CGH HSR Tracking #:_____

Request for Project Determination & Approval – Center for Global Health (CGH)

This form should be used to submit proposals to the CGH Office of the Associate Director for Science/Laboratory Science (ADS/ADLS) for research/nonresearch determination and requirements for IRB review/approval.
Approval Chain: Investigator → Branch Chief/Country Director → Division ADS → CGH Human Subjects Mailbox

☒ **New Request** ☐ **Amendment** ☐ **Laboratory Submission**

Project Title: Routine Surveillance for Babesiosis, Cyclosporiasis, Malaria and Trichinellosis in the United States		Project Location/Country(ies): USA
CDC Principal Investigator(s): Anthony Fiore		
CDC Project Officer(s): Anthony Fiore	Division: DPDM	Telephone: 4047184734
Proposed Project Dates: Start: 02/01/13	End: indefinite	

Please check appropriate category and subcategory:

☒ **I. Activity is NOT human subjects research. Primary intent is public health practice or a disease control activity (Check one)**

- ☐ **A**. Epidemic or endemic disease control activity; if applicable, Epi-AID #
- ☒ **B**. Routine surveillance activity (e.g., disease, adverse events, injuries)
- ☐ **C**. Program evaluation activity
- ☐ **D**. Public health program activity*
- ☐ **E**. Laboratory proficiency testing

*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 data or specimens from animal subjects.*

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

☐ **III. Activity is research involving human subjects but CDC involvement does not constitute "engagement 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)	

- ☐ **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. For the project, CDC staff did not interact with participants and were not involved with data collection (No current CDC funding).
- ☐ **D.** Activity is research involving linked data, but CDC non-disclosure form 0.1375B is signed.*

*Access to linked data is permitted under any of the above sub-categories if CDC investigators and the holder of the key linking the data to identifiable human subjects enter into an agreement using CDC form 0.1375B, prohibiting the release of the key to CDC investigators under any circumstances. The purposes of the planned research do not contradict the terms of consent under which the information or specimens were collected, whether that consent was documented or not documented.

☐ **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, 0.1370-research partners)
- ☐ B. Expedited Review (Use same forms as A above)
- ☐ C. Exemption Request** (Use forms 0.1250X, 0.1370-research partners)
- ☐ D. Reliance**
  - ☐ 1. Request to allow CDC to rely on a non-CDC IRB (Use same forms as A above, plus 0.1371)

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☐ 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).

Amendment: If this request is an amendment to an existing project determination. Please include a brief description of the substantive change or modification below and attach both clean and marked copies of the amended protocol or project outline.

Submission: Attach a protocol or project description (See standard format below) in enough detail to justify the proposed category. Submit your request to your branch chief (or country director for DGHA country staff).

Approval Chain
Investigator → Branch Chief/Country Director →Division ADS → CGH Human Subjects Mailbox

CGH ADS/ADLS Review **Date received in CGH ADS /ADLS office:**

☒ **Project does not require human subject research review beyond CGH at this time.**

☐ **Project constitutes human subject research that must be routed to CDC HRPO.**

Comments/Rationale for Determination: **Routine surveillance of nationally notifiable diseases. Not research.**

1**Approvals/Signatures:**	1**Date:**	**Remarks:**
Anthony Fiore Investigator	**02/04/13**	
Branch Chief/Country Director		
Anthony Fiore Division Human Research Protection Coordinator Division ADS/ADLS or Director	**02/04/13**	
 CGH Human Research Protection Coordinator CGH ADS/ADLS or Deputy ADS/ADLS	**2/4/2013**	**Ongoing surveillance of Babesiosis, Cyclosporiasis, Malaria, and Trichinellosis in the US.**

Note: Although CDC IRB review is not required for certain projects (categories I,II & III) approved 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.

Definitions

Agent – A nonemployee of CDC who conducts research under CDC's FWA. This generally includes all persons cleared for access to CDC networks and who use CDC networks or physical facilities for human research activities.

Emergency response – A public health activity undertaken in an urgent or emergency situation, usually because of an identified or suspected imminent health threat to the population, but sometimes because the public and/or government authorities perceive an imminent threat that demands immediate action. The primary purpose of the activity is to document the existence and magnitude of a public health problem in the community and to implement appropriate measures to address the problem (Langmuir, Public Health Reports 1980; 95:470-7).

Engagement – An institution becomes engaged in human subjects research when its employees or agents (i) obtain data about living individuals through intervention or interaction with them for research purposes; (ii) obtain individually identifiable private information about living individuals for research purposes; or (iii) obtain the informed consent of human subjects (http://www.hhs.gov/ohrp/FWAfaq.html). Furthermore, an institution is automatically considered to be engaged in human subjects research whenever it receives a direct HHS award to support such research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

Human subject or participant – is defined as a living person about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (e.g., medical records, employment records, or school records).

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Program evaluation is the systematic collection of information about the activities, characteristics, and outcomes of programs to make judgments about the program, improve program effectiveness, and/or inform decisions about future program development. Program evaluation should not be confused with treatment efficacy which measures how well a treatment achieves its goals which can be considered as research. CDC guidance on research/non-research

Research – is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research, whether or not these activities are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Surveillance – The ongoing systematic collection, analysis and interpretation of health data, essential to the planning, implementation and evaluation of public health practice, closely integrated to the dissemination of these data to those who need to know and linked to prevention and control.

Links

- CDC Human Research Protections Policy (2010): http://aops-mas-iis.cdc.gov/Policy/Doc/policy556.pdf
- CDC Distinguishing Public Health Research and Public Health Nonresearch (2010): http://aops-mas-iis.cdc.gov/policy/Doc/policy557.pdf
- HHS Title 45 Code of Federal Regulations Part 46, Protection of Human Subjects (Revised 2009):

http://www.cdc.gov/od/science/regs/hrpp/researchDefinition.htm
- OHRP Guidance on Engagement of Institutions in Human Subjects Research: http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html
- OHRP Guidance on Research Involving Coded Private Information or Biological Specimens: http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm

Suggested Protocol Format (Please include protocol as separate attachment)

NOTE: This page is an outline for a proposal to ensure all required information is included for review and approval. You may submit a proposal following the outline provided below, or a full protocol that includes information pertaining to all applicable elements.

I. Project Overview
- Project title
- Investigator(s) and roles
- Collaborator(s) and roles, funding mechanism, FWA# (if engaged in research)
- Other participants in research
- Sponsoring institution(s)

II. Introduction
- Background & Literature review
- Justification for study
- Intended/potential use of study findings
- Design/locations
- Goals and objectives
- Hypotheses or questions
- General approach

III. Procedures / Methods
- Design
  (How address hypotheses, stakeholder participation, cost benefit, timeline, expedited review requested)
- Study Population
  (Source, case definition, inclusion/exclusion criteria, sampling, enrollment, consent process)
- Variables / Interventions
  (Variables, study instruments, IND/IDE, intervention or treatment, outcomes, training for study personnel)
- Data handling and Analysis
  (Data collection, analysis plan, software, data entry, handling, measurement and tests, potential bias, limitations)
- Handling of Unexpected or Adverse Events
- Dissemination, Notification, and Reporting of Results

IV. Ethical considerations
- Informed consent
- Confidentiality/privacy protections
- Autonomy
- Additional safeguard for vulnerable populations
- Culture, values, and beliefs

V. References

VI. Appendix Materials (data collection forms, consent scripts, scientific peer review, other relevant documents)

A detailed protocol development guide is available at http://intranet.cdc.gov/od/oads/osi/hrpo/worksheets.htm.