

**Strengthening United States Response to Resistant Gonorrhea (SURRG)**

**OMB 0920-1242**

**Supporting Statement - Part A**

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**Karen Schlanger, PhD  
Project lead**

**Centers for Disease Control and Prevention  
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention  
Division of STD Prevention  
Epidemiology and Statistics Branch  
1600 Clifton Rd NE, Mailstop E-02  
Atlanta, GA 30329**

**Voice: (404) 718-5660**

**Fax: (404) 639-8608**

**Email: [khs4@cdc.gov](mailto:khs4@cdc.gov)**

## Table of Contents

### A.

#### JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary
2. Purpose and Use of the Information Collection
3. Use of Improved Information Technology and Burden Reduction
4. Efforts to Identify Duplication and Use of Similar Information
5. Impact on Small Businesses or Other Small Entities
6. Consequences of Collecting the Information Less Frequently
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
9. Explanation of any Payment or Gift to Respondents
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents
11. Institutional Review Board (IRB) and Justification for Sensitive Questions
12. Estimates of Annualized Burden Hours and Costs
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers
14. Annualized Cost to the Federal Government
15. Explanation for Program Changes or Adjustments
16. Plans for Tabulation and Publication and Project Time Schedule
17. Reason(s) Display of OMB Expiration Date is Inappropriate
18. Exceptions to Certification for Paperwork Reduction Act Submissions

#### EXHIBITS

Table A.12-1	Estimated Annualized Burden Hours
Table A.12-2	Estimated Annualized Burden Costs
Table A.14	Estimated Cost to the Government
Table A.16	Project Time Schedule

#### LIST OF ATTACHMENTS

Attachment 1.	Authorizing Legislation
Attachment 2.	60 Day Federal Register Notice Publication
Attachment 2a	Public Comments
Attachment 3A.	STD Clinic Facility Data Elements
Attachment 3B.	Non-STD Clinic Facility Data Elements
Attachment 3C-1.	Laboratory Testing Data Elements
Attachment 3C-2	Laboratory Data Elements

- Attachment 3D. Field Investigation Data Elements
- Attachment 4. List of Collaborators
- Attachment 5. IRB Determination
- Attachment 6. Privacy Impact Assessment (PIA)
- Attachment 7. Protocol

## A. Justification

- Goal of the study: Strengthening United States Response to Resistant Gonorrhea (SURRG) was created in 2016 to enhance U.S. state and local public health surveillance and program infrastructure, build capacity to support rapid detection and public health response to antibiotic-resistant gonorrhea (an urgent public health threat), and advance the understanding of epidemiological factors contributing to antibiotic-resistant gonorrhea.
- Intended use of the resulting data: Data from SURRG inform national recommendations on public health responses to antibiotic-resistant gonorrhea.
- Methods to be used to collect: Data and specimens are collected at participating sexually transmitted disease (STD) specialty clinics and other partnering clinics, and during outbreak investigations.
- The populations to be studied: Persons with gonorrhea attending one of the participating STD clinics or other participating clinics in the United States, and sexual partners of persons with gonorrhea.
- How data will be analyzed: Trend analyses will be conducted to identify changes in the burden of antibiotic resistance. Cross-sectional analyses will be conducted to: (1) identify risk factors for resistance, (2) examine differences in antibiotic resistance populations by population and healthcare setting characteristics, and (3) evaluate programmatic prevention and control approaches.

Considerations during COVID-19 pandemic: If clinic closures and health department staffing challenges due to COVID-19 continue into late 2021, then participating state and local health departments might face challenges collecting the requested data. CDC will work with the participating health departments in a collaborative manner to maximize accomplishment of project objectives while also respecting local and state health department capacity. All participating health department staff will follow all relevant local, state, or/and federal COVID-19-related guidance pertaining to social distancing, face coverings, and other recommended measures to protect participants and staff.

### 1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of STD Prevention (DSTD) requests OMB to approve a revision of the currently approved version of 0920-1242, *Strengthening United States Response to Resistant Gonorrhea*, for three years. Data will be collected as part of a sentinel surveillance and public health program response system. This system is funded by CDC and is conducted at eight jurisdictions (state and local health departments) in the United States. This data collection and related programs are authorized by the Public Health Service Act, Sec. 301 and 318 (42 USC 241 and 247c) (**Attachment 1**).

CDC estimates that approximately 1.6 million gonococcal infections occur annually in the United States.<sup>1</sup> Without antibiotic treatment, gonorrhea can cause pelvic inflammatory disease, infertility, and ectopic pregnancy, and can also facilitate HIV transmission. Gonorrhea control in the United States relies on prompt and effective antibiotic therapy. However, treatment has been complicated by the remarkable ability of *Neisseria gonorrhoeae* (the bacterium that causes gonorrhea) to develop antibiotic resistance.<sup>2</sup> CDC designated *N. gonorrhoeae* as an “urgent” antibiotic resistance treat to the United States.<sup>3,4</sup> To support implementation of the federal government’s broad and multipronged Combating Antibiotic Resistant Bacteria (CARB) Action Plan<sup>5</sup>, CDC implemented Strengthening United States Response to Resistant Gonorrhea (SURRG) to address the threat of antibiotic-resistant gonorrhea. The goals of SURRG are to strengthen the timeliness of surveillance systems, to work with state and local health departments to enhance their capacity to monitor and test for antibiotic-resistant gonorrhea, and to develop rapid response activities to effectively contain the spread of detected cases of antibiotic-resistant gonorrhea. SURRG directly supported achievement of the National Target of maintaining the prevalence of ceftriaxone-resistant *N. gonorrhoeae* below 2% through 2020.<sup>5</sup>

As an overview of SURRG, eight funded jurisdictions participate. Within these jurisdictions, healthcare providers (HCPs) collect specimens for *N. gonorrhoeae* culture testing from persons of all genders who are seeking care for possible gonorrhea or sexual health services. We propose expanding the number of clinics from 27 (9 sexually transmitted disease (STD) specialty clinics and 18 other participating non-STD clinic sites) to ~38 (16 STD clinics and ~26 non-STD clinic sites). Specimens that demonstrate active bacterial culture growth of *N. gonorrhoeae* (called “isolates”) undergo antibiotic susceptibility testing (AST) within several days at the local public health laboratory (using *Etest*, a ‘ready-to-use’ strip that has a pre-defined antibiotic gradient embedded within it). AST detects antibiotic resistance. Currently, *N. gonorrhoeae* culture specimens (isolates) are needed to conduct AST to detect resistance. However, because of the widespread availability of molecular tests for diagnosing gonorrhea, few clinics routinely perform culture testing for gonorrhea anymore (apart from enhanced surveillance programs such as SURRG). In SURRG, AST results that demonstrate resistance or emerging resistance are rapidly communicated from local laboratory staff to the healthcare provider and a designated local health department staff member. The health department staff initiates a local outbreak investigation (also called “partner services” or “contact tracing”). The patient from whom the

resistant isolate was collected is interviewed by local health department staff; the local health department staff asks the patient for more information, such as additional epidemiological data and information about recent sexual contacts. The patient is re-tested at a local healthcare setting to make sure that the prescribed antibiotic treatment cured the infection. As part of contact tracing, recent sexual contacts are interviewed and tested for gonorrhea by local health department.

Participating health departments collect and transmit to CDC demographic and clinical data about persons tested for and/or diagnosed with gonorrhea in the participating clinics and results of local *N. gonorrhoeae* culture, molecular tests that detect *N. gonorrhoeae* (nucleic acid amplification tests), and AST of bacterial isolates.

Isolates are shipped by participating local public health laboratories each month to one of four Antibiotic Resistance Regional Laboratory Network (ARLN) laboratories for additional AST (using a lab technique called *agar dilution*) on additional antibiotics and molecular characterization (such as whole genome sequencing). The demographic data does not include any personal identifiers, such as full name, medical record numbers, social security numbers, or home or work addresses. The isolates contain only bacterial DNA and do not contain human DNA.

## **2. Purpose of Use of the Information Collection**

The purpose of SURRG is to improve national capacity to detect, monitor, and respond to emerging antibiotic-resistant gonorrhea. The goals of this activity are to inform a more comprehensive understanding of trends and determinants of drug-resistant gonorrhea, monitor for the emergence of resistance, provide a robust evidence base for directing public health action, pilot novel prevention and control approaches, and evaluate the effectiveness of resistant gonorrhea novel prevention and control approaches.

CDC currently operates the Gonococcal Isolate Surveillance Project (GISP), which monitors long-term trends in antibiotic resistance in *N. gonorrhoeae* in the United States in order to establish a scientific basis for the selection of gonorrhea treatment and to allow pro-active changes to treatment guidelines before widespread resistance and failures of treatment occur. GISP has repeatedly provided impactful data that has led directly to changes in CDC's STD Treatment Guidelines. However, data from GISP are not timely enough to allow rapid local programmatic public health responses to control an outbreak of resistant infections. GISP is complemented by SURRG. A rapid response, involving rapid detection of a resistant infection, rapid (within several days of detection of resistance) interviewing of cases, and rapid interviewing and testing of sexual contacts, is critical for containing the spread of a resistant infection.

During the previous 3-year approval period, participating jurisdictions:

- expanded specimen collection for *N. gonorrhoeae* culture to include collection of specimens from persons of all genders, at all exposed anatomic sites, and from attendees of STD clinics and non-STD clinic healthcare settings,
- implemented local rapid antimicrobial susceptibility testing (AST) by Etest,
- submitted isolates to a regional laboratory participating in CDC's AR Lab Network (ARLN) for expanded AST by agar dilution and whole genome sequencing,
- upgraded capacity to conduct rapid field investigations of gonococcal infections with reduced susceptibility to selected antimicrobials,
- upgraded data systems and informatics to support rapid local detection and epidemiologic analyses,
- enhanced local capacity to manage and analyze data for programmatic use,
- implemented and locally evaluated approaches for specimen collection, laboratory practices, field investigations, and tests of cure,
- developed and instituted local protocols, and instituted standardized project protocols, and
- collected data using standardized protocols and shared data with CDC to allow multisite epidemiological analyses to advance knowledge of gonococcal resistance and optimize public health approaches.

SURRG public health activities will be conducted in the following state and local health departments (SURRG involves partnering of state and local health departments as a single grantee): (1) California Department of Public Health and San Francisco Department of Public Health, (2) Washington Department of Public Health and Seattle-King County Public Health, (3) New York City Department of Health and Mental Hygiene, (4) Pennsylvania Department of Health and Allegheny County Health Department, (5) Colorado Department of Public Health and Environment and Denver Public Health, (6) Wisconsin Department of Health Services and Milwaukee Health Department, (7) Indiana State Department of Health and Marion County Public Health Department, and (8) North Carolina Department of Health and Human Services and Guilford County Health Department. These sites competed for this cooperative agreement and were selected for funding as a result of a review process conducted in May 2021.<sup>6</sup>

### **Proposed Data Collection**

The proposed revision to the data collection is necessary for effectively continuing the activity. Data obtained through these methods has significant utility to the U.S. government, state and local public health departments participating in the project, and other STD prevention partners and stakeholders. These data cannot be obtained in other ways. The data provide insights into optimal approaches to preventing and controlling antibiotic-resistant gonorrhea and will directly inform CDC recommendations, programmatic public health approaches, and resource allocation.

The project will utilize three distinct but complementary strategies to collect the required information.

### **Facility-based data**

The first strategy involves local collection of **healthcare facility-based data**. The local health department data manager abstracts clinical data elements routinely collected as part of clinical care and for patients tested for gonorrhea at participating clinics. Data are de-identified (meaning that personal identifiers are removed). Data are re-coded and a new number is made up and assigned to each data record. These new numbers do not contain any personally identifiable information. The data are sent to CDC through secure file transport mechanisms every two months. The data elements that are electronically sent to CDC and that CDC requests continued approval to receive (for a three-year period beginning on the date of OMB approval) are listed in **Attachments 3A and 3B**.

Funded health departments are required to maintain rigorous procedures to assure the quality and validity of data before submission to CDC. They also complete data verification, re-code and appropriately structure the data to facilitate merging into the national SURRG datasets. In collaboration with data managers in each jurisdiction, CDC has prepared syntax for data validation that were provided for appropriate quality assurance. Jurisdictions apply these validation checks and fix offending records (meaning data records with poor data quality) prior to transmission. Locally prepared SAS datasets used for validation and transmission to CDC do not and will not include patients' names, date of birth, phone number, mailing or work addresses, or medical record numbers. SURRG records from STD clinics will be assigned (by the local or state health department) a new patient number (patient ID) and a new event number for each visit (see "re-coding" in prior paragraph). CDC receives only the new patient and event numbers and lacks the ability to back-convert the patient ID to a medical record number. Funded health departments send data to CDC through the secure data network (SAMS), or equivalent, using specified encryption methods. CDC accepts and securely stores these data, accessible only to enhanced SURRG project staff. These data are combined with laboratory-based and field-investigation SURRG data (see below) and associated laboratory testing data from the ARLN. SURRG data are not and will not be integrated into other datasets maintained by CDC and are stored on secure servers with fully restricted access.

### **Laboratory-based data**

The second strategy employs local performance of AST of *N. gonorrhoeae* isolates and the transmission of testing results from local laboratory staff to the local health department and relevant clinical site. Microbiologists at participating public health laboratories will conduct AST on *N. gonorrhoeae* isolates collected as part of routine clinical care at the participating clinical sites (see **Attachments 3C-1**). In addition to routine laboratory-based reporting, data managers at each public health laboratory will abstract laboratory results on patients included in the



facility-based data collection and will transmit those data to the health department data manager through secure file transfer mechanisms (see **Attachment 3C-2**).

Participating health departments are encouraged to provide adequate training to investigators conducting contact with patient laboratory results and to address local human subject's requirements. Locally prepared SAS datasets used for validation and transmission to CDC will not include patients' names, date of birth, phone number, mailing address or medical record numbers. Health department staff will remove identifiers and will assign new numbers to specimens (specimen ID). This specimen ID number will not contain personally identifiable information, such as parts of a name, social security number, date of birth, or medical record number. CDC will only receive the new specimen numbers and will not have the ability to back-convert the specimen ID to a medical record number. Health departments will send data to CDC through the secure data network (SAMS), or equivalent, using specified encryption methods. CDC agrees to accept and securely store these data, accessible only to enhanced SURRG project staff. These data are combined with facility-based (see above), field investigation (see below) SURRG data, and associated laboratory testing data from the ARLN. SURRG data are not and will not be integrated into other datasets maintained by CDC and are stored on secure servers with fully restricted access.

### **Field Investigation Data**

The third strategy involves local collection of field investigation-based gonorrhea data. Consistent with traditional public health field investigations (also called "partner services" or "contact tracing"), patients found to be infected with gonococcal infections with reduced antibiotic susceptibility or other gonococcal infections of public health significance are interviewed by specially-trained local health department staff using a standardized interview. The interview is done to collect information about the patient's characteristics and behavior and to identify recent sexual partners. The patient will be re-tested locally for gonorrhea to make sure that the patient was cured. Sexual partners will be interviewed by specially-trained local health department staff and locally tested for gonorrhea.

The primary outcome is information addressing epidemiological questions relevant to detection and responding to the threat of antibiotic-resistant gonorrhea. Participating health departments have developed locally-focused protocols and/or data collection instruments, provide comprehensive training to the specially-trained local health department staff doing the investigations, and address local human subjects requirements. Participating health departments addressed local human subjects requirements before data collection began. Where not otherwise formally required, brief verbal informed consent is obtained from patients prior to eliciting information. As described previously, data are de-identified, re-coded, and sent to CDC. Data elements are listed in **Attachment 3D**.

As above, local or state health departments will assign new numbers (patient ID) to data records from interviews. The data that CDC receives only have the newly assigned numbers.

CDC does not and will not have the ability to back-convert the Patient ID or other event ID to a medical record number, name, social security number, or date of birth. Health departments send data through the secure data network (SAMS) or equivalent, using specified encryption methods. CDC accepts and securely stores these data, accessible only to enhanced SURRG project staff. These data are combined with facility-based, laboratory-based (see above), and associated laboratory testing data from the ARLN. SURRG data are not integrated into other datasets maintained by CDC and are stored on secure servers with fully restricted access

The proposed data collection with frequency of administration of the strategies will include:

Activity	Attachment number
<b>Facility-based data collection</b>	
Electronic transmission of clinical variables routinely collected as standard of care by facilities or clinical networks of providers ( <b>STD clinics</b> ) and housed within the clinic’s medical record system. Electronic transmissions by the site data manager occur once every two months. This activity will occur for three years in clinics participating in SURRG.	3A
Electronic transmission of clinical variables routinely collected as standard of care by facilities or clinical networks of providers ( <b>partnering non-STD clinic sites</b> ) and housed within the clinic’s medical record system. Electronic transmissions by the site data manager occur once every two months. This activity will occur for three years in clinics participating in SURRG.	3B
<b>Laboratory-based data collection</b>	
Antibiotic susceptibility testing (by Etest) to detect antibiotic resistance performed by public health laboratory microbiologists at each of the participating jurisdictions. Each test takes ~10 minutes and each jurisdiction will conduct ~700 tests annually.	3C-1
Public health laboratory data managers will transmit testing results and additional associated data to the site data manager for merging with facility-based data	3C-2
<b>Field investigation-based data collection</b>	
Interviews to obtain behavioral and demographic information from patients with gonorrhea and their recent contacts. This activity will occur for three years in state/local health departments participating in SURRG. Electronic transmission of data to CDC will occur once every 2 months.	3D

Funded health departments are required to maintain rigorous procedures to assure the quality and validity of data before submitting to CDC. In collaboration with data managers in each jurisdiction, CDC has prepared syntax for data validation that were provided for appropriate quality assurance. Locally prepared SAS datasets used for validation and transmission to CDC do not and will not include patients' names, date of birth, phone number, mailing or work addresses, or medical record numbers. All records will be assigned (by the local or state health department) a new patient number (patient ID) and a new event number for each visit (event ID). CDC receives only the new de-identified patient and event numbers and does not have the ability to link these assigned numbers to medical record numbers or other personally identifiable information; CDC lacks the ability back-convert the patient ID to a medical record number. Funded health departments send data to CDC through the secure data network (SAMS), or equivalent, using specified encryption methods. CDC accepts and securely stores these data, accessible only to enhanced SURRG project staff. SURRG data are stored on secure servers with fully restricted access.

### **3. Use of Improved Information Technology and Burden Reduction**

CDC provides sites with standardized SAS data structures with variable names, lengths and types defined for all requested datasets. Data are abstracted by local health departments from pre-existing electronic medical records in collaborating clinical facilities. The health departments complete data verification and validity checks on datasets prior to transmission to CDC. In collaboration with data managers in each health department, CDC requires protocols for data validation that ensure appropriate quality assurance. Participating health departments assure validity of the data prior to transmission. Data are uploaded every two months by trained data managers at funded health departments. Record-level data are sent to CDC through SAMS every 2 months. CDC requires automation of local or state data processes wherever possible to significantly lessen the burden on health department staff.

De-identified data are received, stored, and maintained at CDC by a data manager in the Surveillance and Data Management Branch of the Division of STD Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Datasets received at CDC are validated and appended to the national SURRG database within four weeks of receipt. Completeness of reporting and the quality of transmitted data are monitored by CDC. Site visits, regular communications with collaborating health departments, and data quality checks provide opportunities for evaluation and troubleshooting of these processes. CDC also provides intensive technical assistance as needed by health departments for improved data quality and to establish local processes to reduce local data management burdens.

### **4. Efforts to Identify Duplication and Use of Similar Information**

CDC is the only agency that conducts national STD surveillance through the funded assistance of state and local health departments. Monitoring of *Neisseria gonorrhoeae* antibiotic susceptibility is conducted by CDC's Gonococcal Isolate Surveillance Project (GISP) (OMB number 0920-0307 exp. 08/31/2021). GISP is a CDC-supported sentinel surveillance system that monitors long-term trends in resistance and informs treatment guidelines. GISP is the only such surveillance system in the United States. AST is performed by a regional laboratory network (ARLN) and results are available 1–3 months following specimen collection. However, rapid public health action and field investigations to halt or slow the spread of identified resistance must occur within days of specimen collection to be effective. SURRG complements GISP and addresses this gap by supporting local capacity to conduct rapid resistance testing, which facilitates rapid local public health action. SURRG also provides critical multisite information on the effectiveness of rapid public health responses to antibiotic-resistant gonorrhea; such information is not available elsewhere. GISP only includes the bacterial isolates from the first 25 men presenting to participating STD clinics with gonococcal urethritis each month. This population provides a stable population for long-term surveillance of resistance trends. In contrast, SURRG includes all gonococcal isolates collected by participating STD clinics each month, regardless of the gender of the patient or anatomic site of the infection. SURRG also includes non-STD clinic healthcare settings to expand the reach of local detection of resistance and provide additional testing capacity if an outbreak occurs.

Efforts were made to prevent duplication of effort, including conducting extensive, systematic searches of electronic databases of published articles and abstracts, attending local, national, and international conferences relevant to the topic, communication with non-federal colleagues at state and local health departments and colleagues within the government. Apart from SURRG, this type of public health activity and data collection for antibiotic-resistant gonorrhea is not being conducted elsewhere in the United States. Outside of SURRG, jurisdictions lack the capacity and resources to perform these activities.

Some bacterial isolates from men with urethritis who attended participating STD clinics are included in both GISP and SURRG. Results from laboratory testing (by agar dilution technique) of the isolate by a regional lab network (ARLN) are used in GISP long-term surveillance trends. In SURRG, the isolate undergoes local rapid AST (by Etest technique) and results are used for local public health action. SURRG data collection has been carefully harmonized with GISP and the enhanced STD Surveillance Network (SSuN) (OMB 0920-1072, exp. 9/30/2021) to reduce the burden on local jurisdictions as much as possible. Importantly, input from participating jurisdictions on how to minimize the burden on them has been repeatedly sought (through phone calls, in-person discussions, webinars, and by email) and rigorously and extensively incorporated into the processes.

## **5. Impact on Small Business or Other Small Entities**

Respondents include city, county, and state health departments and public health laboratories. Data/information collection instruments have been held to the absolute minimum of questions required for intended use of the data/information and respondents are permitted to report data electronically to reduce burden and improve data quality.

Respondents applied to participate in SURRG and participate voluntarily.

## **6. Consequences of Collecting the Information Less Frequently**

Past experience indicates that gonococcal resistance patterns can change rapidly and outbreaks of resistant infections can occur and spread quickly. SURRG data are reported to CDC every 2 months. Quick detection of trends and emergent issues support timelier implementation of prevention and control effort, resulting in prevention and control of additional gonorrhea transmission. If these data are not available, CDC, state, and local health departments will not have the necessary information to make evidence-based decisions regarding gonorrhea prevention program planning and resource allocation. Further, CDC, state, and local health departments will not be able to support continued implementation of the current National Strategy for Combating Antibiotic Resistant Bacteria.<sup>7</sup>

## **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This request fully complies with the regulation 5 CFR 1320.5.

## **8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

A 60-day Federal Register notice was published in the Federal Register on 9/30, 2020 [Vol. 85, No. 190, pages 61750–61752] (**Attachment 2**).

CDC received one non-substantive comment (**Attachment 2a**).

CDC has repeatedly described the SURRG methodology with external stakeholders and experts for comment, including the STD subcommittee to the Association of Public Health Laboratories (APHL), the STI section of Public Health England (PHE), and national and international STD experts at the International Society for STD Research (ISSTDR) Annual Meeting (2019) and STD Prevention Conference (2018 and 2020). Their responses have been extremely positive.

## **9. Explanation of Any Payment or Gift to Respondents**

No payment or gift is provided to respondents.

## **10. Protection of the Privacy and Confidentiality of Information Provided by Respondents**

The Privacy Officer for CDC / ATSDR has assessed this package for applicability of 5 U.S.C. § 552a, and has determined that the Privacy Act does not apply to the information collection activity. (see **Attachment 6 Privacy Impact Assessment [PIA]**).

Each state has laws requiring certain diseases, including gonorrhea and syphilis, be reported at the local/state level. STD programs in local/state health departments routinely prioritize case investigations on persons with these notifiable STD conditions. This type of required reporting uses personal identifiers and enables the states to identify cases where immediate disease control and prevention is needed. The local/state health departments also collect personal identifiers about recent contacts to conduct disease control activities. The personally identifiable information that is collected at the local level, through their routine activities, includes the patient's name, contact information (including street address and phone number), gender, race/ethnicity, and date of birth to facilitate disease control investigations. The health departments' collection of personally identifiable information is used for 3 purposes: (1) ensuring the proper identification and follow-up of cases, (2) ensuring that infected persons receive appropriate treatment and sexual contacts who need treatment are traced, and (3) investigate and control outbreaks.

Data collection for SURRG provides behavioral, demographic, and clinical information on gonorrhea cases reported to state and local health departments, allowing a better understanding of the epidemiology of STDs and drug-resistant gonorrhea and to inform national and local gonorrhea prevention and control efforts. Locally-collected personally identifiable information is stored locally. None of the patient identifiers such as patient names, medical record numbers, home address or zip codes, or birthdates are included in records sent to CDC as a requirement of this project. Census tract information is used in the aggregate to identify health disparities in treatment, clinical outcomes and access to care based on distance from resident census tract to provider location. Information on gender, age, race/ethnicity, and gender of sex partner are collected (**Attachments 3A-D**) and sent to CDC because STDs disproportionately impact racial/ethnic and other (including sexual) minorities.

In the data sent to CDC, local or state health department or facility data managers assign a new non-name-based number (patient ID) to each data record. The patient ID number, assigned by either the state or local health department or the sentinel facility, is created solely for the purposes of surveillance and is not itself a medical record number or social security number. The patient ID numbers for the STD clinic patients are assigned and maintained by the participating facility. CDC cannot use this number in the identification of individual patients seeking care in these facilities. In the field investigation component of SURRG, the newly assigned patient ID number is assigned by the local health department to each gonorrhea case using data on case reports submitted by providers/ laboratories pursuant to local reporting regulations. These records can only be re-identified at the local level. Data are encrypted and

sent via CDC's Secure Access Management System (SAMS). At CDC, SURRG data are maintained on secure servers behind the CDC firewall. Access is password-protected and directory-specific user access rights are assigned by a CDC data steward. Restricted access to STD data is provided to DSTDP/CDC scientists, researchers, and program managers.

For clinical and demographic variables from the participating facilities, written informed consent was not required at any of the facilities for the collection of de-identified electronic clinical data elements maintained in archived databases at the clinics. This is deemed to be of minimal risk and the data collection could not be conducted with written informed consent. The data sent to CDC do not have any personal identifiers (patient names, initials, date of birth, contact information, or medical record numbers). Patients are identified in the database only by a unique patient ID code and CDC does not receive any information that could be used to personally identify any data records.

For the field investigation-based activity, state and/or local health departments: 1) contact the people diagnosed with gonorrhea under local public health authority to conduct disease investigations, and 2) contact their sexual partners. CDC does not conduct any interviews with patients or partners. The interviews are conducted by specially trained local health department staff in a private location where the questions and responses cannot be overheard by others. The health department staff conducting these investigations (called "disease intervention specialists" or "DIS") are required to undergo specific DIS training that includes education about patient and data confidentiality. Individuals being contacted by DIS for interviews are asked to verbally provide consent over the phone or in-person prior to the administration of the questionnaire. Participants are told they may decline to participate without penalty and that if they agree to participate, they may refuse to answer any of the survey questions. They are informed that the data will be used to improve gonorrhea prevention services for persons at increased risk of STDs and gonorrhea in their area, and that aggregated data may be released in published reports.

#### *Data Transmittals and Safeguards*

Data sent from participating health departments to CDC are restricted to CDC's Secure Access Management Services (SAMS). SAMS is an approved federal information technology system that provides authorized and validated users with secure and encrypted access to CDC file transfer applications. The encrypted data are stored in a secure CDC server with strictly controlled and restricted access rights.

The Division of STD Prevention, Surveillance and Data Science Branch is responsible for maintaining the privacy, security, and scientific integrity of all SURRG databases. The Data Manager is the custodian of the SURRG data files and is responsible for assuring all conditions of use and for security arrangements to prevent unauthorized use of or access to SURRG data. Access to the data is limited to specific SURRG staff members of the Division of STD Prevention and designated collaborators of the study in the performance of their assigned duties. The SURRG Project Officer(s) is responsible for granting access to SURRG data to other CDC staff in

the Division of STD Prevention as needed. The SURRG collaborating health departments will be promptly notified of any CDC personnel changes that affect access to the data for this project. All CDC personnel with data access have completed and will remain current with the annual Health and Human Services Information Security Awareness Training. A record of the completion of security training for all CDC staff is maintained by the CDC Information Technology Services Office (ITSO). State and local surveillance program personnel agree to abide by the Data Security and Confidentiality Guidelines for NCHHSTP. These guidelines can be accessed at the following link: (<http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf>) and will be required to document compliance as part of annual project reporting.

Local health department collaborators retain full control of and rights to analysis, research, and publication of their locally collected data, regardless of whether these data are also provided to CDC as part of SURRG activities.

CDC may retain SURRG data for appropriate analytic purposes as long as the data are protected as described herein. CDC will annually review the need for the data and shall destroy all copies of the data if it is determined that no further analysis will be conducted.

## **11. Institutional Review Board (IRB) and Justification for Sensitive Questions**

### **IRB Approval**

The approved Project Determination of Form (Attachment 5) indicates that because the project is a routine disease surveillance activity. The protocol is exempt from review by CDC's IRB.

### **Justification for Sensitive Questions**



The collection of information about STDs is sensitive because of stigma associated with STDs and HIV infection. In addition, the modes of transmission of STDs (through sexual contact) and contributing risk factors necessitate the collection of sensitive data, including sexual practices, drug use, and HIV status. In keeping with the purpose of this data collection, other sensitive data are collected about specific behaviors, experiences or conditions that have been shown to be associated with STDs (**Attachments 3A, 3B, and 3D**). Although the information requested from STD clinic patients and interviewed participants is highly sensitive, the purposes of SURRG cannot be accomplished without the collection of such data. Collected data are used to understand barriers to engaging in protective behaviors and to using STD prevention services. These data are also used to enhance STD prevention programs designed to reduce high-risk behaviors in persons most likely to acquire or transmit STD/HIV and to control the spread of resistant gonorrhea.

The information will be used only in the aggregate and only for the purposes of this project and will be kept private to the extent allowable by law.

City, county, and state information is collected for the purposes of spatial analysis of the data to understand the geographic distribution of disease and risk and to understand the spread of resistant gonorrhea.

The context in which interview questions are asked help to overcome their potential sensitivity. There are several steps taken SURRG to minimize sensitivity and reiterate to the respondent the legitimate need for the information:

- Most questions allow for responses of “don’t know” or “refuse to answer.”
- The interview questions are carefully organized to lead smoothly from one topic to another.
- Transitions are clear to respondents and the need for the information explained.
- Assurance about the privacy of the information are reiterated.

All interviews are conducted by specially trained local or state health department staff in a private location during established operating hours. No interviews are conducted without the verbal consent of the respondent.

**12. Estimated Annualized Burden Hours and Costs** The respondents for Strengthening United States Response to Resistant Gonorrhea (SURRG) include: (1) data managers at the eight funded SURRG sites, (2) clinic data managers at the non-STD clinic health centers participating in SURRG, (3) public health laboratory microbiologists, (4) public health laboratory data managers, and (5) persons diagnosed at a participating SURRG site with gonorrhea of public health importance, such as a drug-resistant infection, and their sexual partners. The number of SURRG sites decreased from nine to eight; calculations reflect this change.

(1) SURRG data managers:

Every two months, data managers from each of the eight funded jurisdictions will:

- a) Abstract line-listed clinic visit data from participating STD clinics for all patient visits that included testing for gonorrhea that occurred in the previous two months.
- b) Receive line-listed clinic visit data from participating non-STD clinic healthcare sites for all patient visits that included testing for gonorrhea that occurred in the previous two months.
- c) Receive laboratory results (e.g., antibiotic susceptibility testing) from public health laboratory data managers
- d) Merge clinic visit data with public health laboratory results
- e) Abstract line-listed data for any person for whom a SURRG interview was attempted and/or completed in the previous two months
- f) Clean, re-code, and structure data in accordance with SURRG program guidance
- g) Complete data verification and validity checks (per CDC SURRG program guidance) on dataset prior to transmission to CDC, and
- h) Send all data files to CDC through secure file transport mechanisms (SAMS)

Within two months of the end of each project year, the SURRG data manager in each jurisdiction will also compile, clean, validate, and send an annual cumulative project dataset to CDC through secure file transport mechanisms (SAMS) (for a total of 7 data transmissions per year). This final validated annual dataset from each jurisdiction will be archived and become the primary repository for that site's annual reporting. Eight (8) respondents, providing 7 data transmissions per year with an average of 16 burden hours yields 896 burden hours for the local data managers (**Attachment 3A**).

#### Clinic data managers at non-STD clinic health centers:

A total of ~26 non-STD clinic health centers participate in SURRG (e.g., HIV clinics, reproductive health centers, and emergency rooms). Every two months, data managers from each of these locations abstract and clean all required data on all patients tested for gonorrhea. Data managers send the data by secure file transport mechanism to the local SURRG data manager. We have estimated that it takes data managers at each non-STD SURRG location approximately 3 hours each time they abstract, clean, and transmit SURRG data. Data manager at ~26 non-STD clinic health centers, provide 6 responses each with 3 hours per response, yields 468 annual burden hours (**Attachment 3B**).

#### Laboratory-based data:

Public health laboratories from each of the eight funded jurisdictions conduct AST via Etest on all *N. gonorrhoeae* cultures from all 16 STD clinic sites and 26 non-STD clinic sites participating in SURRG. Each Etest takes approximately 10 minutes (10/60) of staff time, and an Etest of control strains is conducted approximately twice per week at each laboratory. On average, each jurisdiction conducts approximately 600 Etests per year for patient care, plus 100 Etests per year on control strains for quality assurance. A total of approximately 700 Etests per year per grantee are performed.

Eight (8) public health laboratory biologists provide 700 laboratory testing data responses each taking 10 minutes per response, yields 933 annual burden hours (**Attachment 3C-1; Part II PRA Worksheet Att 3C-1**).

In addition to routine laboratory result reporting, a laboratory data manager abstracts laboratory data for persons included in the SURRG clinic-based data collections and associated data (such as submitting site and timing of result reporting) and sends those data to the local SURRG data manager through secure file transport mechanisms. The 8 laboratory data managers at each local public health lab spend approximately 1 hour each time they abstract, clean, and perform 6 project data transmissions for a total of 48 annual burden hours (**Attachment 3C-2; Part II PRA Worksheet Att 3C-2**).

Persons diagnosed with gonorrhea and their partners:

Health department staff interview any person diagnosed (via Etest) with antibiotic-resistant gonorrhea or a case of gonorrhea of public health significance and their sexual contacts. On average, each jurisdiction will likely identify on average four drug-resistant isolates each month. These isolates spur field investigations, which will result in six additional interviews each month. An estimated total of 120 interviews occur annually at each site, for a total across the 8 sites of 960 interviews each year. Each interview takes ~20 minutes. This activity produces 480 annual burden hours (**Attachment 3D**).

The Antibiotic Resistance Laboratory Network (ARLN) serves as a referral source for susceptibility testing of multiple bacterial and fungal pathogens of public health importance and is not included in the SURRG burden calculations.

The burden table below reflects the total estimated annualized respondent burden hours for the project.

A12a. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (Hours)	Total Burden Hours
Local SURRG data manager*	Facility Data Elements Attachments 3A	8	7	16	896
Data manager at non-STD clinic health centers	Non-STD clinic Data Elements Attachment 3B	26	6	3	468
Public Health	Laboratory	8	700	10/60	933

Laboratory Microbiologist**	Testing Data Elements Attachment 3C-1				
Public Health Laboratory Data Manager**	Laboratory Data Elements Attachment 3C-2	8	6	1	48
Gonorrhea Patients and Sexual Contacts	Field Investigation Data Elements Attachment 3D	960	1	20/60	320
<b>Total</b>					<b>2,665</b>

\* The SURRG data manager is responsible for abstracting data from the participating STD clinics.

\*\* Burden calculations for Public Health Laboratory Microbiologist shown in Part II PRA Worksheet Att 3C-1; burden calculations for Public Health Laboratory Data Manager shown in Part II PRA Worksheet Att 3C-2

The annualized burden cost is estimated in table A12b below.

Hourly wages for each of the four respondent categories (updated from the initial PRA submission with 2019 wages) were determined as follows:

- The mean hourly wage for non-STD clinic, laboratory, and SURRG database administrators, were all estimated at a rate of \$45.07. Estimates of hourly wage rates are based on the 2019 Bureau of Labor Statistics, National Occupational Employment and Wage Estimates for Database Administrators in the United States (accessed on May 18, 2020 at <https://www.bls.gov/ooh/computer-and-information-technology/database-administrators.htm>).
- The mean hourly wage for a microbiologist was estimated at a rate of \$36.37 based on the 2019 Bureau of Labor Statistics, National Occupational Employment and Wage Estimates for Microbiologists in the United States (accessed on May 18, 2020 at <https://www.bls.gov/ooh/life-physical-and-social-science/microbiologists.htm>).
- The mean hourly wage for gonorrhea patients and their sexual contacts was estimated at a rate of \$25.72, which is the mean hourly wage reported on the 2019 Bureau of Labor Statistics, National Occupational Employment and Wage Estimates across all occupations in the United States (accessed on May 18, 2020 at [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm)).

Table 12.B. Estimated Annualized Burden Costs

Type of Respondent	Total Burden hours	Hourly Wage Rate	Total Respondent Cost
Local SURRG data manager	896	\$45.07	\$40,382.72
Data manager at non-STD clinic health centers	468	\$45.07	\$21,092.76
Public Health Laboratory Microbiologist	933	\$36.37	\$33,933.21
Public Health Laboratory Data Manager	48	\$45.07	\$2,163.36
Gonorrhea Patients and Sexual Partners	320	\$25.72	\$8,230.40
<b>Total</b>	<b>2,665</b>		<b>\$105,802.45</b>

### 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no direct costs to the respondents other than their time to participate in each information collection.

### 14. Annualized Cost to the Federal Government

The total annualized cost to the government is \$5,491,383. The total cost to the government over the 3-year period is \$16,474,150. Funding to the grantees is being provided through the Epidemiology and Laboratory Capacity for Infectious Diseases Funding Opportunity Announcement CK19-190403CONT21.<sup>6</sup> The annual cost is summarized in Table A.14.

**Table A.14: Estimated Annualized Costs to the Federal Government**

Expense Type	Expense Explanation	Annual Cost (dollars)
Direct Costs to the Federal Government	CDC Data Manager (GS-12, 0.2 FTE)	\$16,116
	CDC Laboratory Personnel (GS-13, 0.6 FTE)	\$57,670.20
	CDC Epidemiologist (GS-13, 1.0 FTE)	\$96,117
	CDC Epidemiologist (GS-13, 1.0 FTE)	\$96,117

Operational	Travel (site visits)	\$10,000
Other Expenses	California site cost	\$861,915
	Colorado site cost	\$954,267
	Indiana site cost	\$478,772
	New York City site cost	\$452,866
	North Carolina site cost	\$487,681
	Pennsylvania site cost	\$479,437
	Washington site cost	\$783,949
	Wisconsin site cost	\$716,476
	Total cost to the Federal Government	\$5,491,383

### 15. Explanation for Program Changes or Adjustments

We made several changes in Table A12a that resulted in a change in the total burden hours.

- The number of participating jurisdictions decreased from 9 to 8 since the initial submission. One jurisdiction opted to not continue.
  - o The number of local SURRG data managers thus decreased from 9 to 8 and the burden hours decreased from 1008 to 896.
  - o The number of public health lab microbiologists decreased from 9 to 8 and the burden hours decreased from 1050 to 933.
  - o The number of public health lab data managers decreased from 9 to 8 and the burden hours decreased from 54 to 48.
  - o Because of the decrease in the number of participating sites, the number of gonorrhea patients and contacts decreased from 1080 to 960 and the burden hours decreased from 540 to 480.
- The number of non-STD clinic sites and data managers will increase from 18 to 26. The burden hours will increase from 324 to 468.

In Table 12.B., we updated the hourly rates based on 2019 values

In Table A.14, we made several changes based on recent changes in salary, costs, and staffing changes

- We updated salary estimates based on 2019 figures.
- To provide better oversight of this complex project, the GS level of laboratory personnel was increased to reflect the greater support needs of this complex project.
- We estimated site costs based on 2019 funding levels; costs increased as staffing and supply costs expanded to meet project objectives.
- The funding for grantees (other expenses) decreased slightly to \$5,215,363.
- The total cost decreased slightly from \$5,654,830 to \$5,491,383.

Based on lessons learned about usefulness of specific data elements and feasibility of collecting them, we plan to reduce the time to complete each survey (from 30 minutes to 20 minutes) and update the data elements (see **Attachment 3D**).

**16. Plans for Tabulation and Publication and Project Time Schedule**

We anticipate continued data collection following approval of the revision through September, 2024. Preliminary data analysis is expected to begin 4–6 months after OMB renewal. Interim data analyses will be completed 12 months after OMB approval. Additional data analysis will occur at least annually during the time period of the approved 3-year project period. Data analyses include descriptive analyses, trends in gonococcal antimicrobial resistance over time, and network analyses of partnerships. Analyses of the data have been and will be published in scientific and public health journals and presented at scientific meetings.

Table A.16: Project Time Schedule

Activity	Time Schedule
Collection of isolates and clinical/demographic data from participating clinics and jurisdictions	Every other month after OMB approval
Data management and validation of data collected	Quarterly after OMB approval
Dissemination of results via reports, abstracts, peer-reviewed publications	12 months after OMB approval and annually

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

The display of the OMB expiration date is not inappropriate.

**18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions**

There are no exceptions to the certification for the clinical sites and GISP regional laboratories. OMB/PRA clearance is not required for the Antibiotic Resistance Laboratory Network (as described previously).

**References**

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7. National Action Plan for Combating Antibiotic-Resistant Bacteria, 2020-2025. Available at: <https://www.hhs.gov/sites/default/files/carb-national-action-plan-2020-2025.pdf#:~:text=The%20National%20Action%20Plan%20for%20Combating%20Antibiotic-Resistant%20Bacteria,Americans%20by%20changing%20the%20course%20of%20antibiotic%20resistance.> Accessed May 28, 2021