Gonococcal Isolate Surveillance Project

OMB 0920-0307

Robert Kirkcaldy, Project Officer

Attachment 5

Determination of Non-Research

NCHSTP Determination of Applicability of Human Subjects Regulations, 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 "non-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 **Gonococcal Isolate Surveillance Project**

Project Officer(s) **Susan Wang** Division: **DSTDP** Telephone: **404 639-8373**

Proposed Project Dates: **Ongoing since 1986**

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

_X__ **I. Activity is not research** . Primary intent is a public health practice disease control activity.
- ___ **A.** Epidemic/endemic **disease control** activity; collected data directly relate to disease control needs.
- _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 efficacy and/or adverse effects a new regimen, drug or device.

-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 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)

Approval initials: _____ 2/16/00 _____ 2/17/2000
Branch/Section Chief Date **ADS or Div. Director** Date

Project Title **Gonococcal Isolate Surveillance Project**

Project Officer(s **Susan Wang**

NCHSTP ADS Review **Date rec'd** _____

✓ **Concur,** project does not constitute human subjects research

___ **Project constitutes human subjects research,** submission for Human Subjects review required

Comments/Rationale:

The proposed change to the protocol does not impact the original determination that the project does not constitute human subjects research.

Additional Comments:

1. This form cannot be used to document "IRB Exempt Research," which must instead be submitted to the CDC IRB.

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: K.M. MacQueen

Kathleen M. MacQueen, Ph.D.
Deputy Associate Director for Science
National Center for HIV, STD, and TB Prevention

2-23-00
Date