



Attachment 2a. Research Determination



Determination of Applicability of Human Subjects Regulations

For Any Activities/Projects When Human Information/Specimens Will Be Collected



Project Title: Assessment of Public Knowledge, Attitudes, and Practices Relating to Ebola Virus Disease (EVD) Prevention and Medical Care in Guinea

Date to Begin: _____ **End:** _____ **New Project** or **Changes to Existing Project**

Primary Contact: Katy Irwin **Phone:** _____

Division/Branch: Ebola Response EOC International TF **Supervisor's Name:** Barbara Marston

Below describe the nature of the activity or project, considering the intended purpose and all aspects that are planned to date. This form should be completed by the CDC scientist, project officer, or other staff responsible for the project. Attach a description of the activity or project (i.e. protocol, concept paper, précis, etc).

I. PUBLIC HEALTH NON-RESEARCH: Mark all that apply.
 The activities/project is not intended to include research, but to:

- Identify, control or prevent disease, illness, disability, or death in response to an immediate public health threat
- Assess the implementation, performance, coverage, and/or satisfaction with an existing public health program, service, function, intervention or recommendation
- Routinely monitor indicators of the public's health and known risk factors
- Provide public health services, interventions, education, etc.

II. RESEARCH-NO HUMAN SUBJECTS: Mark all that apply.
 The activities/project is not intended to involve human subjects. CDC will obtain:

- Data in the aggregate only or about groups, organizations, etc. No individual level data will be collected
- Data/specimens from or about deceased persons
- Data/specimens from animal subjects
- Microbiological isolates only without the ability to link to individuals' data/specimens

Data/specimens:

- Not collected specifically for the currently proposed research through interaction or intervention with human subjects;
- Never collected with individually identifiable private information about human subjects or the key or linkages to such information was removed or destroyed by the holders of the data/specimen;
- Individually identifiable private information was collected but the holders of the data/specimens are prohibited from releasing the identifying link due to conditions of IRB approval or non-disclosure agreement.

III. HUMAN SUBJECTS RESEARCH: The activities/project is human subjects research. However, the following is being requested with respect to review for human subjects protections:

- CDC IRB Review Requested** – by completing the CDC form 1250 and other required forms along with the study materials (i.e. Protocols, consent forms, data collection forms, recruitment fliers, collaborator IRB approvals)
- Reliance on a Non-CDC IRB** – to have an outside non-CDC IRB review for human subjects protections review in lieu of CDC IRB.
- Exemption from IRB Review at CDC** – as we believe the study meets one of the criteria for exemption.
- CDC Non-Engagement** - CDC will not be engaged. Mark all that apply.
 - CDC employees (FTE or contractors) will not have contact with human research subjects;
 - CDC employees will not obtain nor access any individual level data/specimens (included coded) for this study;
 - CDC involvement is limited to providing assistance and guidance with technical aspects of the research such as study design, methodology, analytic plan, interpretation of results, and training.
 - All collaborating institution(s) conducting human research or receiving federal funds for research will have appropriate review for human research protections and hold a valid Federal-wide Assurance (FWA).

Note: Non-engagement requests are considered on a case-by-case basis. If non-engagement status is granted then CDC scientists cannot, at any point, have access to data/specimens or research participants for the purposes of this study.

CDC 50.151 (E), February 2011, CDC Adobe Acrobat 10.1, S508 Electronic Version, January 2013

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Other Considerations: Mark all that apply.

- FDA review is required under IND, IDE, or EUA.
- Data security has been addressed, including security of personally identifiable information.
- Clinical, pharmacological, or therapeutic intervention will be involved.
- Involves greater than minimal risk to participants.
- Results may be of clinical relevance for individuals and/or their family members.
- Involves potentially controversial, sensitive, or high profile issues, populations or testing.
- Informed consent will be sought.
- CDC will fund the study through grant, cooperative agreement, or contract mechanisms.
- Findings will be submitted for publication in the peer reviewed literature.

Approvals and Determinations- This section to be completed by reviewers only. Clearance requirements will depend on the NC, division, and branch specific policies and procedures. Please indicate all that provided review and comment.

The proposed project has been reviewed by the following:

- Branch Chief _____
- Division ADS _____
- NC Human Subjects Contact Micah Bass as IMS SRA
- NC ADS _____

Determination of Applicability of Human Subjects Regulations and Review Requirements

The proposed project was determined to be: Public Health Non-Research

No further review required at this time. If changes to the project/activities are considered, re-review is required before implementing the changes.

Further action and review is required. Please complete the forms and submit them division clearance:

- HR Exemption from IRB Review - Include Form(s) 1250X _____
- HR Review by Non-CDC IRB for Reliance - Include Form(s) 1250, 1370, 1371 _____
- HR Review by CDC IRB - Include Form(s) 1250 _____
- HR Oversight of Activities Not Reviewed by CDC HRPO _____
- NR Non-Disclosure Requirements _____
- Public Health Non-Research: Monitoring Human Participation in CDC Public Health Activities

Comments/Rationale:

The purpose of this project is to assess the public's KAPs regarding EVD that are important indicators of the prevalence of risk factors for ongoing transmission and the level of community preparedness for controlling spread of disease to identify barriers and vulnerable groups that warrant special attention in future EVD health communication efforts as well as to assess exposure to community engagement, education, and social mobilization about EVD launched in response to this epidemic and determine if these strategies have had their expected reach and impact and how they should be refined or replaced with more effective, evidence-based methods.

Tracking System ID Number: Ebola Response EOC 2015 1025




Final Determination Made by (print name): Micah Bass

Signature: Micah Bass

Digitally signed by Micah Bass
DN: cn=Micah Bass, o=Centers for Disease Control and Prevention,
ou=NCIRD Office of Science and Integrated Programs,
email=sp1@cdc.gov, c=US
Date: 2015.04.14 16:28:59 -0400

Date: 04/14/2015

Attachment 2b. Ministry of Health Letter of Support

MINISTERE DE LA SANTE N°236/MS/CAB/2015 N°/Réf : V/Réf :		REPUBLIQUE DE GUINEE Travail-Justice-Solidarité
		Conakry, le...4...5.../2015
		<i>Le Directeur</i>
		A Madame la Représentante de Center of Disease Control (CDC) Guinée Conakry.
Objet : Appui et Remerciement.		
Madame la Représentante,		
Dans le cadre de la prévention et du contrôle de l'épidémie de la Fièvre Hémorragique à virus Ebola, le Ministère de la Santé remercie le Centre de prévention et contrôle des épidémies (CDC) et la Fondation CDC, pour leur appui Technique et Financier dans la mise en œuvre des interventions dont les études telle que : “l’Evaluation du niveau des Connaissances, Attitudes et Pratiques (CAP) en matière de prévention et de prise en charge de la Fièvre Hémorragique à Virus Ebola en Guinée” .		
Cette étude a déjà été réalisée en Sierra Léone et les résultats ont été utilisés pour améliorer la communication et la mobilisation sociale axée sur la prévention contre la maladie à virus Ebola.		
Pour la Guinée, Santé Plus, organisation spécialisée en recherche et formation en santé, a été retenue pour réaliser une étude similaire. Les résultats de la présente enquête contribueront à l’atteinte des objectifs du Gouvernement, car ils permettront de cerner les déterminants de l’utilisation des services de santé et d’asseoir une communication basée sur l’exploitation des résultats notamment en ce qui concerne les Connaissances Attitudes et Pratiques des communautés en rapport avec la maladie.		
Nous vous remercions pour l’appui et l’assistance technique financière que vous voudrez bien porter à Santé Plus à cet effet.		
Veillez recevoir Madame la Représentante, l’expression de ma considération distinguée.		
		Dr Robert CAMARA 
		Directeur National de la Prévention et de la Santé Communautaire

Attachment 2b. Ministry of Health Letter of Support - translation

**Ministry of Health
Republic of Guinea**

To: Madame Representative, (CDC)

Subject: Support and Thanks.

Madame Representative:

In the context of the prevention and control of the Ebola hemorrhagic fever epidemic, the Ministry of Health thanks the Centers for Disease Control and Prevention (CDC) and the CDC Foundation for their technical and financial support in the implementation of interventions, such as the study titled "Assessment of the Level of Knowledge, Attitudes and Practices (KAP) for the Prevention and Management of the Ebola hemorrhagic fever in Guinea."

Such a study has already been conducted in Sierra Leone and the results were used to improve communication and social mobilization focused on preventing Ebola disease. In Guinea, Santé Plus, an organization specializing in health research and training, has been retained to carry out a similar study. The results of this survey will help achieve governmental objectives, as these [results] will identify the determinants of the use of health services and help us base our communication efforts on the knowledge, attitudes, and practices of communities in relation to the disease.

We thank you for the support and financial assistance you intend to kindly provide to Santé Plus for this purpose.

Please accept, Madam Representative, the expression of my highest regards.

Dr. Robert Camara
National Director, Prevention and Community Health