DATA USE AND NON-DISCLOSURE AGREEMENT CONCERNING PROTECTED HEALTH INFORMATION OR OTHER CONFIDENTIAL INFORMATION

Michigan Department of Health and Human Services

Parties who are interested in acquiring data from the Michigan Department of Health and Human Services (MDHHS) may be required to complete and submit this application to the Bureau of Information Management. Depending on the nature of the data being requested, third parties may be required to share their security protocols and guidelines with MDHHS for review. In addition, there may be a need to satisfy certain Department of Technology, Management and Budget's security requirements to ensure that the data will be securely maintained by the data recipient, and also to ensure that any potential risk of a breach is minimized.

Instructions:

1. Use this form if the data recipient is an entity outside of the State of Michigan government and is requesting Michigan Department of Health and Human Services data.
2. Spell out all acronyms when initially referenced.
3. Complete and submit to [HYPERLINK "mailto:MDHHS-DataRequests@michigan.gov" \h]within the Bureau of InformationManagement.
4. After the application is logged by the Bureau of Information Management, a review will be conducted by the Compliance Office. Be prepared for additional follow-up questions related to privacy or security.
5. This application is not an agreement until authorized by the Chief Compliance Officer and all signatures have been affixed.

Project Title MDHHS integrated investigations of lead in home drinking water		
Request Number (include number from MDHHS-5614, Request for Data)		
Data Recipient Darren Lytle, Ph.D., P.E.		
Organization U.S. Environmental Protection Agency		
Address 26 West Martin Luther King Dr.		
City Cincinnati	State OH	Zip Code 45268
Phone Number Desk:(513) 569-7432/Mobile Ex. 6 Personal Privacy (PP) Ex. 6 Personal Privacy (PP)	Email Address [HYPERLINK "mailto:Lytle.Darren@epa.gov" \h]	

In accordance with this agreement, data are provided to the Data Recipient by the Michigan Department of Health and Human Services (MDHHS), **Bureau/Division** on full execution of this agreement and full payment of fees as indicated below.

Fees Yes (see separate fee agreement) ☒ No

The parties agree to the provisions specified in this agreement, the Health Insurance Portability and Accountability Act (HIPAA), and all other applicable public health, research, and confidentiality laws.

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SECTION 1: DATA SOURCE AND MDHHS SPONSOR(S)

Identify the MDHHS program area(s) and MDHHS system(s) that serve as the Source of the Requested Data. (e.g., EMS Trauma and Preparedness and Michigan EMS Information System [MI-EMSIS]) Division of Environmental Health, Drinking Water Investigation Unit

Identify the MDHHS program sponsor(s) for the Requested Data. A sponsor is needed for each area providing data. MDHHS - Drinking Water Investigation Unit	
Sponsor Jean Pierre Nshimyimana, Ph.D.	
Title/Program Environmental Engineer	
Phone Number D:517-284-0055/M:517-512-4547	Email Address [HYPERLINK "mailto:nshimyimanaj@michigan.gov"]
Identify the MDHHS program sponsor(s) for the Requested Data. A sponsor is needed for each area providing data. MDHHS - Drinking Water Investigation Unit	
Sponsor Aaron Ward	
Title/Program Unit Manager	
Phone Number D: 517-582-5245	Email Address WardA16@michigan.gov

SECTION 2: DATA SOURCE, PURPOSE, USE, DESCRIPTION, APPROVAL (IF HUMAN SUBJECT RESEARCH)

What is the Data Recipient's Purpose for, and Specific Use of, the Data?

1. Describe with detail why these data are requested (e.g., Research, Statistics, Public Health, Health Care Operations, Administration of the Medicaid Program).

   Environmental Health (Public Health)

   - To assess the nature of lead particles and their contribution to soluble lead in drinking water.

   - To elevate scientific knowledge of drinking water chemistry at the household level to understand the role of corrosive water in scaling home interior plumbing.

   - To reduce human health exposure to potential heavy metals dissolving or forming particles in drinking water from home interior plumbing.

   For additional explanations, please see attached discussion collaboration report.

2. Describe how the data will be used/disclosed, or incorporate by reference **and** attach a copy of the research protocol, work plan, or request letter that details the purpose and use of data, etc.

It will be used to assess the nature of lead particles and their contribution to soluble lead in drinking water. There is a need to understand the scale of the problem of particulates in drinking water at the consumer level and investigate the particulate relationship between reduction or increase of soluble lead in drinking water, what type of particles are present, and what they are made of.

Upon receiving the data, the USEPA will use the attached Quality Assurance Project Plant "Field-Related Corrosion Research Projects and Collaborative Support" Section 4.0 listed requirements for data analysis, data management, data reporting and data storage.

- Refer to point 3(1) about goals in this form
- For a more detail explanation on the use of data, please refer to the meeting report attached to this document
- EPA will be advising MDHHS on an integrated drinking water investigation guide currently still under review.

3. Describe the data requested indicating amount, type, by what medium the data will be provided, how the data will be protected and whether that data recipient is granted access to the data warehouse or state archives.

MDHHS will share particulate and general chemistry data collected from household in Action Level Exceedance (ALE)cities. This De-identified chemistry concentration data will be shared electronically, using password-protected excel files. Upon receival, USEPA will be responsible for data protection using USEPA internal protocol.

Quality Assurance Project Plan (Field-Related Corrosion Research Projects and Collaborative Support) from USEPA provides additional detail about data handling upon receival. Data will only be identified to the level of water source (surface or groundwater). QAPP Section 4 on Procedures for Determining Data Quality discuss how EPA will handle secondary data to meet quality parameters and how records will be retained (Record Schedule 1035)

a. Specify or attach a list of ALL data elements requested (e.g., age, gender, etc.) and time periods (e.g. January 2013 through January 2015)

- Here is the list of the data elements:
- Household code
- Type of water source
- Lead
- Copper
- Particulate (lead, copper, manganese & iron / total and dissolvedconcentration will be included)
- General chemistry (alkalinity, chloride, conductivity, pH, sulfate,
- total solids, calcium, magnesium and hardness)

b.	Specify if the data requested is identifiable, de-identified, or a limited data set as defined by HIPAA. **De-identified**
c.	Specify the medium requested (e.g., electronic, hard copy, etc.). **Electronic, password encrypted**
d.	Specify the method of data transfer from MDHHS to Data Recipient. **Electronic mail (email)**
e.	Specify how the data will be stored and protected (e.g., encryption, password protected). **Password protected; will be stored as per the EPA QAPP on data management**
f.	Specify how access to the data will be managed. **Excel file will be shared using email between MDHHS and USEPA**
g.	Specify with name and title of all whom will have access to the data. **Jean Pierre Nshimyimana, MDHHS, Environmental Engineer** **Aaron Ward, MDHHS, Drinking Water Unit Manager** **Che Xun, MDHHS, Toxicologist** **Darren Lytle, USEPA, Cincinnati** **Simoni Triantafyllidou, USEPA, Cincinnati** **Christy Muhlen - US EPA Cincinnati** **Miley Pham - USEPA Cincinnati** **Steve Harmon - USEPA Cincinnati**
h.	Specify whether the data will be destroyed after it is no longer needed. - **Data will be saved in MDHHS-Drinking Water Investigation Unit lead database** - **EPA Record Schedule 1035 for item E will be applied to data received by EPA.**

Research Project (Complete this box if requested data will be used for human subject research).

Is Institutional Review Board (IRB) (human subjects research) approval required? Yes ☒ No If Yes, MDHHS Approval Number (Attach MDHHS Approval Form)
Is a HIPAA Informed Consent/Authorization Waiver Required? Yes ☒ No If Yes, attach documentation of HIPAA Authorization/Informed Consent Waiver.

SECTION 3: AGREEMENT CONDITIONS

With regard to data provided under this agreement, the Data Recipient agrees to:

1. Use and disclose the data only in accordance with this agreement, or as otherwise required by law;

2. Limit access to these data only to those described and authorized in this agreement; (MDHHS may require the specific identification of the person(s) or the agency/division/office that is permitted access. Identify if needed.)

3. Use appropriate safeguards to prevent use or disclosure of the information other than as provided by this agreement; (MDHHS sponsor may require description of the security procedures that will be in place and followed.)

   Data will be password protected

4. Report to the responsible MDHHS sponsor any use or disclosure of information that is not provided for by this data use agreement;

5. Ensure that any agent(s) or subcontractor(s) who access these data agree to the same restrictions and conditions that apply to the data recipient; (MDHHS sponsor may stipulate that release of data to a subcontractor cannot be done without the written authorization of MDHHS.)

   MDHHS Sponsor will be in charge of preparing and sharing data

6. Make no attempt to identify or contact the individuals, providers, or health plans within the data provided unless approved in this agreement; (Describe any agreed upon exceptions if needed.)

   As EPA is receiving only de-identified data, this provision is inapplicable.

7. Data recipient must provide MDHHS at least thirty days to review and provide comments on papers, publications, or presentations that the data recipient plans to submit for publication or presentation. Data recipient agrees that it will not publish or disseminate any protected health information, personally identifiable information, or data that might make it possible, directly or indirectly, to identify an individual. Data recipient must acknowledge the MDHHS program as appropriate (e.g., source of data, etc.), assume full responsibility for the analysis and interpretation of the data, and provide a copy of the publication or presentation to MDHHS. To the extent data recipient requires technical assistance in analyzing or interpreting the data and when such assistance goes beyond providing non-manipulated data, MDHHS reserves the right to request that these activities be considered a substantial contribution to the research being conducted and that the provision of such assistance may warrant MDHHS be considered as a research collaborator or co-author in any resulting publications or presentations;

   As EPA is receiving only de-identified data, the second sentence of this provision is inapplicable.

8. Return or destroy all originals and copies of any potentially identifiable information upon completion of project, or upon request, unless otherwise approved in this agreement. This includes, but is not limited to: magnetic tape, micro disk files, paper records, etc. If not returned to the MDHHS, then the data must be destroyed; e.g., use a CD/DVD shredder to destroy CD Roms, DVDs, etc., erase floppy/zip disks using a magnet, shred paper records, clean computer hard drives with a program designed to wipe a disk by overwriting, etc. An Affidavit of Destruction of all Department Data (MDHHS-5684) must be completed for data not returned to MDHHS;

9. Not use the data provided to engage in any method, act, or practice which constitutes a commercial solicitation or advertisement of goods, services, or real estate to consumers; and

10. Not use the data provided as a basis for legal, administrative or other actions which may affect particular individuals or establishments as a result of their specific identification in this project.

    As EPA is receiving only de-identified data, this provision is inapplicable.

The MDHHS may cancel this agreement with proper notice.

The unauthorized use or disclosure of confidential information is punishable by imprisonment or fine under applicable laws specific to the data released. This agreement shall be construed in accordance with applicable state and federal ~~the~~ laws. ~~as applied by the Federal courts in the District of Columbia.~~

Commented [EJ1]: EPA's FTTA/OC is asking that this last sentence be taken out.

Commented [NJP(2]: MDHHS Edit

Do not affix signatures until review has been completed by MDHHS Compliance.

DATA RECIPIENT SIGNATURE

I, the data recipient, have read, understand, and agree to the above conditions.

Name of Responsible Data Recipient or authorized person (Type or Print) Gregory Sayles, Ph.D.	Title Director, USEPA ORD CESER
Signature of Responsible Data Recipient	Date

MDHHS SPONSOR SIGNATURE

I, the MDHHS sponsor, understand the role and responsibilities of a sponsor and fully accept this role.

Name of Responsible MDHHS Sponsor (Type or Print) Jean Pierre Nshimyimana, PhD	Title MDHHS-Environmental Engineer
Signature of Responsible MDHHS Sponsor	Date
Name of Responsible MDHHS Sponsor (Type or Print) Aaron Ward	Title MDHHS-Unit Manager
Signature of Responsible MDHHS Sponsor	Date

MDHHS RESPONSIBLE PARTY SIGNATURE

Project Title MDHHS integrated investigations of lead in home drinking water	
Request Number (include number from MDHHS-5614, Request for Data)	
Name of MDHHS Chief Compliance Officer	
Signature of MDHHS Chief Compliance Officer	Date
AUTHORITY: This form is acceptable to the Michigan Department of Health and Human Services as compliant with HIPAA privacy regulations, 45 CFR Parts 160 and 164 as amended. COMPLETION: Is required if disclosure is requested.	

The Michigan Department of Health and Human Services (MDHHS) does not discriminate against any individual or group because of race, religion, age, national origin, color, height, weight, marital status, genetic information, sex, sexual orientation, gender identity or expression, political beliefs or disability.

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