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

Print Date: 4/15/22

Title: NCEH DLS Laboratory Quality Assurance Programs

Project Id: 0900f3eb81e1b52e

Accession #: NCEH-DLSPB-9/30/21-dfba9

Project Contact: Linde J Parcels

Organization: NCEH/ATSDR/DLS/DLSPB

Status: **Pending Regulatory Clearance**

Intended Use: **Project Determination**

Estimated Start Date: 10/01/2021

Estimated Completion Date: 10/01/2024

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #:

Source System #: 2021-0086

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research / Other *45 CFR 46.102(l)* Quality Assurance / Improvement	11/16/21	Davis_Stephanie I. (sgd8) CIO HSC

PRA: **PRA Applies**		11/16/21	Davis_Stephanie I. (sgd8) CIO OMB / PRA

Description & Funding

Description

Priority:	Standard
Date Needed:	11/30/2021
Determination Start Date:	11/16/21
Description:	The CDC DLS QA programs operate out of multiple laboratories within the Division. They establish the baseline measurements and provide calibration and/or QC samples that laboratories around the world rely on to develop and improve methods with acceptable levels of accuracy and reliability and, in some cases, meet certain required certifications or accreditation. Laboratories use DLS-developed samples to test the quality and accuracy of their methods/assays. Participating laboratories enroll in the DLS QA program that fits their needs (I.e.: external quality assurance/performance assessment, proficiency testing, accuracy-based monitoring, or standardization/harmonization). After the laboratories receive DLS QA samples and perform their measurements, they return test results to DLS. DLS then evaluates the data using statistical methods and reports back to the laboratories on their analytical performance. Laboratories may receive additional technical assistance (TA)/troubleshooting to improve their method performance as needed. DLS programs are offered at different frequencies.
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	Accuracy and reliability of laboratory tests is important to identify and to monitor exposures and health biomarkers, which in turn improves diagnosis and treatment. Laboratories that conduct biomonitoring or test for certain environmental or nutritional chemicals participate in quality assurance (QA) activities for many reasons: to assess internal test performance, calibrate methods to standards among other laboratories, receive certification of proficiency to comply with certain regulations, or simply improve quality. Participation may help a laboratory to verify the accuracy of their methods and results or ensure accurate and consistent test results across multiple laboratories. Collectively, these programs improve the quality of laboratory tests that measure environmental exposures and chronic disease

Objective:	biomarkers (including nutritional indicators and hormones) to better inform critical patient care and public health decisions for an expansive host of health outcomes such as rare heritable disorders in newborns, endocrine disorders, maternal health and risk of birth defects, bone, kidney and cardiovascular disease, cancers (including breast cancer), diabetes, thyroid and hormone dysregulation.
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?:	No
Project does not incorporate elements of health equity science:	Yes
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 - Not Applicable
Tags/Keywords:	DLS 2021-0086
CDC's Role:	CDC is the sole institution conducting activity
Method Categories:	QA/QI
Methods:	There are thirteen (13) DLS QA programs conducted by the following five DLS branches. These programs provide materials and test result analysis to laboratories for the purpose of improving and/or standardizing test performance. # Clinical Chemistry Branch (5): Lipid Standardization Program (LSP) for Clinical Biomarkers; Cholesterol Reference Method Laboratory Network (CRMLN); Accuracy-based Laboratory Monitoring Programs (AMP); Hormone Standardization (HoST) Program; Vitamin D Standardization Certification Program (VDSCP) # Nutrition Biomarkers Branch (3): Vitamin A Laboratory # External Quality Assurance (VITAL-EQA); Quality Assurance Method Performance Verification (MPV) for Folate Microbiologic Assay; Quality Assurance Method Performance Verification (MPV) for Micronutrients # Organic Analytical Toxicology Branch (1): Biomonitoring Quality Assurance Support Program (BQASP) # Inorganic Radiation and Analytical Toxicology Branch (3): Proficiency in Arsenic Speciation (PAsS) Program; Ensuring the Quality of Urinary Iodine Procedures (EQUIP); Lead and Multielement Proficiency (LAMP) Testing Program # Newborn Screening and Molecular Biology Branch (1): Newborn Screening and Quality Assurance Program (NSQAP) All thirteen (13) CDC quality assurance programs help improve the accuracy and reliability of tests performed by laboratories in patient care, research, commercial and public health settings. They also help to make measurement results among research studies and among clinical laboratories more comparable. Data will be collected electronically via email and online forms; data reporting forms are returned to DLS via Excel templates, PDFs, or web platforms. Laboratories that participate in the various programs are domestic and international and can include public health
Collection of Info, Data or Biospecimen:	

	laboratories, research laboratories, commercial laboratories, and diagnostic test manufacturers. They can be associated with medical schools, hospital systems, state health departments, universities/academic institutions, ministries of health, nonprofit organizations.
Expected Use of Findings/Results and their impact:	Collectively, these programs improve the quality of laboratory tests that measure environmental exposures and chronic disease biomarkers (including nutritional indicators and hormones) to better inform critical patient care and public health decisions for an expansive host of health outcomes such as rare heritable disorders in newborns, endocrine disorders, maternal health and risk of birth defects, bone, kidney and cardiovascular disease, cancers (including breast cancer), diabetes, thyroid and hormone dysregulation.
Could Individuals potentially be identified based on Information Collected?	No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Funding Intramural	Project Funding and Partners				1762845.00

HSC Review

HSC Attributes

Quality Assurance / Improvement	Yes

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office	No
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 waviers

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 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

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

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
Linde Parcels	09/13/2024				Project Officer		404-498-5892	DLS POLICY BRANCH
Yan Ding	03/01/2024	07/02/2024			Project Officer		770-488-7934	DIVISION OF LABORATORY SCIENCES

Data

DMP

Proposed Data Collection Start Date: 9/30/21

Proposed Data Collection End Date: 9/30/24

Proposed Public Access Level: Non-Public

Non-Public Details:

Reason For Not Releasing Data: Other - QA/QC

Public Access Justification: QA/QC

How Access Will Be Provided for Data: Project data is not public health data

Plans for Archival and Long Term Preservation:

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...									

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