# Determination of Applicability of Human Subjects Regulations

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

**Project Title:** National Disease Surveillance Program - I. Case Reports (OMB No. 0920-0009)

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

**Primary Contact:** J. Michael Miller, Ph.D., D(ABMM) **Phone:** 404-639-3029

**Division/Branch:** NCZVED/OD **Supervisor's Name:**

**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.

**Other Considerations:** Mark all that apply.

- ☐ FDA review is required under IND, IDE, or EUA.
- ☐ 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 Wendy Carr ☑ NC ADS Mike Miller

**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:**

All projects contained in this package are disease surveillance systems involving the regular, ongoing collection of data to monitor the incidence of disease in the population. Per CDC guidance, these activities do not meet the definition of research under 45CFR46.102(d).

**Tracking System ID Number:** OMB No. 0920-0009

**Final Determination Made by (print name):** Wendy Carr

**Signature:** **Date:**

# Determination of Applicability of Human Subjects Regulations
## For Any Activities/Projects When Human Information/Specimens Will Be Collected

**Project Title:** The National Notifiable Diseases Surveillance System (NNDSS): Vaccine Preventable Diseases and Other Diseases and Illnesses

**Date to Begin:** **End:** ☐ **New Project** or ☑ **Changes to Existing Project**

**Primary Contact:** Sandy Roush **Phone:** 639-8741

**Division/Branch:** NCIRD/OD/OSIP **Supervisor's Name:** David Swerdlow/Jane Seward

**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.

**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 ☑ NC ADS Jane Seward (acting)

**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 NNDSS is routinely monitor diseases/illness of public health importance. NNDSS is a platform to assist state, local, and territorial health depts collect, manage, analyze, interpret, and disseminate health-related data for diseases and conditions designated as nationally notifiable. CDC is notified by state/local health depts of cases of diseases and conditions under national surveillance using electronic reporting and data management systems. NCIRD subsequently obtains data for vaccine preventable diseases other diseases and illnesses from NNDSS that are made available on the consolidated statistical platform to routinely monitor certain notifiable diseases. These data are routinely analyzed and reported through CDC MMWRs and other publications.

**Tracking System ID Number:** 2013 6263

**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=hpz7@cdc.gov, c=US Date: 2013.02.04 15:02:08 -05'00' **Date:** February 1, 2013

# REQUEST for Project Determination & Approval - NCHHSTP ADS/ADLS OFFICE

This form should be used to submit proposals to the NCHHSTP ADS/ADLS Office for determination that have not begun and do not require routing to the CDC Human Research Protection Office at this time. Projects eligible for this classification are (1) non-research activities; (2) research that does not involve identifiable human subjects; (3) human subject research in which CDC is not "engaged".

Project Title:
*Sexually Transmitted Disease (STD) Morbidity Surveillance*

Project Location/Country(ies): All 50 states, the District of Columbia, selected cities, & U.S. dependencies & possessions and
Locations/Country(ies): independent nations in free association with the U.S.

Project Officer(s): Darlene Davis, Susan Arrowsmith Division: DSTDP Telephone: (404) 639-1838

Proposed Project Dates: Start: 04/01/2013 End: 00/31/2016 Laboratory Branch Submission: ☐

Please check appropriate category and subcategory:

☒ **I. Activity is not human subjects research.** Primary intent is public health practice or a disease control activity.
- ☐ A. Epidemic or endemic disease control activity; collected data directly relate to disease control (e.g. Epi-AIDs; provide Epi-AID number & documentation of request for assistance, if division policy). Epi-AID #
- ☒ B. Routine disease surveillance activity; data used for disease control program or policy purposes.
- ☐ C. Program evaluation activity; data are used primarily for that purpose.
- ☐ D. Post-marketing surveillance of effectiveness or adverse effects of a new regimen, drug, vaccine, or device.
- ☐ E. Laboratory proficiency testing.

☐ **II. Activity is not human subjects research.** Primary intent is public health program activities.
- ☐ A. Public health program activity (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).
- ☐ B. Activity is purely administrative (e.g., purchase orders or contracts for services or equipment).

☐ **III. Activity is research but does NOT involve identifiable human subjects.**
- ☐ A. Activity is research involving collection or analysis of data about health facilities or other organizations or units which are not individual persons.
- ☐ B. Activity is research involving data or specimens from deceased persons.
- ☐ C. Activity is research using unlinked or anonymous data or specimens: **ALL** (1-4) of the following are required:
  - ☐ 1. No contact with human subjects is involved for the proposed activity...**and**...
  - ☐ 2. Data or specimens are/were collected for another purpose...**and**...
  - ☐ 3. No extra data/specimens are/were collected for this purpose...**and**...
  - ☐ 4. Identifying information was: (one of these must be checked)
    - ☐ a. not obtained
    - ☐ b. removed prior to this submission, or prior to CDC receipt, so that data cannot be linked or re-linked with identifiable human subjects
    - ☐ c. protected through an agreement. (*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. A copy of the agreement must be attached).

☐ **IV. Activity is research involving human subjects but CDC involvement does not constitute "engagement in human subject research".** **Select only one option below: 'A' indicates the project is funded, 'B' or 'C' indicate there is no current funding**
- ☐ A. This project is funded under a grant/cooperative agreement/contract award mechanism.
  **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).

**Although CDC IRB review is not required for projects 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 privacy laws must be followed.**

**Although this project may not constitute "research" involving human subjects, informed consent may be appropriate. Information conveyed in an informed consent process should address all applicable required elements of informed consent.**

**Definitions and Links**

OHRP defines ***research*** 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. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102

OHRP defines a ***human subject*** as a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information.

*Intervention* includes both physical procedures by which data are gathered (for example, venipuncture), and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *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.
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102

OHRP considers that an institution becomes ***"engaged"*** in human subjects research when its employees or agents intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes. An institution is automatically considered to be "engaged" in human subjects research whenever it receives a direct HHS award to support such research. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects under the award.
http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html. ***Agents*** include all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility, e.g., contractors.

CDC defines ***surveillance*** as "the ongoing, systematic collection, analysis, and interpretation of health data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know. The final link of the surveillance chain is the application of these data to prevention and control. A surveillance system includes a functional capacity for data collection, analysis, and dissemination linked to public health programs." (CDC 1986)

***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 http://www.cdc.gov/od/science/regs/hrpp/researchDefinition.htm

For easy access to HHS human subjects regulations, see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
For guidance on differentiating research from nonresearch, see http://www.cdc.gov/od/science/regs/hrpp/researchDefinition.htm
For guidance on engagement of institutions in research, see http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html

---

Attach protocol or project description (standard format at end of this form) in enough detail to justify the proposed category. Submit through division ADS/Director to: nchstphs@cdc.gov

☒ Check here if an OMB determination form has been completed for this project. OMB #0920-0819

☐ Check here 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.

**Brief Description of change/modification:**

Approval initials & printed name: _Susan L. Arrowsmith_____ _06/29/2012__ _____ _____
Deputy Branch Chief Date ADS/ADLS or Division Director Date

**Division Notes/Comments:**

---

**Project Title:** *Sexually Transmitted Disease (STD) Morbidity Surveillance*

---

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

X☐ **Concur, project does not require human subject research review beyond NCHHSTP at this time**

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

## Comments/Rationale for Determination:

**Signed**:_____ _____
Name Date
Associate (or Acting or Deputy Associate) Director for Science, NCHHSTP
OR
Associate Director for Laboratory Science, NCHHSTP
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

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)
  - ☐ 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).

CGH HSR Tracking #:

**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.**

| Approvals/Signatures: | Date: | Remarks: |
|---|---|---|
| **Anthony Fiore**<br>Investigator | **02/04/13** | |
| Branch Chief/Country Director | | |
| **Anthony Fiore**<br>Division Human Research Protection Coordinator<br>Division ADS/ADLS or Director | **02/04/13** | |
|  <br>CGH Human Research Protection Coordinator<br>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.