and learning plans.
- USAID review and approval of data management plans.
- USAID involvement in the substantive direction/re-direction of interrelationships with other projects.
- USAID involvement in monitoring progress toward achievement of the Objectives and Expected Achievements during the course of the Agreement(s) and in monitoring of financial expenditures.

d. Direction and Redirection:

USAID will be involved in the substantive direction/re-direction of inter-relationships with other projects.

4. Authorized Geographic Code

The geographic code for the procurement of commodities and services under this program is 935 (any area or country, except for "prohibited sources").

5. Nature of the Relationship between USAID and the Recipient

The principal purpose of the relationship with the Recipient and under the subject program is to transfer funds to accomplish a public purpose of support or stimulation of the DEEP VZN which is authorized by Federal statute. The successful Recipient will be responsible for ensuring the achievement of the program objectives and the efficient and effective administration of the award through the application of sound management practices. The Recipient will assume responsibility for administering Federal funds in a manner consistent with underlying agreements, program objectives, and the terms and conditions of the Federal award.

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SECTION C: ELIGIBILITY INFORMATION

1. Eligible Applicants

Eligibility for this NOFO is not restricted.

USAID welcomes applications from organizations that have not previously received financial assistance from USAID.

2. Cost Sharing or Matching

USAID has established a suggested cost share of 5% for the Recipient of the award. Such funds may be mobilized from the Recipient; other multilateral, bilateral, and foundation donors; host governments; and local organizations, communities and private businesses that contribute financially and in-kind to implementation of activities at the country level. This may include contribution of staff level of effort, office space or other facilities or equipment which may be used for the program, provided by the recipient. For guidance on cost sharing in grants and cooperative agreements see 2 CFR 200.306. If proposed, the cost-sharing plan should be discussed in the Budget Narrative to the extent necessary to demonstrate its feasibility and applicability to the program.

3. Other

An applicant may submit only one application under this NOFO.

RISK ASSESSMENT

In order for an award to be made, the USAID Agreement Officer must evaluate the risks posed by applicants as outlined in 2 CFR 200.205 and ADS 303.3.9. This means that the applicant must possess, or must have the ability to obtain, the necessary management and technical competence to conduct the proposed program, and must agree to practice mutually agreed-upon methods of accountability for funds and other assets provided or funded by USAID.

In evaluating the risks posed by applicants, the Federal Awarding Agency uses a risk-based approach and may consider:

1. Financial stability;

2. Quality of management systems and ability to meet the management standards prescribed in this part;

3. History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal

awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;

4. Reports and findings from audits performed under Subpart F—Audit Requirements of this part or the reports and findings of any other available audits;

5. The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities; and

6. That applicant is otherwise qualified to receive an award under applicable laws and regulations (e.g., Nondiscrimination, Lobbying, Debarment/Suspension, Terrorist Financing, etc.).

In the absence of a positive risk assessment, an award can ordinarily not be made. Awards to potential new partners may be significantly delayed if USAID must undertake necessary pre-award reviews of these organizations to make an adequate risk assessment. These organizations should take this into account and plan their implementation dates and activities accordingly.

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SECTION D: APPLICATION AND SUBMISSION INFORMATION

1. Agency Point of Contact

For submission of Questions and Applications: deepvzn@usaid.gov.

2. Questions and Answers

Questions regarding this NOFO should be submitted to deepvzn@usaid.gov no later than the date and time indicated on the cover letter, as amended. Any information given to a prospective applicant concerning this NOFO will be furnished promptly to all other prospective applicants as an amendment to this NOFO, if that information is necessary in submitting applications or if the lack of it would be prejudicial to any other prospective applicant.

3. General Content and Form of Application

Preparation of Applications:

Each applicant must furnish the information required by this NOFO. Applications must be submitted in two separate parts: the Technical Application and the Business (Cost) Application. This subsection addresses general content requirements applying to the full application. Please see subsections 5 and 6, below, for information on the content specific to the Technical and Business (Cost) applications. The Technical application must address *technical aspects only* while the Business (Cost) Application must present the costs, and address risk and other related issues.

Both the Technical and Business (Cost) Applications must include a cover page containing the following information:

- Name of the organization(s) submitting the application;
- Identification and signature of the primary contact person (by name, title, organization, mailing address, telephone number and email address) and the identification of the alternate contact person (by name, title, organization, mailing address, telephone number and email address);
- Program name;
- Notice of Funding Opportunity number;
- Date of Submission; and
- Name of any proposed sub-recipients or partnerships (identify if any of the organizations are local organizations, per USAID's definition of 'local entity' under ADS 303).

Any erasures or other changes to the application must be initialed by the person signing the application. Applications signed by an agent on behalf of the applicant must be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

Applicants may choose to submit a cover letter in addition to the cover pages, but it will serve only as a transmittal letter to the Agreement Officer. The cover letter will not be reviewed as part of the merit review criteria.

Applications must comply with the following:

- USAID will not review any pages in excess of the page limits noted in the subsequent sections. Please ensure that applications comply with the page limitations.
- Written in English
- Use standard 8 ½" x 11", single sided, single-spaced, 12 point Times New Roman font, 1" margins, left justification and headers and/or footers on each page including consecutive page numbers, date of submission, and applicant's name.
- 10 point font can be used for graphs, tables and charts. In the event that a graph, chart, or figure cannot be edited or easily recreated, another legible font is acceptable.
- Submitted via Microsoft Word or PDF formats, except budget files which must be submitted in Microsoft Excel.
- The estimated start date identified in Section B of this NOFO must be used in the cost application.
- The technical application must be a searchable and editable Word or PDF format as appropriate.
- The Cost Schedule must include an Excel spreadsheet with all cells unlocked and no hidden formulas or sheets. A PDF version of the Excel spreadsheet may be submitted in addition to the Excel version at the applicant's discretion, however, the official cost application submission is the unlocked Excel version.

Applicants must review, understand, and comply with all aspects of this NOFO. Failure to do so may be considered as being non-responsive and may be evaluated accordingly. Applicants should retain a copy of the application and all enclosures for their records.

4. Application Submission Procedures

Applications in response to this NOFO must be submitted no later than the closing date and time indicated on the cover letter, as amended. Late applications will not be reviewed nor considered . Applicants must retain proof of timely delivery in the form of system generated documentation of delivery receipt date and time/confirmation from the receiving office/certified mail receipt.

Applications must be submitted by email to deepvzn@usaid.gov. Email submissions must include the NOFO number, applicant's name in the subject line heading and whether the email relates to the technical or cost application. In addition, for an application sent by multiple emails, the subject line must also indicate the desired sequence of the emails and their attachments (e.g. "No. 1 of 4", etc.). For example, if your cost application is being sent in two emails, the first email should have a subject line that states: "[NOFO number], [organization name], Cost Application, Part 1 of 2".

USAID's preference is that the technical application and the cost application each be submitted as consolidated email attachments, e.g. that you consolidate the various parts of a technical

application into a single document before sending it. If this is not possible, please provide instructions on how to collate the attachments. USAID will not be responsible for errors in compiling electronic applications if no instructions are provided or are unclear.

After submitting an application electronically, applicants should immediately check their own email to confirm that the attachments were indeed sent. If an applicant discovers an error in transmission, please send the material again and note in the subject line of the email or indicate in the file name if submitted via grants.gov that it is a "corrected" submission. Do not send the same email more than once unless there has been a change, and if so, please note that it is a "corrected" email.

Applicants are reminded that email is NOT instantaneous, and in some cases delays of several hours occur from transmission to receipt. Therefore, applicants are requested to send the application in sufficient time ahead of the deadline. For this NOFO, the initial point of entry to the government infrastructure is the USAID mail server.

There may be a problem with the receipt of *.zip files due to anti-virus software. Therefore, applicants are discouraged from sending files in this format as USAID cannot guarantee their acceptance by the internet server. File size must not exceed 10MG per email.

5. Technical Application Format

The technical application will be the most important factor in selecting the awardee for the proposed cooperative agreement. The technical application should be specific, complete, and concise. The application must demonstrate the applicant's capabilities and expertise with respect to achieving the goals, objectives, and expected results of this Activity. The application should take into account the requirements of the program and merit review criteria found in this NOFO.

The narrative for the technical application must be no more than 25 pages. Pages exceeding this limit will not be evaluated. The cover page, acronyms list, table of contents, executive summary, and required annexes are not subject to the page limitation. Any figures and tables within the technical application (not the annexes) must fit within the 25 page limit. Annexes not specifically required in this NOFO will not be evaluated.

The format of the technical application must follow the outline and order specified below.

(a) Cover Page (See Section D.3 above for requirements) (not included in the 25 page limit)
(b) Acronyms (not included in the 25 page limit)
(c) Table of Contents (not included in the 25 page limit)
Include major sections and page numbering to easily cross-reference and identify merit review criteria.
(d) Executive Summary (One page) (not included in the 25 page limit)
The Executive Summary must provide a high-level overview of key elements of the Technical Application.

(e) Technical Understanding and Proposed Approach

The applicant must submit a technical approach describing how it will achieve the objectives and expected results of the DEEP VZN program description in approximately 12 countries in three different regions. For the purposes of the NOFO, applicants should assume they will have to work in up to 5 countries in Africa, up to 5 countries in Asia, and up to 2 countries in Central/South America.

The Applicant must consider the Program Description in its entirety and provide a clear description of its proposed approach, spelling out a credible and feasible strategy for successfully implementing all four (4) of DEEP VZN's objectives. To make the best use of the available space, applicants are encouraged to not repeat back information that is already in the NOFO in terms of background or justification for the project.

The proposed technical approach must be clear, succinct, and feasible to support in-country institutions to detect and characterize unknown viruses with zoonotic and epidemic/pandemic potential along high-risk chains of transmission in order to provide data which is publicly shared with other partners for development of tools for prevention, detection, and response of emerging zoonotic viruses. The proposed approach must address the challenges, limitations, and opportunities associated with implementing DEEP VZN as well as the varying local, gender, and cultural contexts that need to be considered. In an Annex (3 pages maximum; not included in the 25-page limit), Applicants must include an implementation timeline to illustrate the proposed timing and sequencing of global- and country-level activities under the 4 objectives.

The following must be included in the section on Technical Understanding and Proposed Approach:

1. An overall approach that describes:
    a. how the applicant will achieve the overarching goal, four (4) objectives, and results
    b. how the proposed technical approach will measurably enhance the scale, efficiency, and efficacy of sampling as well as viral discovery and characterization
    c. how the applicant will make decisions on adjusting sampling sites throughout the project and which viruses detected will be prioritized for characterization; if desired, a visual of this process--such as a "decision tree"--can can be submitted in an annex (maximum of 2 pages; not included in the 25-page limit).
    d. an illustrative plan for overall data collection, storage, dissemination, and usage to include the types of data, the processes that will be used, how and when the data will be shared with USAID.

e. a plan to promote capacity strengthening and ownership to include how the Applicant will support the participation of in-country staff in research publications.
f. a sample Monitoring, Evaluation and Learning (MEL) plan that includes results to be achieved, relevant targets, indicators (for outputs, outcomes, and impacts), and a process for integrating learning into activity implementation. This section must also include a learning agenda detailing a set of proposed questions to address during the activity, a process for addressing each of these questions, and a plan to disseminate and use findings to improve activity implementation.

f) Management Approach

The Management Plan must include the following:

a. A concise description of the roles for each consortium partner or sub-recipient and their associated technical capacities and how these capacities would be used under DEEP VZN

b. A clear description of the proposed lines of authority among the prime, other consortium partners, and sub-recipients and a description of the division of roles and responsibilities between these partners as well as other technical or resource organizations

c. A clear approach to managing technical and financial reporting, project logistics, and procurement issues while taking advantage of each organization's strengths, emphasizing cost effectiveness, and avoiding duplication of efforts

d. A clear plan outlining how communications will be managed among the consortium partners and sub-recipients as well as with in-country and external stakeholders to include USAID/Washington, USAID Missions, host governments, academia, research institutions, private sector, NGOs, communities, donors, etc.

e. In an Annex (not included in the 25-page limit), Applicants must include an organizational chart (to include the country teams) to illustrate the proposed management structure.

g) Staffing Plan and Key Personnel

Staffing Plan: Applicants are expected to develop a comprehensive staffing plan to enable successful achievement of all of the DEEP VZN objectives and results described in the Program Description.

The applicant must describe a staffing plan for all staff (both Key Personnel and non-Key Personnel) that demonstrates an appropriate balance of skills, expertise, experience, and staff time across the prime, consortium partners, and sub-recipients to achieve the objectives of DEEP VZN. The staffing plan must include a narrative description that explains how the applicant's proposed combination of key personnel and other long-term and short-term staff will collectively possess the required technical and management expertise and skills to lead the activities and deliver the results expected. The staffing plan must also demonstrate efficient use of resources. In addition, the applicant must describe how it will ensure that there is gender balance among the country-based staff, how it will ensure a high percentage of these staff will be from the host country, and how these staff can be most-effectively embedded in in-country institutions.

As part of the proposed staffing plan, the applicant must include an annex with a table (no more than 3 pages which does not count against the 25-page limit for the technical application) that identifies all staff positions, the percentage of time that each staff member would work on DEEP VZN, their areas of expertise, and their geographic regions of focus.

Key Personnel. Key personnel are those individuals whose performance is critical to the success of DEEP VZN. The applicant shall designate two (2) key personnel, one for each of the positions listed below.

- Project Director
- Deputy Project Director/Operational Lead

Applicants may propose additional key personnel if they choose to do so. If this is the case, the applicant must state the proposed position, the roles and responsibilities, and the minimum qualifications. In addition, applicants must provide CV/resume and letter of commitment as required for all key personnel.

In the main body of the application, at a minimum, applicants must describe, for each of the proposed Key Personnel positions, the applicant's rationale for proposing the individual and explain how the Key Personnel complement each other's skills and qualifications in a manner that will result in a strong, balanced and highly qualified team.

In the annexes (not included in the 25-page limit), the applicant must submit the following documents for each Key Personnel candidate:

- Current CV/resume (maximum 5 pages for each of the Key Personnel) including:
    - all professional work experience with start and end dates (month and year);
    - the names of three (3) professional references, who are not employed by the prime applicant or any of the subcontractors, with contact information (email and telephone number);

- Signed statement of commitment, confirming immediate availability from each Key Personnel candidate (maximum 1 page for each individual).

Key Personnel Qualifications

Project Director: The applicant must designate a full-time Project Director who will serve as the main point of contact for DEEP VZN and provide vision, direction, leadership, management, and outreach for the activity. S/he will serve as the applicant's primary representative for all agreement-related issues, concerns, or problems.

The proposed Project Director must have:

- Master's degree or higher degree in a relevant field;
- At least ten (10) years of demonstrated relevant experience within an international development context, and a demonstrated ability to create and maintain effective working relations with international organizations; US Government agencies; and NGO partners, private sector partners, and host country governments (including senior government officials) in developing countries;
- Minimum of five (5) years of demonstrated senior-level leadership experience (e.g. Chief of Party, Project Director, Principle Investigator, Deputy Director) for infectious disease programs of similar magnitude and complexity; and
- Fluency in English oral and written communication.

Deputy Project Director/Operational Lead: The applicant must designate a full-time Deputy Project Director/Operational Lead who will serve as the secondary point of contact for DEEP VZN, providing back-up support to the Project Director and managing the day-to-day operations to include staffing, finances, sub-awards, and communications. S/he will serve as the applicant's secondary representative for all agreement-related issues, concerns, or problems.

The proposed Deputy Project Director/Operational Lead must have:

- Master's degree or higher degree in a relevant field;
- At least seven (7) years of demonstrated relevant experience within an international development context, and a demonstrated ability to create and maintain effective working relations with international organizations; US Government agencies; and NGO partners, private sector partners, and host country governments (including senior government officials) in developing countries;
- Minimum of three (3) years of demonstrated senior-level leadership (e.g. Chief of Party or Project Director, Principle Investigator, Deputy Director) for health development programs; and
- Fluency in English oral and written communication.

h) Annexes (not included in the 25-page limit)

The annexes must include:

- Organizational chart (maximum 2 pages)
- Implementation timetable to show the timing and sequencing of proposed activities under each of the 4 objectives (maximum 3 pages)
- Illustrative, country-specific plans for Peru, Senegal, and Vietnam (maximum 6 pages per country). (Note: the total of 18 pages for the illustrative country plans are not part of the 25-page limit for the Technical Application). Each country plan must include the following information:
    - a description--organized by the 4 DEEP VZN objectives--of what transmission chains would be prioritized; what activities would be carried out; where, when, how, and how often activities would be carried out; who will conduct the activities (please specify roles of proposed external and in-country partners); and the technical justification and any assumptions for why these choices were made;
    - a description of the proposed in-country DEEP VZN team (e.g, number of individuals, functions, location, etc.); and
    - an estimate for the cumulative number of samples collected, viruses sequenced, and characterization studies over the five (5) years of DEEP VZN.
- Staffing Table (maximum 3 pages)
- Key Personnel CVs (maximum 5 pages per individual)
- Key Personnel Letters of Commitment (maximum 1 page per individual)
- If applicable, Consortium Partner and/or Sub-Recipients Letters of Commitment (maximum 2 pages per letter) -- **not required for in-country partners**

DO NOT SUBMIT promotional literature and materials regarding the applicant or any of the proposed consortium partners and/or sub-recipients, and/or other unsolicited material. Additional annexes to the Technical Application will not be reviewed.

6. Business (Cost) Application Format

The Business (Cost) Application must be submitted separately from the Technical Application. While no page limit exists for the full cost application, applicants are encouraged to be as concise as possible while still providing the necessary details. The business (cost) application must illustrate the entire period of performance, using the budget format shown in the SF-424A.

Prior to award, applicants may be required to submit additional documentation deemed necessary for the Agreement Officer to assess the applicant's risk in accordance with 2 CFR 200.205. Applicants should not submit any additional information with their initial application.

The Cost Application must contain the following sections (which are further elaborated below this listing with the letters for each requirement):

a) Cover Page (See Section D.3 above for requirements)

b) SF 424 Form(s)

The applicant must sign and submit the cost application using the SF-424 series at https://www.grants.gov/web/grants/forms/sf-424-family.html. Standard Forms can be accessed electronically at www.grants.gov or using the following links:

Instructions for SF-424	https://apply07.grants.gov/apply/forms/instructions/SF424_2_1-V2.1-Instructions.pdf
Application for Federal Assistance (SF-424)	https://apply07.grants.gov/apply/forms/sample/SF424_2_1-V2.1.pdf
Instructions for SF-424A	https://apply07.grants.gov/apply/forms/instructions/SF424A-V1.0-Instructions.pdf
Budget Information (SF-424A)	https://apply07.grants.gov/apply/forms/sample/SF424A-V1.0.pdf
Instructions for SF-424B	https://apply07.grants.gov/apply/forms/instructions/SF424B-V1.1-Instructions.pdf
Assurances (SF-424B)	https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf'

Failure to accurately complete these forms could result in the rejection of the application.

c) Required Certifications and Assurances

The applicant must complete the following documents and submit a signed copy with their application:

(1) "Certifications, Assurances, Representations, and Other Statements of the Recipient" document found at https://www.usaid.gov/sites/default/files/documents/1868/303mav.pdf
(2) Assurances for Non-Construction Programs (SF-424B)
(3) Certificate of Compliance: Please submit a copy of your Certificate of Compliance if your organization's systems have been certified by USAID/Washington's Office of Acquisition and Assistance (M/OAA).

d) Budget and Budget Narrative

The detailed Budget must be submitted as one unprotected Excel file (MS Office 2000 or later versions) with visible formulas and references and must be broken out by project year, including itemization of the federal and non-federal (cost share) amount. Files must not contain any hidden or otherwise inaccessible cells. Budgets with hidden cells lengthen the cost analysis time required to make award, and may result in a rejection of the cost application. The Budget Narrative must contain sufficient detail to allow USAID to understand the proposed costs. The applicant must ensure the budgeted costs address any additional requirements identified in Section F, such as Branding and Marking. The Budget Narrative must be thorough, including

sources for costs to support USAID's determination that the proposed costs are fair and reasonable.

The Budget must include the following worksheets or tabs, and contents, at a minimum:

- Summary Budget, inclusive of all program costs (federal and non-federal), broken out by major budget category and by year for activities implemented by the applicant and any potential sub-applicants for the entire period of the program.
- Detailed Budget, including a breakdown by year, sufficient to allow the Agency to determine that the costs represent a realistic and efficient use of funding to implement the applicant's program and are allowable in accordance with the cost principles found in 2 CFR 200 Subpart E.
- Detailed Budgets for each major* sub-recipient, for all federal funding and cost share, broken out by budget category and by year, for the entire implementation period of the project.
- Detailed budgets for each of the 3 countries listed above (Peru, Senegal, and Vietnam) reflecting the proposed activities and office sizes, start and end dates.

*Major sub-recipient is defined as any entity receiving 20% or more of the total estimated budget.

A sample summary budget is shown below:

Cost Element	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Salaries and Wages						
Fringe Benefits						
Travel						
Equipment						
Supplies						
Subawards						
Other Direct Costs						

Total Direct Costs						
Total Indirect Costs						
TOTAL						

The Detailed Budget must contain the following budget categories and information, at a minimum:

1) Salaries and Wages – Must be proposed consistent with 2 CFR 200.430 Compensation - Personal Services. The applicant's budget must include position title, salary rate, level of effort, and salary escalation factors for each position. Allowances, when proposed, must be broken down by specific type and by position. Applicants must explain all assumptions in the Budget Narrative. The Budget Narrative must demonstrate that the proposed compensation is reasonable for the services rendered and consistent with what is paid for similar work in other activities of the applicant. Applicants must provide their established written policies on personnel compensation. If the applicant's written policies do not address a specific element of compensation that is being proposed, the Budget Narrative must describe the rationale used and supporting market research.

2) Fringe Benefits – (if applicable) If the applicant has a fringe benefit rate approved by an agency of the U.S. Government, the applicant must use such rate and provide evidence of its approval. If an applicant does not have a fringe benefit rate approved, the applicant must propose a rate and explain how the applicant determined the rate. In this case, the Budget Narrative must include a detailed breakdown comprised of all items of fringe benefits (e.g., superannuation, gratuity, etc.) and the costs of each, expressed in U.S. dollars and as a percentage of salaries.

3) Travel and Transportation – Provide details to explain the purpose of the trips, the number of trips, the origin and destination, the number of individuals traveling, and the duration of the trips. Per Diem and associated travel costs must be based on the applicant's normal travel policies. When appropriate please provide supporting documentation as an attachment, such as company travel policy, and explain assumptions in the Budget Narrative.

4) Procurement or Rental of Goods (Equipment & Supplies), Services, and Real Property – Must include information on estimated types of equipment, models, supplies and the cost per unit and quantity. The Budget Narrative must include the purpose of the equipment and supplies and the basis for the estimates. The Budget Narrative must support the necessity of any rental costs and reasonableness in light of such factors as: rental costs of comparable property, if any; market conditions in the area; alternatives available; and the type, life expectancy, condition, and value of the property leased.

5) Subawards – Specify the budget for the portion of the program to be passed through to any subrecipients. See 2 CFR 200.330 for assistance in determining whether the sub-tier entity is a subrecipient or contractor. The subrecipient budgets must align with the same requirements as the applicant's budget, including those related to fringe and indirect costs.

6) Other Direct Costs – This may include other costs not elsewhere specified, such as report preparation costs, passports and visas fees, medical exams and inoculations, as well as any other miscellaneous costs which directly benefit the program proposed by the applicant. The applicant should indicate the subject, venue and duration of any proposed conferences and seminars, and their relationship to the objectives of the program, along with estimates of costs. Otherwise, the narrative should be minimal.

7) Indirect Costs – Applicants must indicate whether they are proposing indirect costs or will charge all costs directly. In order to better understand indirect costs please see Subpart E of 2 CFR 200.414. The application must identify which approach they are requesting and provide the applicable supporting information. Below are the most commonly used Indirect Cost Rate methods:

   Method 1 - Direct Charge Only
   Eligibility: Any applicant
   Initial Application Requirements: See above on direct costs

   Method 2 - Negotiated Indirect Cost Rate Agreement (NICRA)
   Eligibility: Any applicant with a NICRA issued by a USG Agency must use that NICRA
   Initial Application Requirements: If the applicant has a current NICRA, submit your approved NICRA and the associated disclosed practices. If your NICRA was issued by an Agency other than USAID, provide the contact information for the approving Agency. Additionally, at the Agency's discretion, a provisional rate may be set forth in the award subject to audit and finalization. See USAID's Indirect Cost Rate Guide for Non Profit Organizations for further guidance.

   Method 3 - De minimis rate of 10% of modified total direct costs (MTDC)
   Eligibility: Any applicant that has never received a NICRA
   Initial Application Requirements: Costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as a non-Federal entity chooses to negotiate an indirect rate, which the non-Federal entity may apply to do at any time. The applicant must describe which cost elements it charges indirectly vs. directly. See 2 CFR 200.414(f) for further information.

   Method 4 - Indirect Costs Charged As A Fixed Amount
   Eligibility: Non U.S. non-profit organizations without a NICRA may request, but approval is at the discretion of the AO
   Initial Application Requirements: Provide the proposed fixed amount and a worksheet that includes the following:

- Total costs incurred by the organization for the previous fiscal year and estimates for the current year.
- Indirect costs (common costs that benefit the day-to-day operations of the organization, including categories such as salaries and expenses of executive officers, personnel administration, and accounting, or that benefit and are identifiable to more than one program or activity, such as depreciation, rental costs, operations and maintenance of facilities, and telephone expenses) for the previous fiscal year and estimates for the current year.
- Proposed method for prorating the indirect costs equitably and consistently across all programs and activities of using a base that measures the benefits of that particular cost to each program or activity to which the cost applies.

If the applicant does not have an approved NICRA and does not elect to utilize the 10% de minimis rate, the Agreement Officer will provide further instructions and may request additional supporting information, including financial statements and audits, should the application still be under consideration after the merit review. USAID is under no obligation to approve the applicant's requested method.

8) Cost Sharing – If proposing cost share, the applicant should estimate the amount of cost-sharing resources to be provided over the life of the agreement and specify the sources of such resources, and the basis of calculation in the budget narrative. Applicants should also provide a breakdown of the cost share (financial and in-kind contributions) of all organizations involved in implementing the resulting award.

e) Prior Approvals in accordance with 2 CFR 200.407

Inclusion of an item of cost in the detailed application budget does not satisfy any requirements for prior approval by the Agency. If the applicant would like the award to reflect approval of any cost elements for which prior written approval is specifically required for allowability, the applicant must specify and justify that cost. See 2 CFR 200.407 for information regarding which cost elements require prior written approval.

f) Approval of Subawards

The applicant must submit information for all subawards that it wishes to have approved at the time of award. For each proposed subaward the applicant must provide the following:

- Name of organization
- DUNS Number
- Confirmation that the subrecipient does not appear on the Treasury Department's Office of Foreign Assets Control (OFAC) list
- Confirmation that the subrecipient does not have active exclusions in the System for Award Management (SAM)
- Confirmation that the subrecipient is not listed in the United Nations Security designation list
- Confirmation that the subrecipient is not suspended or debarred

- Confirmation that the applicant has completed a risk assessment of the subrecipient, in accordance with 2 CFR 200.331(b)
- Any negative findings as a result of the risk assessment and the applicant's plan for mitigation.

g) Dun and Bradstreet and SAM Requirements

USAID may not award to an applicant unless the applicant has complied with all applicable unique entity identifier (DUNS number) and System for Award Management (SAM) requirements. Each applicant (unless the applicant is an individual or Federal awarding agency that is exempted from requirements under 2 CFR 25.110(b) or (c), or has an exception approved by the Federal awarding agency under 2 CFR 25.110(d)) is required to:

1. Provide a valid DUNS number for the applicant and all proposed sub-recipients;
2. Be registered in SAM before submitting its application. SAM is streamlining processes, eliminating the need to enter the same data multiple times, and consolidating hosting to make the process of doing business with the government more efficient (www.sam.gov).
3. Continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by a Federal awarding agency.

The registration process may take many weeks to complete. Therefore, applicants are encouraged to begin the process early. If an applicant has not fully complied with the requirements above by the time USAID is ready to make an award, USAID may determine that the applicant is not qualified to receive an award and use that determination as a basis for making an award to another applicant.

DUNS number: http://fedgov.dnb.com/webform
SAM registration: http://www.sam.gov

Non-U.S. applicants can find additional resources for registering in SAM, including a Quick Start Guide and a video on how to obtain an NCAGE code, on www.sam.gov, navigate to Help, then to International Registrants.

h) History of Performance

The applicant and major sub-recipients must provide information regarding its recent history of performance for all its cost-reimbursement contracts, grants, or cooperative agreements involving similar or related programs, not to exceed three (3) years, as follows:

• Name of the Awarding Organization;
• Award Number;
• Activity Title;
• A brief description of the activity;
• Period of Performance;
• Award Amount;

• Reports and findings from any audits performed in the last three (3) years; and
• Name of at least two (2) updated professional contacts who most directly observed the work at the organization for which the service was performed with complete current contact information including telephone number, and e-mail address for each proposed individual.

If the applicant encountered problems on any of the referenced Awards, it may provide a short explanation and the corrective action taken. The applicant should not provide general information on its performance. USAID reserves the right to obtain relevant information concerning an applicant's history of performance from any sources and may consider such information in its review of the applicant's risk. The Agency may request additional information and conduct a pre-award survey if it determines that it is necessary to inform the risk assessment.

i) Branding Strategy & Marking Plan

The apparently successful applicant will be asked to provide a Branding Strategy and Marking Plan to be evaluated and approved by the Agreement Officer and incorporated into any resulting award.

1. Branding Strategy – Assistance (June 2012)

a. Applicants recommended for an assistance award must submit and negotiate a "Branding Strategy," describing how the program, project, or activity is named and positioned, and how it is promoted and communicated to beneficiaries and host country citizens.

b. The request for a Branding Strategy, by the Agreement Officer from the applicant, confers no rights to the applicant and constitutes no USAID commitment to an award.

c. Failure to submit and negotiate a Branding Strategy within the time frame specified by the Agreement Officer will make the applicant ineligible for an award.

d. The applicant must include all estimated costs associated with branding and marking USAID programs, such as plaques, stickers, banners, press events, materials, and so forth, in the budget portion of the application. These costs are subject to the revision and negotiation with the Agreement Officer and will be incorporated into the Total Estimated Amount of the grant, cooperative agreement or other assistance instrument.

e. The Branding Strategy must include, at a minimum, all of the following:

(1) All estimated costs associated with branding and marking USAID programs, such as plaques, stickers, banners, press events, materials, and so forth.

(2) The intended name of the program, project, or activity.

(i) USAID requires the applicant to use the “USAID Identity,” comprised of the USAID logo and brandmark, with the tagline “from the American people” as found on the USAID Web site at http://www.usaid.gov/branding, unless Section VI of the RFA or APS states that the USAID Administrator has approved the use of an additional or substitute logo, seal, or tagline.

(ii) USAID prefers local language translations of the phrase “made possible by (or with) the generous support of the American People” next to the USAID Identity when acknowledging contributions.

(iii) It is acceptable to cobrand the title with the USAID Identity and the applicant's identity.

(iv) If branding in the above manner is inappropriate or not possible, the applicant must explain how USAID's involvement will be showcased during publicity for the program or project.

(v) USAID prefers to fund projects that do not have a separate logo or identity that competes with the USAID Identity. If there is a plan to develop a separate logo to consistently identify this program, the applicant must attach a copy of the proposed logos. Section VI of the RFA or APS will state if an Administrator approved the use of an additional or substitute logo, seal, or tagline.

(3) The intended primary and secondary audiences for this project or program, including direct beneficiaries and any special target segments.

(4) Planned communication or program materials used to explain or market the program to beneficiaries.

(i) Describe the main program message.

(ii) Provide plans for training materials, posters, pamphlets, public service announcement, billboards, Web sites, and so forth, as appropriate.

(iii) Provide any plans to announce and promote publicly this program or project to host country citizens, such as media releases, press conferences, public events, and so forth. Applicant must incorporate the USAID Identity and the message, “USAID is from the American People.”

(iv) Provide any additional ideas to increase awareness that the American people support this project or program.

(5) Information on any direct involvement from host-country government or ministry, including any planned acknowledgement of the host-country government.

(6) Any other groups whose logo or identity the applicant will use on program materials and related materials. Indicate if they are a donor or why they will be visibly acknowledged, and if they will receive the same prominence as USAID.

e. The Agreement Officer will review the Branding Strategy to ensure the above information is adequately included and consistent with the stated objectives of the award, the applicant's cost data submissions, and the performance plan.

f. If the applicant receives an assistance award, the Branding Strategy will be included in and made part of the resulting grant or cooperative agreement

(END OF PRE-AWARD TERM)

2. Marking Plan – Assistance (June 2012)

a. Applicants recommended for an assistance award must submit and negotiate a "Marking Plan," detailing the public communications, commodities, and program materials, and other items that will visibly bear the "USAID Identity," which comprises of the USAID logo and brandmark, with the tagline "from the American people." The USAID Identity is the official marking for the Agency, and is found on the USAID Web site at http://www.usaid.gov/branding. Section VI of the RFA or APS will state if an Administrator approved the use of an additional or substitute logo, seal, or tagline.

b. The request for a Marking Plan, by the Agreement Officer from the applicant, confers no rights to the applicant and constitutes no USAID commitment to an award.

c. Failure to submit and negotiate a Marking Plan within the time frame specified by the Agreement Officer will make the applicant ineligible for an award.

d. The applicant must include all estimated costs associated with branding and marking USAID programs, such as plaques, stickers, banners, press events, materials, and so forth, in the budget portion of the application. These costs are subject to the revision and negotiation with the Agreement Officer and will be incorporated into the Total Estimated Amount of the grant, cooperative agreement or other assistance instrument.

e. The Marking Plan must include all of the following:

(1) A description of the public communications, commodities, and program materials that the applicant plans to produce and which will bear the USAID Identity as part of the award, including:

(i) Program, project, or activity sites funded by USAID, including visible infrastructure projects or other sites physical in nature;

(ii) Technical assistance, studies, reports, papers, publications, audiovisual productions, public service announcements, Web sites/Internet activities, promotional, informational, media, or communications products funded by USAID;

(iii) Commodities, equipment, supplies, and other materials funded by USAID, including commodities or equipment provided under humanitarian assistance or disaster relief programs; and

(iv) It is acceptable to cobrand the title with the USAID Identity and the applicant's identity.

(v) Events financed by USAID, such as training courses, conferences, seminars, exhibitions, fairs, workshops, press conferences and other public activities. If the USAID Identity cannot be displayed, the recipient is encouraged to otherwise acknowledge USAID and the support of the American people.

(2) A table on the program deliverables with the following details:

(i) The program deliverables that the applicant plans to mark with the USAID Identity;

(ii) The type of marking and what materials the applicant will use to mark the program deliverables;

(iii) When in the performance period the applicant will mark the program deliverables, and where the applicant will place the marking;

(iv) What program deliverables the applicant does not plan to mark with the USAID Identity , and

(v) The rationale for not marking program deliverables.

(3) Any requests for an exemption from USAID marking requirements, and an explanation of why the exemption would apply. The applicant may request an exemption if USAID marking requirements would:

(i) Compromise the intrinsic independence or neutrality of a program or materials where independence or neutrality is an inherent aspect of the program and materials. The

applicant must identify the USAID Development Objective, Interim Result, or program goal furthered by an appearance of neutrality, or state why an aspect of the award is presumptively neutral. Identify by category or deliverable item, examples of material for which an exemption is sought.

(ii) Diminish the credibility of audits, reports, analyses, studies, or policy recommendations whose data or findings must be seen as independent. The applicant must explain why each particular deliverable must be seen as credible.

(iii) Undercut host-country government "ownership" of constitutions, laws, regulations, policies, studies, assessments, reports, publications, surveys or audits, public service announcements, or other communications. The applicant must explain why each particular item or product is better positioned as host-country government item or product.

(iv) Impair the functionality of an item. The applicant must explain how marking the item or commodity would impair its functionality.

(v) Incur substantial costs or be impractical. The applicant must explain why marking would not be cost beneficial or practical.

(vi) Offend local cultural or social norms, or be considered inappropriate. The applicant must identify the relevant norm, and explain why marking would violate that norm or otherwise be inappropriate.

(vii) Conflict with international law. The applicant must identify the applicable international law violated by the marking.

f. The Agreement Officer will consider the Marking Plan's adequacy and reasonableness and will approve or disapprove any exemption requests. The Marking Plan will be reviewed to ensure the above information is adequately included and consistent with the stated objectives of the award, the applicant's cost data submissions, and the performance plan.

g. If the applicant receives an assistance award, the Marking Plan, including any approved exemptions, will be included in and made part of the resulting grant or cooperative agreement, and will apply for the term of the award unless provided otherwise.

(END OF PRE-AWARD TERM)

j) Funding Restrictions

Profit is not allowable for recipients or subrecipients under this award. See 2 CFR 200.330 for assistance in determining whether a sub-tier entity is a subrecipient or contractor.

Construction will not be authorized under this award.

USAID will not allow the reimbursement of pre-award costs under this award without the explicit written approval of the Agreement Officer.

Except as may be specifically approved in advance by the AO, all commodities and services that will be reimbursed by USAID under this award must be from the authorized geographic code specified in Section B.4 of this NOFO and must meet the source and nationality requirements set forth in 22 CFR 228.

k) Conscience Clause Implementation (Assistance) – (February 2012)

(a) An organization, including a faith-based organization, that is otherwise eligible to receive funds under this agreement for HIV/AIDS prevention, treatment, or care—
1) Shall not be required, as a condition of receiving such assistance—
(i) to endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or
(ii) to endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection; and
2) Shall not be discriminated against in the solicitation or issuance of grants, contracts, or cooperative agreements for refusing to meet any requirement described in paragraph (a)(1) above.
(b) An applicant who believes that this solicitation contains provisions or requirements that would require it to endorse or use an approach or participate in an activity to which it has a religious or moral objection must so notify the cognizant Agreement Officer in accordance with the Mandatory Standard Provision titled "Notices" as soon as possible, and in any event not later than 15 calendar days before the deadline for submission of applications under this solicitation. The applicant must advise which activity(ies) it could not implement and the nature of the religious or moral objection.
(c) In responding to the solicitation, an applicant with a religious or moral objection may compete for any funding opportunity as a prime partner, or as a leader or member of a consortium that comes together to compete for an award. Alternatively, such applicant may limit its application to those activities it can undertake and must indicate in its submission the activity(ies) it has excluded based on religious or moral objection. The offeror's proposal will be evaluated based on the activities for which a proposal is submitted, and will not be evaluated favorably or unfavorably due to the absence of a proposal addressing the activity(ies) to which it objected and which it thus omitted. In addition to the notification in paragraph (b) above, the applicant must meet the submission date provided for in the solicitation.

(END OF PRE-AWARD TERM)

l) Conflict of Interest Pre-Award Term (August 2018)

a. Personal Conflict of Interest

1. An actual or appearance of a conflict of interest exists when an applicant organization or an employee of the organization has a relationship with an Agency official involved in the competitive award decision-making process that could affect that Agency official's impartiality. The term "conflict of interest" includes situations in which financial or other personal considerations may compromise, or have the appearance of compromising, the obligations and duties of a USAID employee or recipient employee.

2. The applicant must provide conflict of interest disclosures when it submits an SF-424. Should the applicant discover a previously undisclosed conflict of interest after submitting the application, the applicant must disclose the conflict of interest to the AO no later than ten (10) calendar days following discovery.

b. Organizational Conflict of Interest

The applicant must notify USAID of any actual or potential conflict of interest that they are aware of that may provide the applicant with an unfair competitive advantage in competing for this financial assistance award. Examples of an unfair competitive advantage include but are not limited to situations in which an applicant or the applicant's employee gained access to non-public information regarding a federal assistance funding opportunity, or an applicant or applicant's employee was substantially involved in the preparation of a federal assistance funding opportunity. USAID will promptly take appropriate action upon receiving any such notification from the applicant.

(END OF PRE-AWARD TERM)

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SECTION E: APPLICATION REVIEW INFORMATION

1. Criteria

The merit review criteria prescribed here are tailored to the requirements of this particular NOFO. Applicants should note that these criteria serve to: (a) identify the significant matters which the applicants should address in their applications, and (b) set the standard against which all applications will be evaluated.

Technical and other factors will be evaluated relative to each other, as described here and prescribed by the Technical Application Format. The Technical Application will be scored by a Selection Committee (SC) using the criteria described in this section.

2. Review and Selection Process

Merit Review

USAID will conduct a merit review of all applications received that comply with the instructions in this NOFO. Applications will be reviewed and evaluated in accordance with the following criteria, **in decreasing order of importance**. Each criterion will be assigned an adjectival rating.

- **Technical Approach**
    - Extent to which the application demonstrates a clear understanding of and ability to achieve the 4 objectives of the DEEP VZN Award, to include well-defined indicators of success and a description of how it intends to monitor its own program, including sources of such data.
- **Management Plan**
    - Extent to which the organizational and management plan will enable the project to accomplish the results of the DEEP VZN Award effectively and efficiently.
- **Key personnel and staffing**
    - Extent to which the experience, knowledge, and skills of the suite of proposed personnel are sufficient to achieve the results of the DEEP VZN Award.
    - Extent to which the proposed key personnel meet or exceed the minimum requirements in Section D.5.g.

Other Considerations

In addition to the technical evaluation criteria listed above, applicants may be evaluated for history of performance. Using information provided in Annex 3, USAID may contact the PPI references in order to conduct additional analysis to determine the following criteria:

1. The Applicant and major consortium partners and/or sub-recipients have demonstrated successful experience implementing activities that are similar in matter, size, scope and complexity to this proposed activity.
2. The Applicant and major consortium partners and/or sub-recipients have demonstrated institutional capacity to effectively coordinate and collaborate with a diverse set of organizations working in the same technical areas including, but not limited to other USG agencies, NGOs and PVOs, international organizations, donors and foundations, host governments, and private sector.
3. The Applicant and major consortium partners and/or sub-recipients have demonstrated successful experience working with/through local or regional operational platforms to include embedding of staff in developing country institutions.
4. The Applicant and major consortium partners and/or sub-recipients have demonstrated a solid business management track record to include successful experience in managing sub-contracts and sub-awards with partner organizations in developing countries.

Business Review

The Agency will evaluate the cost application of the applicant(s) under consideration for an award as a result of the merit criteria review to determine whether the costs are reasonable and allowable in accordance with the cost principles found in 2 CFR 200 Subpart E.

The Agency will also consider (1) the extent of the applicant's understanding of the financial aspects of the program and the applicant's ability to perform the activities within the amount requested; (2) whether the applicant's plans will achieve the program objectives with reasonable economy and efficiency; and (3) whether any special conditions relating to costs should be included in the award.

The Business Review will be considered less important than Merit Review but may be considered as part of the overall evaluation.

Proposed cost share, if provided, will be reviewed for compliance with the standards set forth in 2 CFR 200.306, 2 CFR 700.10, and the Standard Provision "Cost Sharing (Matching)" for U.S. entities, or the Standard Provision "Cost Share" for non-U.S. entities.

The AO will perform a risk assessment (2 CFR 200.205). The AO may determine that a pre-award survey is required to inform the risk assessment in determining whether the prospective recipient has the necessary organizational, experience, accounting and operational controls,

financial resources, and technical skills – or ability to obtain them – in order to achieve the objectives of the program and comply with the terms and conditions of the award. Depending on the result of the risk assessment, the AO will decide to execute the award, not execute the award, or award with "specific conditions" (2 CFR 200.207).

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SECTION F: FEDERAL AWARD ADMINISTRATION INFORMATION

1. Federal Award Notices

Award of the agreement contemplated by this NOFO cannot be made until funds have been appropriated, allocated and committed through internal USAID procedures. While USAID anticipates that these procedures will be successfully completed, potential applicants are hereby notified of these requirements and conditions for the award.

2. Administrative & National Policy Requirements

The resulting award from this NOFO will be administered in accordance with the following policies and regulations.

For US organizations: ADS 303, 2 CFR 700, 2 CFR 200, and Standard Provisions for U.S. Non-governmental organizations.

For Non US organizations: Standard Provisions for Non-U.S. Non-governmental Organizations.

See Annex 1, for a list of the Standard Provisions that will be applicable to any awards resulting from this NOFO.

3. Reporting Requirements

Financial Reporting:
The recipient must submit the Federal Financial Form (SF-425) on a quarterly basis via electronic format to the U.S. Department of Health and Human Services. The recipient also must submit a copy of the SF-425 to the Agreement Officer (AO) and the Agreement Officer's Representative (AOR). These financial reports are due no later than 30 calendar days at the end of each quarter based on the federal fiscal calendar. The recipient must submit the original and two copies of all final financial reports to USAID/Washington, M/CFO/CMP-LOC Unit, the AO, and the AOR. The recipient must submit an electronic version of the final financial report to the U.S. Department of Health and Human Services in accordance with the paragraph above.

Performance Reporting
The recipient must submit via email a copy of semi-annual, annual, and final performance reports, in English, to the AOR in accordance with 2 CFR 200.328.

- **Semi-Annual and Annual Reports**
  The recipient will submit semi-annual and annual progress reports based on the federal fiscal calendar. The semi-annual report will be due within 30 days after the end of the reporting period and will cover the first six months of the year (October 1 - March 31). The annual report will cover the entire fiscal year (October 1 - September 30) and will be due within 90 days of the end of the federal fiscal year.

- At a minimum, both semi-annual and annual reports will contain:

- Narrative description of activities completed and major accomplishments achieved during the reporting period in all countries supported by STOP Spillover, presented by objective
- Qualitative and quantitative data on program achievements and results
- Progress on standard and agreed upon indicators, as outlined in the MEL plan, including status towards achieving targets and explanations for significant deviations
- An updated MEL plan, including progress on the learning agenda (annually)
- An updated Data Management Plan
- Problems encountered and whether they were solved or are still outstanding
- Proposed solutions to ongoing or new problems
- Success stories, blogs, articles, publications, press releases, and photographs, if available
- Update on expenditures for the reporting period against the pipeline
- Analysis and explanation of cost overruns or high unit costs, when applicable
- Planned activities for the next performance period

- **Global Health Security Agenda (GHSA) Reports**
  The Recipient will submit semi-annual GHSA performance reports within a timeframe and on a template designated by the AOR. The Recipient will submit the GHSA semi-annual reports to the AOR via email.

- **Ad Hoc Reports**
  There may be additional reporting requirements and ad hoc information requests including, but not limited to, those associated with Mission buy-ins or additional sources of funding provided to DEEP VZN.

- **Final Report**
  Within ninety (90) calendar days after the period performance date, the recipient will submit one (1) original and two (2) copies of the Final Report to the AOR and one (1) copy to the Agreement Officer. In addition, one (1) copy will be submitted to the Development Experience Clearinghouse:
  - 1) Electronically: http://www.usaid.gov/results-and-data/informationresources/developmentexperience-clearinghouse-dec
  - 2) By U.S. Postal Service delivery to:
    U.S. Agency for International Development
    Development Experience Clearinghouse
    M/CIO/ITSD/KM
    Ronald Reagan Building M. 01-010
    Washington, DC 20523-6100

  The final report must include a narrative report and summary table of results, a comparison of actual accomplishments to the objectives established for the period of performance, and a gender analysis that describes how gender equality issues were tracked and addressed. It should highlight accomplishments against implementation plans; outline progress of benchmarks against targets; describe results; document lessons

learned during implementation; and recommend strategies for sustaining the networks and their activities. The Final Report also must contain a three-page executive summary, an index of all reports and information products produced under the agreement, and a summary of the program's finances. More details on the format of the final report will be provided after the award.

Implementation Plans
Annual implementation plans serve as a guide to activity implementation and detail how the recipient will use the implementation year to achieve the objectives of STOP Spillover. The implementation plan is intended to be an annual roadmap for USAID and the recipient. Upon consultation with the AOR, reasonable and justifiable modifications can be made to improve the chances of achieving the medium- and long-term results of the award. The recipient must submit the following implementation and reporting documents in English. The AOR and recipient will agree on the appropriate format and length.

First Year Work Plan and Budget
The recipient will submit a draft work plan for the first year within the 90 calendar days of executing the award. Depending on the start date of the agreement, the first year work plan may be less than a full year or more than a full year. The first year work plan must include a detailed budget for the first year. As part of the First Year Work Plan submission, the recipient will include a supplementary annual work plan describing planned contributions to the GHSA on a template designated by the AOR.

Annual Work Plan and Budget
Starting with the second year of the award and for each subsequent year of performance thereafter, the recipient will submit annual work plans to the AOR for the next federal fiscal year within 30 calendar days prior to the end of the current federal fiscal year in a format agreed upon by the AOR and the recipient. The recipient also will submit supplementary annual work plans describing planned contributions to the GHSA within a timeframe and on a template designated by the AOR.

Monitoring, Evaluation and Learning (MEL) Plan
The recipient will finalize a MEL plan for the life of DEEP VZN that derives from the activities outlined in the Program Description and submit it to the AOR within 90 calendar days of the award for approval. The MEL plan will outline key program interventions, indicators of achievement, associated annual and life-of-Activity targets and a learning agenda. The learning agenda will outline key questions to be addressed, a plan for addressing these questions, and a process for incorporating findings into program implementation and spillover risk reduction. Where appropriate, the MEL plan must track gender equality issues in implementing activities. The recipient will update the MEL plan annually and submit it as an attachment to the annual report.

Gender Action Plan
The recipient will conduct a gender analysis that assesses context and gender needs, including time constraints and participation limitations. This analysis will inform a subsequent gender action plan, which will be developed in collaboration with the USAID management team and

finalized within 90 calendar days of the award and updated annually. The gender action plan will inform the Activity's technical approach as it relates to gender throughout the life of the Activity. It also will be used to inform the design of activities that seek to reduce opportunity gaps between men and women or address power differentials to promote gender equity. The gender action plans should be developed in conjunction with the Activity's monitoring, evaluation and learning plan, and progress should be reflected in annual work plans and performance reports.

Data Management Plan
A Data Management Plan (DMP) is a document that describes how the recipient will manage data during the project and what happens to the data after the project ends. The initial DMP, which will be developed in collaboration with the USAID management team, will be finalized within 90 calendar days of the award and updated semi-annually and annually.

A comprehensive DMP will discuss the following aspects of the data life cycle:

- Collect - How the data is collected and processed by the researcher.
- Assure - How to make sure the data is high quality and free of errors.
- Describe - How the data will be documented so that other researchers can use it.
- Preserve - How and where the data will be stored so that researchers can access it forever.

The data management plan will inform the Activity's technical approach as it relates to data throughout the life of the Activity. The data management plan should be developed in conjunction with the Activity's monitoring, evaluation and learning plan, and progress should be reflected in annual work plans and performance reports.

Closeout Plan
No later than six (6) months prior to the completion date of the agreement, the recipient will submit a demobilization plan for Agreement Officer's approval. The demobilization plan shall include: 1) a draft property disposition plan, 2) a plan for the phase-out of in-country operations, 3) a staffing discharge plan, 4) a delivery schedule for all reports or other deliverables required under the agreement, and 5) a timetable for completing all required actions in the demobilization plan, including the submission date of the final property disposition plan to the Agreement Officer.

4. Program Income

Income earned during the Activity's period of performance must be added to the total program amount and used to further eligible objectives for the Activity.

5. Environmental Compliance

As required by the 22 CFR 216, an Initial Environmental Examination (IEE) was completed by the USAID/GH/ETD Office to ensure that proposed interventions adhere to U.S. and host countries' environmental requirements, and that appropriate environmental safeguards are adopted to prevent negative environmental consequences of USAID investment. The environmental determination for the STOP Spillover IEE was a "negative determination," given the activities proposed under this NOFO will not have a significant effect on the environment.

The partner's environmental compliance obligations under these regulations and procedures are specified in the attached Initial Environmental Examination (IEE). Applicants should reflect illustrative costs for environmental compliance implementation and monitoring in their cost applications.

Please note the project scope written in the IEE should not influence the Applicant's proposal as these may be outdated. The applicant should only consider the Program Description as laid out in Section A of the NOFO.

An annual screening must be conducted to determine whether activities under STOP Spillover contained in the categorical exclusion justification remain within the Activity's scope. Changes to the Activity require an environmental review and possible amendment of the negative determination to reflect the new activities. Per ADS 204, the IEE will need to be amended and environmental determination reviewed if there is any new information or changes in interventions that might require revision of the determination.

6. Other Requirements

During the life of the award, the recipient may be required to prepare and submit other special reports concerning specific activities and/or analyses. These requests will be in writing and will specify the due date.

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SECTION G: FEDERAL AWARDING AGENCY CONTACT(S)

1. NOFO Points of Contact

For submission of Questions and Applications: deepvzn@usaid.gov

2. Acquisition and Assistance Ombudsman

The A&A Ombudsman helps ensure equitable treatment of all parties who participate in USAID's acquisition and assistance process. The A&A Ombudsman serves as a resource for all organizations who are doing or wish to do business with USAID. Please visit this page for additional information: https://www.usaid.gov/work-usaid/acquisition-assistance-ombudsman

The A&A Ombudsman may be contacted via: Ombudsman@usaid.gov

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SECTION H: OTHER INFORMATION

1. Other Information

USAID reserves the right to fund any or none of the applications submitted. The Agreement Officer is the only individual who may legally commit the Government to the expenditure of public funds. Any award and subsequent incremental funding will be subject to the availability of funds and continued relevance to Agency programming.

Applications with Proprietary Data

Applicants who include data that they do not want disclosed to the public for any purpose or used by the U.S. Government except for evaluation purpose, should mark the cover page with the following:

> "This application includes data that must not be disclosed, duplicated, used, or disclosed – in whole or in part – for any purpose other than to evaluate this application. If, however, an award is made as a result of – or in connection with – the submission of this data, the U.S. Government will have the right to duplicate, use, or disclose the data to the extent provided in the resulting award. This restriction does not limit the U.S. Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets {insert sheet numbers}."

Additionally, the applicant must mark each sheet of data it wishes to restrict with the following:

> "Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this application."

3. List of Annexes

Annex 1: Standard Provisions
Annex 2: List of Acronyms
Annex 3: Past Performance Information
Annex 4: Initial Environmental Examination

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ANNEX 1 - STANDARD PROVISIONS

(Note: the full text of these provisions may be found at: https://www.usaid.gov/ads/policy/300/303maa and https://www.usaid.gov/ads/policy/300/303mab). The actual Standard Provisions included in the award will be dependent on the organization that is selected. The award will include the latest Mandatory Provisions for either U.S. or non-U.S. Nongovernmental organizations**.** The award will also contain the following "required as applicable" Standard Provisions:

REQUIRED AS APPLICABLE STANDARD PROVISIONS FOR U.S. NONGOVERNMENTAL ORGANIZATIONS

Required	Not Required	Standard Provision
TBD		RAA1. NEGOTIATED INDIRECT COST RATES - PREDETERMINED (NOVEMBER 2020)
		RAA2. NEGOTIATED INDIRECT COST RATES - PROVISIONAL (Nonprofit) (NOVEMBER 2020)
		RAA3. NEGOTIATED INDIRECT COST RATE - PROVISIONAL (Profit) (DECEMBER 2014)
		RAA4. INDIRECT COSTS – DE MINIMIS RATE (NOVEMBER 2020)
X		RAA5. EXCHANGE VISITORS AND PARTICIPANT TRAINING (JUNE 2012)
	X	RAA6. VOLUNTARY POPULATION PLANNING ACTIVITIES – SUPPLEMENTAL REQUIREMENTS (JANUARY 2009)
X		RAA7. PROTECTION OF THE INDIVIDUAL AS A RESEARCH SUBJECT (APRIL 1998)

X		RAA8. CARE OF LABORATORY ANIMALS (MARCH 2004)
X		RAA9. TITLE TO AND CARE OF PROPERTY (COOPERATING COUNTRY TITLE) (NOVEMBER 1985)
X		RAA10. COST SHARING (MATCHING) (FEBRUARY 2012)
X		RAA11. PROHIBITION OF ASSISTANCE TO DRUG TRAFFICKERS (JUNE 1999)
	X	RAA12. INVESTMENT PROMOTION (NOVEMBER 2003)
X		RAA13. REPORTING HOST GOVERNMENT TAXES (DECEMBER 2014)
X		RAA14. FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)
	X	RAA15. CONSCIENCE CLAUSE IMPLEMENTATION (ASSISTANCE) (FEBRUARY 2012)
	X	RAA16. CONDOMS (ASSISTANCE) (SEPTEMBER 2014)
	X	RAA17. PROHIBITION ON THE PROMOTION OR ADVOCACY OF THE LEGALIZATION OR PRACTICE OF PROSTITUTION OR SEX TRAFFICKING (ASSISTANCE) (SEPTEMBER 2014)
X		RAA18. USAID DISABILITY POLICY - ASSISTANCE (DECEMBER 2004)
	X	RAA19. STANDARDS FOR ACCESSIBILITY FOR THE DISABLED IN USAID ASSISTANCE AWARDS INVOLVING CONSTRUCTION (SEPTEMBER 2004)

	X	RAA20. STATEMENT FOR IMPLEMENTERS OF ANTI-TRAFFICKING ACTIVITIES ON LACK OF SUPPORT FOR PROSTITUTION (JUNE 2012)
	X	RAA21. ELIGIBILITY OF SUBRECIPIENTS OF ANTI-TRAFFICKING FUNDS (JUNE 2012)
	X	RAA22. PROHIBITION ON THE USE OF ANTI-TRAFFICKING FUNDS TO PROMOTE, SUPPORT, OR ADVOCATE FOR THE LEGALIZATION OR PRACTICE OF PROSTITUTION (JUNE 2012)
X		RAA23. UNIVERSAL IDENTIFIER AND SYSTEM OF AWARD MANAGEMENT (NOVEMBER 2020)
X		RAA24. REPORTING SUBAWARDS AND EXECUTIVE COMPENSATION (NOVEMBER 2020)
X		RAA25. PATENT REPORTING PROCEDURES (NOVEMBER 2020)
	X	RAA26. ACCESS TO USAID FACILITIES AND USAID'S INFORMATION SYSTEMS (AUGUST 2013)
X		RAA27. CONTRACT PROVISION FOR DBA INSURANCE UNDER RECIPIENT PROCUREMENTS (DECEMBER 2014)
X		RAA28. AWARD TERM AND CONDITION FOR RECIPIENT INTEGRITY AND PERFORMANCE MATTERS (APRIL 2016)

ANNEX 2 - ABBREVIATIONS AND ACRONYMS

ADS	Automated Directives System
AMR	Antimicrobial Resistance
AO	Agreement Officer
AOR	Agreement Officer's Representative
CDC	U.S. Centers for Disease Control and Prevention
CEPI	Coalition for Epidemic Preparedness Innovations
CFDA	Catalog of Federal Domestic Assistance
CFR	Code of Federal Regulations
CRM	Climate Risk Management
DARPA	Defense Advanced Research Projects Agency
DFAT	Australian Department of Foreign Affairs and Trade
DTRA	Defense Threat Reduction Agency
EID	Emerging Infectious Diseases
EPT	Emerging Pandemic Threats
FAA	Foreign Assistance Act
FAO	Food and Agricultural Organization of the United Nations
GHSA	Global Health Security Agenda
GHSS	Global Health Security Strategy
IFRC	International Federation of Red Cross and Red Crescent Societies
MEL	Monitoring, Evaluation and Learning
MERS-CoV	Middle East Respiratory Syndrome Coronavirus
MTDC	Modified Total Direct Costs
NFO	Notice of Funding Opportunity
NGO	Non-Governmental Organization
NICRA	Negotiated Indirect Cost Rate Agreement
OFAC	Treasury Department's Office of Foreign Assets Control
OHUN	One Health University Networks
OHW	One Health Workforce
OIE	World Organization for Animal Health
P&R	Preparedness and Response
SAM	System for Award Management
SC	Selection Committee
STOP	Strategies to Prevent
USAID	United States Agency for International Development
USG	United States Government
WHO	World Health Organization

THE REMAINDER OF THIS PAGE LEFT BLANK INTENTIONALLY.

ANNEX 3 - PAST PERFORMANCE INFORMATION

Past Performance Information (PPI)

(TO BE COMPLETED BY THE APPLICANT)

1. AWARD NUMBER:
2. CONTRACTOR/RECIPIENT (NAME AND ADDRESS):
3. TYPE OF AWARD:
4. COMPLEXITY OF WORK: DIFFICULT_____ROUTINE_____
5. DESCRIPTION, LOCATION, AND RELEVANCY OF WORK:
6. DOLLAR VALUE OF WORK : STATUS: ACTIVE_____COMPLETE_____
7. DATE OF AWARD:_____ AWARD COMPLETION DATE (INCLUDING EXTENSIONS):_____
8. TYPE AND EXTENT OF SUBAWARDS:
9. NAME, ADDRESS, TELEPHONE NUMBER, AND E-MAIL ADDRESS OF THE AWARDING CONTRACTING/AGREEMENT OFFICER AND/OR THE CONTRACTING/AGREEMENT OFFICER'S REPRESENTATIVE (AND OTHER REFERENCES AS APPLICABLE):

ANNEX 4 - INITIAL ENVIRONMENTAL EXAMINATION

INITIAL ENVIRONMENTAL EXAMINATION

PROJECT/ACTIVITY DATA

Project/Activity Name:	Discovery & Exploration of Emerging Pathogens - Viral Zoonoses (DEEP VZN)
Geographic Location(s) (Country/Region)**:**	Asia and Africa. Priority countries include: Democratic Republic of Congo, Ethiopia, Liberia Uganda, Bangladesh, Cambodia, Indonesia, and Vietnam. But, the project is not limited to these countries.
Amendment (Yes/No), if Yes indicate # (1, 2...):	No
Implementation Start/End Date (FY or M/D/Y)**:**	Estimated FY 2021
If Amended, specify New End Date:	Estimated FY 2025
Solicitation/Contract/Award Number(s):	
Implementing Partner(s):	TBD
Bureau Tracking ID:	GH-20-10509
Tracking ID of Related RCE/IEE (if any)**:**	N/A
Tracking ID of Other, Related Analyses:	N/A

ORGANIZATIONAL/ADMINISTRATIVE DATA

Implementing Operating Unit(s): (e.g. Mission or Bureau or Office)	Emerging Threats Division (GH/ID/ETD)
Other Affected Operating Unit(s):	Missions
Lead BEO Bureau:	GH
Funding Account(s) (if available)**:**	GHP-C-AI
Original Funding Amount:	Anticipated ceiling of $35 million
If Amended, specify funding amount:	N/A
If Amended, specify new funding total:	N/A
Prepared by:	Kendra Chittenden
Date Prepared:	November 10, 2020

ENVIRONMENTAL COMPLIANCE REVIEW DATA

Analysis Type:	☒Environmental Examination	☐Deferral
Environmental Determination(s):	☐Categorical Exclusion(s) ☒Negative ☐Positive ☐Deferred (per 22 CFR 216.3(a)(7)(iv)	
IEE Expiration Date (if applicable)**:**		
Additional Analyses/Reporting Required:	IWMP, EMMP(s), and Annual Environmental Screening Forms and EMMRs	

Climate Risks Identified (#):	Low ___2___	Moderate __7____	High __0____
Climate Risks Addressed (#):	Low _2_____	Moderate __7____	High _0_____

THRESHOLD DETERMINATION AND SUMMARY OF FINDINGS

PROJECT/ACTIVITY SUMMARY

To conduct applied research to deepen knowledge on unknown viruses from wildlife including their zoonotic and pandemic potential. Through DISCOVERY & EXPLORATION OF EMERGING PATHOGENS - VIRAL ZOONOSES (DEEP VZN), the U.S. Agency for International Development (USAID) seeks to build on previous work by assisting a limited number of high-risk/low-capacity countries in Asia and Africa to conduct intensive applied research to detect and characterize previously unknown viruses (from a limited number of viral families) that have originated in wildlife. Monitoring for unknown viruses will be conducted in both wildlife and human populations that are in contact with wildlife or wildlife products. DEEP VZN will build on more than 15 years of USAID investments in promoting a multisectoral (One Health) approach to addressing emerging zoonotic viruses before they pose an overwhelming epidemic or pandemic threat. Specifically, DEEP VZN will assist targeted African and Asian countries in strengthening their research capacities to detect unknown viruses at animal-animal or animal-human interfaces where risk profiles favor spillover, amplification, or spread of emerging zoonotic viruses. Detection will be complemented by efforts to assess the zoonotic and pandemic potential of these viruses. These efforts will appropriately address gender in the development of research tools and strategies and the sharing of results to mitigate spillover of these novel viruses.

ENVIRONMENTAL DETERMINATIONS

Upon approval of this document, the determinations become affirmed, per Agency regulations (22 CFR 216).

TABLE 1**: ENVIRONMENTAL DETERMINATIONS**

Projects/Activities	Categorical Exclusion Citation (if applicable)	Negative Determination	Positive Determination[1]	Deferral[2]
Project/Activity 1: Technical assistance and capacity building of personnel	**Categorical Exclusion** §216.2(c)(2)(i) Education, technical assistance, or training programs except to the extent such programs include activities directly affecting the environment (such as construction of facilities, etc.)	☐	☐	☐
Project/Activity 2: Establish monitoring for unknown viruses		☒	☐	☐
Project/Activity 3: Strengthening the detection of novel viruses		☒	☐	☐

[1] Positive Determinations require preparation of a Scoping Statement and Environmental Assessment.

[2] GH does not grant Deferrals for projects during the IEE Process.

Project/Activity 4: Strengthening the characterization of novel viruses		☒	☐	☐
Project/Activity 5. Rehabilitation and Improvements to laboratory biosafety and biosecurity (if needed)		☒	☐	☐
Project Activity 6. Procurement of Healthcare Commodities, Equipment, and Construction Materials		☒	☐	☐

CLIMATE RISK MANAGEMENT

Within the six activities described in the above table, the climate risk assessment is categorized as low/moderate.

At this time, the project is at the design stage, and all activities listed are illustrative. A majority of expected activities/sub-activities present low risk (with a few moderate risks); please refer to the CRM table analysis in the Annex. The DEEP VZN project will include opportunities to strengthen climate resilience and address the identified risks at the project design stage, and include appropriate language and references to the CRM within the solicitation and award.

IMPLEMENTATION

In accordance with 22 CFR 216 and Agency policy, the conditions and requirements of this document become mandatory upon approval. This includes the relevant limitations, conditions and requirements in this document as stated in Sections 3, 4, and 5 of the IEE and any BEO Specified Conditions of Approval.

USAID APPROVAL OF INITIAL ENVIRONMENTAL EXAMINATION

PROJECT/ACTIVITY NAME: DISCOVERY & EXPLORATION OF EMERGING PATHOGENS - VIRAL ZOONOSES (DEEP VZN)

Bureau Tracking ID: GH-20-10509

Approval:	Paul Mahanna (email clearance attached) Paul Mahanna, Office Director, Office of Infectious Diseases [required]	1/7/21 Date
Clearance:	Cara J. Chrisman (email clearance attached) Cara Chrisman, DEEP VZN AOR/COR [*required*]	1/5/21 Date
Clearance:	for Dennis Durbin, GH Climate Integration Lead [*required*]	1/15/2021 Date
Concurrence:	for Dennis Durbin, GH Bureau Environmental Officer [*required*]	1/15/2021 Date

DISTRIBUTION:

- Environmental Compliance Database (environmentalcompliancesupport@usaid.gov)
- Regional Bureaus for Asia and Africa
- GH ETD

From: Emily Watt
To: Emily Watt
Subject: FW: Reviewed: DEEP VZN GH-20-10509
Date: Tuesday, January 12, 2021 10:26:01 AM

---------- Forwarded message ---------
From: **Paul Mahanna** <>
Date: Fri, Jan 8, 2021 at 2:38 PM
Subject: Re: Reviewed: DEEP VZN GH-20-10509
To: Kendra Chittenden < >

Thanks Kendra. Have a great weekend.

_____
Paul Mahanna
Director, Office of Infectious Disease
Bureau for Global Health
USAID Washington

On Fri, Jan 8, 2021 at 2:23 PM Kendra Chittenden < > wrote:

> Yes, you did. thank you!
>
> On Fri, Jan 8, 2021 at 1:01 PM Paul Mahanna < > wrote:
>
> > Hi Kendra,
> >
> > I signed off on this yesterday, yes? Can you please confirm?
> >
> > Sorry Thai, I should have copied you when I sent this.
> >
> > Paul Mahanna
> > Director, Office of Infectious Disease
> > Bureau for Global Health, USAID
> >
> > Sent from my iPhone
> >
> > > On Jan 8, 2021, at 12:25 PM, Thainan George <tgeorge@usaid.gov> wrote:
> > >
> > > Hi Paul,
> > >
> > > Just flagging this for your awareness.

Best,
Thai.

> From: **Kendra Chittenden** < >
> Date: Tue, Jan 5, 2021 at 4:57 PM
> Subject: Fwd: Reviewed: DEEP VZN GH-20-10509
> To: Paul Mahanna < >
> Cc: Cara Chrisman < >
>
> Hi! Paul
>
> Happy New Year! We'd appreciate it if you could approve and sign the DEEP VZN IEE and CRM. Thank you! Kendra
>
> ---------- Forwarded message ---------
> From: **Cara Chrisman** < >
> Date: Tue, Jan 5, 2021 at 4:34 PM
> Subject: Re: Reviewed: DEEP VZN GH-20-10509
> To: Kendra Chittenden < >
> Cc: Angela Garvey < >
>
> Hi Kendra,
>
> Sorry for the delay! I clear the document and have inserted my name into the clearance line. Please let me know if you need anything else!
>
> Best,
> Cara
>
> Cara J. Chrisman, PhD
> Deputy Division Chief
> Emerging Threats Division
> Office of Infectious Disease, Bureau for Global Health
> U.S. Agency for International Development (USAID)
>
> On Tue, Jan 5, 2021 at 1:39 PM Kendra Chittenden < > wrote:
>
> > Friendly reminder
> >
> > ---------- Forwarded message ---------
> > From: **Kendra Chittenden** < >
> > Date: Mon, Jan 4, 2021 at 12:38 PM
> > Subject: Fwd: Reviewed: DEEP VZN GH-20-10509
> > To: Cara Chrisman <>
> > Cc: Alisa Pereira <>

Cara-

The IEE and CRM are approved. Please sign and I'll send to Paul for his signature and then Jen for the final signature. Hope to get the fully signed and approved IEE/CRM in the next couple of days.

Kendra

---------- Forwarded message ---------
From: **Jennifer Slotnick** < >
Date: Mon, Jan 4, 2021 at 11:51 AM
Subject: Re: Reviewed: DEEP VZN GH-20-10509
To: Kendra Chittenden < >
Cc: Cara Chrisman < >

Thanks Kendra,
That piece looks good to me, so you can start circulating for clearances whenever you're ready.
Happy New Year to both of you!
Best, Jennifer

On Mon, Jan 4, 2021 at 11:32 AM Kendra Chittenden < > wrote:

> Jennifer
>
> Happy New Year! I hope that you had a nice holiday. Please see the attached CRM for your review and approval. Thank you!

INITIAL ENVIRONMENTAL EXAMINATION

CONTENTS

1.0 PROJECT/ACTIVITY DESCRIPTION

1.1 PURPOSE OF THE IEE

The purpose of this document, in accordance with Title 22, Code of Federal Regulations, Part 216 (22 CFR 216), is to provide a preliminary review of the reasonably foreseeable effects on the environment of the USAID intervention described herein and recommend determinations and, as appropriate, conditions, for these activities. Upon approval, these determinations become affirmed, and specified conditions become mandatory obligations of implementation. This IEE also documents the results of the Climate Risk Management process in accordance with USAID policy (specifically, ADS 201mal).

This IEE is a critical element of USAID's mandatory environmental review and compliance process meant to achieve environmentally sound design and implementation. Potential environmental impacts should be addressed through formal environmental mitigation and monitoring plans (EMMPs) and/or Environmental Assessments (EAs), if needed.

1.2 PROJECT/ACTIVITY OVERVIEW

To conduct applied research to deepen knowledge on unknown viruses from wildlife including their zoonotic and pandemic potential. Through Discovery & Exploration of Emerging Pathogens - Viral Zoonoses (DEEP VZN), the U.S. Agency for International Development (USAID) seeks to build on previous work by assisting a limited number of high-risk/low-capacity countries in Asia and Africa to conduct intensive applied research to detect and characterize previously unknown viruses (from a limited number of viral families) that have originated in wildlife. Monitoring for unknown viruses will be conducted in both wildlife and human populations that are in contact with wildlife or wildlife products. DEEP VZN will build on more than 15 years of USAID investments in promoting a multisectoral (One Health) approach to addressing emerging zoonotic viruses before they pose an overwhelming epidemic or pandemic threat. Specifically, DEEP VZN will assist targeted African and Asian countries in strengthening their research capacities to detect unknown viruses at animal-animal or animal-human interfaces where risk profiles favor spillover, amplification, or spread of emerging zoonotic viruses. Detection will be complemented by efforts to assess the zoonotic and pandemic potential of these viruses. These efforts will appropriately address gender in the development of research tools and strategies and the sharing of results to mitigate spillover of these novel viruses.

1.3 PROJECT/ACTIVITY DESCRIPTION

To strengthen host country research capacity and deepen knowledge on unknown viruses from wildlife, including their zoonotic and pandemic potential, this project will: collect samples from animals and people at a range of high risk spillover sites (such as live animal markets in urban environments to remote areas such as caves); strengthen in country laboratory capacity to detect and analyze novel viruses in country, which may include technical and biosafety and biosecurity training, providing equipment and reagents; as needed to ship samples to other regional and international laboratories.

TABLE 2: DEFINED OR ILLUSTRATIVE PROJECTS/ACTIVITIES AND SUB-ACTIVITIES

Project/Activity 1 – Technical assistance and capacity building of personnel

Sub-activity 1.1. Education, technical assistance, capacity building, training, and analysis activities for ecologists, animal and human health experts involved in sampling and personnel who work in the laboratories to collect, detect, and characterize known and unknown viruses as prioritized in this project. Trainings are not clinical and will not cover topics that directly affect the environment.

Project/Activity 2 — Establish monitoring for unknown viruses

Sub-activity 2.1. Collecting samples from animals and people at high-risk spillover sites

Wildlife sampling including taking blood, fecal matter, and sputum samples, from a range of species with a particularly focus on rodents, bats, non-human primates. Human sampling is likely to focus on blood and may include other bodily fluids, such as blood, lymph, saliva, semen, or urine. Live animals may be sampled and in certain situations, such as interactions with bushmeat hunters, samples will be taken from dead animals. The details beyond this description are not yet determined.

Project/Activity 3 — Strengthening detection of novel viruses

Sub-activity 3.1. Provide host country lab(s) with training, equipment, and reagents (as needed) for biosafety, testing, receptor binding and transmissibility studies on the identified DEEP VZN priority viral family/families. If at a later date, activities including the shipment, storage, and/or distribution of the public health commodities are to be implemented, then this IEE will be amended.

Sub-activity 3.2. Provide diagnostic support during an outbreak or pandemic which may include providing technical assistance, training, equipment, and reagents, and/or shipping samples regional or internationally

Project/Activity 4. Strengthen characterization of novel viruses

Sub-activity 4.1. Assess zoonotic potential in host country labs- which may include growing the virus, conducting receptor binding assays including infecting human cells

Laboratory and scientific techniques used to characterize novel viruses which may have the potential to infect humans and/or pandemic potential will need to be conducted in a laboratory with adequate biosecurity, most likely Biosafety Level 3 facilities, to make sure that the viruses are contained and all of the contaminated materials, including liquid and solid, wastes are properly disposed of and the specimens are properly and safely stored, decontaminated or destroyed.

Sub-activity 4.2. Assess pandemic potential in host country lab: transmissibility among mammals

Project/Activity 5. Rehabilitation and Improvements to laboratory biosafety and biosecurity (if needed)

Sub-activity 5.1 Minor refurbishments to laboratory infrastructure:

This sub-activity could include upgrading electricity, repairs to Heating, Ventilation and Air Conditioning (HVAC), refrigerators, freezers, autoclaves, incinerators adding walls to block off areas; cosmetic changes to improve cleanliness (fresh paint, changes to wall or floor materials), may be needed to achieve and maintain properly biosafety and biosecurity & waste management. Some aspects of these minor refurbishments such as (1) refurbishments which include electricity, (2) use of materials that are hazardous to the environment.

Project Activity 6. Procurement of Healthcare Commodities, Equipment, and Construction Materials

Sub-activities 6.1 This activity involves procurement, and management and/or disposal of reagents or chemicals. If at a later date, activities including the shipment, storage, and/or distribution of the public health commodities are to be implemented, then this IEE will be amended.

Will this project/activity involve construction[3] as defined by ADS 201 and 303? ☒ Yes ☐ No

If needed, the project may support minor refurbishments, including upgrading electricity, repairs to Heating, Ventilation and Air Conditioning (HVAC), refrigerators, freezers, autoclaves, incinerators adding walls to block off areas; cosmetic changes to improve cleanliness (fresh paint, changes to wall or floor materials), may be needed to achieve and maintain properly biosafety and biosecurity & waste management. Some aspects of these minor refurbishments such as (1) refurbishments which include water and electricity, (2) use of materials that are hazardous to the environment may unintentionally lead to direct or indirect impact on the natural and physical environment.

2.0 BASELINE ENVIRONMENTAL INFORMATION

2.1 LOCATIONS AFFECTED AND ENVIRONMENTAL CONTEXT (ENVIRONMENT, PHYSICAL, CLIMATE, SOCIAL, THREATENED AND ENDANGERED SPECIES)

DEEP VZN is expected to focus on selected 5-10 countries in Asia and Africa. Priority countries include: Democratic Republic of Congo, Ethiopia, Liberia, Uganda, Bangladesh, Cambodia, Indonesia, and Vietnam. But the project is not limited to these countries. There are no foreseeable restrictions on countries. Note – this is an illustrative list and the final country selection will depend on: (1) host country interest and motivation; (2), availability of data; (3), receptivity of operational environments (including staff and institutional capacities); (4), opportunities to leverage USG and other partner investments; (5) availability of, global capacity assessments; (6), likelihood of success, and (7) potential for knowledge and lessons learned to be used to address similar issues in other countries. Additional country and local information will be provided once specific activities and locations are identified.

2.2 APPLICABLE AND APPROPRIATE PARTNER COUNTRY AND OTHER INTERNATIONAL STANDARDS (E.G. WHO), ENVIRONMENTAL AND SOCIAL LAWS, POLICIES, AND REGULATIONS

The status of country level environmental policies, standards, laws, and regulations vary by country. The final country selection for this project has not yet been made, so this baseline information is not yet available. The appropriate international standard is listed in the mitigation plan. Here is a summary of relevant standards:

- USAID: Healthcare Waste (2019)
- USIAD: Integrated Waste Management Plan (IWMP) (2019)
- WHO: Safe management of waste from health-care activities
- WHO: Laboratory Biosafety Manual- Third Edition (2004)
  - CDC and NIH: Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition (2020)
  - U.S. National Institute of Health: NCCIH Clinical Research Toolbox (2020)
  - Guidelines of the American Society of Mammologists for the use of wild mammals in research (2011)

[3] **Construction, as defined by ADS 201 and 303,** includes: construction, alteration, or repair (including dredging and excavation) of buildings, structures, or other real property and includes, without limitation, improvements, renovation, alteration and refurbishment. The term includes, without limitation, roads, power plants, buildings, bridges, water treatment facilities, and vertical structures. In the box below, describe any construction planned for this project/activity. Refer to ADS 201maw for required Construction Risk Management procedures.

- Canadian Council on Animal Care guidelines on: the care and use of wildlife (2003)
- Applied Research and Ethic National Association (ARENA) Institutional Animal Care and Use Committee Guidebook
- USAID Sector Environmental Guidelines: Construction (2017)
- ENCAP Visual Field Guide: Construction for quick identification of serious environmental & occupational health and safety concerns in small-scale construction.

2.3 COUNTRY/MINISTRY/MUNICIPALITY ENVIRONMENTAL CAPACITY ANALYSIS (AS APPROPRIATE)

To develop country-specific environmental analyses, the IP(s) are expected to first draw from existing USAID or other country-level environmental analysis. The relevant USAID Mission Environmental Officers (MEOs) may also be consulted to provide additional resources or assistance.

To develop country-specific climate analysis, the IPs are expected to first draw from the USAID Climate links website, which provides country- and region-specific profiles on climate vulnerability, risk, and/or adaptation. The relevant USAID Mission Climate Integration Leads (CILs) may also be consulted to provide additional resources or assistance.

3.0 ANALYSIS OF POTENTIAL ENVIRONMENTAL RISK

PROJECT/ACTIVITY 1: **TECHNICAL ASSISTANCE AND CAPACITY BUILDING OF PERSONNEL**

There are no adverse environmental impacts identified for education, technical assistance, capacity building, training, and analysis activities.

TABLE 3A. POTENTIAL IMPACTS – PROJECT/ACTIVITY 1

Project/Activity	Potential environmental and social impacts
Sub-activity 1.1:	**Categorical Exclusion** §216.2(c)(2)(i) Education, technical assistance, or training programs §216.2(c)(2)(iii) Analyses, studies, academic or research workshops and meetings

PROJECT/ACTIVITY 2**: ESTABLISH MONITORING FOR UNKNOWN VIRUSES**

The existing sample collection strategy and targeted animals have not yet been determined and depends on the final selection of countries. There are no adverse environmental impacts identified for education, technical assistance, capacity building, training, and analysis activities. Wildlife sampling requires handling taking bodily fluids from animal and humans and potential dealing with dead animals, which will require strict adherence to appropriate biosafety procedures to mitigate environmental impacts. Additional reagents and chemical that may be used will require proper disposal procedures to mitigate environmental impacts. Once more specific activities are identified, additional environmental review will be conducted in accordance with 22 CFR 216.

TABLE 3B. POTENTIAL IMPACTS – PROJECT/ACTIVITY 2

Project/Activity	Potential environmental and social impacts
Project/Activity 2.1: Collecting samples from animals and people at high-risk spillover sites	Given that sampling requires direct contact between humans and animals, besides the generations of solid waste, some potential environmental impact include: removing an animal specimen from its native habitat, harm or death to the animal specimen; damaging an ecosystem by impacting the distribution of the population of a particular species. Human sampling presents environmental risks for waste management. This activity may involve procurement of reagents or chemicals that will need to be properly disposed of to protect the chemical and the environment. Improper management and storage of the reagents or chemicals pose risks to both the environment and human health. Transportation of workers and others handling healthcare waste may be in direct contact with hazardous or highly hazardous waste during disposal activities, which could lead to health impacts.

PROJECT/ACTIVITY 3**: STRENGTHENING DETECTION OF NOVEL VIRUSES**

The targeted types of viruses, specimen, and laboratory detection methods will be fully determined during the implementation of the project with country representatives. At this time, it

is not possible to provide a clear description of exactly what may be included in this research to detect novel virus and/or the methodologies that will be applied. Additional environmental review may be required once activities are further developed. Activities to detect emerging and zoonotic diseases require strict adherence biosafety and biosecurity management practices. Additionally, reagents and chemical that may be used will require proper disposal procedures to mitigate environmental impacts. Once more specific activities are identified, additional environmental review will be conducted in accordance with 22 CFR 216.

TABLE 3C. POTENTIAL IMPACTS – PROJECT/ACTIVITY 3

Project/Activity	Potential environmental and social impacts
Project/Activity 3.1: Provide host country lab(s) with training, equipment, and reagents (as needed) for biosafety, testing, receptor binding and transmissibility studies on the identified DEEP VZN priority viral family/families	The procuring of certain types of reagents, supplies, equipment may have an impact on the environment if not properly disposed. Detection activities may result in hazardous or highly hazardous medical waste which could pose risks to staff and/or the community if staff are not properly trained, materials are not properly managed and/or routinely monitored. Procuring an oversupply of health commodities increases the probability of products expiring on the shelf and requiring disposal. With higher disposal requirements, damaged and expired chemicals and/or pharmaceuticals create a larger waste stream of potentially hazardous waste and associated environmental impacts. Disposing a larger amount of chemicals also creates greater entry points of chemicals to be diverted from the waste stream into the community for improper use. Procurement or acceptance of donated health commodities that are defective, expired, or counterfeit may lead to public health impacts due to the potential use of commodities being unsafe and/or ineffective if used by consumers. Adverse health and environmental impacts may also occur if defective, expired, or counterfeit health commodities are not properly managed and disposed. Workers and others handling healthcare waste may be in direct contact with hazardous or highly hazardous waste during disposal activities, which could lead to health impacts.

Sub-activity 3.2: Provide diagnostic support during an outbreak or pandemic which may, and/or shipping samples regional or internationally	Environmental risks include the spread of infectious agents from person or properties used during response efforts, and if there are needs to collect samples from animals, or humans, in sensitive habitats, this could unintentionally have short and long term impacts to threatened and endangered species due to untimely or invasive response actions; contamination of soil, sediment or groundwater due to the presence of infectious agents; chemical, etc. at the response site; and contamination of person, property and environment due to inadequate containment planning and implementation Improper transportation, treatment, and disposal of healthcare waste may lead to adverse health and environmental impacts. Workers and others handling healthcare waste may be in direct contact with hazardous or highly hazardous waste during disposal activities, which could lead to health impacts. Environmental impacts may occur from the use of vehicles to transport wastes (e.g., fuel operation, maintenance, spills, etc.) or traffic accidents resulting in spills.

PROJECT/ACTIVITY 4**: STRENGTHEN CHARACTERIZATION OF NOVEL VIRUSES**

The targeted types of viruses, specimen, and laboratory characterization methods will be fully determined during the implementation of the project with country representatives. At this time, it is not possible to provide a clear description of exactly what may be included in this research to characterize novel virus and/or the methodologies that will be applied. Additional environmental review may be required once activities are further developed. Activities to characterize emerging and zoonotic diseases require strict adherence biosafety and biosecurity management practices. Additionally, reagents and chemical that may be used will require proper disposal procedures to mitigate environmental impacts. Once more specific activities are identified, additional environmental review will be conducted in accordance with 22 CFR 216.

TABLE 3D. POTENTIAL IMPACTS – PROJECT/ACTIVITY 4

Project/Activity	Potential environmental and social impacts
Project/Activity 4.1: Assess zoonotic potential in host country labs- which may include growing the virus, conducting receptor binding assays including infecting human cells	Virus detection activities may result in hazardous or highly hazardous medical waste which could pose risks to staff and/or the community if not properly managed and/or routinely monitored. Laboratory research may use hazardous and toxic chemicals and result in the generation of various solid and hazardous wastes, including chemical and biological wastes. Air emissions resulting from laboratory operations and/or disposal of biological waste may generate hazardous air pollutants that can be harmful to human health and the environment. In addition, water used during laboratory research may become contaminated and require control or treatment prior to discharge to avoid contamination of water systems. There are risks of accidental spills, fires, or theft. Other risks may include the use of certain reagents and chemicals to conduct this characterize or decontaminations.
Sub-activity 4.2: Assess pandemic	In addition to the risks outlined in sub-activity 3.1, assessing

potential in host country lab: transmissibility among mammals	pandemic risks may include activities such as infecting a healthy animal with a disease, which creates risks by generating infected animals, which will require an incinerator to properly dispose of the infected animal carcasses and other contained materials. Improper handling, storage, treatment, and disposal of healthcare waste may lead to adverse health and environmental impacts. Workers and others handling healthcare waste may be in direct contact with hazardous or highly hazardous waste during disposal activities, which could lead to health impacts. Improper transportation, treatment, and disposal of healthcare waste may lead to adverse health and environmental impacts. Workers and others handling healthcare waste may be in direct contact with hazardous or highly hazardous waste during disposal activities, which could lead to health impacts. Environmental impacts may occur from the use of vehicles to transport wastes (e.g., fuel operation, maintenance, spills, etc.) or traffic accidents resulting in spills.

PROJECT/ACTIVITY 5: REHABILITATION AND IMPROVEMENTS TO LABORATORY BIOSAFETY AND BIOSECURITY (IF NEEDED)

TABLE 3E. POTENTIAL IMPACTS – PROJECT/ACTIVITY 5

Project/Activity	Potential environmental and social impacts
Sub-activity 5.1:	Some aspects of these minor refurbishments such as (1) refurbishments which include water and electricity, (2) use or rehabilitation of materials that are hazardous to the environment may unintentionally lead to direct or indirect impact on the natural and physical environment. Virus detection activities may result in hazardous or highly hazardous waste which could pose risks to staff and/or the community if not properly managed and/or routinely monitored. Use of certain building materials could lead to adverse environmental impacts due health hazards during construction. In particular, structures with lead-based paint, asbestos, and formaldehyde (sometimes used in products like particle board, plywood, and insulation) are unsafe for both workers and future users of the facilities as residues can present health hazards, especially to children. In addition, buildings and other structures that are constructed in areas prone to natural disasters (e.g., earthquakes, flooding, extreme heat, etc.) may cause health and safety impacts if disturbed. Adverse environmental impacts to soil and water may also occur if hazardous materials (e.g., chemicals, fuel, medical supplies and waste, etc.) stored in buildings are released during normal operation or natural disaster events. Additionally, inefficient energy use practices increase energy consumption, and the use of non-renewable sources may lead to air and water impacts.

	Refurbishments may generate excess debris and wastes that contain both non-hazardous and hazardous materials and require proper disposal. This includes chemicals, solvents, and any materials containing toxic substances, such as asbestos, lead-based paint, and formaldehyde. Workers and others handling construction debris and wastes may also be exposed to hazardous materials if the appropriate personal protective equipment (PPE) is not used. Exposure to hazardous building materials during renovation activities can result in health impacts to workers. Site conditions may also result in health and safety impacts to workers and nearby residents if work sites are not properly managed and secured. In addition, the use of heavy equipment (e.g., graders, scrapers, bulldozers, large trucks, etc.) can result in environmental impacts, including air degradation from air emissions, soil or surface water contamination from fuel and oil releases, and soil and surface water impacts from physical disturbances. Laboratory research may use hazardous and toxic chemicals and result in the generation of various solid and hazardous wastes, including chemical and biological wastes. Air emissions resulting from laboratory operations may generate hazardous air pollutants that can be harmful to human health and the environment. In addition, water used during laboratory research may become contaminated and require control or treatment prior to discharge to avoid contamination of water systems. There are risks of accidental spills, fires or theft. Following construction activities, appropriate measures should be taken to successfully transfer the new or renovated facility to the host country organization. This involves developing and providing guidance materials and training to workers, so they are informed on how to properly use, operate, and maintain the facility so that health and environmental impacts are minimized. This includes guidance on avoiding contamination to soil and nearby water source from power equipment (e.g., generators, pumps, etc.). The level of guidance and training will be dependent on the size and complexity of the facility.

PROJECT/ACTIVITY 6: PROCUREMENT OF HEALTHCARE COMMODITIES, EQUIPMENT, AND CONSTRUCTION MATERIALS

TABLE 3F. POTENTIAL IMPACTS - PROJECT/ACTIVITY 6

Project/Activity	Potential environmental and social impacts
Sub-activity 6.1:	Procuring an oversupply of health commodities increases the probability of products expiring on the shelf and requiring disposal. With higher disposal requirements, damaged and expired chemicals and/or pharmaceuticals create a larger waste stream of potentially hazardous waste and associated environmental impacts. Disposing a larger amount of chemicals also creates greater entry points of chemicals to be diverted from the waste stream into the community for improper use.

	Improper storage of health commodities can result in pharmaceuticals being damaged due to failure to meet storage condition requirements, theft through inadequate security, damage from pests, and hazards such as fire. The ultimate environmental and social impacts are damaged products getting into the environment or local community due to improper storage. In addition, equipment used to operate the storage facility (e.g., mobile equipment, chillers, HVAC systems, fuel storage tanks, etc.) should be properly maintained to prevent accidents or spills from occurring that may lead to health or environmental impacts. Procurement or acceptance of donated health commodities that are defective, expired, or counterfeit may lead to public health impacts due to the potential use of commodities being unsafe and/or ineffective if used by consumers. Adverse health and environmental impacts may also occur if defective, expired, or counterfeit health commodities are not properly managed and disposed.

4.0 ENVIRONMENTAL DETERMINATIONS

4.1 RECOMMENDED ENVIRONMENTAL DETERMINATIONS

The following table summarizes the recommended determinations based on the environmental analysis conducted. Upon approval, these determinations become affirmed, per 22 CFR 216. Specified conditions, detailed in Section 5, become mandatory obligations of implementation, per ADS 204.

TABLE 4**: ENVIRONMENTAL DETERMINATIONS**

Projects/Activities	Categorical Exclusion Citation (if applicable)	Negative Determination	Positive Determination[4]	Deferral[5]
Project/Activity 1. Technical assistance and capacity building of personnel	§216.2(c)(2)(i) Education, technical assistance, or training programs §216.2(c)(2)(iii) Analyses, studies, academic or research workshops and meetings	☐	☐	☐
Sub-activity 1.1. education, technical assistance, capacity building, training, and analysis activities for ecologists, animal and	§216.2(c)(2)(i) Education, technical assistance, or training programs	☐	☐	☐

[4] Positive Determinations require preparation of a Scoping Statement and Environmental Assessment.

[5] GH does not grant Deferrals for projects during the IEE Process.

human health experts involved in sampling and personnel who work in the laboratories to collect, detect, and characterize known and unknown viruses as prioritized in this project.	§216.2(c)(2)(iii) Analyses, studies, academic or research workshops and meetings			
Project/Activity 2. Establish monitoring for unknown viruses		☒	☐	☐
Sub-activity 2.1: Collecting samples from animals and people at high-risk spillover sites		☒	☐	☐
Project/Activity 3: Strengthening detection of novel viruses		☒	☐	☐
Sub-activity 3.1: Provide host country lab(s) with training, equipment, and reagents (as needed) for biosafety, testing, receptor binding and transmissibility studies on the identified DEEP VZN priority viral family/families		☒	☐	☐
Sub-activity 3.2: Provide diagnostic support during an outbreak or pandemic which may include providing technical assistance, training, equipment and reagents, and/or shipping samples regional or internationally		☒	☐	☐
Project Activity 4.0: Strengthen characterization of novel viruses		☒	☐	☐
Sub-activity 4.1: Assess zoonotic potential in host country labs- which may include growing the virus, conducting receptor binding assays including infecting human cells		☒	☐	☐
Sub-activity 4.2: Assess pandemic potential in host country lab: transmissibility among mammals		☒	☐	☐
Project/Activity 5. Rehabilitation and Improvements to laboratory biosafety and biosecurity (if needed)		☒	☐	☐

Sub-activity 5.1. Minor refurbishments to laboratory infrastructure:		☒	☐	☐
Project Activity 6. Procurement of Healthcare Commodities, Equipment, and Construction Materials		☒	☐	☐
Sub-activities 6.1. This activity involves procurement, and management and/or disposal of reagents or chemicals		☒	☐	☐

4.2 CLIMATE RISK MANAGEMENT

This section summarizes the methodology used and findings of the CRM Screening, in accordance with ADS 201mal. The project design team, in consultation with the CIL, considered the potential effect of climate risks/stressors on the sustainability of the project (changing precipitation patterns, rising temperature, floods, droughts, fires, landslides, etc.) in addition to the impact of project activities on the climate (increased greenhouse gas emissions, land use changes, etc.). See Annex 1 for the compete CRM table

GH Office of Infectious Disease (OID) Emerging Threats Division (ETD) and DEEP VZN design team completed the CRM analysis by: (1) Consulting with ETD's technical advisors and reviewing project-specific reports/data to identify any known climate risks and mitigation strategies that are applicable to ongoing ETD awards (2) Reviewing USAID's country/regional climate risk profile fact sheets from Asia and East/West Africa; (3) Using the Climate Risk Screening and Management Tool, referencing the "Health Annex," to assess climate risks and inform project design and (4) referencing CRM documentation for previously approved projects.

At this time, the project is at the design stage, and all activities listed are illustrative. A majority of expected activities/sub-activities present low risk (with a few moderate risks); please refer to the CRM table analysis in the Annex. The DEEP VZN project will include opportunities to strengthen climate resilience and address the identified risks at the project design stage and include appropriate language and references to the CRM within the solicitation and award documentation. Applicants will be encouraged to complete the Climate Risk Tool for any activities that meet the moderate to high-risk rating. ETD will continue to work with the implementing partners, once the projects are awarded, to address climate risk at the work planning level.

Per instructions in the solicitation and award documentation, the implementing partner will be expected to ensure that sub-grantees and subcontractors have the capability to implement CRM. The implementing partner will, if appropriate, provide orientation to sub-grantees and subcontractors on climate risk management. Per Mandatory Reference for ADS Chapter 201 Climate Risk Management for USAID Projects and Activities, implementing partners may integrate "documentation" of the benefits of taking action to reduce climate change impacts and/or increase adaptive capacity" in their performance monitoring in program elements with moderate or high-risk ratings.

5.0 CONDITIONS AND MITIGATION MEASURES

5.1 CONDITIONS

The environmental determinations in this IEE are contingent upon full implementation of the following general implementation and monitoring requirements, as well as ADS 204 and other relevant requirements.

5.1.1 During Pre-Award:

5.1.1.1 **Pre-Award Briefings:** As feasible, the design team (e.g. Project Design Team) and/or the cognizant environmental officer(s) (e.g., MEO, REA, BEO) will provide a pre-award briefing for potential offerors on environmental compliance expectations/responsibilities at bidders' conferences.

5.1.1.2 **Solicitations:** The design team, in coordination with the AO/CO, will ensure solicitations include environmental compliance requirements and evaluation criteria. AO/CO will ensure technical and cost proposal requirements include approach, staffing, and budget sufficient for complying with the terms of this IEE.

5.1.1.3 **Awards:** The AOR/COR, in coordination with the A/CO, will ensure all awards and sub-awards, include environmental compliance requirements and sufficient resources for implementation.

5.1.1.4 **Training:** The AOR/COR and Activity Managers (AM(s)) assigned to this project are to enroll in and successfully complete the Bureau for Global Health (GH) Environmental Management Process Training online course prior to receiving GH BEO clearance on this document.

5.1.2 During Post-Award:

5.1.2.1 **Post-Award Briefings:** The AOR/COR and/or the cognizant environmental officer(s) (e.g., MEO, REA, BEO) will provide post-award briefings for the IP on environmental compliance responsibilities.

5.1.2.3 **Workplans and Budgeting:** The AOR/COR will ensure the IP integrates environmental compliance requirements in workplans and budgets to comply with requirements, including EMMP implementation and monitoring.

5.1.2.4 **Staffing:** The AOR/COR, in coordination with the IP, will ensure all awards have staffing capacity to implement environmental compliance requirements.

5.1.2.5 **Records Management:** The AOR/COR will maintain environmental compliance documents in the official project/activity file and upload records to the designated USAID environmental compliance database system.

5.1.2.6 **Host Country Environmental Compliance:** The AOR/COR will ensure the IP complies with applicable and appropriate host country environmental requirements unless otherwise directed in writing by USAID. However, in the case of a conflict between the host country and USAID requirements, the more stringent shall govern.

5.1.2.7 **Work Plan Review:** The AOR/COR will ensure the IP verifies, at least annually or when activities are added or modified, that activities remain with the scope of the IEE, using the GH Environmental Screening Form (ESF) Template. Activities outside of the scope of the IEE cannot be implemented until the IEE is amended.

5.1.2.8 **IEE Amendment:** If new activities are introduced or other changes to the scope of this IEE occur, an IEE Amendment will be required.

5.1.2.9 **USAID Monitoring Oversight:** The AOR/COR or designee, with the support of the cognizant environmental officer(s) (e.g., MEO, REA, BEO), will ensure monitoring of compliance with established requirements (e.g., by desktop reviews, site visits, etc.).

5.1.2.10 **Environmental Compliance Mitigation and Monitoring Plan(s):** The AOR/COR will ensure the IP develops, obtains approval for, and implements Environmental Mitigation and Monitoring Plan(s) (EMMP(s)) that contain(s) mitigation measures that are responsive to the stipulated environmental compliance requirements. The AOR/COR must review and approve the EMMP(s) and provide a copy to the GH BEO for review and concurrence before work on the project/activities can be initiated.

5.1.2.11 **Environmental Compliance Reporting:** The AOR/COR will ensure the IP includes environmental compliance in regular project/activity reports, using indicators as appropriate; develops and submits the Environmental Mitigation and Monitoring Reports (EMMRs) annually, or as otherwise stipulated in the IEE, within 45 days after the end of each fiscal year to document compliance with the conditions of this IEE and the mitigation measures contained in the applicable EMMP(s); and completes and submits a Record of Compliance (RoC) describing the IP's implementation of EMMP requirements in conjunction with the final EMMR or at the close of sub-activities (as applicable). And, where required by Bureaus or Missions, the AOR/COR will ensure the IP prepares a closeout plan consistent with contract documentation for AOR/COR review and approval that outlines responsibilities for end-of-project operation, the transition of other operational responsibilities, and final EMMR with lessons learned.

5.1.2.12 **Corrective Action:** When noncompliance or unforeseen impacts are identified, IPs must notify the AOR/COR, place a hold on activities, take corrective action, and report on the effectiveness of corrective action(s). The USAID responsible person (e.g., MEO and/or REA) will verify that the Corrective Action Plan (CAP) has been adequately and reasonably completed. Then, the GH BEO will review the applicable corrective and preventive actions and/ when satisfied that they are suitable, adequate, and effective, shall authorize closure of the CAP. Where required by Bureaus or Missions, the AOR/COR will ensure Record of Compliance is completed.

5.2 AGENCY CONDITIONS

5.2.1 **Sub-award Screening:** The AOR/COR will ensure the IP uses an adequate environmental screening tool, such as the GH Environmental Screening Tool, to screen any sub-award applications and to aid in the development of EMMP(s).

5.2.2 **Programmatic IEEs (PIEE):** PIEEs stipulate requirements for further environmental examination of new or country-specific projects/activities. The AOR/COR of any project/activity being implemented under a PIEE will ensure appropriate reviews are conducted, typically through a Supplemental IEE, and approved by the cognizant BEO.

5.2.3 **Supplemental IEEs (SIEEs):** An SIEE will be prepared for any new project/activity being planned which fall under a PIEE. The SIEE will provide more thorough analysis of the planned activities, additional geographic context and baseline conditions as well as specific mitigation and monitoring requirements.

5.2.4 **Other Supplemental Analyses:** The AOR/COR will ensure supplemental environmental analyses that are called for in the IEE are completed and documented.

5.2.5 **Positive Determination:** If a Positive Determination threshold determination was made, the AOR/COR will ensure a Scoping Statement (SS), and if required, an Environmental Assessment (EA), is completed and approved by the BEO before the subject activities are implemented.

5.2.6 **Compliance with human subject research requirements:** The AM(s) or AOR/COR shall assure that the IP and sub-awardees, -grantees, and -contractors demonstrate completion of all requirements. This includes adequate for ethics review and adequate medical monitoring of human subjects who participate in research trials carried out through this IEE. The AOR/COR or AM(s) will also ensure appropriate records are maintained. All documentation demonstrating completion of required review and approval of human subject trials must be in place prior to initiating any trials and cover the period of performance of the trial as described in the research protocol.

5.2.7 **Pesticides or Pesticide Products:** Any activities conducted under this IEE involving the procurement, use, research, or disposal of pesticides and/or larvicides and their waste products will require an SIEE, Supplemental EA (SEA), or Pesticide Evaluation Report or Safer Use Action Plan (PERSUAP) based on consultations with the GH BEO.

5.2.8 **Waste Management Plan (WMP):** The AOR/COR or AM(s) shall ensure that the IP prepares an integrated Waste Management Plan or utilize an equivalent standard operating procedure (SOP) that will define and detail direct and indirect waste management streams generated by IP-managed activities and specify appropriate management practices, including handling, treatment, and/or disposal for each. The AOR/COR or AM(s) will ensure that the IP verifies the use of such WMP or SOP as a part of its environmental mitigation, monitoring, and reporting, including documentation in the annual EMMR.

5.3 MITIGATION MEASURES

The mitigation measures presented in this section constitute the minimum required based on available information at the time of this IEE and the environmental analysis in Section 4. These measures shall provide general direction for completing the project/activity Environmental Mitigation and Monitoring Plan (EMMP) and/or the EA and PERSUAP, if required.

PROJECT/ACTIVITY 1: TECHNICAL ASSISTANCE AND CAPACITY BUILDING OF PERSONNEL

TABLE 5A. SUMMARY OF MITIGATION MEASURES FOR PROJECT/ACTIVITY 1

Project/Activity	Mitigation Measure(s)
Sub-activity 1.1: Technical assistance and capacity building of personnel	§216.2(c)(2)(i) Education, technical assistance, or training programs in line with the objectives of the project to collect, detect, and characterize novel viruses. §216.2(c)(2)(iii) Analyses, studies, academic or research workshops and meetings in line with the objectives of the project to collect, detect, and characterize novel viruses.

PROJECT/ACTIVITY 2: ESTABLISH MONITORING FOR UNKNOWN VIRUSES

TABLE 5B. SUMMARY OF MITIGATION MEASURES FOR PROJECT/ACTIVITY 2

Project/Activity	Mitigation Measure(s)
Sub-activity 2.1: Collecting samples from animals and people at high-risk spillover sites	• Implementing partner shall collect wildlife/animal samples in a humane and ethical manner including a 'no kill 'policy when feasible. Proper training & management will be provided to all staff. Further information can be found at the Guidelines of the American Society of Mammologists for the use of wild mammals in research (2011); and Canadian Council on Animal Care guidelines on: the care and use of wildlife. ● The implementing partner will coordinate with the local environment experts, officials, NGOs, and the MEO to understand the sensitive species and habitats in the regions and to design procedures that ensure the protection of those habitats and species. ● The AOR/COR in consultation with the BEO for the Global Health Bureau shall assure that the implementing Partner and sub-awardees demonstrate completion of all requirements for ethics review and adequate medical monitoring of human subjects who participate in research trials carried out through this agreement. Federal (U.S.) Policy for the Protection of Human Subjects, 45 CFR part 46, outlines the criteria and mechanisms for IRB review of human subjects research. NIH Clinical Research toolbox provides resources to conduct safe, appropriate, high quality research including a template for data and safety monitoring (DSM) plans. ● Waste management will adhere to the guidance in the USAID sector environmental guidelines healthcare waste, specifically the following procedures in the WHO Safe management of wastes from health-care activities handbook to develop an Integrated Waste Management Plan (IWMP) ● Refer to the following document for guidance: ● WHO: Safe management of waste from health-care activities

	• Sector Environmental Guideline USAID: Healthcare Waste (2019) • EHS Manual: WHO. Laboratory Biosafety Manual-Third Edition (2004) • USAID: Integrated Waste Management Plan (IWMP) (2019) • Research and sampling:U.S. National Institute of Health: NCCIH Clinical Research Toolbox (2020)Federal (U.S.) Policy for the Protection of Human Subjects, 45 CFR part 46 • Guidelines of the American Society of Mammologists for the use of wild mammals in research (2011)Canadian Council on Animal Care guidelines on: the care and use of wildlife (2003)

PROJECT/ACTIVITY 3: STRENGTHENING DETECTION OF NOVEL VIRUSES

TABLE 5C. SUMMARY OF MITIGATION MEASURES FOR PROJECT/ACTIVITY 3

Project/Activity	Mitigation Measure(s)

Sub-activity 3.1: Provide host country lab(s) with training, equipment, and reagents (as needed) for biosafety, testing, receptor binding and transmissibility studies on the identified DEEP VZN priority viral family/families	• Commodities and supplies under this funding will be advised to store and dispose of the product according to the information provided on the manufacturer's Safety Data Sheet (SDS).
	• Activities to accomplish targets will be carried out in line with the appropriate international standards for laboratories including International Organization for Standardization (ISO) standards for accreditation; Biosafety Level (BSL) for work as outlined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition; and appropriate standards for sample collection, diagnostic tests, and testing algorithms for the specific disease or syndromes.
	• Laboratory and surveillance systems must meet the appropriate quality assurance (QA) standard established. Waste management will adhere to USAID sector environmental guidelines healthcare waste, WHO Safe management of wastes from health-care activities handbook or national and international regulations, guidelines and best practices to develop an Integrated Waste Management Plan (IWMP) or SOPs
	• Refer to the following document for guidance:
	  • Sector Environmental Guideline: USAID: Healthcare Waste (2019)
	  • WHO: Safe management of waste from health-care activities
	  • EHS Manual: WHO. Laboratory Biosafety Manual-Third Edition (2004)
	  • U.S. National Institute of Health: NCCIH Clinical Research Toolbox (2020)
	  • Canadian Council on Animal Care guidelines on: the care and use of wildlife (2003)

	• USAID: Integrated Waste Management Plan (IWMP) (2019) • CDC and NIH: Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition (2020)

Sub-activity 3.2: Provide diagnostic support during an outbreak or pandemic which may include shipping samples regional or internationally	• During a pandemic there may be quarantining of animals and/or humans which increases urgency and volume of supplies and generate larger amounts of waste. This project will adhere to guidance which is developed for pandemics and to interim guidance for the specific pandemic when developed by the appropriate entity – CDC, USDA, WHO, FAO, OIE.
	• The implementing partner will ensure that staff who are supporting this activity are properly training and protected.
	
	• Refer to the following document for guidance:
	  • Sector Environmental Guideline: USAID: Healthcare Waste (2019)
	  • WHO: Safe management of waste from health-care activities
	  • EHS Manual: WHO. Laboratory Biosafety Manual-Third Edition (2004)
	  • U.S. National Institute of Health: NCCIH Clinical Research Toolbox (2020)
	  • Canadian Council on Animal Care guidelines on: the care and use of wildlife (2003)
	  • CDC and NIH: Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition (2020)
	  • USIAD: Integrated Waste Management Plan (IWMP) (2019)

PROJECT/ACTIVITY 4: STRENGTHEN CHARACTERIZATION OF NOVEL VIRUSES

TABLE 5D. SUMMARY OF MITIGATION MEASURES FOR PROJECT/ACTIVITY 4

Project/Activity	Mitigation Measure(s)

Sub-activity 4.1: Assess zoonotic potential in host country labs- which may include growing the virus, conducting receptor binding assays including infecting human cells	• Develop and implement a laboratory environmental, health, and safety standard operating procedures (SOPs) that address management of waste streams associated with laboratory operations necessary to conduct activities. Ensure that the laboratory has the appropriately Material Safety Data Sheets (SDS) and SOP for accidents, such as spills, if not the partner will assist in the development for the related activities.
	• If animals are used in research, then the project will adhere to the Institutional Animal Care and Use Committee Guidebook including waste management.
	
	• Refer to the following document for guidance:
	  • Sector Environmental Guideline: USAID: Healthcare Waste (2019)
	  • WHO: Safe management of waste from health-care

	activities • EHS Manual: WHO. Laboratory Biosafety Manual-Third Edition (2004) • U.S. National Institute of Health: NCCIH Clinical Research Toolbox (2020) • Canadian Council on Animal Care guidelines on: the care and use of wildlife (2003) • USIAD: Integrated Waste Management Plan (IWMP) (2019)
Sub-activity 4.2: Assess pandemic potential in host country lab: transmissibility among mammals	• Develop and implement a laboratory environmental, health, and safety standard operating procedures (SOPs) that address management of waste streams associated with laboratory operations necessary to conduct activities. • Ensure that the laboratory has the appropriately Material Safety Data Sheets (SDS) and SOP for accidents, such as spills, if not the partner will assist in the development for the related activities. • If animals are used in research, then the project will adhere to the Institutional Animal Care and Use Committee Guidebook including waste management. • Refer to the following document for guidance: • Sector Environmental Guideline: USAID: Healthcare Waste (2019) • WHO: Safe management of waste from health-care activities • EHS Manual: WHO. Laboratory Biosafety Manual-Third Edition (2004) • U.S. National Institute of Health: NCCIH Clinical Research Toolbox (2020) • Canadian Council on Animal Care guidelines on: the care and use of wildlife (2003) • CDC and NIH: Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition (2020) • USIAD: Integrated Waste Management Plan (IWMP) (2019)

PROJECT/ACTIVITY 5: REHABILITATION AND IMPROVEMENTS TO LABORATORY BIOSAFETY AND BIOSECURITY (IF NEEDED)

TABLE 5E. SUMMARY OF MITIGATION MEASURES FOR PROJECT/ACTIVITY 5

Project/Activity	Mitigation Measure(s)
Sub-activity 5.1: Minor refurbishments to laboratory infrastructure:	• Develop a design plan that includes the use of appropriate building materials and complies with international best management practices and host country laws and regulations. • Avoid the use of materials known to cause health impacts, including asbestos-containing materials,

	lead-based paint, and materials that off-gas unsafe levels of formaldehyde. • Include the use of sustainable building materials (e.g., recycled products, renewable materials, etc.) where possible. ● Design storage areas so that hazardous materials are aboveground and in leak-proof containments to avoid spills from occurring during normal operation or natural disaster events. ● Refer to the following document for guidance when developing a design plan: ● USAID. Sector Environmental Guidelines: Construction (Full Technical Update: 2017) ● Conduct a site survey to adequately evaluate site conditions based on the size and complexity of the construction activity. Include maps, as needed. Examples of factors to be considered in the survey include: ● Alteration or degradation of land ● Soil erosion potential ● Storm water management ● Potential impacts to water supply systems ● Proximity of site to sensitive ecological or agricultural areas ● Proximity of site to public or incompatible locations ● Transport and use of required equipment and materials ● Operation and maintenance requirements • Refer to the following documents for guidance when conducting the site survey: ● USAID. Sector Environmental Guidelines: Construction (Full Technical Update: 2017) USAID. ● ENCAP Visual Field Guide: Construction for quick identification of serious environmental & occupational health and safety concerns in small-scale construction (December 2011) ● CDC and NIH: Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition (2020)

PROJECT/ACTIVITY 6: PROCUREMENT OF HEALTHCARE COMMODITIES, EQUIPMENT, AND CONSTRUCTION MATERIALS

TABLE 5F. SUMMARY OF MITIGATION MEASURES FOR PROJECT/ACTIVITY 6

Project/Activity	Mitigation Measure(s)
Sub-activity 6.1:	• Public health commodities may be purchased and/or procured to support the emergency, the project will comply with host country and international regulatory,

	shipping, and packaging requirements to ensure that only appropriate products enter the supply system. This includes products that are manufactured at facilities that meet good manufacturing practice (GMP) certification requirements, as recommended by the World Health Organization (WHO) or are pre-qualified by WHO. Develop and implement an inspection and quality assurance process for assessing and monitoring product quality. The partner should provide training on proper disposal of expired commodities and conduct routine monitoring.
	
	• Develop and implement a laboratory environmental, health, and safety manual with standard operating procedures (SOPs) that address management of waste streams associated with laboratory operations. Recommended components of such a manual include: Chemical hygiene plan
	  • Safety Data Sheets (SDS) for chemicals used in the lab
	  • Use of appropriate personal protective equipment (PPE)
	  • Inspection and permit records
	  • Integrated Waste Management Plan (IWMP), if applicable
	  • Spill prevention plan
	  • Injury and illness prevention plan
	  • Training requirements and records
	  • Conduct regular site visits and monitoring
	
	• Refer to the following document for guidance when developing a laboratory:
	  • EHS Manual: WHO. Laboratory Biosafety Manual-Third Edition (2004)
	
	• Refer to the following documents for guidance:
	
	  • WHO: Safe management of waste from health-care activities
	  • USAID DELIVER Project.
	  • USAID Sector Environmental Guideline: Healthcare Waste (2019)

6.0 LIMITATIONS OF THIS INITIAL ENVIRONMENTAL EXAMINATION

The determinations recommended in this document apply only to projects/activities and sub-activities described herein. Other projects/activities that may arise must be documented in either a separate IEE, an IEE amendment if the activities are within the same project/activity, or other type of environmental compliance document and shall be subject to an environmental analysis within the appropriate documents listed above.

Other than projects/activities determined to have a Positive Threshold Determination, it is confirmed that the projects/activities described herein do not involve actions normally having a significant effect on the environment, including those described in 22 CFR 216.2(d). Any activity that is likely to adversely affect threatened or endangered species or their critical habitat will result in a Positive Determination and necessitate production of a Scoping Statement and Environmental Assessment.

In addition, other than projects/activities determined to have a Positive Threshold Determination and/or a pesticide management plan (PERSUAP), it is confirmed that the projects/activities described herein do not involve any actions listed below. Any of the following actions would require additional environmental analyses and environmental determinations:

- Support project preparation, project feasibility studies, or engineering design for activities listed in §216.2(d)(1);
- Affect endangered and threatened species or their critical habitats per §216.5, FAA 118, FAA 119;
- Provide support to extractive industries (e.g. mining and quarrying) per FAA 117;
- Promote timber harvesting per FAA 117 and 118;
- Lead to new construction, reconstruction, rehabilitation, or renovation work per §216.2(b)(1);
- Support agro-processing or industrial enterprises per §216.1(b)(4);
- Provide support for regulatory permitting per §216.1(b)(2);
- Lead to privatization of industrial facilities or infrastructure with heavily polluted property per §216.1(b)(4);
- Research, testing, or use of genetically engineered organisms per §216.1(b)(1), ADS 211
- Assist the procurement (including payment in kind, donations, guarantees of credit) or use (including handling, transport, fuel for transport, storage, mixing, loading, application, clean-up of spray equipment, and disposal) of pesticides or activities involving procurement, transport, use, storage, or disposal of toxic materials. Pesticides cover all insecticides, fungicides, rodenticides, etc. covered under the Federal Insecticide, Fungicide, and Rodenticide Act per §216.2(e) and §216.3(b).

7.0 REVISIONS

Per 22 CFR 216.3(a)(9), when ongoing programs are revised to incorporate a change in scope or nature, a determination will be made as to whether such change may have an environmental impact not previously assessed. If so, this IEE will be amended to cover the changes. Per ADS 204, it is the responsibility of the USAID A/COR to keep the MEO/REA and BEO informed of any new information or changes in the activity that might require revision of this environmental analysis and environmental determination.

ATTACHMENTS:

Annex 1: Climate Risk Management Summary Table for Projects
Annex 2: Green Meeting Checklist

ANNEX 1. **PROJECT** CLIMATE RISK MANAGEMENT SUMMARY TABLE

Defined or Anticipated Project Elements[6]	**Climate Risks**[7]	**Risk Rating**[8]	**How Risks are Addressed at Project Level**[9]	**Further Analysis and Actions for Activity Design/ Implementation**[10]	**Opportunities to Strengthen Climate Resilience**[11]
Collecting samples from animals and people at high-risk spillover sites	Sampling activities may be delayed for hard to reach areas due to flooding or poor roads	MODERATE		Specific risk assessment will be made specific for country setting when the activities are developed in detail Develop transport systems resilient to climate and consider back-up options to continue transportation if impacted by severe weather	Considering integrating monitoring into field visits to reduce trips Plan to maximize sampling as feasible per trip Consider energy efficient technologies for cold chain transport – such as solar boxes
	Cold chain may be impacted by flooding and/or extreme heat	MODERATE		Assist country plans to develop emergency plans to continue operations	
Provide host country lab(s) with training, equipment, and reagents (as needed) for biosafety, testing, receptor binding and transmissibility studies on the identified	Shipping and disbursement of laboratory reagents or PPEs may be delayed due to extreme weather	MODERATE		Specific risk assessment will be made for specific country setting and once activities are developed in detail. Partner can forecast needs and also determine if there are alternative shipping routes in case there are seasonal or weather-related challenges	Consider minimizing the commodities needed to reduce waste

[6] Purpose/Sub-purpose, Area of Focus, or Activity/ Mechanism, etc.

[7] List key risks related to the project elements identified through either the strategy- or project-level climate risk assessment.

[8] Low/Moderate/ High

[9] Describe how risks have been addressed at the project level. If a decision has been made to accept the risk, briefly explain why.

[10] Describe CRM measures to be integrated into activity design or implementation, including additional analysis, if applicable.

[11] Describe opportunities to achieve development objectives by integrating climate resilience or mitigation measures.

DEEP VZN priority viral family/families				to ship and distribute reagents and PPE	
Assess zoonotic and/or pandemic potential in host country labs- which may include growing the virus, conducting receptor binding assays including infecting human cells	Severe weather such as flooding or storms which shut down electricity and water or knock down walls or restructures could render the laboratory nonfunctional and nonsecure	MODERATE		Specific risk assessment will be made specific for country setting when the activities are developed in detail Provide technical support to safeguard and repair laboratories as needed and within reason Develop back-up plans to continue activities- such as to continue work at another location	Help to assess existing water, sanitation & energy systems and make recommendations to improve resiliency to climate impacts if providing then ensure these systems are energy resilient Use energy efficiencies where possible- such as solar power
	Equipment and/or supplies may get damaged	MODERATE		Help to replace and/or repair as feasible	
	Proper waste management may be compromised	MODERATE		Help to replace and/or repair as feasible or find alternative solution- such as shipping waste to another facilities	
Provide diagnostic support during an outbreak or pandemic which may include providing technical assistance, training, equipment and reagents, and/or shipping samples regional or internationally	All of the above apply	MODERATE		All of the above apply	

Training, assessments, and monitoring	Training, assessments, or monitoring visits may get delayed due to extreme weather	LOW		Build flexibility into the schedule and use virtual platforms	Use virtual platforms as appropriate, integrate field and monitoring and training visits to reduce the number of trips Select medical technologies with lower energy consumption & reduced waste as feasible
Changes in vectors carrying zoonotic diseases	Leads to transmission of merging or re-emerging infectious diseases and has the potential to lead to an outbreak or pandemic	LOW		Project includes flexibility to provide support to provide assistance during an outbreak or pandemic which may include providing technical assistance, training, equipment, and reagents, and/or shipping samples regional or internationally	Incorporate knowledge of risks due to climate changes impacts into relevant trainings

ANNEX 2: GREEN MEETING CHECKLIST

Environmentally aware meetings and events are those planned in such a way as to eliminate, reduce, or recycle waste. This Checklist is intended to heighten the environmental consciousness of event planners and demonstrate the advantages of conducting environmentally aware events. This Checklist was adopted from the US Environmental Protection Agency recommendation of the Green Meeting Industrial Council (GMIC), http://www.epa.gov/oppt/greenmeetings/pubs/basic.html.

Consider the following as you select your environmental priorities:

PREVENTING AND REDUCING WASTE
 Focus on reducing waste, given limited in-country recycling facilities.
 Use double-sided printing, recycled content -where available- for promotional materials and handouts.
 Avoid mass distribution of handouts. Allow attendees to request copies or provide digital copies via CD, thumb drive, or website.
 Provide reusable name badges.
 Purchase large volume plastic bottles of water to dispense into glasses at each table, instead of individual sized plastic bottles
 Other actions:

RECYCLING AND MANAGING WASTE
 Where facilities exist, collect paper and recyclable beverage containers in meeting areas.
 Collect cardboard and paper in exhibit areas.
 Collect cardboard, beverage containers, steel cans, and plastics in food vending areas.
 Separate out organic waste for composting, Provide composting guidelines for conference venues.
 If reusable containers are not used, encourage use of recyclable beverage containers.
 Other actions:

CONSERVING ENERGY AND REDUCING TRAFFIC
 Seek naturally lighted meeting and exhibit spaces.
 Provide shuttle service from hotels to the event site.
 Choose meeting sites that have on-site housing.
 Other actions:

CONTRACTING FOOD SERVICE AND LODGING
 Plan food service needs carefully to avoid unnecessary waste.
 Consider use of durable food service items instead of disposables.
 Donate excess food to charitable organizations, including planning ahead via SOW/contract with the conference venue to ensure this happens.
 Work with non-replacement of linens, soaps, etc.
 Other actions:

BUYING ENVIRONMENTALLY AWARE PRODUCTS
 Use recycled paper for promotional materials and handouts, where available.
 Consider selling or providing refillable containers for beverages.

 Provide reusable containers for handouts or samples (pocket or file folders, cloth bags).
 Where reusable items are not feasible, select products that are made from recovered materials and that also can be recycled.
 Other actions:

EDUCATING PARTICIPANTS AND EXHIBITORS
 Request the use of recycled and recyclable handouts or giveaways.
 Request that unused items be collected for use at another event.
 Encourage participants to recycle materials at the event.
 Reward participation by communicating environmental savings achieved.
 Other actions: