U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

*Print Date:* 9/19/24

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|---|---|
| **Title:** | The National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS) and Select Isolate Response Initiative (SIRI) |
| **Project Id:** | 0900f3eb8244160e |
| **Accession #:** | NCEZID-NARMS-8/23/24-21dd3 |
| **Project Contact:** | Laura A Ford |
| **Organization:** | NCEZID/DFWED/EDEB/NARMS |
| **Status:** | **Pending Regulatory Clearance** |
| **Intended Use:** | **Project Determination** |
| **Estimated Start Date:** | 08/23/2024 |
| **Estimated Completion Date:** | 08/25/2036 |
| **CDC/ATSDR HRPO/IRB Protocol #:** | |
| **OMB Control #:** | |

## Determinations

| Determination | Justification | Completed | Entered By & Role |
|---|---|---|---|
| HSC:<br>**Does NOT Require HRPO Review** | Not Research - Public Health Surveillance<br><br>*45 CFR 46.102(l)(2)* | 9/3/24 | Peterson_James M. (iyr1) CIO HSC |
| PRA:<br>**PRA Applies** | | 9/16/24 | Vice_Rudith (nhr9) OMB / PRA |

# Description & Funding

## Description

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| **Priority:** | Standard |
| **Date Needed:** | 09/26/2024 |
| **Priority Justification:** | |
| **CDC Priority Area for this Project:** | Readiness and Response |
| **Determination Start Date:** | 09/16/24 |
| **Description:** | Each year, approximately 4.9 million bacterial enteric illnesses occur in the United States, resulting in an estimated 35,800 hospitalizations and 1,093 deaths. Most bacterial enteric infections are self-limited and do not require antibiotics, but antibiotics are indicated for patients with severe disease or risk factors for severe disease. The growing proportion of antimicrobial-resistant bacterial enteric infections limits treatment options and creates opportunities for resistance to spread to other pathogens. Extended-spectrum beta-lactamase-producing Escherichia coli and antimicrobial-resistant Campylobacter, nontyphoidal Salmonella, Salmonella serotype Typhi, and Shigella have been classified as serious public health threats, which require prompt and sustained action. The National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS) is a collaboration among CDC, the US Food and Drug Administration, the US Department of Agriculture, and state and local health departments, that monitors resistance in enteric bacteria. Antimicrobial resistance data can inform the development of public health interventions and policies designed to protect people from the threat of resistant enteric infections. Data can be collected through routine surveillance to measure antimicrobial resistance in bacteria isolated from people or through surveillance of antimicrobial resistance during outbreaks. Surveillance of resistance during outbreaks can help investigators identify the source of an outbreak or provide clues about the source of the outbreak. Investigations of outbreaks of resistant Salmonella traced to food-producing animals can show how animal and human health are linked. Additionally, to help focus efforts for preventing antimicrobial-resistant bacterial enteric illness, there is a need to monitor and assess risk factors and outcomes associated with resistance. State and local health departments routinely conduct patient interviews to investigate cases and outbreaks of illness caused by enteric pathogens. The interviews typically include demographics, clinical information such as symptoms, duration, severity, and treatment, and risk factor and exposure information, such as recent travel, food consumption, and animal contact. For patients with bacterial enteric infections that have concerning antimicrobial resistance, the CDC NARMS team would like to request information from initial patient interviews. If additional information would further enhance the existing surveillance data provided by health departments, the CDC NARMS team may want to request medical and pharmacy records, as well as request or perform supplemental interviews, additional phenotypic and genotypic testing on isolates, shopper records, food, environmental, or animal sampling, or field investigations if needed. This enhanced surveillance will both monitor for and assess emerging antimicrobial resistance of concern and inform public health response and mitigation efforts. |
| **IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:** | No |
| **IMS Activation Name:** | Not selected |
| **Submitted through IMS Clearance Matrix:** | Not selected |
| **Primary Scientific Priority:** | Not selected |

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| **Secondary Scientific Priority (s):** | Not selected |
| **Task Force Responsible:** | Not selected |
| **CIO Emergency Response Name:** | Not selected |
| **Epi-Aid Name:** | Not selected |
| **Lab-Aid Name:** | Not selected |
| **Assessment of Chemical Exposure Name:** | Not selected |
| **Goals/Purpose** | NARMS routine and outbreak surveillance: The goal of NARMS routine and outbreak surveillance is to track and report antimicrobial resistance data on enteric bacteria collected from humans through routine frequency-based surveillance and from outbreaks associated with contaminated foods, contact with animals, and human to human transmission. SIRI: The goal of the select isolate response initiative (SIRI) is to enhance public health surveillance and reporting of antibiotic-resistance threats. Characterizing exposures, risk factors, and sources of illness for resistant enteric infections can inform efforts to prevent additional infections and the spread of disease. Additionally, describing risk factors and the clinical outcomes of resistant enteric infections may improve clinical education and awareness of emerging health threats. |
| **Objective:** | NARMS routine and outbreak surveillance: Objectives include, 1. Detect emerging trends of resistance. 2. Link enteric illnesses (resistant and susceptible) to specific sources and risk factors. 3. Monitor for emerging genetic mechanisms that confer resistance and assess their spread among enteric bacteria. 4. Collaborate on investigation of enteric disease, including multistate foodborne outbreaks. 5. Educate consumers about foodborne antimicrobial threats and food safety practices that protect against these threats. 6. Guide public health priorities. 7. Provide information and recommendations that promote the judicious use of antimicrobial agents. SIRI: The objective is to obtain information about persons with bacterial enteric infections that have concerning resistance, their infections, and their environments and food sources to identify potential exposures and clinical consequences of infection. This includes obtaining information from: 1. Initial interview data (e.g., demographics, recent travel, food consumption, and animal contact) 2. Supplementary interview data (e.g., more focused questions about travel, food consumption, and/or animal contact) 3. Medical and pharmacy records 4. Additional testing on isolates (e.g., long-read sequencing, antimicrobial susceptibility testing) 5. Shopper records, food, environmental, or animal testing and field investigations (e.g., request swabs of reptile environments or request collection of leftover foods of interest) 6. Additional testing for patients or contacts (e.g., stool culture, CIDT, or other diagnostic test for screening of symptomatic or asymptomatic contacts, patients with ongoing symptoms, post-symptomatic patients suspected of carriage) |
| **Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:** | No |
| **Does your project investigate underlying contributors to health inequities among populations /groups experiencing social, economic, geographic, and/or environmental disadvantages?:** | No |
| **Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:** | Yes |
| **Activities or Tasks:** | New Collection of Information, Data, or Biospecimens ; Secondary Data or Specimen Analysis ; Purchase, Use, or Transfer of Information, Data, Biospecimens or Materials |

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| **Target Populations to be Included/Represented:** | General US Population |
| **Tags/Keywords:** | Drug Resistance, Bacterial ; Public Health Surveillance ; Salmonella ; Campylobacter ; Shigella ; Shiga-Toxigenic Escherichia coli ; Vibrio |
| **CDC's Role:** | Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided ; CDC employees or agents will obtain data by intervening or interacting with participants ; CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens ; CDC employees will participate as co-authors in presentation(s) or publication(s) |
| **Method Categories:** | Exposure Investigation; Genetic Sequencing; Record Review; Secondary Data Analysis; Secondary Specimen Analysis; Surveillance Support |
| **Methods:** | NARMS routine and outbreak surveillance: State and large urban public health departments submit Salmonella, Campylobacter, Shigella, E. coli, and Vibrio isolates to CDC for antimicrobial susceptibility testing according to a preestablished sampling strategy (routine surveillance) or in response to request by investigators (outbreak surveillance). Isolates that have undergone whole genome sequencing (WGS), either by state health departments or CDC and submitted to PulseNet, are also screened for predicted resistance based on the presence of genes and mutations known to confer antimicrobial resistance. Health departments submit limited metadata along with each isolate (e.g., age, sex, and state of residence). SIRI: CDC investigators identify isolates with concerning resistance patterns based on AST results or WGS data uploaded to PulseNet. Investigators follow up with epidemiologists at state or local health department to obtain additional patient and isolate information, as described below. Depending on the resistance pattern and available information, additional epidemiological records (including primary interview records, medical records, or pharmacy records) and additional laboratory testing (of the original isolate, or environmental or food testing) could be requested. |
| **Collection of Info, Data or Biospecimen:** | NARMS routine and outbreak surveillance: 54 participating state and local public health departments send a sample of enteric bacterial isolates for routine surveillance and a sample of outbreak isolates (when requested) for outbreak surveillance to CDC. Basic metadata (e.g., age, gender, and state of residence) are submitted with the isolates. State and local health departments submit data, or the CDC team enters data, to the NARMS data system by one of two methods: by directly entering the data via a web-based entry form and submitting that data to CDC, or by field mapping an electronic file to NARMS form fields and uploading data en masse to CDC. The CDC NARMS laboratory staff perform broth microdilution antimicrobial susceptibility testing on these isolates using the the Sensititre# semiautomated platform, and the CDC team enters the numerical results into the NARMS system using a SWIN export file (.csv) captured from the laboratory testing device. The SWIN export file and contents must meet NARMS system validation requirements. Additionally, public health laboratories, with state and local health departments, submit sequence data for enteric bacteria isolates to PulseNet. PulseNet has received a non-research determination for their work. Data from PulseNet to NARMS go through the Data Broker, an internal web service that allows the NARMS application to access additional data shared by PulseNet. The NARMS data system receives information nightly on antimicrobial resistance genes, mutations, and plasmids gleaned from whole genome sequence data and limited demographic information submitted to PulseNet. NARMS CDC team members with approval rights review and determine acceptability of laboratory data, predicted resistance data, and demographic data fields through approval interfaces built into the NARMS data system. As only basic metadata is available in the NARMS data system, isolate resistance data may be linked with additional patient epidemiological data collected by other CDC public health surveillance systems to further assess and respond to antimicrobial resistant infections and outbreaks. NARMS data may be linked with data from the National Surveillance Team (OMB Control Number 0920-0728, expiration 3/31/2027), FoodNet (Exempt Research Protocol 6182, reviewed June 23, 2023), the National Outbreak Reporting System (NORS) (OMB Control Number 9020-1304, expiration 8/31/2025), or with data collected as part of a cluster or outbreak investigation and stored in SEDRIC (OMB Control number 0920-0997, expiration 9/30/2026). SIRI: For isolates with concerning resistance, CDC investigators will contact epidemiologists at state or local health departments to request information from the state or local health department#s case investigation, including copies of state/local case report forms which typically capture demographic information, illness information (symptoms, hospitalization, treatment, outcomes), and other exposure or risk factor information (travel, food history, animal and |

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| | water exposures, other risk factor information). We have reached the character limit - please see the attachment for more information on data and biospecimen collection. |
| **Expected Use of Findings/Results and their impact:** | Approved NARMS routine and outbreak surveillance data will be released back to the submitting state or local public health department. Routine and outbreak surveillance data with limited demographic data may also be made available online (e.g., NARMS Now: Human Data, BEAM Dashboard, FDA#s Integrated data platform, Sanford Guide), in agency reports, or outbreak web postings. Additionally, information about resistant infections, including risk factors or exposures and outcomes, may be summarized and disseminated to support public health activities and other infection control and prevention efforts; inform various stakeholders; inform the establishment and revision of criteria used to interpret antimicrobial susceptibility tests; and educate clinical management. The information may be used in public health reports and presentations; peer-reviewed publication; web posts or other health messaging to health care providers, clinical and public health laboratories, and the public; and communications with other stakeholders. |
| **Could Individuals potentially be identified based on Information Collected?** | Yes |
| **Will PII be captured (including coded data)?** | Yes |
| **Does CDC have access to the identifiers (including coded data)?:** | Yes |
| **Is this project covered by an Assurance of Confidentiality?** | No |
| **Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?** | No |
| **Is there a formal written agreement prohibiting the release of identifiers?** | No |

## Funding

| Funding Type | Funding Title | Funding # | Original Budget Yr | # Years Award | Budget Amount |
|---|---|---|---|---|---|
| CDC Cooperative Agreement | ELC Cooperative Agreement | | | | |

## HSC Review

## Regulation and Policy

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|---|---|
| **Do you anticipate this project will require review by a CDC IRB or HRPO?** | No |
| **Estimated number of study participants** | |

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|---|---|
| **Population - Children** | Protocol Page #: |
| **Population - Minors** | Protocol Page #: |
| **Population - Prisoners** | Protocol Page #: |
| **Population - Pregnant Women** | Protocol Page #: |
| **Population - Emancipated Minors** | Protocol Page #: |

**Suggested level of risk to subjects**

**Do you anticipate this project will be exempt research or non-exempt research**

### Requested consent process waviers

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|---|---|
| **Informed consent for adults** | No Selection |
| **Children capable of providing assent** | No Selection |
| **Parental permission** | No Selection |
| **Alteration of authorization under HIPAA Privacy Rule** | No Selection |

### Requested Waivers of Documentation of Informed Consent

| | |
|---|---|
| **Informed consent for adults** | No Selection |
| **Children capable of providing assent** | No Selection |
| **Parental permission** | No Selection |

### Consent process shown in an understandable language

| | |
|---|---|
| **Reading level has been estimated** | No Selection |

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| **Comprehension tool is provided** | No Selection |
| **Short form is provided** | No Selection |
| **Translation planned or performed** | No Selection |
| **Certified translation / translator** | No Selection |
| **Translation and back-translation to/from target language(s)** | No Selection |
| **Other method** | No Selection |

### Clinical Trial

| | |
|---|---|
| **Involves human participants** | No Selection |
| **Assigned to an intervention** | No Selection |
| **Evaluate the effect of the intervention** | No Selection |
| **Evaluation of a health related biomedical or behavioral outcome** | No Selection |
| **Registerable clinical trial** | No Selection |

### Other Considerations

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| **Exception is requested to PHS informing those bested about HIV serostatus** | No Selection |
| **Human genetic testing is planned now or in the future** | No Selection |
| **Involves long-term storage of identfiable biological specimens** | No Selection |
| **Involves a drug, biologic, or device** | No Selection |
| **Conducted under an Investigational New Drug exemption or Investigational Device Exemption** | No Selection |

## Institutions & Staff

### Institutions

Will you be working with an outside Organization or Institution? Yes

| Institution | FWA # | FWA Exp Date | Funding | Funding Restriction Amount |
|---|---|---|---|---|
| All US State Health Departments | | | ELC Cooperative Agreement | |

| Institution | Funding Restriction Percentage | Funding Restriction Reason | Funding Restriction has been Lifted |
|---|---|---|---|
| All US State Health Departments | | | |

| Institution | Institution Role(s) | Institution Project Title | Institution Project Tracking # | Prime Institution |
|---|---|---|---|---|
| All US State Health Departments | Obtaining Consent; Obtaining, Storing or Transferring Identifiable Private Information or Identifiable Biospecimens | | | |

| Institution | Regulatory Coverage | IRB Review Status |
|---|---|---|
| All US State Health Departments | IRB Review is Not Required | |

| Institution | Registered IRB | IRB Registration Exp. Date | IRB Approval Status |
|---|---|---|---|
| All US State Health Departments | | | |

| Institution | IRB Approval Date | IRB Approval Exp. Date | Relying Institution IRB |
|---|---|---|---|
| All US State Health Departments | | | |

## Staff

| Staff Member | SIQT Exp. Date | CITI Biomedical Exp. Date | CITI Social & Behavioral Exp. Date | CITI Good Clinical Practice Exp. Date | CITI Good Laboratory Practice Exp. Date | Staff Role | Email | Phone | Organization |
|---|---|---|---|---|---|---|---|---|---|
| Beth Karp | 08/19/2026 | 12/01/2024 | | | | Co-Investigator | jyo2@cdc.gov | 404-639-5097 | NARMS Team |
| Caroline Snyder | 07/27/2026 | | 07/27/2025 | | | Co-Investigator | qmm3@cdc.gov | 404-718-1673 | NARMS Team |
| Felicita Medalla | 06/12/2025 | 01/02/2022 | | | | Co-Investigator | fhm1@cdc.gov | 404-639-3426 | NARMS Team |
| HAIMANOT KEBBEDE | 08/09/2026 | | | | | Co-Investigator | rcu1@cdc.gov | 404-718-8448 | National Surveillance Team |
| Hayat Caidi | 07/11/2026 | 07/27/2021 | | | | Co-Investigator | foi0@cdc.gov | 404-639-0766 | NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE TEAM |
| Jared Reynolds | 09/01/2026 | 12/26/2021 | 12/26/2021 | 12/26/2021 | | Co-Investigator | uvz6@cdc.gov | 404-639-3519 | NARMS Team |
| Jason Folster | 06/26/2026 | 02/28/2027 | | | | Co-Investigator | gux8@cdc.gov | 404-639-8 | NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE TEAM |
| Jean Whichard | 12/14/2025 | 12/14/2025 | | | | Co-Investigator | zyr3@cdc.gov | 404-639-2000 | ENTERIC DISEASES LABORATORY BRANCH |
| Laura Cooley | 11/09/2026 | | 12/13/2021 | | | Co-Investigator | whz3@cdc.gov | 404-639-2096 | NARMS Team |
| Laura Ford | 05/12/2026 | 06/23/2026 | 06/26/2026 | | | Co-Investigator | qdz4@cdc.gov | 404-718-1141 | NARMS Team |
| Louise Francois Watkins | 08/28/2026 | | 02/17/2025 | 02/20/2025 | | Co-Investigator | hvu9@cdc.gov | 404-639-4755 | NARMS Team |
| Meseret | 08/09 | | | | | Co- | vkl2@cdc. | 404- | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Birhane | /2026 | 09/02/2027 | | | | Investigator | gov | 639-2775 | NARMS Team |
| Naeemah Logan | 09/12 /2026 | 12/31/2021 | | | | Co-Investigator | nqz8@cdc.gov | 404-718-6837 | NARMS Team |

# Data

## DMP

**Proposed Data Collection Start Date:** 8/23/24

**Proposed Data Collection End Date:** 8/25/36

**Proposed Public Access Level:** Restricted

*Restricted Details:*

**Data Use Type:** Other - Data Use Agreement and Non-Disclosure Agreement

**Data Use Type URL:** https://wwwn.cdc.gov/NARMS/Landing_Pages/LandingPageCDCAdmin.aspx; https://dcipher.cdc.gov/

**Data Use Contact:** narms@cdc.gov; sedric@cdc.gov

**Public Access Justification:** Only listed staff and those with access to the NARMS Data System or SEDRIC will have access to the data. However, an aggregate summary of the data or de-identified data may be provided publicly (e.g., NARMS Now). If other individuals inside or outside of CDC request this information, they will be referred to narms@cdc.gov or sedric@cdc.gov or to state/local health departments to request access.

**How Access Will Be Provided for Data:** Data collected will be stored in the NARMS data system, on a secure shared drive, or in SEDRIC. Records will be coded to protect patient privacy and confidentiality. State health departments will retain access to all information from their respective states including keys to coded data (keys will not be shared to CDC). No data will be accessed or used by anyone who is not working on this project or does not have access to the NARMS system or SEDRIC. If other individuals inside or outside of CDC request this information, they will be referred to narms@cdc.gov, sedric@cdc.gov, or state/local health departments for access.

**Plans for Archival and Long Term Preservation:** NARMS routine and outbreak surveillance: Isolate metadata and resistance data are stored in the NARMS data system, which is a web application with two distinct servers hosting the web application and relational database management system. These servers are physically and logically separated from each other. Users of the system consist of both external state users and internal CDC NARMS users. External users access the system by passing through the CDC firewall while internal users access the system from within the firewall. CDC is going through a data modernization initiative, and as part of that initiative, the NARMS application is currently being refactored for relocation from on-premises servers to the cloud by November 1, 2024. Any isolates submitted to CDC will be stored indefinitely in the Enteric Diseases Laboratory Branch#s (EDLB) freezer collections along with all other isolates per EDLB and CDC policy. Audit trail for isolate location and final disposition are captured in the NARMS system. SIRI: Questionnaire data will be transmitted to CDC through via fax, encrypted email, or a secure data sharing platform. Supplementary

questionnaires will be stored on the CDC shared drive. Data will be entered into a secure database (e.g., Excel, Epi Info, RedCap, SEDRIC) stored on the CDC shared drive or share point and analyzed by CDC. Biospecimen data will be linked with questionnaire data by matching isolate information in the NARMS data system with questionnaire data by isolate identifier. Data will be stored at state or local health departments according to state protocols. Coded information will be stored at CDC in folders on a secure share drive or in SEDRIC.

## Spatiality

Spatiality (Geographic Locations) yet to be added .....

## Dataset

| Dataset Title | Dataset Description | Data Publisher /Owner | Public Access Level | Public Access Justification | External Access URL | Download URL | Type of Data Released | Collection Start Date | Collection End Date |
|---|---|---|---|---|---|---|---|---|---|
| Dataset yet to be added... | | | | | | | | | |

# Supporting Info

| Current | CDC Staff Member and Role | Date Added | Description | Supporting Info Type | Supporting Info |
|---|---|---|---|---|---|
| | Peterson_James M. (iyr1)<br>CIO HSC | 09/03/2024 | N/A | HS Research Determination Memo | 090324LF-NR-signed.pdf |
| | Ford_Laura (qdz4)<br>Project Contact | 08/30/2024 | Revised protocol. | Protocol | NARMS Project Determination Request_Aug30clean.docx |
| | Peterson_James M. (iyr1)<br>CIO HSC | 08/29/2024 | HSC added comments and edits using tracked changes. | Protocol | NARMS Project Determination Request_Aug19 HSC edits and comments.docx |
| Current | Ford_Laura (qdz4)<br>Project Contact | 08/23/2024 | Metadata collected with isolate submission. | Other-Metadata collected | A. NARMS Metadata&logsheet Screen grab.docx |
| Current | Ford_Laura (qdz4)<br>Project Contact | 08/23/2024 | SIRI Module 1 | Data Collection Form | Form 5 - NARMS SIRI Module 1.docx |
| Current | Ford_Laura (qdz4)<br>Project Contact | 08/23/2024 | SIRI Module 2 | Data Collection Form | Form 6 - NARMS SIRI Module 2.docx |
| Current | Ford_Laura (qdz4)<br>Project Contact | 08/23/2024 | NARMS Umbrella Project Determination Request | Protocol | NARMS Project Determination Request_Aug19.docx |
| Current | Ford_Laura (qdz4)<br>Project Contact | 08/23/2024 | SIRI Module 3 | Data Collection Form | Form 7 - NARMS SIRI Module 3.docx |
| Current | Ford_Laura (qdz4)<br>Project Contact | 08/23/2024 | SIRI Module 4 | Data Collection Form | Form 8 - NARMS SIRI Module 4.docx |
| Current | Ford_Laura (qdz4)<br>Project Contact | 08/23/2024 | SIRI Module 5 | Data Collection Form | Form 9 - NARMS SIRI Module 5.docx |
| Current | Ford_Laura (qdz4)<br>Project Contact | 08/23/2024 | Verbal consent for additional samples. | Consent Form | G. Verbal Consent - samples.docx |


U.S. Department of Health and Human Services

Centers for Disease Control and Prevention