Request for Project Determination & Approval – Division of Global Migration and Quarantine (DGMQ)

This form should be used to submit and update proposals sent for research/nonresearch determination and IRB review/approval.

Unique ID: [user ID-year- project #]

☑ New Request

☐ Protocol updates

☐ Amendment ☐ Renewal

[If selected, please complete the "Project update" AND "Additional project update information" section at the end of the form]

☐ Progress report

[Indicate any change in the status of the project. If selected, please complete the "Progress report" section at the end of the form]

☐ Closed

Project Title: 2014 Ebola Global Migration Task Force (GMTF) Response After-Action Report (AAR) Survey	
Project location (Country/State/Province/Town): Atlanta	
Principal investigator: Lee Smith SEV #: Contact email: ihf1@cdc.gov	
Project Officer*: *Project officer is required for larger projects that need administrative assistance, management of funds or coordination with PGO/FMO or require extensive fund management	
Proposed Project Dates: Start: 12/01/2015 End: 09/01/2016	Branch/Unit: QBHS
Are there any CDC collaborators**? ☐ Yes / No. ☑ If yes, list and explain their role. **CDC Collaborators: Any other CDC branch/unit, Division or Center outside DGMQ	
Are there any non-CDC collaborator(s)? *** ☐ Yes / ☑ No. If yes, list and explain their role(s): Principal Investigator(s): ***No-CDC collaborators: Any collaborator outside CDC	
DGMQ funding? ☐ Yes / ☑ No. If yes please describe funding mechanism: Non-DGMQ funding? ☐ Yes / ☑ No. If yes please describe funding mechanism:	

Brief Project Summary

The CDC Global Migration Task Force (GMTF) has been engaging in prevention, mitigation, and response operations for the Ebola response since August 2014 until the present. This emergency response has been the most resource intensive

Please post your protocol URL here:

Please check appropriate category and subcategory:

☑ **I. Activity is NOT human subjects research. Primary intent is public health practice or response i.e. disease control activity (Check one)**

- ☑ **A**. Public health response: Epidemic or endemic disease control activity; Epi-AID # if applicable
- ☐ **B**. Surveillance activity (e.g., disease, adverse events, injuries)
- ☑ **C**. Program evaluation activity
- ☐ **D.** Public health program activity*
- ☐ **E**. Analysis of surveillance data or data collected from a non-human subjects research protocol, not linking to another database.

*e.g., service delivery; health education programs; social marketing campaigns; program monitoring; electronic database construction and/or support; development of patient registries; needs assessments; and demonstration projects intended to assess organizational needs, management, and human resource requirements for implementation.

☐ **II. Activity is research but does NOT involve human subjects (Check one)**

- ☐ **A.** Activity is research involving collection or analysis of data about health facilities or other organizations or units (NOT persons).
- ☐ **B.** Activity is research involving data or specimens from deceased persons.
- ☐ **C.** Activity is research involving unlinked or anonymous data or specimens collected for another purpose.
- ☐ **D.** Activity is research involving linked data, but CDC non-disclosure form 0.1375B is signed.*
- ☐ **E.** Activity is research involving data or specimens from animal subjects or dead animals. **

*CDC investigators and the holder of the key linking the data to identifiable human subjects enter into an agreement prohibiting the release of the key to the investigators under any circumstances. It's important to note that use of the 1375B is at the discretion of the Center.

**Note: Approval by CDC Institutional Animal Care and Use Committee (IACUC) may be required for animal subjects.

☐ **III. Research Activity involves human subjects but CDC investigators are not "engaged in human subject research" (Check one)**

- ☐ **A.** This project is funded under a grant/cooperative agreement/contract award mechanism. Award #

  ALL of the following 3 elements are required:

  - ☐ 1. CDC employees or agents will not intervene or interact with living individuals for research purposes.
  - ☐ 2. CDC employees or agents will not obtain individually identifiable private information.
  - ☐ 3. Supported institution must have a Federalwide Assurance (FWA) and project must be reviewed by a registered IRB linked to the supported institution's FWA.

    Supported Institution/Entity Name:

    Supported Institution/Entity FWA # FWA Expiration Date (mm/dd/yyyy):

    Expiration Date of IRB approval: (Attach copy of the IRB approval letter) : URL

- ☐ **B**. CDC staff provide technical support that does not involve possession or analysis of identifiable data or interaction with participants from whom data are being collected (No current CDC funding).
- ☐ **C.** CDC staff are involved only in manuscript writing for a project that has closed. CDC staff did not interact with participants and were not involved with data collection and did/will not access individually identifiable data (No current CDC funding).

Note: Under this category, at the Center's discretion, the receipt of coded data under a non-disclosure agreement may satisfy criteria for being considered not individually identifiable.

☐ **IV. Activity is research involving human subjects that requires submission to CDC Human Research Protection Office (Check one)***

- ☐ A. Full Board Review (Use forms 0.1250, 0.1379-signatures, 0.1370-research partners)
- ☐ B. Expedited Review (Use same forms as A above)
- ☐ C. Exemption Request** (Use forms 0.1250X, 0.1379-Signatures, 0.1370-research partners) **(Check one)**
  - ☐ 1. **R**esearch in established or commonly accepted educational settings, involving normal educational practices.
  - ☐ 2. Research using anonymous educational tests, surveys, interview procedures or observation of public behavior.*
  - ☐ 3. Research as in (B) but identified if subjects are elected or appointed officials.
  - ☐ 4. Research involving existing data, documents, records, pathological specimens, or diagnostic specimens*
  - ☐ 5. Research conducted to evaluate public benefit or service programs, procedures, or alternatives.

*information is recorded such that no PII linked to the subjects.

- ☐ D. Reliance**

☐ 1. Request to allow CDC to rely on a non-CDC IRB (Use same form as A above, plus 0.1371)
☐ 2. Request to allow outside institution to rely on CDC IRB (Use same forms as A above, plus 0.1372)

*There are other types of requests not listed under category IV, e.g., continuation of existing protocol, amendment, incident reports.
**Exemption and reliance request is approved by CDC Human Research Protection Office (HRPO).

☐ **V. OMB Determination (Check one)**

☐ A. **Involves 9 or less non-federal persons or agencies**
☐ B. **Uses publicly available data sources. Data source:**
☐ C. **Epi-aid. State/Agency inviting:**
☐ D. **Technical assistance. State/Agency inviting**
☐ E. A**ctivity using routinely collected data. Data source:**
☐ F. **Facts or opinions obtained:**
  ☐ During public hearings or meetings (including internet engagement) not using surveys
  ☐ Through direct observation (e.g., through visual inspection)
☐ G. **Involves federal staff/materials. Specify**
☐ H. **Evaluations of meetings or Tests (aptitude, abilities, knowledge) using undifferentiated suggestion box format**
☐ I. **Grant/Cooperative Agreement with little federal involvement in data design, collection, methodology, analysis. Specify awardee:**
☐ J. **OMB waiver / exemption**
  ☐ 1. **Vaccine** ☐ 2. **Clinical**
☑ K. **OMB Generic package**
  ☐ 1. **OSTLTS** ☐ 2. **DGMQ communication** ☐ 3. **DGMQ migration health (anticipated)**
  ☑ 4. **Other, specify**

☐ **V. Was a proposal for this project approved by DGMQ-OD** ☑ Yes / No ☐

If yes, what date was it approved?

OMB approval date:

Notes:
(Please indicate any special considerations like waivers, exemptions etc.)

OMB generic package: "Generic Clearance for the Collection of Routine Customer Feedback"

Approvals/Signatures:	Date:	Remarks:
Investigator: Chester L. Smith -S Digitally signed by Chester L. Smith -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, 0.9.2342.19200300.100.1.1=1000509510, cn=Chester L. Smith -S Date: 2015.11.04 16:09:52 -05'00'	11/04/2015	
Branch/Unit Chief: Nicole J. Cohen -S Digitally signed by Nicole J. Cohen -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, 0.9.2342.19200300.100.1.1=1000484411, cn=Nicole J. Cohen -S Date: 2015.11.04 15:53:06 -05'00'	11/04/2015	

Please <u>do not</u> complete the "ADS Review and Determination" section, which will be done by DGMQ-OD

ADS Review and Determination

Submission: Attach a protocol or project description in enough detail to justify the proposed category. Submit your request to your Branch/Unit chief or appropriate Branch/Unit staff).

Approval Chain (via Documentum within DGMQ)

Investigator → Branch ACS (where applicable) →Branch Chief → Division ADS → EZID Human Subjects Mailbox

- ☒ **Project does not require human subject research review beyond DGMQ**
- ☐ **Project requires EZID human subject review**
- ☐ **Project may constitute human subject research and may be routed to CDC HRPO**
- ☐ **Project involves animals and may be routed to CDC IACUC**

Comments/Rationale for Determination:

Approvals/Signatures:	**Date:**	**Remarks:**
Division ADS, Deputy Director/Director: Pamela Diaz -S	11/17/2015	Project consistent with program evaluation
EZID Human Subjects Approval:		
EZID/OGC OMB Approval:		

Note! Determinations should be made at the Division level or higher and not by individual investigators. Although CDC IRB review is not required for certain approved projects under this determination, CDC investigators and project officers are expected to adhere to the highest ethical standards of conduct and to respect and protect to the extent possible the privacy, confidentiality, and autonomy of participants. All applicable country, state, and federal laws must be followed. Informed consent may be appropriate and should address all applicable elements of informed consent. CDC investigators should incorporate diverse perspectives that respect the values, beliefs, and cultures of the people in the country, state, and community in which they work.