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:**

Coates, Ralph (CDC/OSELS/PHSIPO)

From: Youngblood, Laura (CDC/OID/NCEZID)
Sent: Wednesday, January 30, 2013 9:54 AM
To: McMillen, Amy (CDC/OID/NCEZID)
Subject: FW: IRB?

Thanks, Amy. I have reviewed the attached document. The activities described therein are routine non-research public health surveillance activities. Because such activities do not meet the definition of research under 45 CFR 46.102(d), they are not subject to IRB review requirements.

IRB review is not required for the activities described in the attached document.

Please let me know if you need more formal documentation.

Thanks,
Laura

Laura Youngblood, MPH, CIP
Human Subjects Advisor | NCEZID | lyoungblood@cdc.gov | MW: (404) 639-6394 | TThF: (404) 510-0093

From: McMillen, Amy (CDC/OID/NCEZID)
Sent: Wednesday, January 30, 2013 9:45 AM
To: Youngblood, Laura (CDC/OID/NCEZID)
Subject: RE: IRB?

Hi Laura,
Long story but OSELS is rolling in our surveillance systems to their notifiable diseases OMB package. They need a statement about 0920-0004 and I can't find where you let me know about this 2 years ago. Attached is the most recent supporting statement. Thanks for your help.
Amy

SS
0920-0004revisio...

From: Youngblood, Laura (CDC/OID/NCEZID)
Sent: Thursday, September 23, 2010 1:07 PM
To: McMillen, Amy (CDC/OID/NCEZID)
Subject: RE: IRB?

Hi Amy. Yes, I am the correct person (or one of them, anyway!). What is your timeframe on this? I have a few other things in the queue, but I can juggle some things, depending on when you need this.

Thanks,
Laura

Laura Youngblood, MPH, CIP
Human Subjects Advisor | NCEZID | lyoungblood@cdc.gov | MTh: (404) 639-6394 | TWF: (404) 510-0093

From: McMillen, Amy (CDC/OID/NCPDCID) (CTR)
Sent: Thursday, September 23, 2010 12:35 PM
To: Youngblood, Laura (CDC/OID/OD)
Subject: FW: IRB?

Laura
Mike Miller told me you were the person I needed to contact about this? Can you help me? What do I need to send you? Thanks.
Amy McMillen

From: McMillen, Amy (CDC/OID/NCPDCID) (CTR)
Sent: Thursday, September 23, 2010 12:08 PM
To: Stokes, Susan (CDC/OID/NCPDCID) (CTR)
Subject: IRB?

Susan
Are you still the IRB person? I'm back working on OMB clearance and they are telling me that we need a statement saying IRB is not applicable for a disease surveillance system. Can you help me? Attached is the supporting statement. Thanks.
Amy << File: 0920-0004revisionjuly2010.doc >>

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=xgi7@cdc.gov, c=US Date: 2013.02.04 15:02:09 -05'00' **Date:** February 1, 2013

From: IRBOnline@cdc.gov [mailto:IRBOnline@cdc.gov]
Sent: Wednesday, May 30, 2012 8:25 AM
To: Benton, Donna (CDC/OID/NCHHSTP); Carey, Delicia (CDC/OID/NCHHSTP)
Subject: Adding Action (Approved (Center)) - Donna Benton

Current Status: Approved (Center)

Nchstp Protocol Id: 6808

Protocol Number: 0

Protocol Division: HCVJDH

Principal Investigator's Name: Carey, Delicia

User: Benton, Donna

Title: Program Specialist

Telephone: (404)639-6362

Organization: OADS

Protocol Title: Sexually Transmitted Disease (STD) Morbidity Surveillance

Current Submission: Determination

Comments:

Login to IRBOnline

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): Delicia Carey, Hillard Weinstock Division: DSTDP Telephone: (404) 639-6035

Proposed Project Dates: Start: 01/01/2012 End: 12/31/2014 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

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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: Delicia Carey, PhD 05/03/2012
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:**

☐ **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

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.

PROJECT TITLE:

1. Principal Investigator(s):

2. CDC Project Officer(s) including roles and responsibilities:

3. Other participants in research:

4. Sponsoring institution(s):

5. Project Goals:

6. Project Objectives:

7. Program needs to be addressed:

8. Populations to be studied:

9. Methods:

10. Sampling Methodology:

11. Incentives to be provided:

12. Plans for data collection and analysis:

13. Confidentiality protections:

14. Other ethical concerns/issues:

15. Projected time frame for the project:

16. Plans for publication and dissemination of the project findings:

17. Appendices - including informed consent documents, data collection instruments, focus group guides, flyers, etc:

18. References:

Attachment: Project description

PROJECT TITLE: *Sexually Transmitted Disease (STD) Morbidity Surveillance*

CDC Project Officer(s) including roles and responsibilities: Hillard Weinstock, Epidemiology and Surveillance Branch, DSTDP, scientific oversight, surveillance data analysis, interpretation & dissemination; Delicia Carey, Statistics and Data Management Branch, DSTDP, informatics and data management oversight, surveillance data analysis, presentation, and dissemination.

Project Background

The CDC is responsible for the reporting and dissemination of nationally notifiable STD morbidity information for prevention and control purposes in collaboration with state and local health departments.

Recent changes in sexually transmitted disease (STD) epidemiology in the United States indicate that the existing passive surveillance for STD does not include all the elements needed in order to control and prevent STDs in the U.S. Towards this end, CDC has an electronic information collection that includes additional information on nationally notifiable STDs that is beyond the scope of the current collection called Weekly and Annual Morbidity and Mortality Reports (MMWR, OMB #0920-0819, expiration, August 31, 2012). The MMWR STD surveillance includes four of 60 nationally notifiable infectious conditions included in the 0920-0819.

The STD morbidity surveillance is epidemiologically superior to the MMWR surveillance because it includes information on laboratory confirmation of syphilis infection and risk behaviors of persons infected with syphilis and other STDs. This STD Morbidity surveillance data identifies population subgroups at increased risk for STDs, accommodates evidence-based intervention strategies, evaluates the impact of ongoing control efforts and generally enhances our understanding of STD transmission.

The STD Morbidity surveillance activity is authorized under the provisions of Section 301 of the Public Health Service Act (42 USC 241)

Overview of the data collection system

The surveillance case definitions used to confirm STDs is jointly developed and approved by the Council of State and Territorial Epidemiologists (CSTE) and CDC for nationally notifiable STDs. The nationally notifiable STDs include chancroid, genital *Chlamydia trachomatis* infection, gonorrhea, and all stages of syphilis. The information content of the electronic STD morbidity case reports submitted to CDC is defined in collaboration with state and local STD programs.

Physicians and other providers collect demographic, risk, and clinical (including laboratory) information from persons diagnosed with notifiable STDs during a clinical encounter or counseling session. They submit the information in hardcopy or electronic formats, to the state and local public health departments. A subset of the information reported to state health departments is reported electronically as a case report e-record to CDC's Nationally Notifiable Disease Surveillance System (NNDSS, sometimes referred to as the National Electronic Telecommunications System for Surveillance (NETSS) on a weekly basis.

In accordance with state and local laws and regulations and Health Insurance Portability and Accountability Act (HIPAA)'s public health notification exemption, both health care providers and laboratories are required to report demographic, risk, and clinical information data elements describing notifiable STD case-patients to the local or state public health system.

State STD prevention and control programs receive federal funds to support comprehensive STD prevention programs, comprised of eight (8) essential functions – one of which is "surveillance and data management" within their jurisdiction.

Because MMWR STD surveillance does not use paper or hard-copy data collection forms, local and state programs have the flexibility to extract defined morbidity-associated data variables from commercial, locally-developed, or CDC-provided freeware information systems (STD*MIS, URL: http://www.cdc.gov/std/std-mis/). The data elements defining STD morbidity that is needed for the new surveillance will be extracted from these states and local information systems after they are posted on the CDC mainframe. The Division of STD Prevention will extract the information needed by accessing the STD data bases through the CDC mainframe.

Use of the Information Collected

The STD morbidity information is being collected in order to monitor morbidities and risk profiles of persons with specific trends in specific STDs at the local, state, and national level. The feedback to local and state departments improves local STD prevention and control efforts. Reporting selected demographic and risk behavior data on persons infected with notifiable STDs from state and local STD prevention programs to CDC allows cross- jurisdictional, regional, and national STD trends and emerging epidemiologic patterns to be identified to guide public health response.

CDC will use the STD morbidity information for intervention planning and implementation and to guide allocation of prevention resources. Without the STD morbidity information. the distribution of STDs by risk behavior group (e.g. men who have sex with men) across the United States will be unavailable. DSTDP will not be able to make data-based decisions regarding national prevention program planning and resource allocation without STD incidence data.

Data confidentiality and security considerations:

Once STD Morbidity data are reported to CDC, use and release of the data are guided by a June 1996 policy. " Data Release Guidelines of the Council of State and Territorial Epidemiologists for the National Public Health Surveillance System". which defines the subgroups of STD morbidity data that can be released. The policy for data release intends to facilitate the use of national notifiable STD morbidity data while preserving the confidentiality of the data.

This STD Morbidity information collection request includes sensitive information on sexual and drug-using behaviors associated with the case-patient and identified only as a case identification number. The only personally-identifiable information (PII) category collected is date of birth. which is collected in order to assign age of the patient and also to distinguish unique vs. repeat visits of the same client. The STD Morbidity data collection will have no effect on the respondent's privacy because personally-identifiable information that allows identification of an individual will not be available in the MMWR STD case reports that arrive at CDC.

At CDC. the NNDSS data including STD case reports are maintained on secure servers behind the CDC firewall. Password-protected access is required and directory-specific user access rights are assigned by a CDC data steward following review of and sign-off on a data use policy that references the CSTE data release guidelines. Restricted access to STD data is provided to Division of STD Prevention (DSTDP)/CDC scientists. researchers. and program managers via an intranet web-based data query application called STD Net. Epidemiologists and program consultants in the DSTDP create analytic data files from the case report line listing in order to monitor trends in STDs by demographic and geographic characteristics.

Data dissemination:

In order to gain the maximum benefit for existing STD prevention and control efforts, CDC will disseminate aggregated STD morbidity reports with local and state STD prevention programs, policy makers. academia and the general public, in the form of MMWR series of publications. including the weekly MMWR, the MMWR Surveillance Summaries. the Recommendations and Reports. and the annual Summary of Notifiable Diseases. United States. Additionally. DSTDP publishes an annual STD-specific surveillance summary in hard copy and on the Internet (http://www.cdc.gov/std/stats/)and supplements on the Internet (http://www.cdc.gov/std/stats/).

Project duration:

Collection of STD surveillance data in the United States to support STD prevention efforts began prior to 1941. The Division of STD Prevention plans to continue this long tradition. but is currently seeking OMB approval for a 3-year period and plans to renew OMB approval for STD surveillance data collection and use thereafter.

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:
Hepatitis Testing and Linkage to Care Monitoring & Evaluation System (HEPTLC)

Project Location/Country(ies): Multiple (To be updated upon awardees determined)

Project Officer(s): Bryce Smith | Division: DVH | Telephone: 404.639.6277

Proposed Project Dates: Start: 09/30/2012 | End: 09/30/2013 | 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).

Revised 07/15/2009

Approval initials & printed name: [signature] 4.27.12 [signature] 4-27-12
Branch Chief Date ADS/ADLS or Division Director Date

Division Notes/Comments:

Project Title: Hepatitis Testing and Linkage to Care Monitoring & Evaluation System

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NCHHSTP ADS/ADLS Review Date received in NCHHSTP ADS /ADLS office: April 30. 2012

☑ 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:

The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHDTP), Centers for Disease Control and Prevention is requesting a three-year OMB approval for establishing a Hepatitis Testing and Linkage to Care (HEPTLC) Monitoring and Evaluation System to collect standardized, non-identifying, test-level information from the testing sites at multiple settings, that were funded through Prevention Public Health Funding (PPHF). Grantees will be required to use this web-based HEPTLC software application to collect and report testing and linkage to care activities.

The primary purpose of this data collection and reporting is to monitor and evaluate the implementation of hepatitis testing and linkage to care services and activities funded through Prevention Public Health Funding (PPHF),as well as support mandated reporting requirements set forth by the Congress and CDC. Moreover, the design and intent of the data collection and reporting is not to develop or contribute to generalizable research knowledge, and data collected from funded sites will not be generalized to other populations.

As Required: Review and approval by all participating sites and adherence to all relevant procedures, policies, and regulations for protection of participants and integrity of project data needed

Signed: Salaam Semaan, MPH, DrPH May 3, 2012
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

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This document was prepared by the Prevention Research and Evaluation Team (Jianglan White, vyg1@cdc.gov; and Bryce Smith, bli1@cdc.gov).

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

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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

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.

PROJECT TITLE:

1. Principal Investigator(s):

2. CDC Project Officer(s) including roles and responsibilities:

3. Other participants in research:

4. Sponsoring institution(s):

5. Project Goals:

6. Project Objectives:

7. Program needs to be addressed:

8. Populations to be studied:

9. Methods:

10. Sampling Methodology:

11. Incentives to be provided:

12. Plans for data collection and analysis:

13. Confidentiality protections:

14. Other ethical concerns/issues:

15. Projected time frame for the project:

16. Plans for publication and dissemination of the project findings:

17. Appendices - including informed consent documents, data collection instruments, focus group guides, flyers, etc:

18. References:

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 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.