



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

Print Date: 6/24/22

Title: Collaborating with poison centers to collect public health-specific information to aid in incidents of public health significance

Project Id: 0900f3eb819e6e04

Accession #: NCEH-HST-7/31/19-e6e04

Project Contact: Amy H Schnall

Organization: NCEH/ATSDR/DEHSP/EMRCB/HST

Status: **Project In Progress**

Intended Use: **Project Determination**

Estimated Start Date: 03/01/2020

Estimated Completion Date: 02/28/2023

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #: 0920-1166

Determinations

| Determination | Justification | Completed | Entered By & Role |
|---|---|-----------|---------------------------------------|
| HSC: Does NOT Require HRPO Review | Not Research - Public Health Surveillance <i>45 CFR 46.102(1)(2)</i> | 8/8/19 | Garcia_Albert D. (asg9) CIO HSC |
| PRA: PRA Applies | | 8/8/19 | Garcia_Albert D. (asg9) CIO OMB / PRA |
| | | | |

| | | |
|------------------------------------|---------|-------------------------------------|
| ICRO: Returned with No Decision | 8/28/19 | Zirger_Jeffrey (wtj5) ICRO Reviewer |
|------------------------------------|---------|-------------------------------------|

Description & Funding

Description

| | |
|--|---|
| Priority: | Standard |
| Date Needed: | 08/31/2019 |
| Determination Start Date: | 07/31/19 |
| Description: | This RDF serves as the determination for the renewal of the OMB package #Collaborating with poison centers to collect public health-specific information to aid in incidents of public health significance#. This package is set to expire on 2/29/2020 and Health Studies will be renewing the package prior to expiration. The previous package RDF and the updated SSA for the renewal package have been included in the supplemental section. |
| IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission: | No |
| IMS Activation Name: | Not selected |
| Primary Priority of the Project: | Not selected |
| Secondary Priority(s) of the Project: | Not selected |
| Task Force Associated with the Response: | 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 is to renew the OMB package. |
| Objective: | The objective is to renew the OMB package. |
| Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?: | Not Selected |
| Project does not incorporate elements of health equity science: | Not Selected |
| Measuring Disparities: | Not Selected |

| | |
|--|---|
| Studying Social Determinants of Health (SDOH): | Not Selected |
| Assessing Impact: | Not Selected |
| Methods to Improve Health Equity Research and Practice: | Not Selected |
| Other: | Not Selected |
| Activities or Tasks: | All Work Onsite at CDC Facilities |
| Target Populations to be Included/Represented: | Other - The objective is to renew the OMB package. |
| Tags/Keywords: | Poison Control Centers |
| 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: | Other |
| Methods: | No data will be collected as a part of this activity. |
| Collection of Info, Data or Biospecimen: | No data will be collected as a part of this activity. |
| Expected Use of Findings/Results and their impact: | This activity will generate the renewal of the GenICR. |
| Could Individuals potentially be identified based on Information Collected? | No |

Funding

Funding yet to be added

HSC Review

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office

Estimated number of study participants

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 wavers

| | |
|--|--------------|
| Informed consent for adults | No Selection |
| Children capable of providing assent | No Selection |
| Parental permission | No Selection |
| Alteration of authorization under HIPPA 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 |
| 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 | No Selection |

language(s)

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

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 identifiable 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

Institutions yet to be added

Staff

| Staff Member | SIQT Exp. Date | CITI Biomedical Exp. Date | CITI Social & Behavioral Exp. Date | CITI Good Clinical Practice Exp. Date | Staff Role | Email | Phone | Organization |
|--------------|----------------|---------------------------|------------------------------------|---------------------------------------|------------------------|--------------|--------------|----------------|
| Royal Law | 04/27/2021 | 06/26/2022 | 10/21/2023 | | Principal Investigator | hua1@cdc.gov | 770-488-3416 | HEALTH STUDIES |

Data

DMP

| | |
|---|------------|
| Proposed Data Collection Start Date: | 3/1/20 |
| Proposed Data Collection End Date: | 2/28/23 |
| Proposed Public Access Level: | Non-Public |

Non-Public Details:

| | |
|---|---|
| Reason For Not Releasing Data: | Other - No data will be collected as a part of this activity. |
| Public Access Justification: | NA |
| How Access Will Be Provided for Data: | NA |
| Plans for Archival and Long Term Preservation: | NA |

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 |
|---------|--|------------|---|----------------------|--|
| | Garcia_Albert D. (asg9) CIO HSC | 08/08/2019 | SSA-ag-edit | Other | 1 - SSA PPCCPHE Renewal Redline_ag-comments.docx |
| | Law_Royal K. (hua1) Project Contact | 08/05/2019 | clean version of updated SSB | Other | 1 - SSB PCCPHE Renewal CLEAN.docx |
| | Law_Royal K. (hua1) Project Contact | 08/05/2019 | Clean version of updated SSA | Other | 1 - SSA PPCCPHE Renewal CLEAN.docx |
| | Law_Royal K. (hua1) Project Contact | 07/31/2019 | SSB redline version for the extension GenICR. | Other-SSB | 1 - SSB PPCCPHE Renewal Redline.docx |
| | Law_Royal K. (hua1) Project Contact | 07/31/2019 | SSA redline version for the extension GenICR | Other-SSA | 1 - SSA PPCCPHE Renewal Redline.docx |



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