Project Determination

# **Environmental Health Specialists Network (EHS-Net) Program OMB Generic Package**

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| --- | --- |
| **Project ID:** | 0900f3eb81c8e66b |
| **Accession #:** | NCEH-WFEHSB-2/2/21-8e66b |
| **Project Contact:** | Erin Moritz |
| **Organization:** | NCEH/ATSDR/DEHSP/WFEHSB/FT |
| **Status:** | Project In Progress : PRA Revision |
| **Intended Use:** | Project Determination |
| **Estimated Start Date:** | 02/01/25 |
| **Estimated Completion Date:**  | 01/31/28 |
| **CDC/ATSDR HRPO/IRB Protocol#:**  |  |
| **OMB Control#:**  | 0920-0792 |
| **End of Human Research Date:**  |  |
|  |  |

|  |
| --- |
| Description |
| Priority |
| Standard |
| Date Needed |
| 08/05/24 |
| CDC Priority Area for this Project |
| Other CDC Priority - Decreasing health risks from environmental exposures |
| Determination Start Date |
| 06/25/21 |
| Description |
| This is the OMB package for the EHS-Net food safety research program generic clearance. Generic clearance is the OMB terminology for a &apos;blanket&apos; clearance for several studies. Our 8 EHS-Net funded sites conduct 2 or 3 multisite data collections in restaurants per funding cycle. This generic clearance allows for a shortened clearance process (i.e., 6 months) for these data collections. If we did not obtain generic clearance for these EHS-Net studies, clearance for each individual study would take at least 12 months, compared to the 6 months it would take with a generic clearance. The current generic clearance expires 1/31/2025. |
| 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 |
| 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 |
| The goal of this food safety research program (called EHS-Net) is to collect data in retail food establishments that will identify and address environmental factors (e.g., manager food safety certification, equipment condition, etc.) associated with retail-related foodborne illness and outbreaks. |
| Objective |
| The information collected from establishments will be used by CDC to develop food safety prevention and intervention recommendations for environmental public health/food safety programs and the retail food establishment industry. |
| 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? |
| No |
| Activities or Tasks |
| New Collection of Information, Data, or Biospecimens |
| Target Population to be Included/Represented |
| Businesses |
| Tags/Keywords |
| food safety |
| 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 |
| Method Categories |
| Individual Interview (Quantitative); Observation |
| Methods |
| interviews/assessments with restaurant staff; observations of restaurant kitchen environments and food workers preparing food |
| Collection of Info, Data, or Bio specimens |
| interviews/assessments with restaurant staff; observations of restaurant kitchen environments and food workers preparing food |
| Expected Use of Findings/Results and their impact |
| The information collected from establishments will be used by CDC to develop food safety prevention and intervention recommendations for environmental public health/food safety programs and the retail food establishment industry. |
| Could Individuals potentially be identified based on Information Collected? |
| No |

| ****Funding**** |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Funding Type | Funding Title | Funding # | Original Fiscal Year | # of Years of Award | Budget Amount |
| CDC Cooperative Agreement | Environmental Health Specialists Network - $1,540,000 annually | EH-20-001 | 2020 | 5 |  |

| ****HSC Review**** |
| --- |
| HSC Attributes |
| Non-Human/Non-Animal Material |
| Yes |

| ****Regulation and Policy**** |
| --- |
| Do you anticipate this project will require review by a CDC IRB or HRPO? |
| Yes |
| Estimated number of study participants |
| 376 restaurants per study |
| Population - Children |
| **N/A** | **Page:** |
| Population - Minors |
| **N/A** | **Page:** |
| Population - Prisoners |
| **N/A** | **Page:** |
| Population - Pregnant Women |
| **N/A** | **Page:** |
| Population - Emancipated Minors |
| **N/A** | **Page:** |
| Suggested level of risk to subjects |
| Minimal |
| Do you anticipate this project will be exempt research or non-exempt research |
| Exempt |
| Category 1: Education Practices |
| No Selection |
| Category 2: Educational tests, surveys, interviews, or observation of public behavior |
| No Selection |
| Category 3: Benign Behavioral Interventions and Collection of Information |
| No Selection |
| Category 4: Secondary Research for Which Consent is not Required |
| No Selection |
| Category 5: Research and Demonstration Projects |
| No Selection |
| Category 6: Taste and Food Quality Evaluation and Consumer Acceptance Studies |
| No Selection |
| Category 7: Storage or Maintenance for Secondary Use for Which Broad Consent is Required |
| No Selection |
| Category 8: Secondary Research for Which Broad Consent is Required |
| No Selection |

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

| ****Institutions**** |  |  |  |  |
| --- | --- | --- | --- | --- |
| Institution | FWA # | FWA Exp. Date | Funding | Funding Restriction Amount |
| Harris County, Texas Department of Health |  |  | EH-20-001 |  |
| Franklin County, OH Department of Health |  |  | EH-20-001 |  |
| Fund for Public Health NY | FWA00023694 | 08/22/28 | EH-20-001 |  |
| Minnesota Department of Health | FWA00000072 | 07/05/29 | EH-20-001 |  |
| New York State Dept of Hlth | FWA00003700 | 08/26/29 | EH-20-001 |  |
| Rhode Island Department of Health | FWA00006141 | 09/13/27 | EH-20-001 |  |
| Southern Nevada Health District | FWA00023704 | 10/23/24 | EH-20-001 |  |
| Tennessee Department of Health | FWA00000379 | 01/18/27 | EH-20-001 |  |

| Institution | Funding Restriction Percentage | Funding Restriction Reason | Funding Restriction has been lifted |
| --- | --- | --- | --- |
| Harris County, Texas Department of Health |  |  |  |
| Franklin County, OH Department of Health |  |  |  |
| Fund for Public Health NY |  |  |  |
| Minnesota Department of Health |  |  |  |
| New York State Dept of Hlth |  |  |  |
| Rhode Island Department of Health |  |  |  |
| Southern Nevada Health District |  |  |  |
| Tennessee Department of Health |  |  |  |

| Institution | Institution Role(s) | Institution Project Title | Institution Project Tracking # | Prime Institution |
| --- | --- | --- | --- | --- |
| Harris County, Texas Department of Health |  |  |  |  |
| Franklin County, OH Department of Health |  |  |  |  |
| Fund for Public Health NY |  |  |  |  |
| Minnesota Department of Health |  |  |  |  |
| New York State Dept of Hlth |  |  |  |  |
| Rhode Island Department of Health |  |  |  |  |
| Southern Nevada Health District |  |  |  |  |
| Tennessee Department of Health |  |  |  |  |

| Institution | Regulatory Coverage | IRB Review Status |
| --- | --- | --- |
| Harris County, Texas Department of Health |  |  |
| Franklin County, OH Department of Health |  |  |
| Fund for Public Health NY |  |  |
| Minnesota Department of Health |  |  |
| New York State Dept of Hlth |  |  |
| Rhode Island Department of Health |  |  |
| Southern Nevada Health District |  |  |
| Tennessee Department of Health |  |  |

| Institution | Registered IRB | IRB Registration Exp. Date | IRB Approval Status |
| --- | --- | --- | --- |
| Harris County, Texas Department of Health |  |  |  |
| Franklin County, OH Department of Health |  |  |  |
| Fund for Public Health NY | New York City Dept of Hlth & Mental Hygiene IRB #1 | 08/06/23 |  |
| Minnesota Department of Health |  |  |  |
| New York State Dept of Hlth |  |  |  |
| Rhode Island Department of Health | RHODE ISLAND STE DEPT HLTH IRB #1 | 04/03/22 |  |
| Southern Nevada Health District | U of Nevada, Las Vegas IRB #1 -- Biomedical Sciences | 01/03/23 |  |
| Tennessee Department of Health |  |  |  |

| Institution | IRB Approval Date | IRB Approval Exp. Date | Relying Institution IRB |
| --- | --- | --- | --- |
| Harris County, Texas Department of Health |  |  |  |
| Franklin County, OH Department of Health |  |  |  |
| Fund for Public Health NY |  |  |  |
| Minnesota Department of Health |  |  |  |
| New York State Dept of Hlth |  |  |  |
| Rhode Island Department of Health |  |  |  |
| Southern Nevada Health District |  |  |  |
| Tennessee Department of Health |  |  |  |

| ****Staff**** |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Staff Member | SIQT Exp. Date | Citi Biomedical Exp. Date | Citi Social and Behavioral Exp. Date | Citi Good Clinical Exp. Date | Citi Good Laboratory Practice Exp. Date | Staff Role | Email | Phone # | Organization/Institution |
| LauraBrown | 08/07/2026 |  | 07/18/2025 |  |  | Program Lead | lrg0@cdc.gov | 770-488-2 | WATER FOOD AND ENVIRONMENTAL HEALTH SERVICES BRANCH |

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| ****DMP**** |  |
| ****Proposed Data Collection Start Date**** | **02/01/25** |
| ****Proposed Data Collection End Date**** | **08/31/27** |
| ****Proposed Public Access Level**** | **Public** |
| ****Public Access justification**** | **These data will be anonymous so can be shared.** |
| ****How Access Will Be Provided for Data**** | **We will release data files from the studies with our publications through CDC Stacks.** |
| ****Plans for archival and long-term preservation of the data**** | **We will archive for 10 years in CDC Stacks.** |

| ****Spatiality (Geographic Location)**** |  |  |
| --- | --- | --- |
| Country | State/Province | County/Region |
| United States |  |  |

| ****Determinations**** |
| --- |
| Determination | Justification | Completed | Entered By & Role |
| HSC: Does NOT Require HRPO Review | Research Not Involving Human Subjects*45 CFR 46.102(e)* | 07/29/24 | Ding\_Yan (Shirley) (yad6) CIO HSC |
| PRA: PRA Applies |  | 07/29/24 | Ding\_Yan (Shirley) (yad6) CIO OMB / PRA |
| ICRO: PRA Applies | OMB Approval date: 01/26/22 OMB Expiration date: 01/31/25 | 08/05/24 | Zirger\_Jeffrey (wtj5) ICRO Reviewer |