Congenital Syphilis (CS) Case Investigation and Report Form

0920-0128

Attachment 6

Request for Project Determination and Approval

Revised 01/13/2009

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. Projects eligible for this classification are (1) non-research activities; (2) research that does not involve identifiable human subjects, and (3) human subject research in which CDC is not "engaged". See page 3 for helpful definitions and weblinks.) Do **NOT** use this form for "exempt" human subject research, those protocols must be routed to HRPO.

Project Title Congenital Syphilis Case Investigation and Report Form

Project Locations/Country(ies): United States

Project Officer(s) Gail Scogin / Sam Groseclose Division: DSTDP Telephone: (404) 639-8437 / (404) 639-6494

Proposed Project Dates: Start: 01/01/2010 End: 12/31/2012 (and ongoing thereafter)

Please check appropriate category and subcategory:

__x__ **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 # _____
- __x__ **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 conducted under a grant or cooperative agreement award mechanism. **ALL** of the following 3 elements are required:
  - ____1. CDC employees or agents do not intervene or interact with living individuals for research purposes.
  - ____2. CDC employees or agents do 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_____
    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).

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.

☐ 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.

Approval initials & printed name: _____ 1 Dec 09 _____ 12/1/09
Branch Chief Date **ADS/ADLS or Division Director** Date

Division Notes/Comments:

Project Title: Congenital Syphilis Case Investigation and Report Form
* Please complete.

NCHHSTP ADS/ADLS Review **Date received in NCHHSTP ADS /ADLS Office:** Dec 1, 09

1 **Concur, project does not require human subject research review beyond NCHHSTP**

or

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

Comments/Rationale: Surveillance / Reporting form.

Additional Comments:
1. This form cannot be used to document human subject research that is exempt from human subjects regulations; such research must be submitted to the CDC Human Research Protection Office.
2. 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.
3. Although this project may not constitute "research" involving human subjects, informed consent may be appropriate. Information disclosed in the consent process should address all applicable required elements of informed consent.

Signed: Salaam Semaan, MPH — Dec 2. 09

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