

NCHSTP Research/Non-research Determination

(Request to Classify Project as Not Involving Human Subjects or Research)

This form should be used to submit to NCHSTP ADS materials for projects involving CDC investigations that are not subject to human subjects regulations. Projects are eligible for this classification either as Anon-research” projects (primary intent is not to generate generalizable knowledge) or as research projects that do not involve identifiable human subjects. Such projects do not require submission to the CDC Human Subjects Office for IRB review. Do **NOT** use this form for IRB “EXEMPT@ research.

Project Title: National Surveillance for Severe Adverse Events (Hospitalization or Death) Associated with Treatment of Latent Tuberculosis Infection

Project Locations/Sites: Health departments (local/state/territorial) from any of the 60 reporting areas for the national TB surveillance system (the 50 states, the District of Columbia, New York City, Puerto Rico, and 7 jurisdictions in the Pacific and Caribbean)

Project Officer(s): Lilia Manangan, RN, MPH Division: DTBE Telephone: 404-639-8401

Proposed Project Dates: Start: 01/01/2004 End: indefinite

Categories of data collection that do not constitute human subjects research include are listed below. Please check appropriate category:

- I. Activity is not research** . Primary intent is public health practice or a disease control activity.
- A.** Epidemic/endemic **disease control** activity; collected data directly relate to disease control needs.
 - 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 efficacy and/or adverse effects of a new regimen, drug or device.
 - E.** **Activity is purely administrative** (e.g., purchase orders or contracts for services or equipment) and not related to research [this category I-E may be determined by Divisional ADS]

-OR-

- II. Activity is research but does NOT involve identifiable human subjects.**
- A.** Activity is research involving collection/analysis of data about health facilities or other organizations or units which are not individual persons....**or**...
 - B.** Activity is research involving data and/or specimens from deceased persons...**or**...
 - C.** Activity is research using unlinked 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 either was not obtained **or** has been removed so that data cannot be linked or re-linked with identifiable human subjects. (Note: under certain conditions, research *may* qualify as non-human subjects when identifiers are removed by local staff; contact NCHSTP ADS office for details.)

Attach project description (standard format at end of this form) in enough detail to clarify its non-human subject research nature. Submit through division ADS/Director to: NCHSTP ADS, Attn: Janella Dodson (MS E-07)

Check here if this request is an **amendment** of an existing non-research determination.

Approval initials: _____

Branch/Section Chief

Date _____ **ADS or**
Div. Director Date

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Project Title: National Surveillance for Severe Adverse Events (Hospitalization or Death) Associated with Treatment of Latent Tuberculosis Infection

NCHSTP ADS Review **Date rec'd in NCHSTP ADS**
Office: _____

Concur, project does not constitute human subjects research

or

___Project constitutes human subjects research, submission for Human Subjects review required

Comments/Rationale:

Additional Comments:

1. This form cannot be used to document "IRB Exempt Research," which must instead be submitted to the CDC IRB. (Please contact the NCHSTP ADS Office for details).
2. Although CDC Human Subjects (IRB) review is not required in this instance, investigators/project officers are expected to adhere to ethical principles and standards by respecting and protecting to the maximum extent possible the privacy, confidentiality and autonomy of participants. All applicable State and Federal privacy laws must be followed.
3. Although this project does not constitute human subjects research, informed consent may be appropriate. Information disclosed in the consent process should address the eight standard consent elements.
4. Other:

Signed: ___Ida Onorato _____
Terence Chorba, MD, MPH, MPA, MA
Acting Associate Director for Science, NCHSTP
National Center for HIV, STD, and TB Prevention

___10/14/04___
Date

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