

Gonococcal Isolate Surveillance Project

OMB 0920-0307

Sancta St. Cyr, Project Officer

Attachment 5b

Determination of Non-Research: Enhanced GISP

Project Title: enhanced Gonococcal Isolate Surveillance Project (eGISP)

12/18/2015

PROJECT REQUEST

Project Stage

Choose one by selecting a checkbox:

- New:** Fill out entire form, even if a protocol is attached (approval is for work by CDC/NCHHSTP employees).
- Continuation:** For projects expected to continue beyond NCHHSTP approved date; include brief description of changes and attach clean and marked copies of approved determination (approval is for continued work by CDC/NCHHSTP employees).
- Amendment:** Include brief description of changes and attach relevant documentation and a copy of approved project (approval is for continued work by CDC/NCHHSTP employees).

Project Information:

Project Title: enhanced Gonococcal Isolate Surveillance Project (eGISP)

NCHHSTP Project Number:

Division: DSTDP

Project Location/Country(ies):

United States

Telephone: (404) 639-8948

CDC Project Officer or CDC Co-Leads:

Elizabeth Torrone

Project Dates:

Start 07/01/2017

End 09/30/2020

Laboratory Branch Submission:

If applicable, select the checkbox:

Project Categories

Select the corresponding checkbox to choose the category and subcategory.

- I. Activity is not human subject research.** The primary intent of the project is public health practice or a disease control activity.
 - A.** Epidemic or endemic disease control activity; collected data directly relate to disease control. If this project is an Epi-AID; provide the Epi-AID number and documentation of the request for assistance, per division policy. Epi-AID no.
 - B.** Routine disease surveillance activity; data will be used for disease control program or policy purposes.
 - C.** Program evaluation activity; data will be 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.

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NCHHSTP ADS/DEPUTY ADS OR ADLS REVIEW AND APPROVAL

Project Title: enhanced Gonococcal Isolate Surveillance Project (eGISP)

Date received in NCHHSTP ADS or ADLS office:

Date received by NCHHSTP Deputy ADS or ADLS:

Select the checkbox for each applicable comment for Nos. 1–5 or select the checkbox for No. 6 if all of the comments apply. Additional applicable comments may be added to No. 7. If additional information is required before approval can be granted, select No. 8.

- 1. This project is approved by NCHHSTP/CDC and CDC (per CDC policies and federal regulations) for CDC staff participation.
- 2. Participating partners and sites must obtain project review and approval, according to their institutional policies and procedures and according to local, national, and international regulations and laws, including 45 CFR 46 regulations and state laws. CDC project officers must maintain a current copy of local sites' approvals in project records.
- 3. CDC investigators and project officers need to adhere to the highest ethics standards of conduct and to respect and protect the privacy, confidentiality, autonomy, data, welfare, and rights of participants and integrity of the project. All applicable country, state, and federal laws and regulations must be followed.
- 4. Informed consent or script is needed as required by laws and regulations. Information conveyed in an informed consent or script process needs to address all applicable required elements of informed consent. Consent of employees in related projects about their institutions needs to include a statement that their voluntary participation or withdrawal would not affect their employment status or opportunities.
- 5. OMB Paperwork Reduction Act determination by the NCHHSTP OMB/PRA Coordinator might be needed for this project.
- 6. All previous comments apply.
- 7. **Other applicable comments:** Type your comment in the box. The space will expand as you type.

- 8. **More information is required before approval is granted:** Explain what additional information is requested by typing in the box. The space will expand as you type.

Date Information was requested:

Date Information was received:

Approval must be granted by the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Associate Director for Science (ADS), Acting ADS, or Deputy ADS, or for laboratory-associated projects, by the Associate Director for Laboratory Science (ADLS) or Acting ADLS.

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X Janela
Dodson -S

Digitally signed by Janela
Dodson -S
Date: 2016.12.06 15:24:56
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NCHHSTP ADS, Acting ADS, or Deputy ADS

X

[Redacted Signature]

NCHHSTP ADLS or Designee

Or