1. PROGRAM/ACTIVITY DATA:

Program/Activity Number: 936-6100
Program Activity Title: Health Research Program (HRP) 2.0
Country/Region: Global
Functional Objective: 3: Investing In People (Health)
Program Elements:

- Program Area 3.1: Health
  - Program Element: 3.1.1 HIV/AIDS
  - Program Element: 3.1.2 Tuberculosis
  - Program Element: 3.1.3 Malaria
  - Program Element 3.1.4 Avian Influenza
  - Program Element 3.1.5 Other Public Health Threats
  - Program Element: 3.1.6 Maternal Health and Child Health
  - Program Element: 3.1.7 Family Planning and Reproductive Health
  - Program Element: 3.1.8 Water Supply and Sanitation
  - Program Element: 3.1.9 Nutrition

IEE Prepared By: Amendment prepared by Ann Yang (anyang@usaid.gov). The original IEE was prepared by Sara Sulzbach (ssulzbach@usaid.gov) and Stefanie Evans.

Bureau Contact Point: Neal Brandes (nbrandes@usaid.gov)
Period Covered: FY2017-2021
LOP Amount: USD$160.3 million
Current Date: November 22, 2017
Expiration Date: September 30, 2021
IEE Amendment: Yes. The original IEE was completed on August 10, 2015 and this Amendment was completed on November 22, 2017.

Other Relevant Environmental Compliance Documentation: USAID’s Sector Environmental Guidelines for Healthcare Waste (http://www.usaidgems.org/Sectors/healthcareWaste.htm) contains guidance which must inform compliance with these conditions, particularly in the section titled, “Minimum elements of a complete waste management program.” Also refer to WHO’s “Safe Management of Wastes from Healthcare Activities.”
ENVIRONMENTAL ACTION RECOMMENDED

Categorical Exclusion X Negative Determination X
Positive Determination ___ Deferral ___

ADDITIONAL ELEMENTS:
EMMP: X Conditions: X PVO/NGO: ___ Pesticides:* X

*22 CFR 216.3 (b)(1) applies

2. SUMMARY OF FINDINGS:

2.1 Scope
The purpose of this document is to review the overall activities undertaken by the Health Research Program (HRP) 2.0 and to provide threshold determinations of environmental impact and any conditions for mitigation. This IEE addresses the entire portfolio of research activities anticipated under the HRP 2.0 portfolio. The portfolio may include a technical support contract, a cooperative agreement(s) for evaluation and product development as well as broad agency announcements for implementation research and research utilization. Each prime award will be required to have an EMMP and may include subawards. The goal of HRP 2.0 is to support applied research and development using a managed research-to-use process to achieve the goal of Investing in People – namely the introduction, adoption, sustained utilization and progress to scale of new or refined products, technologies, tools or interventions that will improve health, strengthen health systems and increase survival of target populations. Specifically, the project will address the following programmatic areas:
1. Stakeholder engagement, research translation and collaborative learning: effective, continuous communication, knowledge management and priority setting processes to inform the research-to-use process.
2. Accelerated product introduction and evaluation research leading to the scale-up of new health technologies and interventions which are appropriate, affordable, and acceptable for distribution and use in low-resource settings.
3. Implementation research and research utilization: implementation research to identify barriers to use of proven products and services and research utilization to facilitate uptake of results at the country level to improve maternal and child health outcomes.

The original IEE was developed to apply to all anticipated research activities expected under HRP 2.0, except for activities covered by another IEE (for example, microbicides (OHA) and insecticides (PMI) as was the case under the original HaRP program). The original IEE was approved in August 2015. This first amendment was completed after a review of a new contract and two new cooperative agreements awarded under HRP 2.0. The amended language reflects a more accurate description of existing and future activities under HRP 2.0, including clarification on any anticipated research that would include pesticides.

2.2 Recommended Determinations
The following table summarizes the recommended determinations for the HRP 2.0 portfolio, per the intervention categories established by this IEE for purposes of environmental review. Upon approval of this IEE, these recommendations become affirmed Categorical Exclusions and Threshold Decisions, and implementation of recommended conditions becomes mandatory.
<table>
<thead>
<tr>
<th>Activity Category</th>
<th>Categorical Exclusion(s)</th>
<th>Negative Determination(s)</th>
<th>Positive Determination(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Education, Technical Assistance, Training</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Convene research meetings and workshops</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facilitate collaborative learning and information transfer/research utilization</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perform secondary data analysis</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technical assistance to facilitate research utilization not involving the use of health commodities, medical waste, small scale construction or water and sanitation</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Technical assistance to facilitate research utilization involving the use of health commodities, medical waste, or water and sanitation</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Building capacity of local research organizations</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Research and Development</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Applied and development research to evaluate barriers and facilitators to implementation of new products, technologies or interventions not involving activities requiring a negative determination with conditions e.g. involving health commodities, medical waste, small scale construction or water and sanitation</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Applied and development research to evaluate barriers and facilitators to implementation of new products, technologies or interventions involving activities requiring a negative determination with conditions (e.g. involving health commodities, medical waste or small-scale construction or water and sanitation)</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Applied and development research to evaluate barriers and facilitators to implementation of new products, technologies or interventions involving pesticides(^1)</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) Bed nets do not necessarily trigger a positive determination.
### Product Evaluation

<table>
<thead>
<tr>
<th>Description</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product evaluation of new health tools and technologies for potential introduction in developing countries <strong>not</strong> involving public health commodities, medical waste, small scale construction or water and sanitation</td>
<td>✓</td>
</tr>
<tr>
<td>Product evaluation of new health products, tools and technologies for potential introduction in developing countries <strong>involving</strong> public health commodities, medical waste, small scale construction or water and sanitation</td>
<td></td>
</tr>
<tr>
<td>Product evaluation of new health products, tools and technologies for potential introduction in developing countries involving <strong>pesticides.</strong></td>
<td></td>
</tr>
</tbody>
</table>

### 2.3 General Implementation & Monitoring Conditions.

In addition to the specific conditions enumerated in Section 3, the negative determinations recommended in this IEE are contingent on full implementation of a set of general monitoring and implementation requirements specified in Section 4 of the IEE. These monitoring and implementation requirements are summarized as follows:

1. **Environmental Management Training.** The GH AOR/COR and Activity Manager(s) assigned to this program are to enroll in and successfully complete the Bureau for Global Health Environmental Management Process Training course. The course is offered through GHPOD.

2. **IP Briefings on Environmental Compliance Responsibilities.** The health team shall provide each Implementing Partner (hereinafter IP), with a copy of this IEE; each IP shall be briefed on their environmental compliance responsibilities by their cognizant C/AOR. During this briefing, the IEE conditions applicable to the IP’s activities will be identified.

3. **Development of EMMP.** Each IP whose activities are subject to one or more conditions set out in Section 3 of this IEE shall develop an Environmental Mitigation and Monitoring Plan (EMMP) within 90 days or with the annual work plan, whichever is sooner, and provide for C/AOR review and approval. The EMMP will document how their project will implement and verify all IEE conditions that apply to their activities. An EMMP template is attached. These EMMPs shall identify how the IP shall assure that IEE conditions that apply to activities supported under subawards are implemented. (The IP may elect to require the subgrantee/subcontractor to develop their own EMMP.)

4. **Integration and Implementation of EMMP.** Each IP shall integrate its EMMP into its project workplan and budgets, implementation, and report on its effectiveness as an element of regular annual project performance reporting as specified in the IP’s contract, not to exceed 90 days after the end of the project year. An Environmental Mitigation and Monitoring Report (EMMR) will be prepared to document compliance with the conditions of this IEE and must be submitted to the AOR/COR for review. The EMMR template is attached to the IEE. IPs shall assure that subcontractors and sub-grantees integrate implementation of IEE conditions, where applicable, into their own project work plans and budgets and report on their implementation as an element of sub-contract or grant performance reporting.
5. **Integration of compliance responsibilities in prime and sub-contracts and grant agreements.**
   a. The C/AOR team shall assure that any future contracts or agreements for implementation of HRP portfolio activities, and/or significant modification to current contracts/agreements shall reference and require compliance with the conditions set out in this IEE, as required by ADS 204.3.4.a.6 and ADS 303.2.e.
   b. IPs shall assure that future sub-contracts and sub-grant agreements, and/or significant modifications to existing agreements, reference and require compliance with relevant elements of these conditions.

6. **Assurance of sub-awardee capacity and compliance.** IPs shall assure that sub-grantees and subcontractors have the capability to implement the relevant requirements of this IEE. The IP shall, as and if appropriate, provide training to subgrantees and subcontractors in their environmental compliance responsibilities and in environmentally sound design and management (ESDM) of their activities.

7. **HRP team monitoring responsibility.** As required by ADS 204.5.4, the C/AOR team will actively monitor and evaluate whether the conditions of this IEE are being implemented effectively and whether there are new or unforeseen consequences arising during implementation that were not identified and reviewed in this IEE. If new or unforeseen consequences arise during implementation, the C/AOR team will suspend the activity and initiate appropriate, further review in accordance with 22 CFR 216. USAID Monitoring shall include regular site visits.

8. **New or modified activities.** As part of Annual Work Plans, IPs, in collaboration with their C/AOR, shall review all on-going and planned activities to determine if they are within the scope of this IEE. If health sector activities outside the scope of this IEE are planned, the C/AOR team shall assure that an amendment to this IEE addressing these activities is prepared and approved prior to implementation of any such activities. Any ongoing activities found to be outside the scope of the approved Regulation 216 environmental documentation shall be modified to comply or halted until an amendment to the documentation is submitted approved.

9. **Human subjects research.** In compliance with Federal regulations (22 CFR 225) and USAID policies (ADS303mab, RAA18. Protection of Human Research Subjects and ADS 200 Mandatory Reference, “Protection of Human Subjects in Research Supported by USAID”), Institutional Review Board (IRB) review will be sought for all human subjects research. The C/AOR shall assure that the implementing partner and sub-awardees demonstrate completion of all requirements for ethics review in compliance with USAID, implementing partner and local human subjects regulations and policies. If the C/AOR is unsure whether a research activity qualifies as human subjects research, he or she will consult the GH Cognizant Human Subjects Officer. The BEO for Global Health may request copies of documentation from the AOR to demonstrate compliance with applicable requirements of human subject research.

10. **Compliance with Host Country Requirements.** Nothing in this IEE substitutes for or supersedes IP, sub-grantee and subcontractor responsibility for compliance with all applicable host country laws and regulations. The IP, sub-grantees and subcontractor must comply with host country environmental regulations unless otherwise directed in writing by USAID. However, in case of conflict between host country and USAID regulations, the latter shall govern.

11. **Pesticides or pesticide products.** Program activities conducted under this Agreement involving
the research or disposal of pesticides and their waste products will not require a supplemental IEE, SEA, or PERSUAP if they are within the limited scope of work described in this IEE. However, any activities outside the scope of work will require additional environmental review and a supplemental IEE, SEA, or PERSUAP based on consultation with the GH BEO.
APPROVAL OF THE RECOMMENDED ENVIRONMENTAL ACTION

Clearance:
Office Director, GH/MCHN

Signed:  
Date: 12/21/17

Agreement Officer Representative

Signed:  
Date: 12/21/17

Concurrence:
Global Health Bureau Environmental Officer

Signed:  
Date: 12/26/17

Distribution List:

AOR/COR, or designee, is responsible for distributing the IEE to stakeholders on the distribution list below.

- Bureau Environmental Officers (BEO): Primary environmental compliance decision makers and leaders for their bureaus.
  - Africa Bureau – Brian Hirsch
    - Deputy Bureau Environmental Officer – vacant
  - Asia Bureau – Will Gibson
    - Deputy Bureau Environmental Officer - Mary Melnyk
  - Bureau for Policy, Programming and Learning – Dennis Durbin
  - Economic Growth, Education and Environment Bureau (E3) – Teresa Bernhard
  - Global Health Bureau – Rachel Dagovitz
  - Global Development Lab - Dennis Durbin
  - Multilateral Development Banks Environmental Advisor- Leslie Johnston and Teresa Bernhard
APPROVAL OF THE RECOMMENDED ENVIRONMENTAL ACTION

Clearance:

Office Director, GH/MCHN

Signed: ____________________ Date: ______

Barbara Hughes

Agreement Officer Representative

Signed: ____________________ Date: ______

Neal Brandes

Concurrence:

Global Health Bureau Environmental Officer

Signed: ____________________ Date: ______

Rachel Dagovitz

Distribution List:

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- Multilateral Development Banks Environmental Advisor: Leslie Johnston and Teresa Bernhard
1.0 BACKGROUND AND PROGRAM DESCRIPTION

1.1 Purpose and scope of IEE

This IEE addresses the entire portfolio of activities anticipated under the HRP 2.0 program.

For purposes of analysis, this IEE synthesizes anticipated HRP activities into a set of 8 categories, each of which spans specific activities. The original IEE was developed to apply to all anticipated research activities expected under HRP 2.0, except for activities covered by another IEE (for example, microbicides (OHA) and insecticides (PMI) as was the case under the original HaRP program). The original IEE was approved in August 2015. This first amendment was completed after a review of a new contract and two new cooperative agreements awarded under HRP 2.0. The amended language reflects a more accurate description of existing and future activities under HRP 2.0, including clarification on any anticipated research that would include pesticides.

As with all IEEs, and in accordance with 22 CFR 216, it reviews the reasonable foreseeable effects of these activities on the environment. On this basis, this IEE recommends Categorical Exclusions or Threshold Decisions for these activities. Upon approval of this IEE, these recommendations become affirmed Categorical Exclusions and Threshold Decisions, and implementation of recommended conditions becomes mandatory.

In addition, this IEE sets out team- and project-level implementation procedures intended to assure that conditions in this IEE are translated into activity-specific mitigation measures, and to assure systematic compliance with this IEE during project and program implementation. These procedures are themselves a general condition of approval for the IEE, and their implementation is therefore mandatory.

This IEE is a critical element of a mandatory environmental review and compliance process meant to achieve environmentally sound activity design and implementation.

1.2 Program background (context and justification)
Health Research Program 2.0 is a Bureau for Global Health research-to-use program managed by the Office of Maternal and Child Health and Nutrition. It builds on the predecessor HRP program that supported coordinated and collaborative research-to-use activities. The new program will help to accelerate USAID’s efforts to create evidence and strengthen systems that promote health and reduce mortality and severe morbidity of newborns, children, and mothers; reduce the burden of malaria and other infectious diseases; as well as respond to other health and development priorities, as needed. HRP 2.0 will work to align global and country level priorities, undertake coordinated and collaborative research and development, and promote research utilization/introduction activities. This is anticipated to result in accelerated development, adoption, sustained utilization, and support planning for scale of new and improved health tools, technologies, policies, strategies and approaches. To achieve this vision, HRP will engage with diverse stakeholders including host country governments, USAID implementing partners, USAID staff in Missions and at headquarters, the President’s Malaria Initiative (PMI) and the Center for Accelerating Innovation and Impact (CII), academia, civil society, and the private sector among others. It will also build research and research utilization capacity in low and middle income country (LMIC) partners as a core business practice; strengthening capacity of researchers, implementers, and policy makers through achieving results.

1.3 Health and Research Program Goal, Purpose and Sub-purposes

HRP 2.0: Goal, Purpose and Sub-Purposes:

GOAL: To accelerate the achievement of USAID health and development objectives that support PCMD, AIDS-Free Generation and other global health priorities.

PROJECT PURPOSE: To support the successful research and development, introduction, adoption, sustained utilization and progress to scale of new or refined products, technologies, tools, interventions and systems that will contribute to reduced mortality, morbidity and infectious disease threats in newborns, children and women.

SUB-PURPOSE 1: Effective, continuous communication, research translation and priority setting/consensus building processes inform research to use efforts.

SUB-PURPOSE 2: Accelerated product development and evaluation research helps identify, introduce and support the scale-up of new health technologies and interventions which are appropriate, affordable, and acceptable for distribution and use in low-resource settings.

SUB-PURPOSE 3: Implementation research and research utilization/introduction activities improve country level adoption, sustained utilization, and progress to scale.

Targeted health research activities (sub-sectors): The HRP 2.0 portfolio envisions implementing research activities across the following sub-sectors:

1. HIV/AIDS
2. Tuberculosis
3. Malaria
4. Avian Influenza
5. Other Public Health Threats
6. Maternal Health and Child Health
7. Family Planning and Reproductive Health
8. Water Supply and Sanitation
9. Nutrition

Individual projects may carry out activities in more than one sub-sector, and the projects are designed to be mutually supportive and synergistic so that the portfolio overall embodies an integrated approach.

1.4 Intervention categories for purposes of environmental review.

Research activities may be undertaken in more than one—and sometimes several—of the health subsectors listed above. For example, product evaluation may cut across MNCH, HIV/AIDS, FP and malaria areas.

The potential adverse environmental and health impacts of concern for product evaluation are similar across health subsectors. Analyzing these impacts separately for each sub-sector would be highly redundant and make for an inefficient and unmanageably long IEE. Therefore, for purposes of environmental review and compliance, interventions in the HRP 2.0 portfolio are therefore consolidated into the following intervention categories:

1. Convening research meetings and workshops
2. Facilitation of collaborative learning and information transfer/research utilization
3. Secondary data analysis
4. Development research: Market, formative, social science, operational, health services, implementation and behavioral research, including water supply and sanitation
5. Applied and development research to evaluate barriers and facilitators to implementation of new products, technologies, including water supply and sanitation
6. Product evaluation of new health tools and technologies for potential introduction in developing countries, including water supply and sanitation
7. Technical assistance to facilitate research utilization, including water supply and sanitation
8. Building capacity of local research organizations

Each intervention category has a number of related activities; these are set out, and, where not self-explanatory, annotated in Section 3 of this IEE.

2.0 Country and Environmental Information (Baseline Information)

2.1 Description of environment

It is envisioned that the majority of HRP 2.0 activities will take place in the 25 maternal and child health focus countries. As such, activities under HRP 2.0 will invariably take place in a country which houses a USAID Mission, or is covered by a USAID Regional Mission. Under HRP 2.0, evaluation and analysis may occur in host-country institutions and/or in domestic workspaces, offices, laboratories, or in the field. Evaluation of interventions, product introductions, and scale-up are intended for low resource settings, including but not limited to rural health facilities and communities. Research activities would be tightly controlled and implemented in compliance with in-country laws and regulations, and specifically with local institutional review board (IRB) approval. All facilities are already established and no new construction will occur as part of this project. Water supply and sanitation research and activities may be undertaken in communities to evaluate existing or new interventions, as well as potentially post marketing surveillance like activities, as needed.
2.2 Environmental laws and regulations

HRP 2.0 is responsible for complying with applicable country and environmental information for identified activities that have potential to have a negative impact on the environment. HRP 2.0 will comply with the appropriate environmental laws and regulations established in each country in which it implements activities. Specific requirements may vary by country, but activities will conform to environmental management laws, environmental impact regulations, including health care waste management policies. In addition, the C/AORs will consult WHO guidelines\(^2\), USAID sector guidelines, and CDC (where applicable) to ensure compliance with internationally recognized environmental procedures. Research organizations are expected to provide their medical waste management procedures to demonstrate how they will manage waste for their research. In the EMMP, the implementing partner will outline how host country environmental laws, regulations and possible permit requirements will be identified and adhered to as part of their program management. Implementing partners are responsible for documenting consultations with the relevant host country agency(ies) to ensure that environmental discharges (air, water, soil) meet host country environmental standards and permits are obtained where required.

3.0 Potential Environmental Impacts & Recommended Determinations, Including Conditions

This section presents potential environmental impacts of the HRP 2.0 program (3.2-3.9), preceded by a general discussion and analysis of waste-related impacts of health care activities (3.1). As introduced in Section 1.4, for the purpose of environmental review, current and anticipated activities in the HRP 2.0 portfolio are grouped into the following intervention categories, labelled by section number:

3.2 Convening research meetings and workshops
3.3 Facilitation of collaborative learning and information transfer
3.4 Secondary data analysis
3.5 Development research: Market, formative, social science, operational, health services, implementation and behavioral research not related to potential negative health and environmental impacts, including water supply and sanitation
3.6 Applied research to evaluate barriers and facilitators to implementation of new products, technologies, including water supply and sanitation
3.7 Product evaluation of new health tools and technologies for potential introduction in developing countries, including water supply and sanitation
3.8 Technical assistance to facilitate research utilization, including water supply and sanitation
3.9 Building capacity of local research organizations

Each category contains a number of related activities. In sections below, illustrative activities are described and their potential impacts analyzed. On this basis, Recommended Determinations are made. In most cases, Negative Determinations entail conditions. Upon approval of this IEE, implementation of these conditions becomes mandatory.

3.1 ADVERSE IMPACTS OF HEALTH CARE SERVICE DELIVERY DUE TO FAILURE TO PROPERLY

MANAGE RESULTING WASTE

This section is a general discussion and analysis of waste-related impacts of health care activities. It is referenced in the analyses of the specific intervention categories that follow. It supports this subsequent analysis; no recommended determinations are attached specifically to this section.

Although healthcare activities including research provide many important benefits to communities, they can also unintentionally do harm via poor management of the waste generated. This waste generally falls into three categories in terms of public health risk and recommended methods of disposal:

- **General** healthcare waste, similar or identical to domestic waste, including materials such as packaging or unwanted paper. This waste is generally harmless and needs no special handling; 75–90% of waste generated by healthcare facilities falls into this category, and it can be burned or taken to the landfill without any additional treatment.

- **Hazardous** healthcare waste including infectious waste (except sharps and waste from patients with highly infectious diseases), small quantities of chemicals and pharmaceuticals, and non-recyclable pressurized containers. All blood and body fluids are potentially infectious.

- **Highly hazardous** healthcare waste, which should be given special attention, includes sharps (especially hypodermic needles), highly infectious non-sharp waste such as laboratory supplies, highly infectious physiological fluids, pathological and anatomical waste, stools from cholera patients, and sputum and blood of patients with highly infectious diseases such as TB and HIV. They also include large quantities of expired or unwanted pharmaceuticals and hazardous chemicals, as well as all radioactive or genotoxic wastes.

**Pharmaceutical Wastes and Medical Supplies, including condoms:** Pharmaceutical drugs including vaccines have specific storage time and temperature requirements, and may expire or lose efficacy before they are used, particularly in remote areas where demand is low and/or infrequent. Pharmaceutical waste may also accumulate due to inadequacies in stock management and distribution and/or lack of a routine system of disposal.

The effects of pharmaceutical waste in the environment are different from conventional pollutants. Drugs are designed to interact within the body at low concentrations to elicit specific biological effects in humans, and which may also cause biological responses in other organisms. There are many drug classes of concern, including antibiotics, antimicrobials, antidepressants, and estrogenic steroids. Their main pathway into the environment is through household use and excretion, and through the disposal of unused or expired pharmaceuticals.

Effects on aquatic life are a major concern in disposal of pharmaceuticals. A wide range of pharmaceuticals have been discovered in fresh and marine waters globally, and even in small quantities some of these compounds have the potential to cause harm to aquatic life.

Additional health risks related to disposal include burning pharmaceuticals and plastic medical supplies (including new or used condoms) at low temperatures or in open containers results in release of toxic pollutants into the air. Inefficient and insecure sorting and disposal may allow drugs beyond their expiry date to be diverted for resale to the general public.

**Potentially infectious waste:** Improper training, handling, storage and disposal of the waste generated in health care facilities or activities can spread disease through several mechanisms.
Transmission of disease through infectious waste is the greatest and most immediate threat from healthcare waste. If waste is not treated in a way that destroys the pathogenic organisms, dangerous quantities of microscopic disease-causing agents—viruses, bacteria, parasites or fungi—will be present in the waste. These agents can enter the body through punctures and other breaks in the skin, mucous membranes in the mouth, by being inhaled into the lungs, being swallowed, or being transmitted by a vector organism. Those who come in direct contact with the waste are at greatest risk. Examples include healthcare workers, cleaning staff, patients, visitors, waste collectors, disposal site staff, waste pickers, substance abusers and those who knowingly or unknowingly use "recycled" contaminated syringes and needles. Although sharps pose an inherent physical hazard of cuts and punctures, the much greater threat comes from sharps that are also infectious waste. Healthcare workers, waste handlers, waste-pickers, substance abusers and others who handle sharps have become infected with HIV and/or hepatitis B and C viruses through pricks or reuse of syringes/needles.

Contamination of water supply from untreated healthcare waste can also have devastating effects. If infectious stools or bodily fluids are not treated before being disposed of, they can create and extend epidemics. The absence of proper sterilization procedures is believed to have increased the severity and size of cholera epidemics in Africa during the last decade.

3.2 Convening research meetings and workshops

Throughout the life cycle of the research-to-use continuum, promotion of continuous stakeholder engagement, systematic multi-disciplinary analyses of advances and challenges, consensus building and communication within and across global, national, and local settings are critical to successful planning, priority setting and roll out of applied implementation research and uptake of new or refined tool, technology, policies, and products. From early on, research planning will include preparation for research translation and use, both to capture technical information and to target technical assistance for research and research utilization. This approach, will build a foundation to inform improvement of ongoing work and serve as a platform to communicate and discuss lessons learned with stakeholders at different levels.

This intervention category consists of the following primary activity:

- **Research workshops and meetings** to reach consensus on and prioritize implementation and evaluative research needed to accelerate progress towards the PCMD goal of preventing child deaths by 2035. Whether held at the global, regional or country level, the purpose of these gatherings may include, for example:
  a. Consensus building
  b. Strategic planning
  c. Prioritization
  d. Advocacy

Potential Adverse Impacts & Considerations Regarding Recommended Determinations

Research workshops and meetings is one of a class of activities under 22 CFR 216 eligible for categorical exclusion. Given that the envisioned HRP 2.0 workshops and meetings will be focused on facilitating researchers to set priorities, plan and prioritize research studies, the categorical exclusion of these activities is warranted.

**Recommended Determination.** Pursuant to the discussion above, the following determinations are recommended:
3.3 Facilitation of collaborative learning and information transfer

This intervention category consists of the following activities:
1. Convening researchers, policymakers, implementers and donors to share research results, discuss their implications, and agree on a plan to transfer knowledge and information to inform future health programs and policies.
2. Building on the knowledge and information sharing plan, ensure effectively and timely transfer of information, results and implications through a variety of mechanisms (e.g. web platform, list serves, conferences and meetings, technical working groups, and publications).

Potential Adverse Impacts & Considerations Regarding Recommended Determinations

Convening stakeholders and information transfer comprise two classes of activities under 22 CFR 216 eligible for categorical exclusion. Convening stakeholders to share research findings and facilitate the integration of results into programs and policies, and ensuring the effective and real-time transfer of this information across the spectrum of intended users pose no adverse environmental risk, and thus qualify for the categorical exclusion determination.

Recommended Determinations. Pursuant to the discussion above, the following determinations are recommended:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Recommended Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Convene researchers and related stakeholders to facilitate collaborative learning</td>
<td>Categorical Exclusion per 22 CFR 216.2(c)(2)(iii) analyses, studies, academic or research workshops and meetings.</td>
</tr>
</tbody>
</table>
3.4 Secondary data analysis

This intervention category consists primarily of the conduct of statistical analysis of existing data sets, which may include but not be limited to:

- Demographic and Health Surveys
- AIDS Impact Surveys
- Service Provision Assessments
- MICS Surveys
- National population- or facility-based surveys
- Use of data from an existing study or studies, for a new individual or combined analysis

**Potential Adverse Impacts & Considerations Regarding a Recommended Determination**

As this activity does NOT entail the collection of new/primary data, but rather the use of data already collected, the potential environmental effects are negligible.

**Recommended Determinations.** Pursuant to the discussion above, the following determinations are recommended:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Recommended Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary data analysis</td>
<td>Categorical Exclusion per 22 CFR 216.2(c)(2)(v) analyses, studies, academic or research workshops and meetings.</td>
</tr>
</tbody>
</table>

3.5 Development research

This intervention category consists of the following activities:

Development research **not involving** activities that involve healthcare commodities, generate medical waste or conduct small scale construction or water and sanitation. Specific types of research include:

a. Market research to assess the readiness of the market to support introduction of a new or refined product, tool or technology; or to gauge consumer preferences or willingness to pay for a new or refined product or technology.

b. Formative research to describe a context or characteristic of an environment or a population.
c. Social science, implementation, health services, and operational research – applied research that focuses on how service implementation impedes effective uptake and delivery of priority interventions across different country contexts.

d. Behavioral research to better understand the determinants of behavior change to adopt a proven intervention, approach, product or drug at the provider and consumer level.

**Potential Adverse Impacts & Considerations Regarding Recommended Determinations.**

Based on the fact that this category of research activities does not involve activities that would involve healthcare commodities, generate medical waste or conduct small scale construction or water and sanitation the majority of these activities meet the categorical exclusion determination. However, due to the nature of implementation and health services research specifically that it may be conducted in conjunctions with the delivery of health services, this class of research is determined to have a negative determination with conditions.

As detailed in Section 3.1, the delivery of health services presents a set of potentially significant adverse environmental and health impacts, particularly related to medical waste. Expansion of these services—while delivering health benefits—may result in adverse impacts on the environment and present health risks to the community, health workers and patients arising from improper handling of medical waste.

These impacts may be direct or indirect, thus where USAID support for service delivery is direct, USAID bears full responsibility for adverse impacts when its support fails to address waste management or to consider the capacity of medical facilities to properly handle, label, treat, store, transport and properly dispose of medical waste.

For example, proper waste management requires that the systems and structures governing health care delivery address and require appropriate management. Where USAID’s support means that USAID has substantial influence over these systems and structures, USAID and IPs must work to best assure that these systems and structures support appropriate health care waste management. This activity is considered negative determination with conditions. Also in the case of human subjects research if an IRB determines a research activity is not exempt from review, human subjects considerations must be addressed as noted in the human subjects section.

**Recommended Determinations**

Pursuant to the discussion above, the following determinations are recommended:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Recommended Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market research</td>
<td>Categorical Exclusion per 22 CFR 216.2(c)(2)(iii) analyses, studies, academic or research workshops and meetings.</td>
</tr>
<tr>
<td>Formative research</td>
<td>Categorical Exclusion per 22 CFR 216.2(c)(2)(iii) analyses, studies, academic or research workshops and meetings.</td>
</tr>
<tr>
<td>Social science, implementation, health services, and operational research</td>
<td>Negative Determination with Conditions, 22 CFR 216.3 (a) (2) (iii) in cases where USAID is supporting health facilities and service delivery research but not directly providing care with pharmaceuticals or involving a health or environmental impact.</td>
</tr>
</tbody>
</table>
Behavioral research | Categorical Exclusion per 22 CFR 216.2(c)(2)(iii) analyses, studies, academic or research workshops and meetings.  
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3.6 Applied and development research to evaluate barriers and facilitators to implementation of new products, technologies

HRP seeks to support rigorous multi-disciplinary, globally relevant health research and evaluation that advance USAID's global health goals of PCMD, achieving an AIDS-free generation, protecting communities from infectious diseases, and other emerging health and development priorities as directed. As articulated in the table that follows, there are three categories of applied research, and each carries a different environmental determination.

This intervention category consists of the following activities:

- Applied and development research to evaluate barriers and facilitate implementation of new products, technologies or interventions **NOT** involving health commodities, medical waste, small scale construction or water and sanitation.
- Applied and development research to evaluate barriers and facilitators to implementation of new products, technologies or interventions **involving** health commodities, medical waste, small scale construction or water and sanitation.
- Applied and development research to evaluate barriers and facilitators to implementation of new products, technologies or interventions involving **pesticides**.

Potential Adverse Impacts & Considerations Regarding Recommended Determinations.

Whereas the first category of applied research poses little to no environmental impact, and is thus considered a categorical exclusion, the other two categories require further assessment. Potential environmental impacts for applied and development research involving public health commodities, medical waste, including the use of health commodities under non-highly controlled research environments. As described in Section 3.1, the delivery of health services and commodities poses potentially adverse environmental and health impacts, particularly related to medical waste. Expansion of these services—while delivering health benefits—may result in adverse impacts on the environment and present health risks to the community, health workers and patients arising from improper handling of medical waste. Given the potential for impact, this activity is considered negative determination with conditions.

The third type of research activity in this category, applied research involving pesticides, has the potential for environmental impact, warranting a negative determination with conditions. Research activities involving pesticides, such as a field study to test insecticide-treated bednets for the control of mosquitoes, are typically conducted in controlled trial settings. Under field trial sites involving pesticides, environmental impacts or risks are anticipated to be minimal as sites are expected to be confined to a small area and carefully monitored. As of November 2017, the HRP 2.0 has not implemented research activities involving pesticides. In the event that an activity is identified involving the procurement, use, or disposal of pesticides for research or limited field evaluation purposes, the IP and A/COR team will ensure that activities remain within the scope of the IEE. However, if activities are outside the limited scope of work described in this IEE, the IP and A/COR team will reassess the

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3 Except if IRB is determined necessary.
environmental risks and develop a supplemental IEE (SIEE), SEA, or PERSUAP based on consultation with the GH BEO. The SIEE, SEA, or PERSUAP will comply with the pesticide procedures set forth in 22 CFR 216.3(b).

**Recommended Determinations**
Pursuant to the analysis above, the following determinations are recommended for this intervention category.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Recommended Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applied research NOT involving health commodities, medical waste, small scale construction or water and sanitation</td>
<td><strong>Categorical Exclusion</strong> per 22 CFR 216.2(c)(2)(iii) analyses, studies, academic or research workshops and meetings.</td>
</tr>
<tr>
<td>Applied research involving health commodities, medical waste, small scale construction or water and sanitation</td>
<td><strong>Categorical Exclusion</strong> per 22 CFR 216.2(c)(2)(iii) analyses, studies, academic or research workshops and meetings if the conditions are met to demonstrate that the study is conducted in a highly controlled research environment.</td>
</tr>
</tbody>
</table>
| Applied research involving pesticides, within a controlled trial setting | **Negative Determination with Conditions**, 22 CFR 216.3(a)(2)(iii) for activities involving the procurement, use, or disposal of pesticides for research or limited field evaluation purposes:  
  - If activities are outside the limited scope of work described in this IEE, the IP and A/COR team will reassess the environmental risks and develop a SIEE, SEA, or PERSUAP based on consultation with the GH BEO. |

3.7  **Product evaluation of new health tools and technologies for potential introduction in developing countries**

HRP 2.0 seeks to catalyze advances in the field of implementation research as well as undertake implementation research and research utilization to provide critically needed evidence and real-time support to program implementers and policy-makers. The program will also advance research on feasibility, alongside experimental studies to establish proof-of-concept, superiority/inferiority, cost-effectiveness, and efficacy as required to answer the research questions of interest in order to achieve the objective of sustained use, and contribute to progress-to-scale.

This intervention category consists of the following research activities:

- Product evaluation of new health tools and technologies for potential introduction in developing countries not involving public health commodities, medical waste, small scale.
construction or water and sanitation.

- Product evaluation of new health tools and technologies for potential introduction in developing countries involving public health commodities, medical waste, small scale construction or water and sanitation
- Product evaluation of new health tools and technologies for potential introduction in developing countries involving pesticides

Potential Adverse Impacts & Considerations Regarding Recommended Determinations

As referenced for applied and development research above, this category also has three types of activities with unique environmental considerations. The first activity is recommended for categorical exclusion, in that it is research that does not involve elements that would require a negative with conditions determination. The second activity does involve health commodities, medical waste or water and sanitation elements, and because of this is considered negative with conditions as described in the table below. The final activity in this category involves evaluation of pesticides, and as such is recommended for a negative determination with conditions.

Recommended Determinations
Pursuant to the analysis above, the following determinations are recommended.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Recommended Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product evaluation NOT involving health commodities, medical waste, small scale construction or water and sanitation</td>
<td>Categorical Exclusion per 22 CFR 216.2(c)(2)(iii) analyses, studies, academic or research workshops and meetings.</td>
</tr>
<tr>
<td>Product evaluation involving health commodities, medical waste, small scale construction or water and sanitation</td>
<td>Negative Determination with Conditions, 22 CFR 216.3 (a) (2) (iii) for activities involving procurement, storage, management and disposal of public health commodities; for household water treatment and safe storage; and for activities potentially involving construction and renovation activities</td>
</tr>
</tbody>
</table>
| Product evaluation involving pesticides | Negative Determination with Conditions, 22 CFR 216.3(a)(2)(iii) for activities involving the procurement, use, or disposal of pesticides for research or limited field evaluation purposes:  
- If activities are outside the limited scope of work described in this IEE, the IP and A/COR team will reassess the environmental risks and develop a SIEE, SEA, or PERSUAP based on consultation with |

3.8 Technical assistance to facilitate research utilization
Beyond the conduct and sharing of development, applied and product evaluation research, ultimately it is important that the research is utilized such that it informs health programs and policies for greater
impact. As such, providing technical assistance to ensure the uptake and utilization of HRP-supported research is critical to achieving the aims of the program.

This intervention category consists of the following activities:

- Technical assistance to facilitate research utilization not involving the use of health commodities, medical waste, small scale construction or water and sanitation
- Technical assistance to facilitate research utilization involving the use of health commodities, medical waste, or water and sanitation

Potential Adverse Impacts & Considerations Regarding Recommended Determinations

One of the activities in this category will not involve elements that carry a negative determination with conditions classification, and as such is determined to qualify as a categorical exclusion. However, given the potential for technical assistance around health commodities, medical waste or water and sanitation to have a possible environmental impact, as described in 3.1, this activity is assigned a negative with conditions determination.

Some potential environmental impacts of water supply and sanitation include:

- Degradation of surface and groundwater quality and land habitats due to the release of human waste from sanitation facilities.
- Increased human risks from contamination of surface water, groundwater, soil, and food by human waste and disease pathogens.

Recommended Determinations

Pursuant to the analysis above, the following determinations are recommended:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Recommended Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical assistance not involving health commodities, medical waste or water and sanitation</td>
<td>Categorical Exclusion per 22 CFR 216.2(c)(2)(i) education, technical assistance or training</td>
</tr>
<tr>
<td>Technical assistance involving health commodities, medical waste or water and sanitation</td>
<td>Negative Determination with Conditions, 22 CFR 216.3 (a) (2) (iii) for activities involving procurement, storage, management and disposal of public health commodities as well as for household water treatment and safe storage</td>
</tr>
</tbody>
</table>

3.9 Building capacity of local research organizations

The activities occurring in this category primarily include efforts to engage local research institutions (e.g. firms, organizations or universities) in LMICs early on in the research process, and to strengthen their capacity to conduct rigorous research to inform local health practices, programs and policies.

Potential Adverse Impacts & Considerations Regarding Recommended Determinations

This activity is recommended for a categorical exclusion under 22 CFR 216.

Recommended Determination

Pursuant to the discussion above, the following determinations are recommended:
<table>
<thead>
<tr>
<th>Activity</th>
<th>Recommended Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Build capacity of local research institutions</td>
<td>Categorical Exclusion per 22 CFR 216.2(c)(2)(xiv) develop capability of recipient countries</td>
</tr>
</tbody>
</table>

### 4.0 GENERAL PROJECT IMPLEMENTATION AND MONITORING REQUIREMENTS

In addition to the specific conditions above, the negative determinations recommended in this IEE are contingent on full implementation of the following general monitoring and implementation requirements:

1. **Environmental Management Training.** The GH AOR/COR and Activity Manager(s) assigned to this program are to enroll and successfully complete the Bureau for Global Health Environmental Management Process Training course. The course is offered through GHPOD.

2. **IP Briefings on Environmental Compliance Responsibilities.** The health team shall provide each Implementing Partner (hereinafter IP), with a copy of this IEE; each IP shall be briefed on their environmental compliance responsibilities by their cognizant C/AOR. During this briefing, the IEE conditions applicable to the IP's activities will be identified.

3. **Development of EMMP.** Each IP whose activities are subject to one or more conditions set out in Section 3 of this IEE shall develop an Environmental Mitigation and Monitoring Plan (EMMP) within 90 days or with the annual work plan, whichever is sooner, and provide for C/AOR review and approval. The EMMP will document how their project will implement and verify all IEE conditions that apply to their activities. An EMMP template is attached.

   These EMMPs shall identify how the IP shall assure that IEE conditions that apply to activities supported under subawards are implemented. (The IP may elect to require the subgrantee/subcontractor to develop their own EMMP.)

4. **Integration and implementation of EMMP.** Each IP shall integrate their EMMP into their project work plan and budgets, implement the EMMP, and report on its implementation as an element of regular project performance reporting as specified in the IP's contract, not to exceed 90 days after the end of the project year. An Environmental Mitigation and Monitoring Report (EMMR) will be prepared to document compliance with the conditions of this IEE and must be submitted to the AOR/COR for review. The EMMR template is attached to the IEE. IPs shall assure that sub-contractors and sub-grantees integrate implementation of IEE conditions, where applicable, into their own project work plans and budgets and report on their implementation as an element of sub-contract or grant performance reporting.

5. **Integration of compliance responsibilities in prime and sub-contracts and grant agreements.**

   The C/AOR team shall assure that any future contracts or agreements for
implementation of HRP portfolio activities, and/or significant modification to current contracts/agreements shall reference and require compliance with the conditions set out in this IEE, as required by ADS 204.3.4.a.6 and ADS 303.2.e.

IPs shall assure that future sub-contracts and sub-grant agreements, and/or significant modifications to existing agreements, reference and require compliance with relevant elements of these conditions.

6. **Assurance of sub-awardee capacity and compliance.** IPs shall assure that subgrantees and subcontractors have the capability to implement the relevant requirements of this IEE. The IP shall, as and if appropriate, provide training to subgrantees and subcontractors in their environmental compliance responsibilities and in environmentally sound design and management (ESDM) of their activities.

7. **HRP team monitoring responsibility.** As required by ADS 204.5.4, the C/AOR team will actively monitor and evaluate whether the conditions of this IEE are being implemented effectively and whether there are new or unforeseen consequences arising during implementation that were not identified and reviewed in this IEE. If new or unforeseen consequences arise during implementation, the C/AOR team will suspend the activity and initiate appropriate, further review in accordance with 22 CFR 216. USAID Monitoring shall include regular site visits.

8. **New or modified activities.** As part of Annual Work Plans, IPs, in collaboration with their C/AOR, shall review all on-going and planned activities to determine if they are within the scope of this IEE. If health sector activities outside the scope of this IEE are planned, the C/AOR team shall assure that an amendment to this IEE addressing these activities is prepared and approved prior to implementation of any such activities.

Any ongoing activities found to be outside the scope of the approved Regulation 216 environmental documentation shall be modified to comply or halted until an amendment to the documentation is submitted approved.

9. **Human subjects research.** In compliance with Federal regulations (22 CFR 225) and USAID policies (ADS303mab, RAA18. Protection of Human Research Subjects and ADS 200 Mandatory Reference, “Protection of Human Subjects in Research Supported by USAID”), Institutional Review Board (IRB) approval will be sought for all human subjects research. The C/AOR shall assure that the implementing partner and sub-awardees demonstrate completion of all requirements for ethics review in compliance with USAID, implementing partner and local human subjects regulations and policies. If the C/AOR is unsure whether a research activity qualifies as human subjects research, he or she will consult the GH Cognizant Human Subjects Officer. The BEO for Global Health may request copies of documentation from the AOR to demonstrate compliance with applicable requirements of human subject research.

10. **Compliance with Host Country Requirements.** Nothing in this IEE substitutes for or supersedes IP, sub-grantee and subcontractor responsibility for
compliance with all applicable host country laws and regulations. The IP, subgrantees and subcontractor must comply with host country environmental regulations unless otherwise directed in writing by USAID. However, in case of conflict between host country and USAID regulations, the latter shall govern.

11. **Pesticides or pesticide products.** Program activities conducted under this Agreement involving the research or disposal of pesticides and their waste products will not require a supplemental IEE, SEA, or PERSUAP if they are within the limited scope of work described in this IEE. However, any activities outside the scope of work will require additional environmental review and a supplemental IEE, SEA, or PERSUAP based on consultation with the GH BEO.