UNITED STATES DISTRICT COURT FOR THE DISTRICT OF RHODE ISLAND

Document 84

STATE OF NEW YORK, et al.,

Plaintiffs,

v.

Case No. 1:25-cv-00196-MRD

ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

DECLARATION OF ANDRES IVAN NAVEDO

Pursuant to 28 U.S.C. § 1746, I, Andres Ivan Navedo, do hereby state:

- 1. I am an Assistant Attorney General in the Office of the Attorney General for the State of New York, and I appear on behalf of the State of New York in this action and am a member in good standing of the bar of the State of New York.
- 2. I am admitted to appear in this action in the United States District Court for the District of Rhode Island pursuant to this Court's Text Order from May 6, 2025.
- 3. I submit this Declaration and its attached Exhibits in support of Plaintiff States' Opposition to Defendants' Motion to Modify the Preliminary Injunction.
- 4. I make the following statements on the basis of my own knowledge or a review of files in my possession.

- 5. For the ease of the Court and the parties, I have begun numbering the exhibits to my declaration at Exhibit 78 because the May 9, 2025, Declaration of Andres Ivan Navedo, ECF No. 44 (First Navedo Declaration), together with the May 19, 2025, Declaration of Molly Brachfeld, ECF No. 55 (Brachfeld Declaration), attached Plaintiffs' Exhibits 1–77.
- 6. Attached as Exhibit 78 is a true and accurate copy of the Supplemental Declaration of Dr. Jerome Larkin, M.D., Director of the Rhode Island Department of Health. This is a supplemental declaration by the same declarant who submitted Exhibit 24 to First Navedo Declaration, ECF No. 44-24.
- 7. Attached as Exhibit 79 is a true and accurate copy of the Supplemental Declaration of Katie Eilers, Director of the Office of Family and Community Health Improvement at the Washington State Department of Health. This is a supplemental declaration by the same declarant who submitted Exhibit 27 to the First Navedo Declaration, ECF No. 44-27.
- 8. Attached as Exhibit 80 is a true and accurate copy of the Declaration of Yolanda Jacobs, President of the American Federation of Government Employees (AFGE) Local 2883.
- 9. Attached as Exhibit 81 is a true and accurate copy of the Supplemental Declaration of Kristin J. Cummings, MD, MPH, ATSF, Public Health Medical Administrator and Branch Chief of the Occupational Health Branch, of the California Department of Public Health. This is a supplemental declaration by the same declarant who submitted ECF No. 44-52.
- 10. Attached as Exhibit 82 is a true and accurate copy of the Second Supplemental Declaration of John Doe 2. This is the third declaration by John Doe 2 who previously submitted Exhibit 47 to the First Navedo Declaration, ECF No. 44-47, and Exhibit 68 to the Brachfeld Declaration, ECF No. 55-3.

- 11. Attached as Exhibit 83 is a true and accurate copy of the Supplemental Declaration of Jane Doe 4. This is the second declaration by Jane Doe 4, who previously submitted Exhibit 70 to the Brachfeld Declaration, ECF No. 55-5.
- 12. Attached as Exhibit 84 is a true and accurate copy of the Supplemental Declaration of John Doe 7. This is second declaration by John Doe 7, who previously submitted Exhibit 73 to the Brachfeld Declaration, ECF No. 55-8.
- 13. Attached as Exhibit 85 is a true and accurate copy of the Declaration of Jane Doe 8, an employee of the Division of Reproductive Health within the National Center for Chronic Diseases Prevention and Health Promotion, within CDC.
- 14. Attached as Exhibit 86 is a true and accurate copy of the Declaration of Kristen Good, Health Equity Branch Deputy Chief within the Disease Control and Public Health Response Division of the Colorado Department of Public Health and Environment.
- 15. Attached as Exhibit 87 is a true and accurate copy of the Supplemental Declaration of Eli Rosenberg, PhD, Director of the Office of Science at the New York State Department of Health. This is a supplemental declaration by the same declarant who submitted Exhibit 25 to the First Navedo Declaration, ECF No. 44-25, which was filed with exhibits as Exhibit 75 to the Brachfeld Declaration, ECF No. 55-10.
- 16. Attached as Exhibit 88 is a true and accurate copy of the Supplemental Declaration of Michelle Davis, Deputy Commissioner of the Office of Public Health within New York State Department of Health. This is a supplemental declaration by the same declarant who submitted Exhibit 37 to the First Navedo Declaration, ECF No. 44-37.

Dated: New York, New York

July 25, 2025

/s/ Andres Ivan Navedo
Andres Ivan Navedo
Assistant Attorney General
Office of the New York State Attorney General

EXHIBIT 78

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF RHODE ISLAND

Document 84-1

STATE OF NEW YORK, et al.

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Defendants.

Case No. 1:25-cv-00196

DECLARATION OF DR. JEROME LARKIN

- I, Jerome Larkin, M.D., declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:
- 1. I am the Director of the Rhode Island Department of Health (RIDOH). The information set forth in this Declaration is based on my personal knowledge, information gathered by and in consultation with RIDOH personnel, and a review of business records that have been provided to and reviewed by me.
- 2. I submit this Declaration in support of the States' Opposition to Defendants' Motion to Clarify and Modify the Preliminary Injunction and Plaintiff States' Cross-Motion to Clarify the Preliminary Injunction.

Professional Background

3. I have held the position of Director of RIDOH since May 21, 2024. I am boardcertified in Internal Medicine and Infectious Diseases by the American Board of Internal Medicine and in General Pediatrics by the American Board of Pediatrics. For the 16 years prior to my appointment as Director of RIDOH, I served as the Medical Director of Inpatient

Infectious Diseases Consultation Services at Rhode Island Hospital, the Co-Director of Pediatric HIV Clinic at Hasbro Children's Hospital, and the Medical Director of the Infectious Disease Clinic at Rhode Island Hospital.

- 4. The mission of RIDOH, founded in 1878, is to prevent disease and protect and promote the health and safety of the people of Rhode Island.
- 5. The execution of RIDOH's mission relies heavily on the personnel, funding, information, expertise, technical assistance, communications, data and resources provided by the U.S. Department of Health and Human Services (HHS), its Centers for Disease control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), the Administration for Community Living (ACL) and the Substance Abuse and Mental Health Services Administration (SAMHSA).
- 6. Unlike many other States, the Rhode Island Department of Health serves as the singular public health resource - an agency that serves over one million residents and over 28 million tourists, annually.
- 7. I am providing this Declaration to explain the impact on Rhode Island due to Defendant's failure to abide by the Preliminary Injunction, which was granted on July 1, 2025.

Rhode Island State Tobacco Program

- 8. The CDC's Office on Smoking and Health runs the National Tobacco Control Program, which provides core funding for RIDOH's Tobacco Control activity through a cooperative agreement. This funding supports the Rhode Island Nicotine Helpline and the Statewide Tobacco Network.
- 9. The Rhode Island Nicotine Helpline provides free individualized support for tobacco cessation, through the use of trained "quit coaches" who develop customized plans to

quit smoking for callers. The helpline offers free multi-session telephone or online counseling, self-help materials, and free Nicotine Replacement Therapy for medically eligible callers. Counseling services are offered in over 100 languages, to best meet the needs of the people of Rhode Island in formulating effective nicotine reduction strategies.

Document 84-1

- The Statewide Tobacco Network is a group of organizations, community partners 10. and individuals working together across the state to reduce tobacco and nicotine use, which is the leading cause of preventable death in Rhode Island.
- 11. The Rhode Island Nicotine Helpline and Statewide Tobacco Network addresses disparities of use within populations targeted by the tobacco industry, collects state and local data on use to identify emerging trends, and directs marketing campaigns for education and promotion of resources to help quit tobacco use.
- 12. As a result of the loss in the sixth year of funding, on April 21, 2025, RIDOH was forced to terminate funding in nine (9) community contracts
- 13. The impacts include the dissolution of a state-wide tobacco network that coordinated tobacco prevention and control activities among community organizations, individuals, and state agencies. The loss of this funding created a severe reduction in cessation resources and treatment for nicotine and tobacco addiction. It also led to a loss of technical assistance to schools in implementing policies aimed at reducing chronic absenteeism, including programs that offer alternatives to suspension for tobacco-related offenses. Additionally, the loss of funding hindered efforts to reach and educate vulnerable communities on the harms and risks of using tobacco and nicotine, along with efforts to connect them with cessation resources available to help quit. The State is further disadvantaged insofar as Rhode Island is not able to effectively reduce health disparities and improve health equities in the state. Rhode Island is

further prevented from providing essential training in the form of nicotine replacement therapies to individuals in the justice system who are forced to stop using tobacco.

- 14. In addition to the above halt in programming, the lack of expected funding has resulted in in the termination of employees within these community organizations, the absence of a coordinated response to address tobacco industry threats, and the fracturing of long-term partnerships.
- 15. After terminating the above community contracts, on July 15, 2025, the CDC offered RIDOH one-time funding for an additional twelve (12) month period (April 29, 2025 – April 28, 2026) to allow for completion of program activities and extended evaluation of the program. The terms of the offer required that RIDOH complete its application in four (4) business days, and did not indicate the amount of the funding that would be provided.
- 16. RIDOH has unsuccessfully attempted to seek information from CDC personnel about the status of funding. However, RIDOH has learned that efforts have been hampered because there is only one person at the CDC reviewing all 50 states' one-time funding applications and that alternative staff is not available.
- 17. The three-month lapse in the RI State Tobacco Program has resulted in collapse in the community partnerships. Together with the inability to access basic information from CDC personnel, the future of the RI State Tobacco Program is left in a precarious state.

Overdose Data to Action Grant (OD2A)

18. The CDC Overdose Data to Action in States (OD2A-S) cooperative agreement with state health departments track nonfatal and fatal overdoses and emerging threats and support state health departments in preventing non-fatal and fatal overdoses. RIDOH is funded for four program components.

- 19. RIDOH's Drug Overdose Prevention Program educates clinicians on best practices for prescribing and screening for Substance Use Disorder, builds system-wide clinical capacity to support trauma-informed care, enhances the Prescription Drug Monitoring Program's (PDMP) data sharing capacity, implements community-level interventions in high burden areas, leverages partnerships with public safety, expands harm reduction services using peer navigators, and improves linkage to care services in Rhode Island. It does so by providing access to timely data on nonfatal and fatal overdoses to inform prevention strategies in Rhode Island, particularly for groups that are disproportionally impacted by the overdose epidemic. RIDOH uses robust data and surveillance systems to rapidly respond to the increasingly complex nature of the overdose epidemic and to evaluate and improve strategies to address overdose prevention.
- 20. RIDOH receives \$3,453,142 for all four of its programs: prevention (Drug Overdose Prevention Program), surveillance and epidemiology, data linkages (Substance Use Epidemiology Program, SUEP) and biosurveillance (State Health Laboratory, SHL).
- 21. On or around the week of July 7, CDC staff communicated to RIDOH that States should expect a 50% reduction in funding with a possible award at a later date. The CDC staff indicated that there may not be funding for the OD2A program in the future.
- 22. This loss of funding will significantly impede RIDOH's ability to prevent avoidable overdoses in the State of Rhode Island. If these proposed cuts are enacted, the Drug Overdose Prevention Program will need to lay off contracted staff who have twenty (20) years of combined expertise in overdose prevention, terminate community contracts that provide outreach services such as overdose prevention education, basic needs, harm reduction and treatment and recovery support, and reduce staffing levels of eight state employees. Similar reductions would occur within SUEP and SHL, weakening the State's ability to respond to and monitor statewide

drug overdose activity, or implement data driven evidence-based strategies to reduce nonfatal and fatal overdoses.

Conclusion

23. HHS's failure to reinstate staff and expertise and funding to pre-March 27 Directive levels are creating a loss of programmatic support, expertise, resources, data and services which will decimate the work of my agency and will jeopardize the health, safety and welfare of those who live in and visit the State of Rhode Island.

Derome M. Suroma [NAME]

Date: 7 24/25

EXHIBIT 79

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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF RHODE ISLAND

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Defendants.

Case No. 1:25-cv-00196

SUPPLEMENTAL DECLARATION OF KATIE EILERS

- I, Katie Eilers, hereby declare:
- 1. I am over the age of 18, competent to testify as to the matters herein, and make this declaration based on my personal knowledge and the records of the Washington State Department of Health (DOH) to which I have access.
- 2. I previously submitted a declaration in this matter. It is in the docket as ECF No. 44-27. I reincorporate and restate the matter in that declaration.
- 3. With regard to the Pregnancy Risk Assessment Monitoring Systems (PRAMS) program, the Centers for Disease Control (CDC) is continuing to operate with skeletal staff and limited communication on expectations and processes. The CDC has encouraged us to begin data collection for the 2025 birth cohort. Attached to this declaration as Exhibit 1 is a true and correct copy of an email dated May 27, 2025 indicating that Washington "may begin to conduct data collection." The PRAMS Integrated Data System (PIDS) is back online, and Washington completed user testing for the system. Washington has not, however, started 2025 data collection because Washington does not yet have an active Data Sharing Agreement in place with the CDC

#: 17

for sharing data through the PIDS. We have asked Natalie Brown at the CDC for a contact to

discuss the Data Sharing Agreement and have had no reply. Attached to this declaration as

Exhibit 2 is a true and correct copy of an email dated June 12, 2025, requesting technical

assistance to which no reply has been received as of the date of this declaration.

4. With regard to the Early Hearing Detection, Diagnosis, and Intervention (EHDDI)

program, the CDC has not reviewed the application that Washington submitted last March for a

new five-year cooperative agreement. The CDC has offered a one-year cost extension that has

allowed us to apply for continued CDC funding through June 30, 2026. We applied for this

extension at the end of June.

5. Shortly after we submitted our application, we received a technical review

document. Attached to this declaration as Exhibit 3 is a true and correct copy of the technical

review document we received. It notes in several places that certain obligations of the Washington

DOH in connection with the cost extension will not receive the necessary cooperation from the

CDC because the CDC "will not have the capacity" to provide the required cooperation.

6. I declare under penalty of perjury under the laws of the United States of America

that the foregoing is true and correct.

DATED and SIGNED this 18 day of July 2025 at Gig Harbor , Washington.

Katie Eilers

Director of the Office of Family and Community

Health Improvement

K H Cilers

Washington State Department of Health

Exhibit 1

From: Brown, Natalie (CDC/NCCDPHP/OD)

Cc: Raman, Jayalakshmi (Jaya) (CDC/NCCDPHP/OD); Kroelinger, Charlan (CDC/NCCDPHP/DRH); Chandra, Gyan

(CDC/NCCDPHP/DRH)

Subject: PRAMS Update; Data Collection and 2024 Unweighted Data Files

Date: Tuesday, May 27, 2025 11:54:39 AM

Importance: High

External Email

Thank you for the questions related to Year 05 of your award under the Notice of Funding Opportunity Announcement RFA-DP-21-001, Pregnancy Risk Assessment Monitoring System (PRAMS). Your jurisdiction may begin to conduct data collection.

CDC will provide updates on availability of the PIDS system in the near future. Please contact Charlan Kroelinger at dwz8@cdc.gov if you have not received the 2025 questionnaire print files.

Additionally, CDC has uploaded your raw, unweighted 2024 PRAMS data and a data cleaning file with guidance into CDC-SAMS Secure Data Exchange (SDX).

- Please **respond** to confirm that individual(s) receiving the PRAMS 2024 data files that contain direct identifiers of individuals and institutions (*personally identifiable information or PII*) have obtained human subjects training and are covered by your institution's current IRB approval.
- Please contact Gyan Chandra at ylr2@cdc.gov if you have any questions about data transfer using the CDC-SAMS SDX.

CDC will continue to provide additional updates for activities.

Natalie

Natalie Gilles Brown Health Scientist Centers for Disease Control & Prevention Department of Health and Human Services (HHS)

Exhibit 2

From: Skiles, Martha P (DOH)

To: Brown, Natalie (CDC/NCCDPHP/OD)

Subject: RE: DP-21-001, Pregnancy Risk Assessment Monitoring System (PRAMS)

Date: Thursday, June 12, 2025 7:07:48 AM

Attachments: <u>image001.png</u>

Good Morning Natalie,

Thank you for your email, we appreciate as much communication as you can provide during this time.

We have a few follow up questions in Washington and may benefit from a technical assistance call to get into the details.

- We do not have a current Data Sharing Agreement (DSA) between WA and CDC that
 covers data entered in PIDS and shared with the CDC. We will not be able to share
 any data in PIDS without a signed and executed DSA. Previously this DSA was
 signed by Aspy J. Taraporewall as the Business Contact and IT Project Manager.
 Who should we communicate with about a new DSA? This process typically can take
 1-3 months to execute, so the sooner we can move forward with a CDC contact, the
 better
- WA also has a DUA with CDC (signed by Lee Warner) to include WA PRAMS data in the Automated Research File (ARF). Just a note that our DUA with CDC specifies all the variables that WA agrees to include in the ARF. Currently that list only covers data elements from the P8 survey. To add 2023 data (P9), we will need to update that DUA.
- WA received our raw, unweighted 2024 data thank you. My understanding from emails is that CDC will no longer clean or weight our PRAMS data. Will you be modifying our NOA to note that this is now the responsibility of sites?
- Given our anticipated delay to data collection (per DSA requirements), can we redirect some of our CDC funding to focus on 2024 data weighting with a vendor and in-house data analysis and report production?
- Note, we also received the P9.2 questionnaire from Charlan and followed up directly
 with them to request a copy of the CDC IRB approval of the revised questionnaire.
 This is something we need to support our WA IRB review process.

Thank you for your assistance. I look forward to your reply.

Best.

Martha Skiles, WA PRAMS PI

Note: I sometimes work flexible hours, so while it suits me to email now, I don't expect a response or action outside of your own working hours.

Martha Skiles, PhD, MPH (she/her)

Senior Epidemiologist, Data Collection & Reporting Section Office of Family & Community Health Improvements (OFCHI)

Washington State Department of Health

martha.skiles@doh.wa.gov

doh.wa.gov | 360-236-3506 | 360-890-0398 (cell)





From: Brown, Natalie (CDC/NCCDPHP/OD) Sent: Monday, June 9, 2025 7:27 AM

Subject: DP-21-001, Pregnancy Risk Assessment Monitoring System (PRAMS)

External Email

Hello,

CDC is currently working to process awards consistent with internal procedures and policies for DP-21-001, Pregnancy Risk Assessment Monitoring System (PRAMS), Year 05, May 1, 2025 – April 30, 2026. We will provide you an update as soon as we are able.

We ask that you continue to conduct activities under your current award as set out in the NOFO and your Notice of Award. If you believe you need to revise your workplan or budget, please reach out to Natalie Brown (fmc7@cdc.gov) to discuss.

Please note:

CDC will provide your jurisdiction with the OMB approved 2025 PRAMS questionnaire.

CDC will provide additional information on your jurisdiction's user acceptance testing in PIDS so that you may begin data collection.

CDC may schedule a technical assistance call with your jurisdiction to provide additional updates to ensure a full year of data collection.

Thank you,

Natalie

Natalie Gilles Brown Health Scientist Centers for Disease Control & Prevention Department of Health and Human Services (HHS)

Exhibit 3

NOFO CDC-RFA-DD20-2006

Document 84-2

#: 1806

Improving Timely Documentation, Reporting, and Analysis of Diagnostic and Intervention Data through Optimization of EHDI Surveillance Practices and Information Systems

Technical Review

Grant Number: NU50DD000058

Recipient Name: Washington State Department of Health

Program Official: Carlinda Nelson

Period of Performance: July 1, 2025 – June 30, 2026

Requested Funding Amount: \$169,000

Recommended Award Amount: \$169,000

Date of Review: 06/26/2025

Application Recommendation

Recommend Application for funding (Please answer the questions below)

Are there any special conditions for the award, including budgetary restrictions?

☐ Yes \boxtimes No

If yes, please indicate conditions or restrictions in the budgetary and/or recommendations section.

☐ Do Not Recommend Application for funding (Please provide a justification in the "Review of Application" section)

Review of Application: In 2025-2026, programmatic technical assistance from CDC/NCBDDD will be reduced. Specifically, CDC subject matter experts will not be available for routine, day-to-day questions related to the programmatic work of the cooperative agreement and are not expected to support the following as stated in the Notice of Funding Opportunity:

Collaborations

With other CDC programs and CDC-funded organizations:

Recipients are required to collaborate with CDC and other jurisdictional EHDI programs, if applicable, to achieve the outcomes of this NOFO. Recipients should explore improved connections and collaborations with other CDC funded jurisdictional public health programs.

Note: Currently, CDC will not have the capacity to participate in or facilitate collaborations.

CDC Evaluation and Performance Management Strategy

Evaluation and performance measurements help demonstrate achievement of project outcomes; build a stronger practice base for specific project strategies; clarify applicability of the evidence-based interventions to different populations, settings, and contexts; and support continuous program improvement. The EHDI-IS evaluation strategies can be supported by the following resources: EHDI Guidance Manual - Chapter 6: Monitoring and Evaluation, available at: www.cdc.gov/ncbddd/hearingloss/guidancemanual/chapter6.html

the document: Planning an Evaluation of an EHDI Information System available at www.cdc.gov/ncbddd/hearingloss/documents/planning-an-evaluation.pdf and the "Updated Guidelines for Evaluating Public health Surveillance Systems" July 27, 2001/50(RR13); 1-35 available at: www.cdc.gov/mmwr/preview/mmwrhtml/rr5013a1.htm

Over the course of this cooperative agreement, CDC will:

Work individually and collectively with each of the recipients to evaluate its own EHDI-IS assessing the following EHDI –IS system attributes:

- Usability of the audiology reporting module/functions in the EHDI-IS: this evaluation will focus on describing how well users can learn and use the EHDI-IS audiology reporting module to achieve intended goals and how satisfied users are with that process.
- Usefulness of the EHDI-IS: this evaluation will focus on assessing and reporting the level of usefulness of the EHDI-IS by describing: The actions taken to improve EHDI tracking and surveillance as a result of analysis and interpretation of the data.

The entities that have used the data to make decisions and take actions.

The instances of use of EHDI surveillance data leading to improve public health (e.g., making referrals to Part C).

Monitor and assess the processes and outcomes of the project using performance measures. Recipients are required to: 1) Develop project-specific Process Measures in the Work Plan and use them to monitor the progress of proposed activities. Examples of process measures including: 1) Number of new EHDI-IS modules/functions added to generate patient-level data file, number of trainings on diagnostic reporting conducted, number of presentations/manuscripts produced based on analysis findings (including collaborative work), etc. 2) Use the Outcome Measures defined below to assess the degree to which short-term, mid-term, and long-term outcomes for the logic model have been achieved 3) Collect and report process and outcome measurements to CDC at the end of each budget period using the Annual Performance Measurement Report. The format will be specified in post-award guidance.

Note: Currently, CDC will not have the capacity to monitor and evaluate progress.

CDC Monitoring and Accountability approach

Monitoring activities include routine and ongoing communication between CDC and recipients, site visits, and recipient reporting (including work plans, performance, and financial reporting). Consistent with applicable grants regulations and policies, CDC expects the following to be included in post-award monitoring for grants and cooperative agreements:

Tracking recipient progress in achieving the desired outcomes.

- Ensuring the adequacy of recipient systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities deemed necessary to monitor the award:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that recipients are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with recipients on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.
- Monitoring and reporting activities that assist grants management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk recipients.
- The recipient and CDC staff will work collaboratively to assess and monitor progress on strategies and make adjustments as needed to ensure overall program objectives are met.
- Immediate post-award collaboration and monitoring between CDC and the recipient will include at a minimum working to:
- Revise the technical assistance/program implementation plan, as needed
- Revise the evaluation plan, as needed
- Review the work plan timeline to ensure it is feasible based on the budget and consistent with the intent of the award

Monitoring activities will include routine and ongoing communication between CDC and the recipient site via virtual and in-person meetings, conference calls, site visits, and recipient reporting (including work plans, process and outcome performance measures, monthly summary reports, and financial reporting). Consistent with applicable grants regulations and policies, CDC expects the following to be included in post-award monitoring for grants and cooperative agreements:

- Tracking recipient progress in achieving the desired outcomes.
- Ensuring the adequacy of recipient systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities deemed necessary to monitor the award:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the
- Ensuring that recipients are performing at a sufficient level to achieve outcomes within the stated timeframes.
- Working with recipients on revising the work plan based on achievement of outcomes, evaluation results and changing budgets.

- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels. The findings from the performance measure will be used to identify areas of program improvement for broader technical assistance needs.
- Monitoring implementation of Data Access and Management Plans.

Note: Currently, CDC will not have the capacity to monitor program activities beyond financial reporting.

CDC Program support to recipients

CDC staff will be substantially involved beyond site visits and regular performance and financial monitoring during the project period of this cooperative agreement. Substantial involvement means that recipient can expect federal programmatic partnership in carrying out the efforts under the award. The CDC program will work in partnership with the recipient to ensure the success of the cooperative agreement by:

- Supporting recipient in implementing cooperative agreement requirements and advancing program activities to meet outcomes.
- Providing technical assistance to revise annual work plans and budgets. Collaboration on enhancing and expanding outcomes surveillance activities, including the collection, management, analysis, and dissemination of EHDI data. Collaborating with recipient to develop and implement strategies and evaluation plans and use evaluation findings.
- Providing technical assistance to define and operationalize performance measures and implement recipients' performance measurement plans.
- Collaborating on and co authoring scientific reports, white papers, manuscripts, book chapters, and other derivative works arising from data collected and analyzed through this cooperative agreement consistent with CDC policies and procedures.

Note: Currently, CDC will not have the capacity to provide support and technical assistance to recipients in the above outlined activities.

For programmatic questions related to this award, recipients are asked to contact Carlinda Nelson (cjr2@cdc.gov).

Programmatic Budgetary Comments

Note: Programmatic budget restrictions, concerns, and comments should be addressed prior to the award being made. This will take place during the OGS Budget negotiations.

Marked-Up Budget Certification (select one)

This box signifies the Program official's review of the applicant's proposed budget.

☑ I certify that I support the recipient's proposed categorical budget submitted in this application as it
relates to the technical aspects of the project. No changes are required, and no restrictions are
recommended.

 $\hfill \square$ I wish to make changes to the recipient's proposed categorical budget.

• If additional space is needed to justify the <u>recommended</u> funding amount, please use this space below to provide detailed comments for the recipient:

EXHIBIT 80

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF RHODE ISLAND

STATE OF NEW YORK, et al.

Plaintiffs,

V.

ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

Case No. 1:25-cv-00196

DECLARATION OF YOLANDA JACOBS

- I, Yolanda Jacobs, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:
- I am the President of the American Federation of Government Employees
 (AFGE) Local 2883. I am familiar with the information in the statements set forth below either through personal knowledge, consultation with the staff and members of AFGE Local 2883, or documents that have been provided to and reviewed by me.
- 2. I submit this Declaration in support of the Plaintiff States' Opposition to Defendants' Motion to Modify the Injunction.
- 3. I am a disabled veteran of the U.S. Army and have been deployed around the world. I am a registered neutral in the state of Georgia and a trained EEO specialist. In December 2021, I joined Local 2883 as a union steward. I have been president of Local 2883 since July 2024.
- 4. I am a Health Communications Specialist in the Office of the Chief of Staff for the Centers for Disease Control and Prevention ("CDC"). I have worked for the CDC since 2004,

first as a contractor and then as a full-time employee beginning in 2008. I have a bachelor's degree in Sociology and have held numerous positions throughout the CDC, including as a Technical Writer/Editor.

- 5. AFGE Local 2883 represents over 2,000 employees at the Centers for Disease Control and Prevention (CDC), including many who received reduction in force (RIF) notices on April 1, 2025. Our mission is to advocate for fair working conditions, better benefits, and a supportive work environment. While many of our members are based at CDC headquarters in Georgia, we represent CDC employees located across the United States.
- 6. On April 1, 2025, approximately 2,674 CDC employees received RIF notices, with approximately 635 of those being our current members.
- 7. Of those RIF notices, it was evident to us that some of them had been issued in error. For example, some people received RIF notices that indicated that they worked in a different competitive area than the one where they actually worked. While their actual competitive area was not subject to RIFs, the competitive area listed (erroneously) on their RIF notices was subject to mass RIFs. I have notified the authorities of over a dozen of these erroneous termination notices since and following the April 1, 2025, notices that were distributed by email, but most of those errant termination notices have not been rescinded.
- 8. Beginning on or around June 10, 2025, CDC reinstated approximately 467 employees, by which I mean that employees were moved from administrative leave status to active-duty status. We have compiled this estimate based on reports from our members and public reporting. CDC has not been transparent and has not publicly confirmed these reinstatements, making our work very difficult.

- 9. Some employees who returned to active-duty status were able to return to performing the same work that they did prior to April 1. However, I also know of many employees who have not returned to performing the same work that they did prior to April 1. For instance, the Division of HIV Prevention (DHP) has directed workers to "reorient" toward shutting themselves down. Workers in that division were told that there was most likely no role for their work in the new "Administration for a Healthy America." They have not been allowed to work on new projects, but instead, are tasked with closing down programs. Furthermore, some of DHP's work was transferred to other parts of the National Center for HIV, Viral Hepatitis, STD, and Tuberculosis Prevention after the April 1 RIF. For example, HIV Nexus (https://www.cdc.gov/hivnexus/hcp/index.html), which provided information and resources for clinicians regarding HIV testing, prevention, and treatment, is now managed by the Center's Division of Viral Hepatitis. I also know of workers who have been transferred to work on matters unrelated to what they did prior to April 1.
- approximately 1,874 CDC employees in total have not been reinstated. These employees remain on administrative leave. Again, due to lack of transparency and no public confirmation of the number of reinstatements from HHS, it has been very difficult to track the exact number of our CDC employees and members that remain on administrative leave.

Yolanda Jacobs

Date: 7/23/2025

EXHIBIT 81

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF RHODE ISLAND

Document 84-4

STATE OF NEW YORK, et al.

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

Case No. 1:25-cv-196

SUPPLEMENTAL DECLARATION OF KRISTIN J. CUMMINGS, MD, MPH, ATSF

- I, Kristin J. Cummings, MD, MPH, ATSF, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:
- 1. Since December 2022, I have served at the California Department of Public Health (CDPH) as Public Health Medical Administrator and Branch Chief of the Occupational Health Branch (OHB). I have personal knowledge of the facts set forth in this declaration, and if required to testify, would and could competently do so.
- 2. In May 2025, I submitted a Declaration in support of the States' Motion for Preliminary Injunction. The Declaration, ECF No. 44-52, summarizes my professional and educational background, describes the mission and work of CDPH and OHB, and explains the many ways that CDPH has depended on the National Institute for Occupational Safety and Health (NIOSH) to help CDPH fulfill its mandates.
- 3. I submit this supplemental Declaration in support of the States' Opposition to the defendants' Motion to Modify the Preliminary Injunction.

Ongoing Adverse Impacts to CDPH

- 4. CDPH continues to experience negative impacts as a result of the massive reduction in force (RIF) and dismantling of NIOSH. In particular, OHB has not been able to benefit from the valuable expertise and support of many NIOSH employees because more than 70% of NIOSH employees are still on administrative leave. Unless those employees are reinstated, the RIF will perpetuate significant negative impacts across CDPH.
- 5. Because many NIOSH staff remain on administrative leave, CDPH is not receiving essential expertise from those employees. The NIOSH staff who remain on administrative leave include health surveillance experts in Cincinnati, Ohio in the Health Informatics Branch who coordinate multi-state tracking of workplace injuries and illnesses. In addition, we previously received expert input for our evaluations of traumatic fatalities among workers in California from the Fatality Assessment and Control Evaluation (FACE) Program in the Division of Safety Research in Morgantown, West Virginia; it is my understanding that program is no longer staffed. As a result, we have no partners at NIOSH who collect national data on lead poisoning, pesticide poisoning, or traumatic fatalities. Therefore, although we now have funding to conduct health surveillance and investigations, we lack expert scientific input from NIOSH that is critical to the success of our programs.
- 6. The Health Informatics Branch was also responsible for the NIOSH Industry and Occupation Computerized Coding System that CDPH relies on to identify and support worker populations at risk of injury or illness. The Branch's system helps our office update our occupational disease registries, including our analysis of death registries, workers' compensation claims, and pesticide illnesses. Through the system, OHB can determine at-risk occupational groups and then design education and outreach for employers and workers to promote

prevention. The absence of the Branch's employees means that employees are unavailable to share their valuable input when we have questions. Given that this is a software system, there is also a concern that there are no employees maintaining the system and ensuring its effective functioning over time.

- 7. Moreover, due to the RIF, NIOSH staff for the Western States Division in Spokane, Washington remain on administrative leave. Normally, those staff would support California and other western states by focusing on research and outreach related to industries and occupations that are predominant in the West, including wildland firefighting and cannabis production and distribution. Additionally, every September, the Western States Division convenes a meeting of occupational public health professionals to share important projects and findings. This year, NIOSH is not organizing that meeting, depriving CDPH of the latest developments in occupational health issues relevant to western states, including heat illness, wildfire smoke, avian influenza, and other urgent issues.
- 8. NIOSH staff in the Division of Field Studies and Engineering in Cincinnati, Ohio who evaluate ventilation and other engineering controls are also on administrative leave. Without their active employment, CDPH does not have access to their expertise. For example, CDPH relies on those NIOSH staff to help us understand how to control exposures to toxic chemicals in industrial settings.
- 9. Many important NIOSH-led projects have been halted because the staff from the Health Effects Laboratory Division in Morgantown, West Virginia are on administrative leave. Laboratories have been decommissioned, and the animals that were required for the projects have been re-housed or euthanized. This Division conducted cutting-edge research that CDPH relied on to inform our preventive activities. For instance, the Division was performing a

toxicological assessment of emissions from fabricating engineered stone countertops; a study of an organosilane coating to block silica-induced lung toxicity; and another study characterizing regulation of gene expression in pulmonary fibrosis from mixed silica dusts. These studies are directly relevant to the ongoing epidemic of silicosis related to countertop fabrication in California, and the results could have supported efforts to protect workers at risk here. Until the Division's employees are reinstated, those important research projects will not proceed.

- 10. Although a small percentage of NIOSH staff have been reinstated, they are unable to effectively complete some of their job functions because they depend on colleagues who remain on administrative leave. For example, reinstated staff working for the Health Hazard Evaluation Program are limited in their ability to respond to requests because they relied on the Health Effects Laboratory Division for laboratory analyses and on the Division of Field Studies and Engineering for ventilation and engineering control experts who are on administrative leave. Consequently, we cannot rely on the Health Hazard Evaluation program to provide expert evaluations and technical assistance as we did in the past. This is a serious loss. Prior to the RIF, we relied on and collaborated with the Health Hazard Evaluation Program to understand new and emerging exposure and health issues affecting California workers. NIOSH's ability to collect new data to answer specific questions is critical to protecting workers' health. CDPH cannot answer these questions adequately using existing information.
- 11. It is my understanding and belief that due to the RIF and dismantling of NIOSH, the notification process for NIOSH's grant awards has been very delayed. Because nearly all the staff in the NIOSH Office of Extramural Coordination and Special Programs are on administrative leave, there are not enough employees to timely manage grant award notifications for all extramural program grantees in the country. In fact, I understand that there are only three

employees currently working in the Office of Extramural Coordination and Special Programs, whereas prior to the RIF, there were at least 20. Since 1987, California has received funding (approximately \$700,000 annually in recent years) from NIOSH for occupational health surveillance through a competitive application process. In addition, since 2021, California has received funding (approximately \$80,000 annually) from NIOSH for a project on silicosis related to artificial stone (quartz) countertop fabrication, also through a competitive application process. These awards support the salaries of staff from a non-profit organization who are assigned to CDPH as contractors and work alongside state employees. The final year of the current agreement for the health surveillance funding was to begin on July 1, 2025, and the final year of the agreement for the silicosis funding was to begin on September 1, 2025. Normally, we receive informal communications about our grant awards months before the start date and the official notice of award days to weeks before the start date; these communications are essential for project planning and contractor staffing. However, since the RIF occurred, communication from NIOSH has been extremely limited, and for months it has been unclear whether we would receive the awards at all. We did not receive any communication from NIOSH until mid-June 2025, at which time we were informed that official notification would be delayed. We received official notification of the health surveillance funding on July 8, 2025; we have not yet received official notification of the silicosis funding. The lack of communication and delayed notifications have been extremely disruptive.

12. Furthermore, we are very concerned about future funding opportunities.

Competing for funding involves a lengthy application process and multiple levels of review, among other time-intensive tasks. The new funding application process is overseen by the staff from the NIOSH Office of Extramural Coordination and Special Programs. These NIOSH staff

conduct activities that may include writing the announcement, answering questions from applicants about the process, receiving applications, conducting preliminary reviews of proposals for completeness, establishing a panel of subject matter experts to conduct in-depth review and scoring of proposals, confirming institutional review board approval for human subjects research, and communicating funding decisions and next steps to applicants. Under normal circumstances, a call for proposals for new NIOSH funding would be posted by these NIOSH staff more than a year in advance of the funding start date; that has not happened. This is evident from Grants.gov, which is an E-Government initiative operating under the governance of the Office of Management and Budget and managed by the Department of Health and Human Services. For example, currently this site (https://www.grants.gov/search-results-detail/357417) lists a "Grant Opportunity Forecast" for "State Occupational Safety and Health Surveillance Program (U60)," the program through which California has received health surveillance funding since 1987. The forecast states that the estimated post date is May 30, 2025, the estimated application due date is September 30, 2025, the estimated award date is June 1, 2026, and the estimated project start date is July 1, 2026. There is an "Apply" button at the top of the page, but it is grayed out. The grant opportunity has not yet been posted nearly two months after the expected date, and it is not currently possible to apply to this opportunity. Thus, it is unclear when this grant opportunity will be posted or if there will be sufficient time to complete the application process in time for a July 1, 2026 start date. Without a full team of NIOSH Office of Extramural Coordination and Special Programs staff available to manage the new funding applications process, we are concerned that the new funding process will be substantially delayed or halted altogether, which would negatively impact OHB's ability to promote safe and healthy workplaces through health surveillance and prevention activities.

- 13. The bottom line is that although some staff have been reinstated, the RIF continues to negatively impact programs and stakeholders across California. Prior to the RIF, NIOSH's Divisions did not function independently, each a separate unit unto itself. Instead, they worked collaboratively, relying on unique expertise across the Institute to conduct research and provide service to the states. Without the full complement of experts and support staff, NIOSH is unable to adequately carry out its functions.
- 14. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

EXECUTED on July 24, 2025 in Richmond, California.

Kristin J. Cummings, MD, MPH, ATSF Branch Chief, Occupational Health Branch California Department of Public Health

STATE OF NEW YORK, et al.

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

Case No. 1:25-cv-00196

SECOND SUPPLEMENTAL DECLARATION OF JOHN DOE 2

I, John Doe 2, an employee at the National Institute for Occupational Safety and Health (NIOSH), declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

- 1. I am over the age of 18 and have personal knowledge of all the facts stated herein through personal experience, through conversations with my colleagues, and through review of the records to which I have access.
- 2. I submit this Second Supplemental Declaration and as a continuation of the two Declarations I have already submitted in this case. I am doing so anonymously, and withholding certain identifying details, because I am still employed by the Federal Government and fear retaliation for my participation in this lawsuit.
- 3. Following this Court's Order Granting Plaintiffs' Motion for Preliminary Injunction on July 1, 2025, to my knowledge, there have been no further reinstatements or restorations of any staff at NIOSH, including both the Spokane and Pittsburgh Mining Research Divisions. The Spokane Mining Research Division (SMRD), for instance, remains woefully

understaffed, with only three Public Health Service workers and its Director working full time, though the Director has not been taken off administrative leave. Most of the remaining employees are currently working less than 10% of the time, not conducting any research, though have been allowed to respond to some select requests for technical assistance.

- 4. Moreover, it remains my understanding that no employee in NIOSH's Western States Division (WSD), also housed in Spokane, have yet received RIF rescissions. Only WSD's Director remains in active employment with NIOSH, and their teams have, to my knowledge, not been able to conduct any of their region-focused work since their employees were RIFed.
- 5. Outside of SMRD, with the majority of its employees subject to a RIF and still on administrative leave (and thus unable to work), NIOSH remains severely hindered in its ability to fulfill its statutory missions without the entire staff being fully reinstated. For example, to my knowledge, the staff in NIOSH's intramural programs, including the Spokane Mining Research Division, the Western States Division, and the teams responsible for the update of the NIOSH Pocket Guide to Chemical Hazards and the NIOSH Manual of Analytic Methods (among others) that were laid off have not been restored. Those programs that have been restored are severely limited in their ability to conduct their research and service work because employees in critical support offices in other parts of NIOSH and the Centers for Disease Control and Prevention were also laid off.
- 6. I am still unaware of any transition plan to transfer the duties performed across NIOSH to anywhere else in the government, and to my knowledge, no such organization exists with the requisite knowledge and expertise to take this work over. I believe NIOSH's broader research and service capabilities to protect the health and safety of American workers remain crippled absent full reinstatement.

7. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

JOHN DOE 2 JOHN DOE 2, NIOSH EMPLOYEE Spokane, Washington

Date: July 23, 2025

Document 84-6

STATE OF NEW YORK, et al.

Plaintiffs,

V.

ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

Case No. 1:25-cv-00196

SUPPLEMENTAL DECLARATION OF JANE DOE 4

I, Jane Doe 4, hereby declare:

- 1. I am over the age of 18, competent to testify as to the matters herein, and make this declaration based on my personal knowledge of the Office on Smoking and Health (OSH), part of the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) within the Centers for Disease Control and Prevention (CDC).
- 2. I previously submitted a declaration in this matter. It is in the docket as ECF No. 55-5. I reincorporate and restate the matter in that declaration.
- 3. I am submitting this declaration pseudonymously because I fear retaliation. But if the Court would like to know my name or job position, I would be willing to provide it ex parte and under seal.
- 4. To date, no one has been reinstated at OSH. If unaddressed, this will lead to many problems.

- 5. First, on Wednesday, July 16, CDC asked states to submit their National Tobacco Control Program continuation application by Monday, July 21—giving states just three business days to apply for continued funding and technical support for state tobacco control programs. Additionally, state program managers remain unavailable to process and approve the submissions, so there is no reason to expect the applications will be approved and submitted on time. CDC does not have any tobacco experts on staff to work on OSH's programmatic portfolio, determine whether the activities planned by awardees are allowable, or provide technical assistance on program delivery.
- 6. Second, the Department of Health and Human Services have begun transitioning the management of the contract for the National Youth Tobacco Survey (NYTS), which had been run by experts within OSH for years, to the U.S. Food & Drug Administration (FDA). Although FDA maintains data analysts who may be capable of analyzing the 2025 survey, it is unclear whether the FDA will be able to issue a contract in time to field a 2026 survey.
- 7. The State Tobacco Activities Tracking and Evaluation (STATE) System, which presents data used to assess tobacco prevention and control activities and tobacco cessation policies in states as well as serves as a national clearinghouse information source and resource for the public, is typically updated quarterly, but has not been updated since September 2024.
- 8. The Media Campaign Resource Center, which provides free and low-cost tobacco education campaign materials, is still "unable to process orders at this time." A true and correct copy of the Media Campaign Resource Center website is attached hereto as Exhibit A. Media Campaign Resource Center, U.S. Ctrs. for Disease Control and Prevention, https://nccd.cdc.gov/MCRC/Index.aspx (last visited July 23, 2025).

9. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

DATED and SIGNED this 24 day of July 2025 at Atlanta, GA

Jane Doe 4

Office on Smoking and Health

National Center for Chronic Disease Prevention and Health

Promotion

Centers for Disease Control and Prevention

Exhibit A







We are currently unable to process orders at this time.



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https://nccd.cdc.gov/MCRC/Index.aspx

Document 84-7

STATE OF NEW YORK, et al.

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

Case No. 1:25-cv-00196

SUPPLEMENTAL DECLARATION OF JOHN DOE 7

- I, John Doe 7, hereby declare:
- 1. I am over the age of 18, competent to testify as to the matters herein, and make this declaration based on my personal knowledge and the records of the Center for Tobacco Products (CTP), within the U.S. Food Drug & Administration (FDA), to which I have access.
- 2. I previously submitted a declaration in this matter. It is in the docket as ECF No. 55-8. I reincorporate and restate the matter in that declaration.
- 3. I am submitting this declaration pseudonymously because I fear retaliation. But if the Court would like to know my name or job position, I would be willing to provide it ex parte and under seal.
- Since my declaration dated May 19, 2025, some staff at CTP in the Office of 4. Regulations, Office of Compliance and Enforcement, Office of Management, and Office of Health Communication were reinstated, by which I mean they were returned to active status and their initial RIF notices were rescinded.

- 5. Roughly 130 staff at CTP have not had their initial RIF notice rescinded since the
- July 1, 2025 Preliminary Injunction and remain on administrative leave or on active status

pending final separation. This includes the Division of Human Capital, Acquisition and

Assistance staff, Information and Technology (IT) staff, Management and Logistics staff,

Management Analysis Team, Division of Public Health Education, and Division of External

Programs and Resource Management.

6. At least two groups that have been reinstated, the Division of Financial

Management and the Freedom of Information Act (FOIA) group, were moved out of CTP

involuntarily on a "temporary" detail to perform work reporting to non-CTP personnel within

FDA. Employees from the Division of Financial Management have been involuntarily detailed to

perform some non-tobacco budget execution work for the FDA's Center for Devices and

Radiological Health (CDRH), which was previously funded by medical device user fees. Their

work detail is currently categorized as "non-reimbursable" wherein their salary will not be

reimbursed by other funding sources despite performing work required to be funded by those

sources. Rather, their salaries and benefits are still paid for out of CTP's budget, which is funded

by tobacco user fees.

7. I declare under penalty of perjury under the laws of the United States of America

that the foregoing is true and correct.

DATED and SIGNED this 24th day of July 2025 at 7:53 A.M.

John Doe 7

Center for Tobacco Products

Food & Drug Administration

STATE OF NEW YORK, et al.

Plaintiffs,

V.

ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

Case No. 1:25-cv-00196

DECLARATION OF JANE DOE 8

I, Jane Doe 8, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

- 1. I am employed by the Division of Reproductive Health (DRH), within the National Center for Chronic Diseases Prevention and Health Promotion (NCCDPHP), within CDC. I have been on administrative leave status since April 1, 2025. I am over the age of 18, competent to testify as to the matters herein, and make this declaration based on my personal knowledge.
- 2. I am submitting this declaration pseudonymously because I fear retaliation. But if the Court would like to know my name or job position, I would be willing to provide it ex parte and under seal.
- 3. I am providing this declaration to explain the impacts of the reductions in force (RIFs) of April 1, 2025, on the operations of DRH since the court in this case entered its injunction on July 1, 2025.

4. I submit this Declaration in support of the Plaintiff States' Opposition to Defendants' Motion to Modify the Preliminary Injunction.

Professional Background

5. I have worked in public health for over 20 years, all of which were at CDC, and over 10 of those years were in DRH. Prior to joining DRH, I worked in violence prevention, infectious disease epidemiology, and environmental health at other Centers within CDC. At DRH, I participated in technical assistance to state grantees and managing surveillance methodology.

Status of Employees Affected by the RIFs and Reorganizations

- 6. The April 1 RIFs stalled much of DRH's work which previously included public health surveillance activities on maternal and infant health outcomes, in vitro fertilization (IVF) tracking, abortion surveillance, and contraception safety guidelines. Nor will DRH be able to continue its field work to provide direct assistance to states through assignment of senior maternal and child health epidemiologists, or capacity building to address the needs of reproductive-aged, pregnant, and postpartum women and their infants for an emergency response, such as a pandemic or natural disaster.
- 7. Since the July 1, 2025, Preliminary Injunction, none of the roughly 76 RIF'd employees at DRH have been reinstated and some reorganization efforts continue to progress.
- 8. These RIF'd employees are not easily replaced—many have decades of experience in reproductive health and are highly qualified experts. RIF'd employees include epidemiologists, health scientists, physicians, public health advisors, public health analysts, health communication specialists, mathematical statisticians, social scientists,

and administrative support staff. It would likely take years to find and hire replacements for the individuals.

DRH, Office of the Director

- 9. All employees of DRH, Office of the Director (DRH OD), are on administrative leave and are, therefore, unavailable to manage either DRH branches or the many teams and offices within those branches. The DRH OD plays a pivotal role in supporting states to advance optimal reproductive, maternal, and infant health. DRH OD establishes the strategic vision for research, programs, and surveillance systems, ensuring CDC's efforts address critical gaps in the field through collaboration with state, federal, and non-federal partners.
- 10. DRH OD provides direct support to states through developing guidance for campaigns like "Hear Her" to reduce maternal mortality, facilitating technical assistance and training through national partners, and building stillbirth surveillance capabilities. Furthermore, DRH OD provides essential scientific and operational leadership, managing human subjects research, data agreements, IT needs, economic analyses, and ensuring the scientific integrity of all products used by states.
- 11. The office also assesses the impact of divisional activities through evaluations, reports state success stories, and broadly disseminates scientific information to ensure states have access to the latest data-driven guidance. Crucially, DRH OD manages the budget and develops funding opportunities, directly supporting state maternal and child health programs. Without DRH OD, states would face significant challenges in accessing vital messages, guidance, data, and funding necessary to sustain and advance their critical work in maternal and infant health.

DRH, Women's Health and Fertility Branch

12. The Women's Health and Fertility Branch employed 36 people as of April 1 and, currently, all of them remain on administrative leave and unavailable for work. This Branch oversaw the Fertility Epidemiology Studies team, which conducts research on the relationship between contraception and medical conditions including chronic and infectious diseases and develops, evaluates, and disseminates recommendations and guidelines for reproductive and contraceptive health practice. Currently, this team has stopped its efforts to survey contraception safety and contraception guidelines.

Document 84-8

- 13. The Branch also oversaw the Assisted Reproductive Technology (ART) team and its statutorily-mandated responsibilities to collect data and publish annual reports on national and state-level use, safety, and effectiveness of assisted reproductive technologies including IVF, gestational carrier, and oocyte and embryo banking cycles. For decades, the ART team oversaw the ART Surveillance System (NASS) which recorded ART cycles in the U.S. since 1992 and maintained catalogs of sensitive data on patients undergoing ART and children born after ART.
- 14. While contractors should continue to collect data through December 31, 2025, there is no available ART staff to supervise collection, standardize data collection practices, or to verify data accuracy. Nor will there be any ART staff to turn that data into annual reports which have previously provided states and researchers comprehensive, unbiased information on ART performed in the U.S.
- 15. Further, since all ART team members were RIF'd on April 1, 2025, and remain on administrative leave, no one is available to continue preserving and protecting the

- sensitive ART data the contractors collect, or to ensure the data already collected is properly stored consistent with security protocols.
- 16. Infertility affects millions of Americans and the elimination of this team has devastating consequences for all people who rely on this information to make thoughtful decisions and safely grow their families.
- 17. Aside from the ART team, the Women's Health and Fertility Branch also oversaw the Pregnancy Risk Assessment Monitoring System (PRAMS) team. PRAMS is a survey of those who recently gave birth, which seeks to learn about their behaviors and experiences before, during, and after pregnancy. Topics include preconception, prenatal and postpartum care, maternal tobacco/alcohol/substance use, intimate partner violence, contraception, economic status, maternal stressors, early infant development and health status, mental and physical health, breastfeeding, housing, occupational status and workplace leave, safe sleep practices, health insurance, vaccines, food/housing insecurities, and social determinants of health. The team was responsible for developing and implementing PRAMS survey through coordination and continuous monitoring of data collection across fifty jurisdictions to ensure proper and timely completion and delivery of data to states and external researchers; offered system support to the fifty PRAMS grantees to ensure standardized data collection, monitored adherence to human subjects protections and other ethical standards, data collection protocols and data privacy/security; managed the PRAMS data collection system (PIDS) making it available for grantee use; and cleaned and weighed data for the states to use, package, and share to the public.

- 18. The entire PRAMS team was RIF'd in early April and, today, all members remain on administrative leave, stopping and hobbling PRAMS team efforts to collect the data that would be used in the annual report for 2025 and beyond. This lack of support and oversight presents significant challenges for state grantees who now have to self-coordinate data collection activities, likely leading to fragmented and inconsistent data collection that cannot be combined into a national dataset. Because of a lack of oversight and support, 43 of 50 jurisdictions began 2025 birth cohort data collection in July—a three-month delay—and operated without any support or oversight from CDC. Ultimately, due to the absence of CDC PRAMS staff to coordinate and assist, 2025 data collection efforts lack standardization, making cross-state data comparisons impossible. States also faced two imminent risks of shutdown as the result of the RIFs: PRAMS staff may not be reinstated in time to analyze the collected data, and there may be no PRAMS staff to renew essential IRB and secure OMB approvals by the end of March 2026. Either risk jeopardized the entire 2025 report and is enough to drive down participation. The initial three-month delay, combined with the risk of early termination and anticipated lower survey responses due to these disruptions, and the absence of CDC PRAMS staff to coordinate and assist in standardized data collection, all cast serious doubt on the usability and reliability of the 2025 data.
- 19. CDC's surveillance support staff for the 50 PRAMS grantees has plummeted, with oversight now consolidated from 18 staff members to a single individual outside of WHFB who has never worked on PRAMS before this year.
- 20. States received 2024 raw, unusable PRAMS data and have no funding to secure another consultant to weigh the data. Without 2024 (and 2025) PRAMS weighted (useable) data,

Page 8 of 10 PageID

states are uncertain how they will be able to fill the Maternal and Child Health (MCH) data infrastructure gap in their state as PRAMS data are used to support Title V and other grant funding, needs assessments, program development and evaluation, and inform policy. For most states, PRAMS is the only statewide source of data for countless MCH data (e.g., maternal mental health, intimate partner violence, infant safe sleep, social determinants of health) that are absolutely critical for measuring risks and outcomes for mothers and babies to ensure healthy outcomes.

21. The elimination of CDC PRAMS staff members has also resulted in the loss of a crucial national dataset, the PRAMS Automated Research File (formerly PRAMS Analytic Data File), that has been used by the U.S, dating back to 1988. This burden now falls entirely on individual states, which are already inundated with requests from external researchers for this data. States do not have the capacity to produce these Automated Research File data files.

DRH, Field Support Branch

- 22. Separate from the Women's Health and Fertility Branch, DRH oversaw the Field Support Branch which provided direct support and technical assistance to state and local health departments through its teams. All full-time employees within the Field Support Branch were RIF'd on April 1 and remain on administrative leave, today. The only remaining employees, non-civilians Commissioned Corp, have been reassigned out of the Branch.
- 23. All employees of the Field Support Branch, Office of the Chief, were RIF'd and remain on administrative leave creating a void of leadership throughout the branch.
- 24. The Field Support Branch oversaw two teams that provided direct support and technical assistance to state and local health departments: the Maternal and Child Health

- Epidemiology (MCHEP) Team, and the Emergency Preparedness and Response (EPR) Team. A third team, the Global Reproductive Evidence for Action Team, improves global maternal and infant health by strengthening the evidence base and public health capacity.
- 25. The MCHEP Team has provided direct assistance to states since 1986 through the assignment of CDC maternal and child health epidemiologists as field assignees. These experienced epidemiologists serve in states across the country by analyzing public health data, advising leadership on applying evidence to programs, providing subject matter expertise, overseeing scientific projects, training other epidemiologists, improving quality and use of data systems, and evaluating public health programs. Field assignees are requested by states, who fund 80% of the salary and benefits for their field assignee, with the other 20% funded by CDC. There were 11 field assignees whose positions were terminated on April 1. State and local capacity to optimize maternal and child health in their jurisdictions will be reduced, including complicating efforts in these jurisdictions to collect, analyze, and publish PRAMS data.
- 26. The EPR Team worked with other federal agencies, state and local jurisdictions, and clinical professional associations to protect the health of maternal and infant populations during public health emergencies. The EPR Team contributed to national diagnostic and treatment guidance and prevention recommendations in the context of new diseases such as Zika Virus and COVID-19, and conducted critical epidemiological studies to determine how these diseases specifically affect pregnant women and infants, as well as measure the effectiveness of preventive measures (such as vaccines) and treatment options. CDC is currently responding to outbreaks of the viral diseases dengue, oropouche, and measles, all of which have specific implications for pregnant women,

breastfeeding women, and/or pregnancy outcomes. These responses are occurring without the specialized expertise of EPR Team epidemiologists and physicians, and with the team's trusted partnerships with clinical and public health organizations and maternal and child health preparedness partners, and vast knowledge, tools, and resources honed over 10 years of emergency response experience. Since 2018 the EPR Team has collaborated with public health and maternal and child health organizations such as the National County and City Health Officials (NACCHO) and the Association of Maternal and Child Health Programs (AMCHP) on maternal and infant health capacity-building programs for state and local jurisdictions. With the elimination of most of DRH, these impactful programs will not continue past September 30, 2025. In addition, the EPR Team had critical collaborations with FEMA and U.S. Census Bureau teams to obtain data on the impact of disasters on pregnant, postpartum, and lactating women. At a time when the severity of weather-related emergencies such as extreme heat, wildfires, and Atlantic hurricanes is increasing, cutting the EPR Team and eliminating funding for state capacity-building projects could lead to reduced planning for maternal and infant health, impacting access to critical services during emergencies like prenatal care and infant feeding support.

27. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

DATED and SIGNED this 24 day of July 2025 at 3:25 pm.

Division of Reproductive Health

Centers for Disease Control and Prevention

Document 84-9

STATE OF NEW YORK, et al.

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

Case No. 1:25-cv-00196

DECLARATION OF KRISTEN GOOD

- I, Kristen Good, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:
- 1. I am a resident of the State of Colorado. I am over the age of 18 and have personal knowledge of all the facts stated herein, except to those matters stated upon information and belief; as to those matters, I believe them to be true. If called as a witness, I could and would testify competently to the matters set forth below.
- 2. I am currently employed by the Colorado Department of Public Health and Environment (CDPHE) as the Health Equity Branch Deputy Chief, within the Disease Control and Public Health Response Division...
- 3. As the Health Equity Branch Deputy Chief, I oversee several programs and initiatives within our branch, one of which is the Occupational Health & Industrial Hygiene Program. I also maintain subject matter expertise in Occupational Health and Safety and serve as the division's primary technical expert in Occupational Health.

- CDPHE works in conjunction with the National Institute for Occupational Safety 4. and Health (NIOSH) within the Centers for Disease Control (CDC). NIOSH operates a Western States Division that provides support to the states west of the Mississippi, including Alaska and Hawaii.
- 5. CDPHE traditionally relied on NIOSH and the Western States Division for essential occupational health programs and education, outreach, and research support, particularly in high-risk industries such as oil & gas and wildland firefighting. NIOSH also provides technical guidance and best-practice reports and resources for safety for workers who do cleanup after a wildland fire. They have significantly contributed to firefighter safety through programs like the Wildland Firefighting Safety and Health Program, which identifies and mitigates on-the-job hazards. They've also conducted long-term studies, such as the Wildland Firefighter Exposure and Health Effects Study, to understand the impact of hazards on long-term firefighter health. Their operation of the National Firefighter Registry for Cancer, a crucial program for researching cancer risk among firefighters, has been helpful for CDPHE as it does important work related to establishing the connections between on-the-job exposures and health risks among firefighters, which CDPHE can then use to inform our public health outreach.
- 6. CDPHE does not have a comprehensive internal occupational health program. That program is limited to two individuals: along with myself, we have one medical epidemiologist with specialized training in occupational health located in the CDPHE's Communicable Disease Branch. These two individuals provide limited occupational health support during incidents. This support often includes triaging public inquiries by redirecting the public to other agencies or resources.

- 7. As a result of this limited internal occupational health program, CDPHE has long relied on its partnership with the Western States Division to meet statewide needs when CDPHE's program needs additional assistance.
- 8. Due to recent layoffs within the CDC, however, the Western States Division has been effectively dismantled. As of the date of this declaration, and based on information and belief, only one staff member remains within the Division. This means that only one staff member is available to provide occupational health expertise and support to the entire western half of the United States.
- 9. This lack of staffing will severely limit crucial expertise and support available to CDPHE. This will impact CDPHE's ability to provide occupational health support during public health incidents. For example, in 2024 we used NIOSH's webpages and resources around avian flu and workers extensively with the H5N1 outbreaks. We followed NIOSH's extensive best practices for protecting poultry and dairy farm workers from avian flu, including their extensive instructions on how to enact engineering controls, administrative controls, and PPE protocols to reduce exposures in the workplace. We also distributed training materials, infographic flyers, and other educational/outreach materials designed by NIOSH, sharing them directly with impacted workers and farm managers. Without these resources, we would not have been able to deploy a rapid, high-quality response to support impacted Coloradan farmworkers, as we lacked the capacity and subject matter expertise to quickly produce this types of guidance and educational/outreach materials ourselves.
- 10. Moreover, CDPHE anticipated receiving federal funding for fiscal years 2026-2031 through NOISH's State Surveillance Program. The application process for this program

was originally scheduled to open in May 2025. CDPHE anticipated applying for and receiving these federal grant funds.

11. But to my knowledge, the process has not moved forward due to layoffs within NOISH. This lack of funding will limit CDPHE's ability to provide comprehensive occupational health services moving forward.

Executed on July 24, 2025, at Denver, Colorado.

Kristen Good Digitally signed by Kristen Good Date: 2025.07.24 11:52:47 -06'00'

Kristen Good

#: 1853

Document 84-10

STATE OF NEW YORK, et al.

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

Case No. 1:25-cv-00196-MRD-PAS

SUPPLEMENTAL DECLARATION OF ELI ROSENBERG

- 1. I, Eli S. Rosenberg, PhD, am the Director of the Office of Science at the New York State Department of Health (NYSDOH). I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with NYSDOH staff, or from documents that have been provided to and reviewed by me.
- 2. I submit this Declaration in support of Plaintiffs' Opposition to Defendants' Motion to Clarify and Modify the Preliminary Injunction Order. ECF No. 75.
- 3. This Declaration supplements the Declaration signed by me dated May 8, 2025, and filed in this action. ECF No. 44-25; exhibits attached to ECF No. 55-10. I reincorporate and restate the matter in those declarations, and provide updated information regarding the Pregnancy Risk Assessment Monitoring System (PRAMS).
- 4. Since April 2025, NYSDOH still has received only limited communication with the Centers for Disease Control and Prevention (CDC) regarding data and operations. Instead of coming from a CDC PRAMS project officer, as had been the prior precedent, communication

that began on April 16, 2025, has come from a new CDC contact whose relationship to the PRAMS program is unclear.

Document 84-10

- 5. In relation to program operations, CDC turned on the PRAMS Integrated Data Collection System (PIDS), which is required for survey data collection operations, and allowed NYSDOH to test its functionality. We successfully completed that testing, however we have several outstanding questions out to CDC that we need answered before we can resume use of PIDS for survey data collection. CDC has been unresponsive to those questions.
- Additionally, CDC has provided NYSDOH with the raw (not cleaned) 6. unweighted 2024 PRAMS data, instead of finalized (clean) weighted data, which is their responsibility as stated in the Notice of Award. A true and correct copy of the Notice of Award is attached hereto as Exhibit A. To do this requires first data cleaning and then the computation of statistical weights on the clean data set. Thus, CDC did not clean or calculate the survey weights for the data. CDC did provide guidance to NYSDOH as to how to do the data cleaning for ourselves, which is a series of complex programs that we are reviewing. CDC stated that they will provide guidance for weighting the raw data in the near future so that states can do the statistical weighting steps themselves, too. For PRAMS, this is a complicated process requiring trained statisticians, and our PRAMS grant budget is not sufficient to hire any additional staff.
- 7. Furthermore, a new gap has come to light since our original filing. According to the Notice of Award, CDC is to "Facilitate the dissemination of weighted analytic datasets to researchers". Exhibit A at 5-6. This has been previously accomplished through the CDC PRAMS team's creation of the Automated Research File (ARF), which can be requested and provided to researchers online (https://www.cdc.gov/prams/php/data-research/index.html). A true and correct copy of the website as it appeared on July 23, 2025, is attached hereto as Exhibit B.

At that webpage, CDC has posted a new box at the top stating "PRAMS ARF data requests are

not currently being processed. Researchers wanting to analyze data can contact each site

separately to request access to their data. Please email the point of contact or visit the website for

each of these sites for more information." This section then directs data requestors to contact our

team in order to fulfill this function that was formerly conducted by CDC. In the prior two

months, we have been contacted by five researchers who have requested that we fulfill these data

requests in lieu of CDC. The requestors explained they were contacting NYSDOH at CDC's

direction.

8. In summary, CDC is still not completely fulfilling its parts under the Notice of

Award, and communication from CDC has been limited. NYSDOH is still unable to move

forward on key tasks and is still at risk for missing the time window for collecting data for the

birth samples in the early months of 2025.

9. I, Eli S. Rosenberg, PhD declare under the penalty of perjury pursuant to 28

U.S.C. § 1746 that the foregoing is true and correct.

Date: 7/25/25

ELI ROSENBERG

EXHIBIT A

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Award# 5 U01DP006608-05-00

FAIN# U01DP006608

Federal Award Date: 04/08/2025

Recipient Information

1. Recipient Name

HEALTH RESEARCH, INC.

150 Broadway STE 280

Riverview Center

Health Research, Inc.

Menands, NY 12204-2732

[NO DATA]

2. Congressional District of Recipient

3. Payment System Identifier (ID)

1141402155A1

4. Employer Identification Number (EIN) 141402155

- 5. Data Universal Numbering System (DUNS) 153695809
- 6. Recipient's Unique Entity Identifier (UEI)
 WJ37AD42G8A5
- 7. Project Director or Principal Investigator

Trang Q Nguyen trang.nguyen@health.ny.gov 518-4742543

8. Authorized Official

Mr. Michael Saglimbeni Director, Office of Sponsored Programs HRINGA@healthresearch.org (518) 431-1265

Federal Agency Information

CDC Office of Financial Resources

9. Awarding Agency Contact Information

Tracy Rice

Grants Management Specialist

tjn4@cdc.gov

678-475-4964

10.Program Official Contact Information

Mrs. Natalie Brown Program Officer

fmc7@cdc.gov

404-639-4601

Federal Award Information

11. Award Number

5 U01DP006608-05-00

12. Unique Federal Award Identification Number (FAIN)

U01DP006608

13. Statutory Authority

Section 317K of the Public Health Service Act, [42 U.S.C. 247b-12], as amended

14. Federal Award Project Title

DP21-001 Pregnancy Risk Assessment Monitoring System (PRAMS)

15. Assistance Listing Number

93.946

16. Assistance Listing Program Title

Cooperative Agreements to Support State-Based Safe Motherhood and Infant Health Initiative Programs

17. Award Action Type

Non-Competing Continuation

18. Is the Award R&D?

Yes

Summary Federal Award Financial Information

19. Budget Period Start Date	05/01/2025	- End Date	04/30/2026

20. Total Amount of Federal Funds Obligated by this Action	\$175,000.00
20a. Direct Cost Amount	\$151,978.00
20b. Indirect Cost Amount	\$23,022.00

21. Authorized Carryover22. Offset

23. Total Amount of Federal Funds Obligated this budget period

25. Total Federal and Non-Federal Approved this Budget Period \$175,000.00

26. Period of Performance Start Date 05/01/2021 - End Date 04/30/2026

24. Total Approved Cost Sharing or Matching, where applicable

27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Period of Performance

\$845,040.00

\$0.00

\$0.00

\$0.00

\$0.00

28. Authorized Treatment of Program Income

ADDITIONAL COSTS

29. Grants Management Officer - Signature

Ms. Manal Ali

Grants Management Specialist / Officer

30. Remarks

Notice of Award

Award# 5 U01DP006608-05-00 FAIN# U01DP006608

Federal Award Date: 04/08/2025

Recipient Information

Recipient Name

HEALTH RESEARCH, INC.

150 Broadway STE 280

Riverview Center

Health Research, Inc.

Menands, NY 12204-2732

[NO DATA] Congressional District of Recipient

Payment Account Number and Type

Employer Identification Number (EIN) Data

Universal Numbering System (DUNS)

153695809

Recipient's Unique Entity Identifier (UEI)

WJ37AD42G8A5

31. Assistance Type

Cooperative Agreement

32. Type of Award

Research

33. Approved Budget

(Excludes Direct Assistance)

- I. Financial Assistance from the Federal Awarding Agency Only
- II. Total project costs including grant funds and all other financial participation

a. Salaries and Wages	\$85,188.00
b. Fringe Benefits	\$33,479.00
c. TotalPersonnelCosts	\$118,667.00
d. Equipment	\$0.00
e. Supplies	\$1,419.00
f. Travel	\$2,814.00
g. Construction	\$0.00
h. Other	\$29,078.00
i. Contractual	\$0.00
j. TOTAL DIRECT COSTS	\$151,978.00
k. INDIRECT COSTS	\$23,022.00
1. TOTAL APPROVED BUDGET	\$175,000.00
P. J. al Chan	•

m. Federal Share \$175,000.00

n. Non-Federal Share \$0.00

34. Accounting Classification Codes

FY-ACCOUNT NO.	DOCUMENT NO.	ADMINISTRATIVE CODE	OBJECT CLASS	ASSISTANCE LISTING	AMT ACTION FINANCIAL ASSISTANCE	APPROPRIATION
2-939ZRDR	21U01DP006608	DP	41.41	93.946	\$0.00	75-22-0948
3-939ZRDR	21U01DP006608	DP	41.41	93.946	\$0.00	75-23-0948
4-939ZRDR	21U01DP006608	DP	41.41	93.946	\$0.00	75-24-0948
5-939ZRDH	21U01DP006608	DP	41.41	93.946	\$175,000.00	75-25-0948

AWARD ATTACHMENTS

HEALTH RESEARCH, INC.

5 U01DP006608-05-00

1. Terms and Conditions dp006608

AWARD INFORMATION

Incorporation: In addition to the federal laws, regulations, policies, and CDC General Terms and Conditions for Research awards at https://www.cdc.gov/grants/federal-regulationspolicies/index.html, the Centers for Disease Control and Prevention (CDC) hereby incorporates Notice of Funding Opportunity (NOFO) number DP-21-001, entitled Pregnancy Risk Assessment Monitoring System (PRAMS), award DP006608 - Health Research Inc., New York State Department of Health, and application dated December 27, 2024, as may be, which are hereby made a part of this Research award hereinafter referred to as the Notice of Award (NOA).

Note: Due to grants management administration system parameters, the budget category names on Page 1 of this NOA may be altered from the budget categories submitted with the SF-424 Research and Related Budget application.

Applicability of 2 CFR 200 Provisions Beginning October 1, 2024

This award is subject to the requirements in 45 CFR Part 75, except as amendated by the following provisions of 2 CFR Part 200, which apply to new, continuation, and supplemental awards made on or after October 1, 2024.

- 2 CFR § 200.1. Definitions, "Modified Total Direct Cost", "Equipment", and "Supplies"
- 2 CFR § 200.313(e). Equipment, Disposition
- 2 CFR § 200.314(a). Supplies
- 2 CFR § 200.320. Procurement methods
- 2 CFR § 200.333. Fixed amount sub awards
- 2 CFR § 200.344. Closeout
- 2 CFR § 200.414(f). Indirect costs, De Minimis Rate
- 2 CFR § 200.501. Audit requirements

2 CFR 200 citation	Replaces 45 CFR 75 citation
2 CFR § 200.1. Definitions, "Modified Total Direct Cost"	45 CFR § 75.2. Definitions, "Modified Total Direct Cost"
2 CFR § 200.1. Definitions, "Equipment"	45 CFR § 75.2. Definitions, "Equipment"
2 CFR § 200.1. Definitions, "Supplies"	45 CFR § 75.2. Definitions, "Supplies"
2 CFR § 200.313(e). Equipment,	45 CFR § 75.320(e). Equipment,
"Disposition"	Disposition"
2 CFR § 200.314(a). Supplies	45 CFR § 75.321(a). Supplies
2 CFR § 200.320. Procurement methods	45 CFR § 75.329. Procurement procedures
2 CFR § 200.333. Fixed amount subawards	45 CFR § 75.353 Fixed amount subawards
2 CFR § 200.344. Closeout	45 CFR § 75.381 Closeout
2 CFR § 200.414(f). Indirect costs, De Minimis Rate	45 CFR § 75.414(f). Indirect (F&A) costs, De Minimis Rate
2 CFR § 200.501. Audit requirements	45 CFR § 75.501. Audit requirements

Total Approved Funding is included in Summary Federal Award Financial Information on page 1 of the NOA. All future year funding will be based on satisfactory programmatic progress and the availability of funds.

The federal award amount is subject to adjustment based on total allowable costs incurred and/or the value of any third-party in-kind contribution when applicable.

Note: Refer to the Payment Information section for draw down and Payment Management System (PMS) subaccount information.

Approved Component/Project Funding: The NOFO provides for the funding of multiple components under this award. The approved component funding levels for this notice of award are:

NOFO Component	Amount
Component A	\$175,000
Total Approved Budget	\$175,000

Recipients are to review the **Payment Management System (PMS) Subaccount** section in this document to determine the appropriate subaccount document number for the referenced Component. Program specific authorizing legislation, budgetary appropriations, or similar authority may require the creation of more than one subaccount document number per award.

Financial Assistance Mechanism: Cooperative Agreement

Substantial Involvement by CDC: It is anticipated that CDC will have substantial programmatic involvement after the award is made. Substantial involvement is in addition to all post-award monitoring, technical assistance, and performance reviews undertaken in the normal course of stewardship of federal funds.

CDC program staff will assist, coordinate, or participate in carrying out effort under the award, and recipients agree to the responsibilities as detailed in the NOFO and included below.

Component A:

- 1. Maintain CDC Institutional Review Board approvals as required when engaged in research involving human subjects.
- 2. Obtain Office of Management and Budget (0MB) approval in accordance with the PaperworkReduction Act (PRA), as required.
- 3. Provide model procedures and assist with development of jurisdiction-specific written procedures. Conduct periodic review of written procedures and provide recommendations for improvement if needed.
- 4. Provide CDC-provided software system for use in data collection procedures and monitoring of PRAMS operational data.
- 5. Provide training, operations management and ongoing technical support for CDC supported software.
- 6. Assist with the specification of variable descriptions and format layouts of all data files.
- 7. Assist with the development of computer programs for sampling and analysis.
- 8. Provide statistical guidance on development, implementation, and modification of sampling plan.
- 9. Provide technical assistance to resolve problems in data collection procedures.
- 10. Conduct regular operational evaluations and provide recommendations for improvements if needed.

- #: 1862
- 11. Provide technical assistance for data editing.
- 12. Provide technical assistance on implementation of survey supplements to address emerging issues that may arise during the project.
- 13. Assist with implementation of a new version of the questionnaire (Phase 9) with potential adaptions to the existing PRAMS methodology (e.g. online data collection) in conjunction with awardees and stakeholders in maternal and infant health.
- 14. Provide awardees with epidemiologic technical assistance including identifying relevant data sources, developing descriptive analyses and preparing reports on a range of topics.
- 15. Conduct the statistical weighting and create annual data sets for awardees. Processing of data for weighted data sets by CDC is subject to awardees' adherence to protocol and meeting a minimum response rate target.
- 16. Assist awardee staff in obtaining training in software to analyze PRAMS data.
- 17. Facilitate the dissemination of weighted analytic datasets to researchers per data sharing agreement.
- 18. Facilitate dissemination and translation of findings for use in development and evaluation of MCH programs.
- 19. Organize on-going opportunities for exchange of information on challenges and best practices in establishing surveillance or other enhanced activities.
- 20. Participate with awardees in workshops, trainings, meetings, and coordinating committees to exchange information among awardees.
- 21. Coordinate and participate in PRAMS National Awardee Meetings.
- 22. Participate in the voluntary PRAMS Coordinating Committee comprised of CDC Project Scientists and awardees to promote exchange of information and best practices for program development and evaluation.
- 23. Assist awardee with complying with the CDC PRAMS Standard Data Management Plan for AR25 https://www.cdc.gov/grants/additionalreguirements/ar-25.html.

Additionally, an HHS/CDC Project Officer or other HHS/CDC staff will provide day-to-day programmatic, administrative, and fiscal management in support of the project as defined above.

Additionally, an HHS/CDC agency Program Official will be responsible for the normal scientific and programmatic stewardship of the award. The SPO will be:

- · Named in the Notice of Grant Award (NGA) as the Program Official to provide oversight and assure overall scientific and programmatic stewardship of the award.
- Monitor performance against approved project objectives; and
- Assure assessment of the public health impact of the research conducted under this funding opportunity announcement and promote translation of promising practices, programs, interventions, and other results from the research.

Areas of Joint Responsibility include: Participation in the PRAMS Coordinating Committee:

• The PRAMS Coordinating Committee (CC) is comprised of CDC Project Scientists and the Awardee Working Group (AWG). This work group been established to help with project planning and to promote exchange of information and best practices for program development and evaluation. CDC Project Scientists and awardees meet to discuss a variety of programmatic, operational, and methodologic subjects. Topics include questionnaire revision, national meeting, training activities, software issues, alternative data collections methods, and others. The AWG consists of a primary and secondary representative from 7 defined regions.

• Primary representatives actively participate in calls and serve as the liaison between the AWG and the awardee in their assigned region as needed (i.e., take the lead in conveying or gathering information). Secondary representatives participate in calls and back up the primary representatives as needed. Representation rotates each year so that secondary representatives become primary representatives and each jurisdiction in the region has an opportunity to participate during the grant cycle. The AWG meets quarterly by phone. The frequency of the meetings is subject to change depending on the operational and methodologic issues underway.

Awardees and CDC Project Scientists are expected to participate in the following:

- 1 Routine conference calls to discuss operational and analytic activities at the jurisdiction-level.
- 2. All awardee calls to discuss emerging issues that affect all awardees; and
- 3. In-person awardee meetings.

Technical Review Response: Any strengths and weaknesses of the proposal performance progress will be communicated via email directly from the CDC Scientific Program Officer/Program Official (SPO/PO) noted in the Staff Contacts section of this NOA. A response must be submitted via email to the SPO/PO by the due date of, June 1, 2025. Failure to respond will cause delay in programmatic progress and may adversely affect the future funding of this project.

Data Management Plan: As identified in the NOFO, a data management plan is required. The recipient is required to submit a Data Management Plan to the Scientific Program Official noted in the Staff Contacts section of this NOA, no later than 30 days from the budget period start date.

Expanded Authority: The recipient is permitted expanded authorities in the administration of the award.

The expanded authorities selected below apply to this NoA.

- ☑ Carryover of unobligated balances from one budget period to a subsequent budget period. Unobligated funds may be used for purposes within the scope of the project as originally approved. Recipients will report use, or intended use, of unobligated funds in Section 12 "Remarks" of the annual Federal Financial Report submitted in eRA Commons. If the GMO determines that some or all the unobligated funds are not necessary to complete the project, the GMO may restrict the recipient's authority to automatically carry over unobligated balances in the future, use the balance to reduce or offset CDC funding for a subsequent budget period, or use a combination of these actions.
- ⊠ Extension of final budget period of a period of performance without additional funds up to 12 months with no change in the scope of work to ensure adequate completion of the originally approved project or program. The recipient must notify the awarding office, in writing, of the extension 10 days before the expiration date of the period of performance. Upon notification, the awarding office will revise the period of performance ending date and provide an acknowledgement to the recipient.

#: 1864

Program Income: Any program income generated under this grant or cooperative agreement will be used in accordance with the Addition alternative.

<u>Addition alternative</u>: Under this alternative, program income is added to the funds committed to the project/program and is used to further eligible project/program objectives.

Certificate of Confidentiality: Institutions and investigators are responsible for determining whether research they conduct is subject to Section 301(d) of the Public Health Service (PHS) Act. Section 301(d), as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, CDC supported research commenced or ongoing after December 13, 2016 in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate and therefore required to protect the privacy of individuals who are subjects of such research. Certificates issued in this manner will not be issued as a separate document but are issued by application of this term and condition to this award. See Additional Requirement 36 to ensure compliance with this term and condition. The link to the full text is at: https://www.cdc.gov/grants/additional-requirements/ar-36.html

Indirect Costs:

Indirect costs are approved based on the negotiated indirect cost rate agreement dated June 30, 2024, which calculates indirect costs as follows, a Provisional is approved at a rate of 19.4% of the base, which includes direct salaries and wages including all fringe benefits. The effective dates of this indirect cost rate are from April 1, 2024 to March 31, 2027.

REPORTING REQUIREMENTS

The CDC General Award Terms and Conditions include annual and final FFR, RPPR, FFATA, FISMA, and FAPIIS reporting requirements.

PAYMENT INFORMATION

Payment Management System Subaccount: Funds awarded in support of approved activities have been obligated in a newly established subaccount in the PMS, herein identified as the "P Account". Funds must be used in support of approved activities in the NOFO and the approved application. All award funds must be tracked and reported separately.

The grant document number identified on the bottom of page 2 of the NOA must be known to draw down funds.

Subaccount Title: 21U01DP006608

CLOSEOUT REQUIREMENTS

Standard closeout reporting requirements are identified in the General Terms and Conditions, which are published on the CDC website at https://www.cdc.gov/grants/federal-regulations-policies/index.html.

CDC STAFF CONTACTS

Grants Management Specialist: The GMS is the federal staff member responsible for the day-to-day management of grants and cooperative agreements. The GMS is the primary contact of recipients for business and administrative matters pertinent to grant awards. Many of the functions described in the GMO section are performed by the GMS, on behalf of the GMO.

Grants Management Specialist

Tracy Rice
Centers for Disease Control and Prevention
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Research Branch 2, Team 1

Tel: 678-475-4964 Email: tjn4@cdc.gov

Scientific Program Official/Project Officer: The SPO is the federal official responsible for monitoring the programmatic, scientific, and/or technical aspects of grants and cooperative agreements, as well as contributing to the effort of the award under cooperative agreements.

Programmatic Contact:

Natalie Brown
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway
Atlanta, GA 30341

Tel: 770-488-5740 Email: fmc7@cdc.gov

Grants Management Officer: The GMO is the federal official responsible for the business and other non-programmatic aspects of grant awards. The GMO is the only official authorized to obligate federal funds and is responsible for signing the NOA, including revisions to the NOA that change the terms and conditions. The GMO serves as the counterpart to the business officer of the recipient organization.

Grants Management Officer

Ahmad Chabkoun
Centers for Disease Control and Prevention
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Research Branch 2, Team 1

Tel: 404-498-4164 Email:jwg6@cdc.gov

EXHIBIT B





PRAMS Data



AUG. 22, 2024



⚠ PRAMS ARF DATA REQUESTS

PRAMS ARF data requests are not currently being processed. Researchers wanting to analyze data can contact each site separately to request access to their data. Please email the point of contact or visit the website for each of these sites for more information. (Participating PRAMS Sites)

WHAT TO KNOW

PRAMS data are available to researchers. Researchers may access data for multiple jurisdictions by downloading the datasets from the PRAMS Automated Research File (ARF) web portal. The process is outlined below.



How to access the PRAMS ARF and other PRAMS datasets

- 1. Complete and submit the PRAMS Automated Research File Data Portal Access Form.
- 2. You will receive an email from sams-no-reply@cdc.gov inviting you to create a Secure Access Management System (SAMS) account on CDC's SAMS portal.
- 3. Create your SAMS account following the instructions in the email.
- 4. Your SAMS account will then automatically be routed for approval. It must be approved before you can access the PRAMS ARF portal. Once approved, you will receive an email from sams-no-reply@cdc.gov confirming activation of your account.
- 5. Log into SAMS using your newly created account.
- 6. Access the PRAMS ARF portal from your SAMS homepage.
- 7. You must consent to the PRAMS data sharing agreement to access datasets from the portal.
- Follow the prompts to select the datasets you wish to use and download them.
- Please refer to section below on "Years of Data Available" for information on which sites and years are available on the ARF portal.
- Five current or former PRAMS sites (Connecticut, Florida, North Carolina, Oklahoma, and Texas) are not participating in the PRAMS ARF portal. Researchers wanting to analyze data from these sites can contact each site separately to request access to their data. Please email the point of contact or visit the website for each of these sites for more information. (Participating PRAMS Sites)

Variables in the PRAMS Automated Research File (ARF)

The PRAMS ARF contains a standard set of variables. There are five categories of the variables provided:

1. Birth Certificate: Selected variables from the birth certificate file are included in the dataset; information on maternal and infant demographics are primarily from this source.

- 2. Operational: These variables come from the data collection process, i.e., mode the questionnaire was answered by mail or phone.
- 3. **Weighting**: These variables account for the PRAMS survey design and the statistical weighting of the data. These variables are needed to analyze PRAMS data using complex sample software.
- 4. Questionnaire: This is the information collected from the PRAMS survey.
- 5. **Analytic Variables**: These are precalculated variables that combine different variables in the dataset, often those that are restricted (e.g., body mass index [BMI] created by combining variables on maternal weight and height).

PRAMS Automated Research File Codebooks

Phase 6 PRAMS ARF Codebook
Phase 7 PRAMS ARF Codebook
Phase 8 PRAMS ARF Codebook

Additional PRAMS Datasets Available for Download

Additional files with standard, site-developed and supplement questions that PRAMS sites added to their PRAMS survey are also available for download through the PRAMS ARF portal. These files will include a unique identifier variable "ID" that can be used to link to records in the ARF. You can find more information about standard, site-developed and supplement question variables available on the <u>PRAMS Questionnaires</u> page. The <u>Topic Reference Document by Phase</u> lists all questions by topic and indicates which sites used standard and site-developed questions on these topics.

Questionnaires Available

The <u>PRAMS questionnaire</u> is revised periodically. With each revision or new phase of the questionnaire, some of the questions change. Although most indicators can be compared across phases, it is often easiest to analyze data within a single phase. Below is a list of the years of available data covered by the different phases:

- Phase 8 (2016—2022)
- Phase 7 (2012—2015)
- Phase 6 (2009—2011)
- Phase 5 (2004—2008)
- Phase 4 (2000—2003)
- Phase 3 (1996—1999)
- Phase 2 (1990—1995)
- Phase 1 (1988—1989) Pilot Phase

The PRAMS questionnaire has three parts: a core that all sites use; a bank of standardized optional questions that sites may select from; and site-developed questions that are usually used only by the site that developed them. Between questionnaire phases, some PRAMS sites used short question supplements that they appended to the end of the regular PRAMS survey.

The following documents may be useful:

Questions Lists by Phase

(Phase 8 Core Questions, Phase 8 Standard Questions, etc.)

Topic Reference Document by Phase

(Lists all questions by topic and indicates which sites used standard and site-developed questions on these topics).

Years of Data Available

PRAMS currently has a policy that sets a minimum overall response rate threshold for the release of data for each year. This threshold has changed over the years as follows:

- 2006 and earlier: 70%
- 2007—2011: 65%
- 2012—2014: 60%
- 2015—2017: 55%
- 2018—2022: 50%

Although a majority of all sites meet the threshold, some do not. For this reason, the number of sites with data available may vary from year to year. The PRAMS datasets available for download include data from sites that met the response rate threshold for the specific year and that are participating in the PRAMS ARF.

For more information, see:

Data Availability by Site and Year EXCEL (standard version).

Data Availability by Site and Year EXCEL (508-compliant version, accessible to people with disabilities).

Site-Specific Response Rate Tables

2022 PRAMS Response Rate Table

2021 | 2020 | 2019 | 2018 | 2017 | 2016 | 2015 | 2014 | 2013 | 2012

Publication of PRAMS Analytic Results

Researchers should carefully review the terms of the data sharing agreement before submitting presentations or manuscripts using PRAMS data for publication. In particular, please note:

- All oral or written presentations of the results of the analyses will be submitted to PRAMSProposals@cdc.gov at least **3 weeks prior** to a presentation or submission to a journal.
- Publications using PRAMS data should include the following acknowledgement:

We thank the PRAMS Working Group, which includes the PRAMS Team, Division of Reproductive Health, CDC and the following PRAMS sites for their role in conducting PRAMS surveillance and allowing the use of their data: [insert names of PRAMS included in your analyses (e.g., PRAMS Alabama, PRAMS Alaska, etc.].

• Notify PRAMS staff at PRAMSProposals@cdc.gov upon final publication of an article and provide citation information.

For more information about the data access process, please send an inquiry to PRAMSProposals@cdc.gov.

SOURCES

CONTENT SOURCE:

National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP); Division of Reproductive Health

EXHIBIT 88

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF RHODE ISLAND

STATE OF NEW YORK, et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

Case No. 1:25-cv-00196-MRD-PAS

SUPPLEMENTAL DECLARATION OF MICHELLE DAVIS

- 1. I, Michelle Davis, am the Deputy Commissioner of the Office of Public Health (OPH), within the New York State Department of Health (DOH). I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with DOH staff, or from documents that have been provided to and reviewed by me.
- 2. I submit this Declaration in support of Plaintiffs' Opposition to Defendants' Motion to Clarify and Modify the Preliminary Injunction Order. ECF No. 75.
- 3. This Declaration supplements my previously filed Declaration of May 7, 2025. ECF No. 44-37. I reincorporate and restate the substance of that declaration, and provide updated information about how the changes to the Centers for Disease Control and Prevention's (CDC) Office on Smoking and Health (OSH) and U.S. Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) have impacted DOH's Tobacco Control Program.
- 4. In the two months since the previous Declaration was filed with the court, there has been no change in the interactions between DOH's Bureau of Tobacco Control employees

and U.S. Department of Health and Human Services (HHS) employees, specifically those within OSH. To our knowledge, that office remains unstaffed and/or dismantled due to the April 1 reductions in force (RIFs).

- 5. DOH's Bureau of Tobacco Control attempted to contact CDC's Media Campaign Resource Center (MCRC), who is currently not accepting orders through their website, to seek guidance on the proper licensing of an advertisement for the 2025–2026 media year. To that end, DOH staff emailed ICF Next, CDC's manager of the MCRC, on June 30, 2025, with questions and, to date, have not received a response. A true and correct copy of the June 30, 2025, email to MCRC is attached hereto as **Exhibit A**.
- 6. Further, on Tuesday, July 15, 2025, at 3:22 PM EST, the CDC issued an announcement via GrantSolutions (FY25 DP20-2001 Supplemented Extension Guidance) regarding a one-time supplemental funding opportunity to the recipients currently funded under CDC-RFA-DP20-2001: National and State Tobacco Control Program to support the implementation of the National and State Tobacco Control Program. A true and correct copy of the July 15, 2025, 3:22 PM EST announcement is attached hereto as **Exhibit B**. This announcement included an attachment that did not work and was re-issued with a corrected attachment at 5:35 PM EST on the same day. A true and correct copy of the July 15, 2025, 5:35 PM EST announcement is attached hereto as **Exhibit C**, and its attachment, entitled "Supplemented Extension" is available as **Exhibit D**.
- 7. It is unclear from Exhibit D what the timing is for the supplemental funding, when a notice of award will be issued, and whether this supplemental funding will allow the program to recruit or retain additional staffing positions. In short, there is no way to know when the additional funding would become available, or how DOH could plan to use it.

8. Due to the April 1 RIFs and subsequent lack of continuation funding for the National Tobacco Control Program, DOH's Tobacco Control Program has lost 10 full-time staff positions, and three staff impacted by the layoffs were shifted to temporary funding.

9. I, Michelle Davis, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct.

Date: 7/25/25

MICHELLE DAVIS

Michelle S. Davis

EXHIBIT A

Document 84-11 #: 1875

From: Courtney, Matthew (HEALTH)

To: Baker, Brittney; Linkins, Tyler

Cc: O"Sullivan, Gina M (HEALTH)

Subject: Nicotine Equals Licensing for NYS Use

Date: Monday, June 30, 2025 3:19:56 PM

Hi Brittney & Tyler,

Hope you both are doing well and enjoying your summer! It seemed to be constant rain here in NY, then followed by an oppressive heat wave, and then finally this past weekend it was beautiful out and felt more like summer.

I am reaching out to you both seeking any guidance or assistance in the proper licensing for NYS to use the Nicotine Equals ad: 'The Fallout' and 'The Unraveling' for our upcoming 25-26 media year. From what I found in older emails, the talent fees were covered by California until 05/06/2027 but I believe the 'Future Prefect' music license was something we only had for a 52 week cycle.

We understand that the MCRC is unable to process orders currently but if you have any information regarding this licensing, that would be a huge help!

Thank you so much and I look forward to hearing from you.

Sincerely,

Matt

Matthew Courtney

Health Communications Associate, Bureau of Tobacco Control New York State Department of Health
Empire State Plaza, Corning Tower, room 1055
Albany, NY 12237

Phone: (518) 474-1515 | matthew.courtney@health.ny.gov

EXHIBIT B

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PR Ner Pro

View / Reply to Grant Message

X

Subject: Subject: FY25 DP20-2001 Supplemented Extension Guidance

Communication Type: Correspondence 😂 Category: Bulk Message

AUTHOR	MESSAGE	DATE / TIME	ACTIONS
Darryl Mitchell	Dear Recipient, Attached is the guidance for applying for the additional funding available to the current CDC-RFA-DP20-2001 recipients to support the implementation of the National and State Tobacco Control Program. Should you have any questions, please feel free to reach out to your assigned Grants Management Specialist or Project Officer. Thank you	07/15/2025 03:22 PM EST	0
Gina OSullivan	Good afternoon, I cannot open the attachment.	07/15/2025 03:37 PM EST	

Add Reply

Subject: Subject: FY25 DP20-2001 Supplemented Extension Guidance

Communication Type: Correspondence

AUTHOR	MESSAGE	DATE / TIME	ACTIONS
Darryl Mitchell	Dear Recipient, Attached is the guidance for applying for the additional funding available to the current CDC-RFA-DP20-2001 recipients to support the implementation of the National and State Tobacco Control Program. Should you have any questions, please feel free to reach out to your assigned Grants Management Specialist or Project Officer. Thank you	07/15/2025 03:22 PM EST	
Gina OSullivan	Good afternoon, I cannot open the attachment.	07/15/2025 03:37 PM EST	

Subject: Subject: FY25 DP20-2001 Supplemented Extension Guidance

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AUTHOR	MESSAGE	DATE / TIME	ACTIONS
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Gina OSullivan	Good afternoon, I cannot open the attachment.	07/15/2025 03:37 PM EST	

#: 1880

Subject: Subject: FY25 DP20-2001 Supplemented Extension Guidance

Communication Type: Correspondence

View / Reply to Grant Message

AUTHOR	MESSAGE	DATE / TIME	ACTIONS
Darryl Mitchell	Dear Recipient, Attached is the guidance for applying for the additional funding available to the current CDC-RFA-DP20-2001 recipients to support the implementation of the National and State Tobacco Control Program. Should you have any questions, please feel free to reach out to your assigned Grants Management Specialist or Project Officer. Thank you	07/15/2025 03:22 PM EST	
Gina OSullivan	Good afternoon, I cannot open the attachment.	07/15/2025 03:37 PM EST	

EXHIBIT C



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PR Ner Pro

View / Reply to Grant Message



Subject: FY25 DP20-2001 Supplemented Extension Guidance

Communication Type: Correspondence **♦** Category: Bulk Message

AUTHOR	MESSAGE	DATE / TIME	ACTIONS
Darryl Mitchell	Dear Recipient, Attached is the guidance for applying for the additional funding available to the current CDC-RFA-DP20-2001 recipients to support the implementation of the National and State Tobacco Control Program. Should you have any questions, please feel free to reach out to your assigned Grants Management Specialist or Project Officer. Thank you	07/15/2025 05:35 PM EST	0

Add Reply

Subject: FY25 DP20-2001 Supplemented Extension Guidance

Communication Type: Correspondence

AUTHOR	MESSAGE	DATE / TIME	ACTIONS
Darryl Mitchell	Dear Recipient, Attached is the guidance for applying for the additional funding available to the current CDC-RFA-DP20-2001 recipients to support the implementation of the National and State Tobacco Control Program. Should you have any questions, please feel free to reach out to your assigned Grants Management Specialist or Project Officer. Thank you	07/15/2025 05:35 PM EST	

Subject: FY25 DP20-2001 Supplemented Extension Guidance

Communication Type: Correspondence

AUTHOR	MESSAGE	DATE / TIME	ACTIONS
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Subject: FY25 DP20-2001 Supplemented Extension Guidance

Communication Type: Correspondence

AUTHOR	MESSAGE	DATE / TIME	ACTIONS
Darryl Mitchell	Dear Recipient, Attached is the guidance for applying for the additional funding available to the current CDC-RFA-DP20-2001 recipients to support the implementation of the National and State Tobacco Control Program. Should you have any questions, please feel free to reach out to your assigned Grants Management Specialist or Project Officer. Thank you	07/15/2025 05:35 PM EST	

EXHIBIT D

Page 18 of 23 PageID

Supplemented Extension

#: 1887

Centers for Disease Control and Prevention (CDC) Office of Financial Resources Catalog of Federal Domestic Assistance (CFDA): 93.387 Notice of Funding Opportunity Number (NOFO): CDC-RFA-DP20-2001

National and State Tobacco Control Program

National Center for Chronic Disease Prevention and Health Promotion Office on Smoking and Health

Purpose:

The purpose of this supplement is to announce that additional funding is available to the current CDC-RFA-DP20-2001 recipients to support the implementation of the National and State Tobacco Control Program.

The supplement will fund this cooperative agreement for an additional 12 months (April 29, 2025 – April 28, 2026) to allow for completion of program activities and extended evaluation of the program.

Eligibility:

These one-time funds will be awarded to the recipients currently funded under CDC-RFA-DP20-2001: National and State Tobacco Control Program.

Anticipated Funding Level:

For this award, recipients are required to prepare their fiscal year 25 budget based on the current year's award amount. Please refer to the most recent Notice of Award for the award amount.

Application Submission:

Applications must be submitted through www.grantsolutions.gov as an amendment following the steps below:

- 1. **Go to:** www.grantsolutions.gov
- 2. Access: My Grants List Screen
- 3. Click the Link: "Manage Amendments"
- 4. Click Button: "New"
- 5. **Select Amendment Type**: Supplement 6. Click Button: "Create Amendment"

Applications must be submitted to GrantSolutions by Monday, July 21, 2025, 11:59 p.m. Eastern Standard Time. If you encounter any difficulties submitting your application at www.grantsolutions.gov, please contact the GrantSolutions helpdesk at 866-577-0771 or email help@grantsolutions.gov prior to the submission deadline. If you need further information regarding the supplemented extension, please contact Darryl Mitchell, Grants Management Specialist, at dvm1@cdc.gov and Keisha Thompson at dwt2@cdc.gov. For programmatic information, please contact Leslie Norman, Project Officer, at lanO@cdc.gov.

Annual Reporting Requirements:

Progress Performance Report: Due to the extension of the final budget period, CDC must receive Annual Progress Reports (APR) every 12 months. Recipients are required to submit an APR for reporting period January 1, 2024 – December 31, 2024. The APR must be submitted with this supplement application.

Annual Federal Financial Report (FFR): Annual financial reporting is required every twelve-month period. Due to the extension period, the final budget period has been extended and an additional annual financial report will be required. A completed FFR SF- 425 covering the original final budget period of April 29, 2024 – April 28, 2025 is due to the GMS/GMO by July 28, 2025. The report must be submitted in the Payment Management System (PMS).

Checklist of required contents of application packet:

- 1. Performance Progress and Monitoring Report (PPMR)
- 2. SF-424 Application for Federal Domestic Assistance Version 3 (online form)
- 3. SF-424A Budget Information-Non-Construction (online form) and Budget Justification (attachment)
- 4. Indirect Cost Rate Agreement (attachment)
- 5. Performance Narrative
- 6. SF-LLL Disclosure of Lobbying Activities (online form and instructions), if applicable^[1], are located at www.grants.gov/forms/forms-repository/post-award-reporting-forms
- 7. Interim Federal Financial Report (FFR) SF-425 (if applicable) instructions are located at www.grants.gov/forms/forms-repository/post-award-reporting-forms
- 8. Additional Program Requirements, if applicable

1. Performance Progress and Monitoring Report:

PPMR instructions the **PPMR** are attached to form located at https://www.cdc.gov/grants/documents/Performance-Progress-and-Monitoring-Report-PPMR.pdf.

2. <u>SF-424 Application for Federal Domestic Assistance-Version 2</u>:

Instructions for completing SF-424 Application for Federal Domestic Assistance Version 3 https://www.grantsolutions.gov/gs/pdf/SF424V3_Instructions.pdf

3. SF-424A Budget Information and Justification:

- Instructions for completing SF-424A Budget Information-Non-Construction online form are located at https://www.grantsolutions.gov/gs/pdf/ophs-1 SF424A Instruction.pdf
- The proposed supplement budget should be based on the federal funding level, which is stated on page one of this document.
- In a separate narrative, provide a detailed, line-item budget justification of the funding amount requested to support the activities to be carried out with those funds. Travel for program implementation should be justified and related to implementation activities.
- The budget justification must be prepared in the general form, format, and to the level of detail described in the CDC Budget Preparation Guidelines. The budget guidance is provided on CDC's internet at http://www.cdc.gov/grants/applying/application-resources.html.
- For any new, proposed subcontracts, provide the information specified in the Budget Guidance.
- When non-federal matching is required, provide a line-item list of non-federal contributions including source, amount, and/or value of third-party contributions proposed to meet a matching requirement.

4. Indirect Cost Rate Agreement (This is not applicable to institutions of higher education. The rates stay the same as the first-year award.):

A. If indirect costs are requested, include a copy of the current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter for those recipients under such a plan.

^[1] The form has instructions that indicate when the form is required.

- B. Clearly describe the method used to calculate indirect costs. Make sure the method is consistent with the Indirect Cost Rate Agreement.
- C. To be entitled to use indirect cost rates, a rate agreement must be in effect at the start of the budget period.
- D. If there is no Indirect Cost Rate Agreement or the agreement has expired, indirect costs may be charged as direct if (1) this practice is consistent with the recipient's/applicant's approved accounting practices; and (2) if the costs are adequately supported and justified.
- E. If applicable, attach and name the document, "Indirect Cost Rate."
- F. If applicable, the recipient's indirect costs are based on a rate of ten percent of modified total direct costs (MTDC) as defined in 45 CFR Part 75.2.
- G. For institutions of higher education, indirect costs are based on the negotiated indirect cost rate agreement used for the first-year award, and rates in that agreement are to be used for the remainder of the competitive segment in accordance with 45 CFR Part 75. Indirect cost/facilities and administration rates for subcontracts will be treated in the same manner as those for the recipient if the subcontractor is covered by 45 CFR Part 75.
- H. For grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S., indirect costs are based on a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of \$25,000.

4. Performance Narrative:

Section I. Current Budget Period Progress (January 1, 2024 – December 31, 2024):

Provide a brief report addressing the following elements of each objective or activity.

Annual Progress Report (Component 1 and Component 2): Recipients must provide a brief summary for Component 1 and/or Component 2 of key deliverables conducted thus far, successes, challenges, and technical assistance needs for each Strategy. The Annual Progress Reports should be labeled as follows: "Component 1 APR", and "Component 2 APR" for submission to GrantSolutions.

Successes

- Report progress on completing deliverables, activities, and logic model outcomes outlined in the Component 1 and Component 2 work plans. <u>Progress should be measurable and demonstrate</u> impact.
- Highlight successes with implementing evidence-based policy, systems, and environmental strategies during the budget period.
- Describe any additional successes (e.g., identified through evaluation results or lessons learned)
 achieved during the budget period.

Challenges

- Describe challenges that might affect their ability to achieve selected strategies, conduct performance measures, or complete the activities in the work plan.
- Discuss additional challenges (e.g., identified through evaluations or lessons learned) encountered in the past year.
- Describe how CDC could help overcome challenges to achieving strategies, performance measures, and completing activities outlined in the work plan.

Lessons Learned

Provide lessons learned under each Strategy for the Population-Specific Disparities
Requirements (Statewide, Community-Based, and Preventing Initiation of Emerging Tobacco
Products). Do not repeat what was provided under Successes and Challenges.

- Spend Plan for Activities brought forward from previous budget periods (Carryover) In order to assess programmatic plans to address unobligated funds, please include the following information in a separate document. The information should detail the activities/funding brought forward from previous budget periods (Year 4) into the current budget period (Year 5). Name the document "Spend Plan for use/intended use of unobligated".
- A breakdown of the amount of unobligated funds by component brought forward from previous budget periods into the current budget period.
- Detailed plans for the use of or intended use of the unobligated funds carried forward into the current budget period.
- Categorize the information by Component/strategy/activity, with the associated dollar amounts.
- Include overhead, administration, and/or staffing costs as appropriate.

Section II. Supplemental Budget Period Proposed Objectives and Activities (April 29, 2025 – April 28, 2026):

CDC recommends that recipients develop the work plan and budget concurrently, making sure the activities identified in the work plan are reflected in the budget and vice versa. Recipients are expected to clearly explain how their organization plans to use the funding to implement the NOFO strategies and achieve performance measure targets. Each activity listed in the work plan should be attached to an expenditure in the budget, and recipients are required to justify and itemize all expenditures.

Work Plan: Recipients should update their Year 5 Work Plan(s) for Component 1 and/or Component 2 to describe the work that will be accomplished during the supplemental performance period. The work plans should be labeled as follows for submission to GrantSolutions: "Component 1 Work Plan" and "Component 2 Work Plan".

- Select proposed strategies for the upcoming budget period. The strategies must support the intent of the original Notice of Funding Opportunity (NOFO).
- Each strategy should contain a performance or outcome measure that assesses the effectiveness of the project.
- For each Strategy:
 - o Identify the priority population, geographic area, and key deliverables/outputs proposed.
 - Use the exact names provided in the table for the priority populations.
 - Do not select both "general population" and other population groups.
 - o Only use "Other" if the selected priority population is not listed in the table.
- List activities that will be implemented, include the setting the activity is being implemented, the contributing partner(s), and the key contractors and consultants responsible for completing each activity; and
- Provide a timeline for accomplishment of activities.

Priority Populations		
General Population	Mental Health	
African American or Black	Substance Use	
American Indian or Alaska Native	Rural	
 Asian American, Native Hawaiian, or Pacific Islander 	Veteran/Active Military	

Disability/Limitation	 Geographical Region or Area with High Commercial Tobacco Use
Hispanic/Latino	Young Adults (18-24)
• LGBTQ+	Youth (below 18)
Low SES	Other (include in description)

Budget Narrative: Recipients must submit a separate 12-month budget for Component 1 and/or Component 2. The budgets should be labeled as follows: "Component 1 Budget" and "Component 2 Budget".

- **Direct Assistance:** Direct Assistance is available through this NOFO for Statistical Analysis Software (SAS) licenses and SUDAAN licenses.
 - **Trainings and Conferences:** Attending required trainings and conferences is critical for building and maintaining the skills of the staff with responsibility for carrying out the program requirements of this NOFO. CDC's Office on Smoking and Health (OSH) requires attendance at specific trainings and conferences as a term and condition of this award. Specific conference dates, location, and guidance related to travel will be provided at a later date.
 - Recipients should budget for a minimum of three staff members to attend the National Tobacco Control Program Technical Assistance Meeting, August 25, 2025, and the National Conference on Tobacco or Health (NCTOH), August 26-28, 2025, in Chicago, Illinois. Staff members should include, at minimum, the tobacco control program manager and evaluator.
- Local Lead Agency: For the Community-Based Disparities Requirement, recipients must allocate funds from their Component 1 award or state dollars to fund one local lead agency to implement tobacco control strategies and activities in a community. The Local Lead Agency should be funded at an amount that will allow them to accomplish the strategies and activities outlined in their work plan. A line item should be included in the budget and labeled "Local Lead Agency" with the Name of Organization in parenthesis (i.e., Local Lead Agency (ABC Organization).

5. Additional Program Requirements

Impact Statements: Recipients must develop and submit at least 1 impact statement with the application. Impact Statements should be 1 page or less and include the following information:

- Burden/problem statement/priority population
- What your state/jurisdiction is doing (including timeframe start and end date of highlighted activities)?
- How your state/jurisdiction used CDC resources to do the work?
- What happened?
- What was the impact/health outcomes (include numerical data if available, including number and percent impacted)?

The Impact Statement should be submitted as a separate attachment with the Application and labeled "Impact Statement_State Abbreviation".

Community-Based Disparities Requirement: Recipients should continue to collaborate with the local lead agency, coalition, and community stakeholders to advance the work of this requirement. Activities may include one or more of the following:

 Implement a workplan with culturally appropriate tobacco control policy, systems, and environmental strategies and activities which seek to improve health equity and is led by the local lead agency and community.

- Evaluate the requirement and share findings.
- Provide technical assistance, training, and guidance to the local lead agency.

A work plan should be submitted as a separate attachment with the Application and labeled "Local Lead Agency Work Plan".

Evaluation and Performance Measurements: Recipients are required to collect and report on evaluation results and performance measures.

- Performance Measurement Reports: Recipients are required to report relevant performance measure
 data annually. The performance measures for DP20-2001 standardize the assessment of strategies and
 outcomes across the funded tobacco control programs. Recipients will update their Performance
 Measurement Reports by submitting measurement data for Year 5 and performance measure targets
 for Year 6. The Performance Measurement Reports should adhere to the evaluation report guidance
 provided by OSH, titled "Guidance for Updating DP20-2001 Annual Performance Measures." The report
 must be submitted by July 28, 2025.
- Evaluation Report: Recipients are required to implement evaluation plans and collect evaluation data annually. Recipients will report evaluation findings from Year 4 and Year 5 together. The report must be submitted by July 28, 2025.
- Updated Evaluation Plan: If updates or revisions have been made by the recipient or requested by the OSH Evaluator, recipients are required to submit an updated Evaluation Plan by March 31, 2025. If there are no updates or revisions, the recipient is not required to submit an updated evaluation plan.