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LEGAL HANDBOOK FOR

Establishing a Public Health Registry

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LEGAL HANDBOOK FOR ESTABLISHING A PUBLIC HEALTH REGISTRY

Foreword

Dr. Mona Hanna-Attisha, MD, MPH, FAAP

In what is likely one of the most egregious environmental and public health disasters of our time, the lessons from the Flint Water Crisis are many and still unfolding. It is a story about usurped democracy and the effects of unrepresentative governance. It's also a story about the consequences of austerity and crumbling infrastructure, racism and indifference, public health disinvestment, and disrespect of science.

But above all, the lessons that we are still learning are steeped in our recovery. How does a city recover from such a crisis? And how can our recovery efforts help similarly impacted communities? The Flint story may seem isolated and extreme; however, communities across the nation are increasingly dealing with the consequences of both natural and manmade public health crises. Be it climate crisis–induced extreme weather conditions, global pandemics, or population-level contaminations, lessons learned from the Flint crisis are timely and critical to help communities recover and thrive.

Central to Flint's recovery was the science-driven recognition that the manifestation of the water crisis may take years, if not decades, to actualize. Not only was the city unknowingly exposed to a potent neurotoxin, but its residents were also victims of community-level trauma. Both lead exposure and trauma (especially repetitive and compound trauma) can disrupt multiple physiologic systems, leading to lifelong deleterious consequences. Public health crises are often a failure of primary prevention—individuals should never be exposed to lead; however, the application of secondary prevention is critical to mitigate the long-term consequences of an exposure.

The Flint Registry was conceived as an effort rooted in secondary prevention to longitudinally support victims of the Flint Water Crisis. We knew what we wanted to do—find everyone exposed to the water crisis, get them connected to public health promoting resources, and follow them over time. However, translating that vision into a reality was only possible with the partnership of expert public health lawyers who navigated every step of the way.

This handbook shares our lessons learned regarding the legal nuances of public health registries. It is our hope that this playbook of sorts will inform future registries and their efforts to recovery from a crisis and improve public health.

I. INTRODUCTION

This handbook, based on our experience with the Flint Registry, describes and examines the essential legal issues a public health registry must resolve to obtain relevant patient-level data. The Flint Registry (the Registry) is designed to evaluate and improve health outcomes for people exposed to lead in their water during the Flint Water Crisis. Because the Flint Registry operates separately from the state and local health departments, access to data raises complex legal issues that similar public health registries need to consider.

In the remainder of this introductory section, we describe public health registries generally and the purpose of the Flint Registry specifically, as well as general legal considerations relevant to establishing and operating a public health registry. In Part II, we examine potential sources of legal authority to establish and operate a public health registry, including via a grant of legal authority from a health department. Part III describes broad legal considerations associated with collecting data. Part IV explores legal issues specifically related to obtaining data for recruitment purposes, and Part V explores legal issues specific to obtaining patient outcomes data. Part VI addresses legal considerations relative to obtaining patient consent for various purposes, including participation in a public health registry and collecting and sharing data. Part VII discusses several other data laws the Flint Registry assessed for relevance, including the federal Privacy Act, federal confidentiality protections, and federal and state electronic signature laws. Finally, Part VIII examines practical considerations and lessons learned from our experience operationalizing the Flint Registry.

Public health registries (generally)

Public health registries—sometimes referred to as patient registries, disease registries, clinical registries, or similar—provide a systematic way to collect and monitor health information, typically regarding individuals who share a common health-related characteristic. The U.S. Agency for Healthcare Research and Quality (AHRQ) registry user guide, *Registries for Evaluating Patient Outcomes,* defines patient outcome registries as follows:

> A patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure and that serves predetermined scientific, clinical, or policy purpose(s).[1]

Registries may serve a variety of purposes, such as one or more of the following: (1) documenting a disease's natural history (i.e., its characteristics, management, and outcomes); (2) evaluating the clinical- or cost-effectiveness of health care products or services; (3) tracking adverse events associated with health care services or products; (4) monitoring and improving quality of health care; (5) conducting public health surveillance; and (6) tracking disease control measures such as vaccination.[2]

Public health registries serve two functions: to advance the collective knowledge of diseases and treatments, and to improve individual health by providing referrals and services to registry participants. The key to designing a successful registry is to focus on its intended purpose.[3] For example, a registry used to evaluate patient outcomes requires different design considerations than a registry that simply lists information. Studies based on properly designed and implemented patient outcome registries "can provide a real-world view of clinical practice, patient outcomes, safety, and clinical, comparative, and cost-effectiveness, and can serve a number of evidence development and decisionmaking purposes."[4]

The Flint Registry

Approximately 99,000 Flint, Michigan residents were exposed to lead-poisoned drinking water between April 2014 and October 2015.[5] Under the direction of an emergency financial manager, the city had switched from obtaining treated water from the Detroit Water and Sewerage Department (DWSD) to treating its own water drawn from the Flint River.[6] As a result of the city's failure to implement federally required corrosion control treatment, lead and other

Lead pipe replacement in a Flint neighborhood

contaminants leached into the drinking water.[7] Michigan State University (MSU) researchers detected elevated blood lead levels among Flint children that corresponded to the location and timing of increased water lead levels.[8] Even though the city returned to receiving pre-treated water from the DWSD in October 2015,[9] in January 2016, officials declared a public health emergency in Flint.[10]

In response to this tragedy, a team led by the MSU-Hurley Children's Hospital Pediatric Public Health Initiative (PPHI), the Greater Flint Health Coalition (GFHC),[11] and the City of Flint's Public Health Advisor developed the Flint Registry.[12] The Registry's overarching purpose is "to identify exposed individuals for long-term surveillance, and to determine the neurodevelopmental, medical and socioeconomic impact of the crisis."[13] The Registry's specific aims are as follows:

> Building on registry pilot and planning efforts, we will establish the *Flint Lead Exposure Registry (FLExR)* [now *Flint Registry*], to accomplish the following aims: 1) register eligible Flint residents; 2) conduct baseline health and development assessments on all registrants; 3) assess service needs and eligibility of all registrants and refer them to available clinical, preventive, and lead elimination services; and 4) track and evaluate changes in population lead exposure and in health and development outcomes in response to service utilization via follow-up assessment. FLExR will directly address the public health problems resulting from the Flint Water Crisis by improving the health and development outcomes among registrants and expanding the use of lead exposure reduction methods, as all allied agencies strive towards lead elimination.[14]

The Registry's primary funding has been a grant from the U.S. Centers for Disease Control and Prevention (CDC), under the federal Water Infrastructure Improvements for the Nation (WIIN) Act of 2016, Pub. L. 114-322, § 2203(b), codified at 42 U.S.C. § 300j-27(b).[15] In addition to providing financial support, the CDC also granted MSU's PPHI legal authority to conduct public health activities, including surveillance and intervention activities as discussed further in Part II of this handbook.[16]

After extensive preparatory work, including a pilot study in December 2016 and registry planning and implementation activities in January 2017, the Registry began pre-enrollment (i.e., recording contact information and soliciting community feedback) for interested community members in January 2018. After a small pilot, the Registry officially launched in December 2018, with staff assessing eligibility of those who had pre-enrolled and obtaining individual consent to participate in the Registry. As of July 15, 2021, the Registry had fully enrolled 15,875 individuals and made 22,533 referrals to services. In addition, 3,948 participants had completed one-year follow-up surveys.

This handbook explores the Flint Registry team's specific experiences and challenges navigating federal and Michigan data laws. Nevertheless, many aspects of the Flint Registry experience can be generalized to guide other entities seeking to establish public health registries.

15,875
individuals enrolled

22,533
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As of July 15, 2021

Navigating law generally

Establishing a public health registry raises many legal issues related to collecting, storing, using, and disclosing identifiable health data. One of the first legal issues that a registry must consider is whether its primary function is to conduct human subjects research or public health practice.

Human subjects research includes conducting surveys and collecting and using identifiable private data for research purposes or to create a research repository or database. Most human subjects research conducted or supported by a federal agency must comply with the Federal Policy for the Protection of Human Subjects, known as the Common Rule.[17] The Common Rule specifies how human subject research is to be conducted and reviewed, including institutional review board (IRB) requirements, informed consent, and privacy and confidentiality protections. Public health practice, on the other hand, does not need to comply with the Common Rule.

"Research" means "a systematic investigation … designed to develop or contribute to generalizable knowledge."[18] The purpose of public health research is to contribute to generalizable knowledge with intended benefits beyond the population or program being studied.[19] In comparison, public health practice activities are designed to identify and control a health problem or improve a public health program or service. Defining features of a public health practice activity include: "intended benefits of the project are primarily or exclusively for the participants (or clients) or the participants' community; data collected are needed to assess or improve the program or service, the health of the participants or the participants' community; knowledge that is generated does not extend beyond the scope of the activity; and project activities are not experimental."[20]

The CDC funded the Flint Registry for non-research purposes. Registry funds are intended to address health-related harms experienced by people exposed to lead-contaminated drinking water

Senator Debbie Stabenow with members of the Flint Registry team

The Flint Registry team at a local church engaging and enrolling participants

through the Flint water system. The benefits of participation in the Registry are designed primarily to accrue to Flint residents (e.g., through greater transparency, referrals to services, and improvements in programs and services for residents with lead exposure) rather than persons beyond the Flint community. Because the Registry was designed for non-research purposes, the Common Rule does not apply.

Though the Common Rule imposes a high compliance burden and it may be time-consuming to work through an Institutional Review Board process, there are some potential advantages that accrue to public health research registries because they are subject to its requirements. For one, the federal research regulations provide an existing infrastructure, presenting answers to many legal, ethical, and logistical issues. There are also thousands of similar projects that have worked through the same process, so the potential for peer support is much greater. In contrast, no specific laws govern the process for a university or nongovernmental organization establishing a public health practice registry under a grant of public health authority from a federal agency, nor are there many similarly situated registries from which to derive support. Navigating the legal issues associated with establishing a public health practice registry has required careful consideration of many areas of federal and state law, including public health authority, data protection, and electronic consent, and has involved considerable legal ambiguity.

II. LEGAL AUTHORITY TO ESTABLISH AND OPERATE A PUBLIC HEALTH REGISTRY

State law establishes health departments and typically grants them legal authority to establish public health registries and populate registries with data reported by health care providers or others. Other entities, such as universities, are not health departments. Lacking public health powers, they rely on specific legislative authority, becoming a public health authority, or using patient consent to establish and operate a public health registry. In this part, we describe and compare the authority of the state health department and the university to establish a public health registry and collect personal and health information about individuals for the registry. While public health authority is essential, we also describe its limitations in securing data that are important to fully realizing the Registry's purpose.

Authority of governmental public health agencies to collect data for a public health registry

Michigan's Public Health Code establishes the state health department, the Michigan Department of Health and Human Services (MDHHS).[21] MDHHS is responsible for collecting health and other data to identify and investigate the sources of illness, injury, and death, implementing programs and services to mitigate these causes, and evaluating prevention and control efforts to ensure they are effective.[22] The U.S. Supreme Court has held that health departments, such as MDHHS, have broad authority to collect data, including electronic health information, for statistical and public health purposes.[23]

The Public Health Code and implementing regulations establish and require reporting to several MDHHS information systems and registries (see accompanying text box). Health care providers—such as physicians, hospitals, and clinical laboratories—supply important health information, including individually identifiable health information, to these information systems and registries. Most health care providers are covered entities that are subject to privacy standards established by the U.S. Department of Health and Human Services (HHS) in rules[24] adopted under the Health Insurance Portability and Accountability Act (HIPAA).[25] HIPAA prohibits health care providers from disclosing identifiable information about their patients or their patients' families without written authorization unless HIPAA allows the disclosure.[26]

HIPAA allows covered entities to disclose identifiable health information, without authorization, to "public health authorities," including governmental public health agencies and their employees, agents, or contractors. A provider can disclose data to a state health department without an individual's permission if required by law. Examples include state laws that require providers to report serious communicable diseases, blood lead levels for children and adults, child immunizations, cancer diagnoses, and birth and death information. Moreover, the provider can disclose an individual's information to a public health agency for public health purposes even if there is no reporting mandate as long as the public health agency is legally permitted to collect the information, such as MDHHS' collection of immunization information for adults.[27]

HIPAA also allows covered entities to disclose identifiable health information, without authorization, to persons or entities to whom public health agencies have granted authority:

> *Public health authority* means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate. [Emphasis added].[28]

As discussed below, a public health authority, namely, the CDC, granted public health authority to MSU for the Flint Registry, enabling HIPAA-covered entities to report an individual's health data to it without obtaining permission from the individual.

The Public Health Code and implementing regulations establish and require reporting to several state information systems and registries, including the system of vital records, disease surveillance system, Michigan Care Improvement Registry (which tracks immunizations), lead safe housing registry, Childhood Lead Poisoning Prevention Program blood lead surveillance database management system, birth defects registry, cancer registry, and trauma registry. Under its general powers, MDHHS might create additional registries, although reporting to the registry would be voluntary unless reporting is legally required. MDHHS also collects and maintains data related to federal health programs that it administers, including Medicaid and the Women, Infants, and Children Supplemental Food Program (WIC).

Authority of a university to collect data for a public health registry

At times, a university might establish a registry that provides advantages over a state or local health department registry. For example, a university might support a registry with an advanced data center and analytics, recognized experts and researchers, and positive relationships

The right to collect and use public health data is typically accompanied by a duty to avoid unwarranted disclosures. In other words, if you collect it, you must protect it. The duty to protect data from unauthorized disclosure or access can be statutory, regulatory, or ethical. Regardless of the source, protecting data is essential to ensure the public's trust and protect individuals from embarrassment, stigma, or discrimination that may result from disclosing personal information.

with the subject community. In Flint, MSU's leadership (which had no role in the tragedy) engendered greater community support for and participation in the Registry. While universities often make valuable contributions to the public's health, they are not public health departments or agencies. As such, a university generally lacks the authority to collect identifiable health information without the individual's permission, even for public health-related purposes.

Fortunately, federal law allowed MSU to become a public health authority. The federal Public Health Service Act, as amended, directs the HHS Secretary to establish a Flint Water Crisis lead exposure registry to collect data on a voluntary basis.[29] Under this authority, the Secretary established the Flint lead exposure registry through a CDC grant award to the MSU-Hurley Children's Hospital Pediatric Public Health Initiative.

The CDC explained that it considers the registry to be a public health surveillance and intervention activity for which HIPAA permits covered entities to disclose identifiable health information. (See Appendix A for CDC Grant of Authority to Flint Registry.) This written statement documents the Registry's health authority status, acting on behalf of HHS/CDC. It also explains the legal basis under which the Registry may request information, helping a covered entity verify that HIPAA permits the disclosure. In this regard, HIPAA permits a covered entity to rely on a written statement of authority for disclosing information, as long as the statement of authority is reasonable.[30] Accordingly, HIPAA allows an entity to provide any Registry-related data (including identifiable health information) to MSU that it could provide to the CDC.

Challenges in obtaining identifiable public health data, notwithstanding CDC's grant of authority

A public health grant of authority can help a university or another type of entity that is not a public health agency collect data. For the Flint Registry, the grant of authority allows a health care provider or a health plan (such as Medicaid) to provide identifiable data, without an individual's authorization, to the Registry without violating the HIPAA Privacy Rule. While helpful to facilitate data exchange, the grant of public health authority failed to convince MDHHS to provide some of the requested data absent each individual's consent. The grant of public health authority was ultimately insufficient to obtain certain MDHHS data for several reasons, including limitations on data disclosure under state law, as discussed further in Parts IV and V.

The Flint Registry Team participating and connecting at a community event.

III. GENERAL LEGAL CONSIDERATIONS FOR DATA COLLECTION

Operationalizing a public health registry generally involves two major phases of data collection: recruitment data and outcomes data. First, registries must obtain information needed to recruit potentially eligible participants. Second, they must obtain the data that the registry was created to monitor (e.g., patient outcomes). These two data collection phases have many legal aspects in common but also implicate several distinct legal issues—for example, with regard to obtaining participant consent as discussed in Parts IV through VI.

For recruitment purposes, the Flint Registry needed names and addresses of all potentially eligible individuals, birthdate (to enable de-duplication of records), and current contact information. In its second phase of data collection, the Registry needed outcomes data to assess and monitor individual health status and to evaluate changes in population health outcomes. Together, this amounts to a considerable volume of data needed from various sources, ranging from state and federal agencies and local school districts to health care providers and individual Registry participants. Each data type and source implicates different federal and state laws and legal challenges.

As noted in Part II, the CDC's grant of public health authority to the Flint Registry enabled data holders to disclose identifiable data to the Flint Registry. Still, the grant of authority was not sufficient for the Registry to obtain all relevant data or, in many instances, even to simplify the process of collecting data. In part, this is because providing data is generally voluntary (i.e., left to the data holder's discretion) rather than being legally mandated. As a result, the party requesting the data must make both a legal case and a business case for data sharing. In other words, identifying a legal pathway for the proposed data sharing is only half of the equation. The other half involves persuading a data holder that the proposed sharing is worth the often considerable time, expense, and effort required to agree upon and implement a legal pathway.

The voluntary nature of data sharing underscores the importance of relationship-building for successful data sharing. Of course, relationships are crucial to a public health registry for other important reasons, including engendering community trust and, in turn, encouraging participation. For all of these reasons, the Registry invested tremendous resources into building relationships and assembling a diverse team of stakeholders and partners to contribute to and guide the Registry's development. In addition to local nonprofits, philanthropies, coalitions, and parent groups, the Registry team included representatives from state and local government, local health care systems, and providers—each of which holds data crucial to the Registry's successful operation.

All team members, including these data holders, participated in monthly group calls and regularly met with Registry leadership in smaller groups. Through their involvement, representatives of the data holders developed a nuanced understanding of the Registry's goals and operations, alerted the Registry team to potential data sharing obstacles, and helped shepherd data requests through their agencies/organizations. Significantly, these data holders also developed a stake in the Registry's success. Registry leadership took additional steps to cultivate relationships with data holders who were not involved in the day-to-day work of creating the Registry (e.g., local public school districts). This involved identifying how the Registry's data collection and analysis could help these groups carry out their mission and responsibilities. Despite these intensive efforts, the Registry was not ultimately successful in obtaining all of the data needed.

Many aspects of the Flint Registry's experience with navigating data sharing laws can be generalized. For example, an initial step for any proposed data sharing is to identify what data are needed and why; the why is crucial because most laws restrict and permit data sharing based on the purpose for which the data are requested. The next step is to consider all potential parties from whom the data can be obtained. It is essential to identify all potential data providers because different laws may apply to each, rendering some sharing arrangements simpler than others. Additional considerations include: How much data is needed to accomplish the intended purpose? With whom will the data be shared and why? What protections are in place to safeguard the data? These and other questions are explored more fully in the Network for Public Health Law resource, "Checklist of Factual Information Needed to Address Proposed Data Collection, Access and Sharing to Improve the Health of Communities," reprinted with permission in Appendix B.[31]

IV. LEGAL ISSUES ASSOCIATED WITH RECRUITING REGISTRY PARTICIPANTS

One of a public health registry's first legal hurdles is obtaining data needed to recruit participants. Since the purpose of recruitment data is to make initial contact, the data must be obtained without individual consent. In addition, the data often must be gathered from sources not typically associated with health data, such as a state department of motor vehicles or a local school district. Non-health agencies may pose unique obstacles to obtaining data for a variety of reasons. For example, the agencies may be less familiar with public health registries, they may not have standardized processes in place to request data, or they may be subject to laws that do not provide exceptions for disclosing data for public health purposes (in contrast to most health-related data laws).

The Flint Registry's first phase of data collection involved obtaining contact information for eligible individuals to invite enrollment in the Registry. Although many people learned about the Flint Registry through their health care providers, the media, community groups, churches, and the Registry's dedicated community outreach efforts, many eligible individuals were unlikely to hear about the Registry through these channels—especially those who had moved out of the city. Thus, the Registry sought to identify and contact eligible individuals directly by requesting names, current contact information, and birthdate (to match and de-duplicate records) from the Michigan Department of State (DOS), Flint's local public school systems, and MDHHS. The Registry's experience with each of these sources of information and applicable laws is described below. The Registry's successes and challenges may help to inform other registries' efforts to obtain similar data in other states.

Obtaining recruitment data from the Michigan Department of State

In Michigan, the DOS issues driver's licenses and state identification cards, similar to the Department of Motor Vehicles in most states. The Flint Registry sought name, birthdate, address, and phone number from the DOS's driver's license and personal identification holder records. This data request implicated the federal Driver's Privacy Protection Act,[33] the Michigan Vehicle Code,[34] and the State Personal Identification Cards law.[35]

Eligible persons included those who lived, worked, attended school or daycare, or regularly visited Flint between April 2014 and October 2015, including children born before August 1, 2016.[32]

Federal and Michigan laws generally prohibit the DOS from releasing personal information. However, they provide an exception allowing for disclosure of certain data for use by a federal, state, or local governmental agency in carrying out its functions or for use by a private person or entity acting on behalf of a governmental agency to carry out the agency's functions.[36] Disclosure under this exception is discretionary ("may disclose") rather than mandatory ("shall disclose") under both federal and state law.[37] Generally, data may not be disclosed for research activities if it will be used to contact individuals, nor may it be disclosed for nongovernmental bulk solicitations.[38]

The Registry sent a request letter to the Michigan DOS (see Appendix C) as required by DOS policy.[39] With the letter, the Registry provided documentation of the CDC's Grant of Authority, which treats the Registry as a public agency and public health authority for purposes of implementing the Registry. Accordingly, the Registry requested data under the governmental agency exception. The letter further explained that the Registry would use the information for the public health purpose of compiling and confirming contact information for eligible persons to facilitate outreach and enrollment in the Registry, a public health surveillance and intervention activity. The DOS granted the Registry's request and provided the information.

Obtaining recruitment data from local school districts

Schools maintain education records that directly relate to each student. Education records include contact information for students and their parents such as an address, phone number, email address, and birthdate (collectively referred to as directory information), as well as more sensitive information related to student performance and student health, such as transcripts, attendance records, disciplinary records, special education assessments, and medical or health-related records. The Flint Registry requested student directory information from the Genesee Intermediate School District (GISD) and the Flint Community Schools (FCS) for recruitment purposes. The request letters are included in Appendix D.

Public schools must comply with the Family Educational Rights and

Before requesting information from a school district, it is helpful to review the district's policies for disclosure of student information. It is also helpful to review the district's annual notice to parents regarding its policies and the parent's rights under FERPA, which may include opting out of certain disclosures. A school district's policies and annual parental notice are often posted on its website and will be helpful in evaluating the likelihood of obtaining wanted information and in framing a request to meet any prerequisites or conditions for disclosure.

Privacy Act (FERPA),[40] which prohibits disclosing identifiable information without consent unless FERPA permits the disclosure.[41] FERPA requires that school districts adopt disclosure policies and inform parents of these policies in an annual notice.[42]

The Registry submitted a written request for directory information to each school district based on the following two exceptions to FERPA's consent requirement.

DESIGNATED DIRECTORY INFORMATION EXCEPTION

FERPA permits disclosure of specified directory information without consent if the information would not generally be harmful or an invasion of privacy if disclosed.[43] Nevertheless, both school districts denied the Registry's request for directory information, each for different reasons.

The GISD denied the request because its own policy permitted disclosure of only a student's name and the student's participation in officially recognized activities and sports. The district policy did not permit non-consented disclosure of information enabling the Flint Registry to contact students and their families.

The FCS policy permitted disclosure of the directory information the Registry requested unless the parent opted out. A school must tell parents about its policy on disclosing directory information, allowing them to opt out within a reasonable amount of time. In this case, the school district declined to provide directory information because it did not track opt-out requests in a manner that permitted efficient determination of which students' parents had opted out and, therefore, which information needed to be excluded.

HEALTH AND SAFETY EXCEPTION

As discussed earlier, HIPAA permits a covered entity to disclose identifiable information, without consent, concerning an individual or the individual's family to a public health authority for public health purposes such as surveillance, investigation, and intervention. Although the Registry is a public health authority, FERPA contains no such provision to allow disclosure to a public health authority for routine public health purposes.

FERPA allows information to be disclosed to appropriate parties in connection with an emergency if necessary to protect the health or safety of the student or other individuals.[44] In its request for information, the Registry explained that exposure to lead-contaminated water posed and continues to pose a significant threat to the health or safety of a student or other individuals. In this regard, lead is a known neurotoxin that has been associated with reduced intellectual abilities, learning deficits, and neurobehavioral disorders in children. Lead is long-acting; it can stay in the body for years with long-term consequences that continue after exposure. Testing and support services must be provided to children as soon as possible to reduce the long-term health and educational consequences from exposure. Participation in the Registry would help address this threat by connecting persons exposed to lead-contaminated water to services that may reduce this exposure's negative impact.

To qualify for this exception, the school must determine that it is necessary to disclose personally identifiable information to appropriate parties to protect the health or safety of the student or other individuals.[45] In making a determination, the school:

- May take into account the totality of the circumstances pertaining to a threat to the health or safety of a student or other individuals.
- Must determine that there is "an articulable and significant threat to the health or safety of a student or other individuals."
- Can only disclose information from education records to an individual or entity that is able to use the information to protect health or safety.[46]

Both school districts denied the request, determining that it did not satisfy FERPA's criteria for disclosure. In particular, the districts concluded that this exception to FERPA's general consent requirement is limited to the emergency period, which would be 2014-2015 when the exposure occurred.

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In summary, the Registry failed to obtain directory information from either school district. Both districts agreed to assist the Registry with its recruitment efforts by providing information about the Registry to the parents. However, the districts provided information in ways that reduced the likelihood of the parent receiving the information, such as sending the information home with the child or publishing information on their district website. While the districts' efforts were useful, they were not as effective as the Registry's direct outreach.

Obtaining recruitment data from the Michigan Department of Health and Human Services

The Registry identified MDHHS as a key data source due to the volume and variety of data it collects via public health surveillance systems and registries and the programs it administers. For recruitment purposes specifically—i.e., to inform individuals about the Registry and invite them to participate—the Registry requested data without prior individual consent. The Registry sought data from the following MDHHS data systems:

- Michigan Medicaid data[47]
- Michigan Care Improvement Registry (MCIR)[48]
- Childhood Lead Poisoning Prevention Program (CLPPP)[49]

Generally, MDHHS has legal authority to share data, but the exercise of its authority depends on the Michigan Public Health Code's general confidentiality and disclosure requirements, federal and state laws specific to each data type, and MDHHS's discretion and professional judgment.

GENERAL REQUIREMENTS UNDER THE MICHIGAN PUBLIC HEALTH CODE

Part 26 of the Michigan Public Health Code, applicable to all of the data MDHHS maintains, provides for confidentiality of MDHHS data systems, records, and information. Part 26 recognizes the importance of protecting privacy and sharing data for research, evaluation, demonstration, and health statistical activities and studies. It requires that MDHHS establish a procedure for disclosing identifiable information that considers many interests, including individual rights and the public's interest.[50] We knew these factors would be central to MDHHS's analysis of the Registry's data requests, so we used them to frame our legal assessment, weigh considerations for sharing data, and develop proposed terms and conditions for the requested disclosures.

SPECIFIC DATA LAWS

In addition to the Public Health Code's general data provisions, each data system is subject to varying federal or state laws with unique disclosure criteria. Accordingly, we analyzed laws governing each data system to determine the legal pathways for obtaining data at the recruitment stage.

Medicaid data are the only data the Flint Registry requested that are HIPAA covered.[51] Although HIPAA compliance was not relevant to most of the requested data, it was necessary for obtaining Medicaid data. The Registry also had to satisfy other laws governing Medicaid, specifically, the Social Security Act, federal Medicaid regulations, and Michigan's Social Welfare Act. Each of these laws contain unique criteria for disclosure.

Under MDHHS's hybrid designation,[52] MCIR program data are not HIPAA covered but are confidential under Michigan law.[53] MDHHS may share MCIR data with an authorized user for permitted purposes.[54] MDHHS could also disclose data to a study or research project reviewed by the scientific advisory panel and approved by MDHHS's director.[55] Therefore, the Registry may obtain MCIR data at MDHHS's discretion.

Under MDHHS's hybrid designation, CLPPP data are not HIPAA covered but are confidential under Michigan law.[56] MDHHS may share CLPPP data "if necessary for the purpose of public health activities designed to prevent or mitigate lead poisoning within a community."[57] Therefore, the Registry may obtain CLPPP data in its role as a public health authority.

Further discussion of the laws affecting each database, the laws' criteria for disclosing information about individuals, and satisfaction of these criteria are in Appendix E.

COLLABORATING WITH MDHHS LEGAL COUNSEL

MDHHS provided the Registry with memoranda describing the agency's analysis of its legal authority to disclose information from each requested data source. We used the MDHHS memoranda as a starting point for our research. For the most part, our research aligned with the MDHHS memoranda, but there were several instances of differing legal interpretation. We created a matrix that showed a breakdown of the legal requirements for disclosure for each database, MDHHS's interpretation of their legal authority to disclose information, and our interpretation. We then held a meeting to review the matrix

Michigan Medicaid data includes claims data and demographic information regarding enrollees.[47]
The Michigan Care Improvement Registry (MCIR) is an immunization database that compiles comprehensive immunization records for Michiganders of all ages.[48]
The Childhood Lead Poisoning Prevention Program (CLPPP) data system houses blood lead test results for children and adults.[49]

and discuss any points of departure. In some instances, we agreed on a legal mechanism for disclosure, but not in other cases.

MDHHS's memoranda highlighted issues requiring further clarification. For example, it became clear that MDHHS needed detailed information about the Registry's intended data uses and confirmation that data would be used only for public health purposes. The Registry provided this assurance via the parties' data use agreement, discussed below.

MDHHS also expressed concern about the Registry's data retention and use in the event its public health authority status ends. This concern is heightened for a nongovernmental registry whose public health authority status is derived from a governmental agency rather than law because the grant of authority may be withdrawn with relative ease. For example, the CDC might withdraw the Registry's grant of public health authority if the Registry's federal funding ends. Accordingly, the Registry included provisions in its data management plan to address this concern.

Even if legal criteria are satisfied, HIPAA's public health exception does not mandate sharing information for public health purposes, so providing identifiable data under HIPAA's public health exception is discretionary. MDHHS may deny the request or impose burdensome restrictions. In this sense, a registry's CDC grant of public health authority may make some agencies more comfortable providing requested data and minimizing restrictions even if the grant of authority does not fully assure all desired data sharing.

DATA USE AND NONDISCLOSURE AGREEMENT

To address the above concerns, MDHHS and the Registry developed a Data Use and Nondisclosure Agreement (DUA) to enable MDHHS's initial information sharing to the Registry for recruitment purposes (see Appendix F). The agreement describes the terms for sharing information and identifies the data elements to be shared. Under the agreement, the Registry obtained data from MDHHS's Medicaid, MCIR, and CLPPP data systems to use for recruitment purposes under its grant of public health authority. The DUA also had to satisfy additional legal criteria, as described above, that allowed for the disclosure of data to the Registry without the need for individual authorization.

V. LEGAL ISSUES ASSOCIATED WITH OBTAINING HEALTH OUTCOMES DATA FROM THE MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

For participant health outcomes specifically—i.e., to evaluate the impact of Registry participation and improvements to Flint residents' health—the Registry requested data under several legal pathways, discussed below. In addition to new data requests from the Medicaid, MCIR, and CLPPP data systems, the Registry sought to obtain data from the following MDHHS data systems:

- Michigan Disease Surveillance System (MDSS)[58]
- Vital Records[59]
- Lead Safe Home Program (LSHP)[60]
- Michigan WIC's management information system (MI-WIC)[61]

See Appendix G for a list of health outcomes data elements requested from each MDHHS data system.

As described above with respect to recruitment data, each MDHHS program must comply with the Michigan Public Health Code's general confidentiality and disclosure requirements as well as program-specific laws. The disclosure further depends on MDHHS's exercise of discretion and professional judgment.

Unlike the recruitment stage, the Registry had already established contact with participants when seeking outcomes data. This provided the Registry with an opportunity to seek participants' consent to obtain data, discussed below. Additionally, data elements previously obtained from MDHHS were limited in scope and used solely to identify and contact potential participants. Outcomes data involves more sensitive health information, such as diagnostic information and health status. At this stage, we looked at all possible mechanisms for the Registry to obtain data from each MDHHS data system, including: (1) without consent under the Registry's public health authority; (2) without consent under other legal frameworks; and (3) with participants' consent.

General requirements under the Michigan Public Health Code

As discussed above, Part 26 of the Michigan Public Health Code applies to all of the data MDHHS maintains and provides for confidentiality of MDHHS data systems, records, and information.[62]

The Michigan Disease Surveillance System (MDSS) is a communicable disease reporting system developed to provide for the secure transfer, maintenance, and analysis of communicable disease surveillance information and facilitate coordination among local, state, and federal public health agencies.[58]
The Michigan Vital Records data system maintains records for vital events in Michigan, including birth, pregnancy, mortality, infant mortality, marriage, and divorce.[59]
The Lead Safe Home Program (LSHP) helps families identify and remove lead hazards from homes. As part of the program, MDHHS maintains a database with information on families and buildings that have received free lead remediation services through the program.[60]
Michigan WIC's management information system (MI-WIC) maintains records on clients enrolled in Michigan's Women, Infants, and Children program. MDHHS uses this robust data to guide interventions and decision making to improve enrollees' health outcomes.[61]

Specific data laws

In addition to the Public Health Code's general data provisions, each data system is subject to varying federal or state laws with unique disclosure criteria. For example, the Women, Infants, and Children (WIC) Program must comply with U.S. Department of Agriculture confidentiality requirements set forth in federal regulations.[63] Accordingly, we analyzed the laws governing each data system to determine the legal pathways for obtaining individual health outcomes data.

For several data systems, the Registry could obtain information either by participant consent or through its grant of public health authority. Because the CDC can rescind the Registry's grant of public health authority, the Registry took a two-pronged approach to obtain data from MDHHS. First, the Registry and MDHHS executed a DUA for health outcomes data that allowed for the disclosure of data pursuant to its public health authority. This included data from Medicaid, CLPPP, Vital Records, and LSHP. Second, the Registry sought consent from Registry participants to obtain data from Medicaid, MCIR, CLPPP, MI-WIC, and LSHP.

Please refer to Part IV for discussion of the Registry's authority to obtain Medicaid, MCIR, and CLPPP data under the Registry's grant of public health authority. Under MDHHS's hybrid entity designation, MDSS, Vital Records, LSHP, and MI-WIC data are not HIPAA covered.

MDSS data are confidential under Michigan law.[64] Michigan law requires that MDSS data identifying an individual may only be disclosed with the individual's consent or by consent of the individual's guardian.[65] Ultimately, the Registry chose not to pursue obtaining MDSS data because there was extensive

overlap in data elements with other MDHHS data systems.

Michigan's Vital Records law allows MDHHS to provide data to "federal, state, local, and other public or private agencies for statistical or administrative purposes on the terms or conditions prescribed by" MDHHS and the data may only be used "for the purpose for which" it was requested.[66] Therefore, the Registry may obtain Vital Records data at MDHHS's discretion.

LSHP data are confidential under Michigan law.[67] MDHHS may share LSHP data "if necessary for the purpose of public health activities designed to prevent or mitigate lead poisoning within a community."[68] Therefore, the Registry may obtain LSHP data in its role as a public health authority.

Federal WIC regulations restrict disclosures of confidential applicant or participant information to persons directly connected with the administration or enforcement of the WIC program who need to know the information for WIC program purposes. The regulations allow for disclosing confidential applicant or participant information outside the WIC agency for non-WIC purposes under limited exceptions.[69] MDHHS determined that the process for releasing participant information from MI-WIC to the Registry without participant consent would be administratively burdensome because MDHHS would need to amend its WIC State Plan. Therefore, MDHHS determined that participant consent was the only viable pathway for the Registry to obtain WIC data.

Further discussion of the laws affecting each database, the laws' criteria for disclosing information about individuals, and satisfaction of these criteria are in Appendix E.

Consent considerations

Whenever an entity seeks to obtain data, it should consider all legal pathways. Obtaining data without individual consent has administrative and logistical benefits. Still, there are many benefits to requesting participant consent in place of or in addition to receiving data through other means. For example, a consent process can provide transparency and foster participants' trust in the Registry.

However, a consent process can also be administratively burdensome in some instances and could slow the speed by which data are obtained. For example, some Michigan laws require photo identification and a notary or magistrate to witness consent before it is considered valid. As mentioned above, the Registry ultimately decided to take a two-pronged approach that included seeking participant consent to obtain data from MDHHS. The consent process is described in more detail below.

Collaboration with MDHHS legal counsel

The process of resolving legal issues and arriving at a shared understanding of the legal pathways for obtaining MDHHS data required close collaboration between the Registry and MDHHS and far more time than anticipated. As noted above, MDHHS has legal authority to release information to the Registry if the Registry fulfills all applicable legal requirements, but it is not legally compelled to do so. As a result, the Registry bore the burden of proving that any disclosure is legally permissible and complies with applicable data protection laws.

Though it might seem that developing a DUA would be a first step to sharing information and could facilitate overcoming bureaucratic hurdles, we found it impossible to start the DUA process before determining the legal pathway through which each dataset could be obtained (i.e., through the Registry's grant of public health authority or through participant consent). The Registry and MDHHS also had to resolve differing interpretations regarding certain points of law.

For example, there was a difference in interpretation regarding HIPAA's general prohibition on "compound authorizations," which are authorizations that are combined with any other legal permission. We provided MDHHS with our legal interpretation, supported by evidence from HIPAA's preamble, federal agency guidance, and customary practice in the field. After extensive discussion, MDHHS found our analysis unpersuasive and the Registry had to modify its participant consent form and electronic consent process to comply with MDHHS's guidance. Resolving each issue took considerable time.

Once we resolved MDHHS's legal concerns and determined the legal pathway for obtaining data from each database, the Registry developed its consent process and executed a DUA with MDHHS.

Data Use and Nondisclosure Agreement

As discussed above, the Registry utilized a DUA to obtain information under its grant of public health authority. The DUA, included in Appendix G, describes the legal basis for disclosure. MDHHS data systems included in the DUA are Medicaid, CLPPP, Vital Records, and LSHP.

In the DUA, the Registry provides a detailed description of the purpose for which they are requesting data from each MDHHS data system and its intended use of the data. It also includes a detailed list of requested data elements from each data system, contained in Appendix G. The agreement establishes terms for sharing information between the parties, such as restrictions on the use of data, the method by which data will be shared, and data retention and destruction requirements.

VI. LEGAL ISSUES ASSOCIATED WITH PARTICIPATION AND CONSENT

The Flint Registry requested participant consent for several purposes, including to participate in the Registry, to allow third parties (e.g., MDHHS) to share the individual's health information with the Registry, and to allow the Registry to share the individual's health information with service providers (e.g., to make referrals). Legally and ethically, consent must be competent, voluntary, informed, and understood.[70] Additional informed consent standards vary based on which laws govern the collection of the relevant type of data. More than one data protection law may apply, and informed consent requirements must be met for all applicable laws.

It is also important to recognize that fully realizing one's ethical duties may require steps beyond existing legal requirements. For example, when collecting data from or about Registry participants, there is an ethical duty to respect each participant. The principle of respect for persons requires individuals to be treated as autonomous agents, including by providing all information necessary to make considered decisions, and requires protection for individuals with diminished autonomy, such as children, individuals with relevant intellectual or developmental disabilities, and people whose liberty is restricted (e.g., by incarceration).[71]

The Belmont Report, produced in 1979 by the congressionally created National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, enshrines three basic ethical principles to guide human subjects research: respect of persons, beneficence, and justice. The Belmont Report's ethical principles are useful to guide development of an informed consent process even for activities that fall outside the traditional definition of human subjects research, including public health activities that may not be considered human subjects research under U.S. HHS or U.S. Food and Drug Administration (FDA) research regulations. The Belmont Report states that respect for persons requires that prospective subjects "be given the opportunity to choose what shall or shall not happen to them."[73]

Law defines what an agency can do. Ethics define what an agency should do.

Any data collection from individuals should be conducted ethically and following best practices.[74] It is also essential to respect a participant's right to confidentiality. Confidentiality is the duty of someone in possession of an individual's personally identifiable information to keep that information private.[75] Confidentiality comes into play when someone has a legal or ethical obligation not to disclose information about an individual without consent or to unauthorized individuals. These duties are often codified within data protection laws to ensure that entities or persons who control an individual's personal information maintain its confidentiality.

Below is a discussion of legal requirements that apply to consent to participate in the Registry, consent for third parties to share with the Registry, and consent for disclosure of information to service providers. We then discuss development of the consent form and special considerations for legal representatives.

Consent to participate in the Registry

Some laws prescribe how consent should be obtained from participants in a health information registry like the Flint Registry. We analyzed laws that could be relevant to the Flint Registry, including federal research regulations, HIPAA, and Michigan's Public Health Code.

Public health activities may or may not be considered human subjects research under HHS or FDA research regulations. According to the Belmont Report, if any aspect of an activity constitutes research, then the entire activity should undergo regulatory review.[76] However, CDC only considers an activity to be research if the primary intent is to contribute to or generate generalizable knowledge.[77] The primary intent of the Flint Registry's data collection activities

When asking an individual for their consent, it should be:

1. **Competent - The individual has legal capacity to make a decision.**
2. **Voluntary - The individual's decision is freely made.**
3. **Informed - The individual's decision making is based on knowledge.**
4. **Understood - The individual understands information needed to give informed consent.[70]**

In addition to consent for participation, the Registry sought survey data directly from registry participants. There are several advantages to obtaining data directly from participants. Such data produces information based on bona fide observations. Additionally, surveys can quickly and cheaply generate a large amount and great diversity of data. Surveys are conducted over a defined period which assists project staff in planning and delivering results. Finally, surveys can derive information from participants not captured in data from other sources, such as state data registries or medical records. Therefore, the registry can tailor questions to participants that help fill in gaps in knowledge and get a complete picture of participants' experiences and outcomes.[79]

is to increase the quality and quantity of data available to inform policy and program administration for the Flint community's lead poisoning prevention and elimination efforts.[78] Under this standard, the Registry would be exempt from consent requirements under Federal research regulations.

The Registry is also exempt from HIPAA consent requirements because it is not a HIPAA covered entity. However, the Registry's consent form was designed to comply with HIPAA's authorization requirements because MDHHS required this for the Registry to obtain Medicaid claims data, as discussed below.

Additionally, the Registry does not need to comply with any consent requirements in the Michigan Public Health Code because it is not a state or local public health authority within the law's definition.

Consent for third parties to share data with the Registry

The Registry sought information about participants from MDHHS and other external sources. Generally, laws require individuals to consent before their personally identifiable information can be shared with a third party. We analyzed applicable laws to determine whether they require consent for such sharing.

Some MDHHS data systems, such as the Michigan Medicaid data system, are HIPAA covered. Under HIPAA's public health exception, the Registry is not required to obtain participants' consent before requesting HIPAA covered data for public health purposes. But the Registry was concerned with requesting information solely under its grant of public health authority because the grant of public health authority could be revoked and the Registry would no longer have access to that data. Additionally, some of the laws governing MDHHS data systems that are not covered by HIPAA either do not have an exception for the release of data to a public health authority or require individual consent to share any personally identifiable data.

Given the variation in legal requirements across MDHHS data systems, the Registry decided to use a two-pronged approach to obtain this data, requesting some data as a public health authority and some data with the consent of Registry participants. Medicaid data was part of the data requested pursuant to participant consent. Because the Michigan Medicaid data system is HIPAA covered, the Registry needed to structure its consent form to meet the HIPAA Privacy Rule's standards for a HIPAA authorization, described in detail below.

For some types of data, consent might be the only option to obtain identifiable data. For example, if the Registry had sought to obtain student performance and health information from education records governed by FERPA for outcome assessment purposes, consent would provide the only avenue for obtaining the information.[80]

Consent for disclosure of information to service providers

The Registry's primary goal is to connect individuals exposed to lead-contaminated water during the Flint Water Crisis to services mitigating lead poisoning's harmful effects. For example, the Registry can help participants access services to assist with obtaining medical insurance, nutrition support, early learning support for children, and home lead identification and remediation.

Example: External Service Provider
Through the Flint Registry, children exposed to lead-contaminated water may be referred to the Neurodevelopmental Center for Excellence (NCE), a division of Genesee Health System that offers neuropsychological assessments to individuals impacted by the Flint Water Crisis. According to the NCE website, neuropsychological assessments look into how a child problem solves, remembers information in the short and long term, uses and understands language, processes information visually and verbally in different ways, and learns. A neuropsychological assessment can help children and families in many ways. The assessment can identify a child's strengths and areas of difficulty, helping parents, educators, and physicians figure out what reasons are behind a child's difficulties. It can also identify educational and behavioral health treatment needs, provide a comprehensive list of recommendations and next steps, and help the child and family access recommended services, such as educational, behavioral health, and medical health care services.[81]

The Registry uses survey responses regarding participants' health, household information, and exposure to lead to identify services within the community for which the participant may be eligible.

To make these referrals, the Registry needs to share participants' identifiable information with external service providers.

The Registry is not legally required to obtain consent to share personally identifiable information with service providers because it is not a HIPAA covered entity. We did not identify other applicable laws that required consent to share such information. Though not required by law, the Registry decided to seek participant consent for uses and disclosures of personally identifiable information to assure transparency and build community trust. Consent to share information for referrals and services is not a requirement of participation in the Registry, and participants may opt out or change their designation at any time. The Registry also requested consent to obtain preventive service outcomes and process metrics data to evaluate the impact of the Registry's referrals on service utilization.

Developing a consent form

Though the Registry is not legally required to obtain consent from individuals for participation in the Registry, the Registry determined that complying with existing ethical standards for obtaining informed consent would provide transparency and preserve community trust. Implementing a consent process can have many benefits. For example, obtaining individuals' consent makes it possible to cover data uses that might not be allowed under narrow statutory provisions covering unconsented data disclosures, such as a public health exception. Having a consent process also helps address any concerns about data retention and use as well as disposal after the project concludes.

The Registry developed a consent form that participants must sign before participating in the Registry. When drafting a consent document, it is necessary to balance providing sufficient detail so that the decision is informed and limiting content to the essential points so that the information is understandable. For most participants, consent was obtained electronically on a tablet or mobile device, so considerations for viewing the consent document in this way also had to be taken into consideration.

When drafting the consent document, a primary consideration was seeking permission to obtain information from several MDHHS data systems with varying consent requirements. The Registry included a section for participants to consent to have personally identifiable information from MDHHS data systems shared with the Registry. The Registry listed each of the MDHHS data systems and programs in the body of the consent, except for Medicaid data.

For the Registry to obtain MDHHS Medicaid data, a separate form that met HIPAA authorization requirements was required, discussed below. For the electronic consent document, the HIPAA authorization was presented on a screen without any additional information so that it met MDHHS's interpretation of the HIPAA Privacy Rule's restriction of a compound authorization. Outside of MDHHS's HIPAA authorization requirements, no other legal requirements dictated the form of the consent document.

In developing its consent forms, the Registry benefitted tremendously from lessons learned by other public health registries that obtained data through participant consent, particularly the World Trade Center (WTC) Health Registry (created in New York City after the September 11, 2001 attacks[82]) and the Michigan-based PBB Registry (created in 1976 following widespread exposure to polybrominated biphenyl (PBB)[83]). For example, WTC Health Registry representatives recommended including a question in the enrollment consent form about participants' willingness to be contacted about the registry, such as for media interviews or quality assurance projects. PBB Registry representatives advised the Flint Registry to avoid using overly restrictive language about future uses of Registry data; for example, a participant's consent should ideally allow the Registry to disclose de-identified, aggregate data for research purposes, while still assuring confidentiality of identifiable data.

HIPAA authorization

A HIPAA covered entity's release of protected health information (PHI) generally requires authorization from the individual or the individual's legally authorized representative before it can be disclosed. Under the HIPAA Privacy Rule, six core elements must be included in a valid written authorization:

- A meaningful description of the information to be disclosed;
- The name of the individual or the name of the person authorized to make the requested disclosure;
- The name or other identification of the recipient of the information;
- A description of each purpose of the use or disclosure;
- An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure; and
- Signature of the individual and date. If the individual's legally authorized representative signs, a description of the representative's authority to act for the individual must also be provided.[84]

HIPAA also requires the inclusion of three statements in a valid written authorization:

- A statement of the individual's right to revoke the authorization in writing, and either: (1) a description of how to do so and the exceptions to the right to revoke authorization; or (2) reference to the corresponding section of a notice of privacy practices.
- Whether treatment, payment, enrollment, or eligibility for benefits can be conditioned on the individual's signing the authorization and consequences of refusing to sign the authorization, if applicable.
- A statement of the potential for the PHI to be re-disclosed by the recipient and no longer protected by the Privacy Rule. This may be a general statement that the Privacy Rule may no longer protect health information disclosed to the recipient.[85]

Finally, a HIPAA authorization must be written in plain language at a level appropriate to the target population. It is generally advised to aim for an 8th-grade reading level. The document should be tailored to the target population, avoid technical jargon or overly complex terms, and use straightforward, understandable language.[86] The Registry revised the consent form through several iterations to ensure it used clear, understandable language targeted to the Flint community.

Legal representatives

As noted above, consent is legally valid only if it is competent. Accordingly, minors and legally incompetent adults may not provide valid legal consent to participate in the Registry or for disclosure of their information. Also, as detailed above, if a legal representative is signing a HIPAA authorization on behalf of another individual, they must describe their authority to act for that individual. Therefore, the Registry had to address all legal and ethical requirements for obtaining proxy consent—i.e., consent from a parent, legal guardian, or other legal representative.

MINORS

The law authorizes parents to give informed consent on a minor's behalf.[87] Outside of parental consent, guardianship is a legal process used to protect minor children and other individuals who cannot care for themselves.[88] A court appoints a legal guardian to care for an individual requiring special protection, known as a ward. Courts may appoint an adult guardian for a minor who is not their child if, for example, a minor is abandoned, the minor's parents have died, or the minor's parents are incapable of providing proper care.[89] Guardians generally have authority to give informed consent on the child's behalf unless a specific limitation exists.[90]

In Michigan, foster parents are typically unable to consent for foster children to participate in certain activities requiring informed parental consent, such as research studies[91] and non-emergency, elective surgery.[92] Instead, informed parental consent is required for temporary court wards and judicial authorization for permanent court wards. We conducted extensive research but could not find anything in law or agency guidance that directly addressed the authority of a foster parent to consent for a foster child to participate in a public health registry. Because a public health registry is analogous to a research study, the Registry decided to require informed consent from a minor child's parent rather than from a foster parent.

ADULTS

For adults, the most common instrument used to appoint a legal representative is a durable power of attorney.[93] Power of attorney broadly refers to one's authority to act and make decisions on behalf of another person in all or specified legal matters. It also refers to the specific form or document that allows one to appoint a person to manage their affairs. A durable power of attorney is a specific document that remains in effect even after the represented party becomes mentally

incapacitated.[94] Guardianship may also be used to consent on behalf of elderly or incompetent adults.[95]

DOCUMENTING PROXY CONSENT

It is generally good practice to document a proxy representative's relationship to an adult and have the representative attest to possessing the legal authority to consent on the person's behalf. It may also be good practice to obtain a copy of the legal instruments providing authority to the proxy because the burden for compliance rests on the organization receiving the personally identifiable information. Although Michigan law does not explicitly require organizations to request the legal instrument, the Flint Registry asked adult participants' proxy representatives to identify their legal authority in the consent form and attest to having the authority to consent on the individual's behalf. The proxy was then required to sign and date the consent form.

VII. OTHER LEGAL CONSIDERATIONS

The Flint Registry team analyzed several potentially relevant laws that do not fit into the broad categories of legal concerns described above. Of potential interest to other public health registries, we examined the federal Privacy Act, the federal Public Health Service Act's certificate of confidentiality and assurance of confidentiality provisions, and state and federal laws governing the use of electronic signatures.

Federal Privacy Act

As a federally funded registry operating under a grant of authority from the CDC, we evaluated whether the Flint Registry was subject to the federal Privacy Act. The federal Privacy Act regulates federal agencies' data maintenance, collection, use, and dissemination practices, protecting against inappropriate governmental intrusion into individual privacy.[96] The Privacy Act applies to any federal agency that controls and maintains a system of records from which data are retrieved by an individual identifier.[97]

For purposes of the Act, "'agency'... includes any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency."[98] Although legislative history indicates that the term agency is to be interpreted broadly, it does not apply to state or local governments or private entities merely because they receive federal funding or are subject to federal regulatory control.[99] Instead, the Privacy Act's application to a federally funded or federally regulated state, local, or private entity turns on the degree to which a federal agency exercises control and supervision over the entity's day-to-day activities. Where the federal government does not exercise close supervisory control over a contractor or grantee, the entity is generally not subject to the Privacy Act.[100]

In the context of the Flint Registry, neither the enabling legislation for the Registry[101] nor the Terms and Conditions of the Registry's Grant Award[102] suggest that it is to be treated as a federal agency or subject to the Privacy Act. Furthermore, the Registry's day-to-day operations are not conducted or closely supervised by a federal agency or employees. Accordingly, the Flint Registry team concluded that the Privacy Act does not apply to its activities.

Federal Certificate / Assurance of Confidentiality

The Registry considered federal laws that provide additional protection for identifiable information through a certificate of confidentiality or assurance of confidentiality. As discussed below, we concluded that neither the federal certificate of confidentiality nor the assurance of confidentiality are relevant to this project.

A federal certificate of confidentiality is automatically granted under the Public Health Service Act[103] for all CDC-funded research projects involving the collection of identifiable,[104] sensitive[105] information. If a research project is not federally funded, the researcher may still apply to the CDC and request a certificate of confidentiality.[106] This certificate protects information about research subjects from subpoena and from being used as evidence in legal proceedings unless the individual consents to these uses. Since the Flint Registry was established and implemented for non-research purposes, the certificate of confidentiality provision does not apply.

The Public Health Service Act[107] provides for an assurance of confidentiality protecting identifiable information for both non-research (e.g., surveillance) and research projects. The federal assurance of confidentiality prohibits the use of identifiable information obtained by CDC programs or contractors for any purpose other than the purpose for which it was provided.[108] However, the assurance does not apply to the Flint Registry because the Registry is a grantee rather than a CDC contractor.

Electronic Transactions

The Flint Registry conducts a significant portion of its interactions electronically. For example, individuals may enroll in the Registry, complete and submit surveys, and consent to uses and disclosures of data through electronic means. Thus, the Registry must comply with federal and state electronic transaction laws. As described below, three particular laws are important to the Registry: the Michigan Uniform Electronic Transactions Act; the Federal Electronic Signatures in Global and National Commerce Act; and the HIPAA Privacy Rule.

MICHIGAN UNIFORM ELECTRONIC TRANSACTIONS ACT

Michigan, like most other states,[109] has adopted the Uniform Electronic Transactions Act (UETA).[110] The law authorizes and establishes conditions under which information and signatures may be electronically transmitted, received, and stored.[111] It defines an electronic record as "a record created, generated, sent, communicated, received, or stored by electronic means."[112] An electronic signature is defined as "an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record."

The UETA recognizes the legal validity of electronic signatures, records, and contracts, allowing them to be used with the same legal effect as analog (paper) signatures.[113] The

Act allows parties to select the media for their transactions.[114] An individual's agreement to conduct a transaction electronically is "determined from the context and surrounding circumstances, including the [individual's] conduct."[115] Of particular importance to the Registry, for the record to be enforceable when using electronic signatures, the UETA requires that a recipient must be able to store or print the information.[116]

ELECTRONIC SIGNATURES IN GLOBAL AND NATIONAL COMMERCE ACT

Like the Michigan UETA, the Federal Electronic Signatures in Global and National Commerce Act (ESIGN Act) similarly recognizes the legal validity of electronic signatures, contracts, and records in transactions affecting interstate or foreign commerce.[117] A transaction may be conducted electronically if both parties consent. If applicable law requires that information be shared with a consumer in writing, the requirement may be met in electronic form only if the consumer consents.[118] When a record is legally required to be in writing, it must be accessible to all parties in a form that is capable of being stored for future reference.[119]

HIPAA PRIVACY RULE

The Flint Registry team also evaluated HIPAA Privacy Rule requirements for electronic transactions because the Registry needed HIPAA-compliant authorizations to obtain MDHHS Medicaid data. Neither HIPAA nor the HIPAA Privacy Rule provides standards for electronic signatures. In the context of Business Associate Agreements, the HHS Office for Civil Rights stated that absent specific HIPAA standards, "covered entities must ensure any electronic signature used will result in a legally binding contract under applicable State or other law."[120] Thus, the Registry concluded that electronic signatures would be valid under HIPAA if they were valid under both the UETA and ESIGN Act.

APPLICATION TO THE FLINT REGISTRY

The Flint Registry allowed participants to engage with the Registry through multiple channels, including electronic communications, phone, mail, email, or in person. For individuals who chose to engage electronically, the Registry needed to assure compliance with the Michigan UETA and federal ESIGN Act. To accomplish this, the Registry provided participants with a printed or emailed copy of any electronically signed consent or other forms, including HIPAA authorizations.

VIII. PRACTICAL CONSIDERATIONS – IMPLEMENTATION CHALLENGES AND LESSONS LEARNED

To understand the context of implementing the Registry, we conducted informal interviews with selected members of the Registry and the Flint community. We asked a small group of respondents to identify key barriers and challenges to implementation, along with policy changes that would facilitate the Registry's goals. While the Registry will be conducting a formal evaluation as part of its funding arrangements, our interviews serve a more limited objective—to supplement our legal analysis with guidance on anticipating and possibly overcoming barriers to operational success. Keep in mind that the COVID-19 pandemic interrupted various aspects of the Registry's development, especially outreach to the community. All quotations are from the interview respondents.

As a general overview, our interviews consistently offered four common observations. First, completing the numerous organizational tasks to operate the Registry took much longer than expected. This Handbook will help streamline the process, but it will still take a long time to sort through the many legal and practical matters. Second, there is considerable interagency back and forth that can be very time-consuming. Each agency and department has its own data release processes and workload demands. Third, consequently, it is important to pursue multiple simultaneous approaches to avoid any particular impasse from obstructing progress. Fourth, the Registry has made considerable progress in addressing its challenges, especially through outreach to the community.

Our interviews broadly identified challenges along two dimensions—one internal to the Registry, the other external to it. Internal challenges refer to those largely under the Registry's control. In contrast, the Registry could only indirectly influence the external challenges. In this part, we first discuss the challenges facing the Registry. Then we offer policy and practice recommendations.

Internal challenges

In retrospect, the internal challenges identified seem like the inevitable hurdles any registry will face, and in some cases may be addressed through planning. But they also reflect organizational choices and the specific context following the Flint Water Crisis. In either case, a lesson from the internal challenges is to plan ahead to avoid delays and added expenses that can undermine a registry's success.

STAFFING CAPACITY

The first and perhaps the biggest challenge the Registry faced was building staff capacity. "From the outset, we wanted the Flint Registry to be based in Flint, built by Flint, for Flint." The Registry's commitment to hiring a local workforce and being connected to the community required a significant training and pipeline process. In addition, a university's hiring process is often not quick. It took too long to hire a project manager. As a result of insufficient staffing, "community relations suffered" and it took longer than expected to develop and field the survey instruments and build the information technology (IT) infrastructure. Perhaps most importantly, this created a time gap between Registry enrollment, service referrals, and the distribution of "thank you checks for registering." There is no way to know what effect these delays had on enrollment and receiving appropriate service referrals. Nevertheless, "hiring within Flint was worth it."

THE IT INFRASTRUCTURE

The Flint Registry involves collaborating across institutions with differing and sometimes conflicting IT systems. To overcome this challenge, the Registry utilizes three separate data systems. One system, typically used to administer hospital treatment and reimbursement, is used to track participant communications and contacts. Another system, designed to support human subjects research, is used to deliver surveys and store survey data. A third was developed specifically to analyze the survey data and identify participant referrals. Unfortunately, a direct connection between the Registry's referral identification system and the Community Referral Platform never occurred. As a result, the referrals identified had to be manually entered on a daily basis into the Community Referral Platform, a system used among service providers in Flint to send and track referrals. The need for manual entry contributed to delays in processing referrals.

THE ENROLLMENT PROCESS

Interview respondents recognize that the enrollment process has been somewhat cumbersome. For instance, the enrollee needs to fill out a form and then get a code which provides access to the survey. Enrollees have "been lost" during the time lag. The Registry is now seeking ways to make the enrollment immediate without waiting for a code.

An important part of the enrollment process is the survey that serves several functions, including identifying and assessing eligibility for needed service referrals. One of the enrollment barriers has been the survey's length. "It's long." Part of the reason is a lengthy nutritional survey that is now being scaled back. Another reason is that the Registry wanted questions added to reflect input from the Flint community about overall health concerns.

Other enrollment barriers are beyond the Registry's control. For example, one observer noted that residents on Flint's north side face particular challenges

in lacking online access or not being computer literate, along with other communication barriers. Another noted the difficulty in reaching foster families and navigating similar custodial issues. Further, some families just above the poverty line do not complete the enrollment survey because they assume they will not qualify for free services through the Registry's referral process, but they are unable to pay for them. It is understandable that potential enrollees would not want to complete a survey if they and their children would not be eligible for services. Several respondents noted the community's frustration with income limits on services: "Everyone was exposed, so everyone should be served."

To address these challenges, the Registry adopted a more aggressive outreach strategy involving marketing, focus group activity, and personal contact. For example, building texting capability and increasing the amount of "thank you" checks from $25 to $50 improved survey response. As a result, enrollment increased significantly from December 2019 to early 2020. Then COVID-19 hit, limiting in-person contact.

INTERAGENCY COOPERATION

A less significant but essential aspect of building a registry is the IRB process. Universities generally require all projects involving human subjects to undergo IRB review, even just to obtain official determination that the project is not human subjects research and therefore not subject to further IRB review. When more than one IRB is involved, confusion and delay usually follow. In this instance, the issue is that university IRBs are less comfortable assessing non-research projects as compared to traditional research studies. The Registry should be exempt from IRB requirements, but explaining why to those unfamiliar with the laws governing public health practice can be time-consuming.

Obtaining data from MDHHS also required significant interagency cooperation. Despite some delays in the consent process, Registry staff report a high level of cooperation from MDHHS and its attorneys. But the back and forth to reach agreement as to which data the Registry could obtain and under what authority was quite time-consuming. Ultimately, the Registry's data sharing consent forms for Medicaid and other MDHHS data were not finalized and integrated into online surveys until December of 2020—almost two years after the first participants enrolled in the Registry—adding an extra step to an already cumbersome enrollment process for the earliest enrollees. The Registry estimates that it lost over 5,500 of its likely consents due to this delay.

THE CONSENT PROCESS

"Another challenge has been the fact that we're a voluntary registry. People have to enroll in this process." Getting lists of potential enrollees from other organizations, especially schools and WIC programs, discussed below, limits how quickly the enrollment process can even begin. Further, feedback from the community indicates concerns about data privacy, confidentiality, and disclosure. According to one respondent, some enrollees were apprehensive about the amount of data requested and how it would be shared. Some enrollees also expressed unease about having a child labeled as either exposed to lead or having "special needs." As a result, the process of obtaining individual consent was arduous.

External challenges

The external challenges present a different set of concerns than the internal challenges. By definition, the external challenges lie beyond the Registry's control, hence requiring cooperation from a variety of stakeholders. Dealing with the external barriers is time-consuming. But if not addressed, the Registry potentially faces community dissatisfaction and decreased enrollment.

THE COMMUNITY'S DISTRUST OF GOVERNMENT AND INSTITUTIONS

The primary barrier to enrollment appears to be lingering, widespread, and understandable community distrust. Even though the Registry is designed with extensive community input, the process needs to be "respectful to the trauma the community has gone through. People are skeptical of interventions because of what has happened to them and need a reason to believe."

To its credit, the Registry has taken several steps to reassure the community that it would be a trusted partner. These steps include fostering a culture of transparency (e.g., clear messaging to the community about its processes and limits), creating a Community Advisory Board, conducting focus groups, and implementing an ongoing marketing campaign. Fortunately, recent increases in enrollment suggest that the Registry's outreach strategies are working and "the Registry is becoming a trusted source."

THE REFERRAL PROCESS AND AVAILABILITY OF SERVICES

An area for improvement is the service referral process. Across our interviews, respondents consistently identified the difficulty both in obtaining referrals for clinical and educational services and in accessing those services as a major barrier. While the Registry's success is not dependent on the service delivery referral process, the difficulty in obtaining services reduces the incentives for increasing enrollment rates. For legitimate reasons, Flint residents may focus on service delivery as the Registry's most significant value. To counter that perception, the Registry may need a messaging strategy to convey the Registry's value beyond the service referral process.

One observer noted that service delays and gaps in available services undermine the Registry's stature in the

community. Nonetheless, the observer also conceded that "the Registry can track and refer, but not provide the service." It appears as though the entire process is opaque to enrollees, particularly because there are breaks in the referral chain. In fact, the community seems frustrated with the limits of the referral process, not the Registry.

At this point, the Registry is trying to simplify the process and make it faster, recognizing that there may only be one opportunity for the enrollee to obtain the needed services. One potential strategy is to fine-tune eligibility for services and reduce over-referrals. Refining the eligibility screening process in this manner would avoid placing an unnecessary burden on service providers to sort through ineligible referrals and would ensure enrollees interact with only the service providers from whom they are most likely qualified to receive services. This strategy is not currently employed because it would increase the likelihood of under-referral. Another potential strategy for improving the referral process is to reduce the time lag between enrollment and initial contact for a particular service. As one observer noted, navigating the process requires an active parent. In sum, the demanding process means that the referral loop is too much work, frequently remains incomplete, and is a cause of dissatisfaction.

To date, the Registry has made approximately 20,000 referrals for approximately 15,000 enrollees. But our interview results indicate the Registry has been unable to track how some of those referrals have been handled. About 3,000 of those referrals have been to the Neurodevelopmental Center for Excellence (NCE), a division of Genesee Health System offering neuropsychological assessments to children exposed to lead during the Flint Water Crisis. "One of the biggest heartbreaks is so many of our referrals to the NCE never fully get assessed."

Part of the problem is structural—for instance, contacting hard-to-reach populations. In addition, one consequence of COVID-19 has been staffing shortages among service providers. For example, some interviewees perceived the NCE as lacking capacity (i.e., PhD neuropsychologists) to serve all those who could be contacted. Another part of the problem is a disconnect between how the referral process is explained to enrollees and the services that are actually available. Enrollees need to better understand exactly what services can be provided and when. There may also be a disconnect in the expectations between service providers and the Registry. Thus, the Registry's challenge is to follow up with enrollees and service providers to track whether they are receiving the services and which services are available. Nonetheless, "Without the Registry, people would not be getting the same amount of services."

OBTAINING LISTS OF POTENTIAL ENROLLEES

A major challenge in stimulating enrollment has been the inability to obtain cooperation from schools—a key service provider for children. Despite the Registry's efforts to secure lists of potential enrollees, neither local school district was willing to provide the requested information. "We spent all this time convincing community schools that [they] can legally provide the data, [only to be told] we have no way to keep track of who opted out of having their directory information shared, so we can't provide it." This matters because the Registry can use the lists to make direct contact rather than relying on schools to make the contact. Also, it is especially important to contact young families because they may be the most hard hit and in need of services. One respondent offered a cynical view of why schools might not be anxious to share the lists, speculating: "Schools are terrified of the costs of providing services. They lack resources to evaluate and place children in the most appropriate settings."

LEGAL BARRIERS

As this Handbook has detailed, the Registry confronted a host of legal challenges. For example, federal and state privacy laws are fragmented, confusing, and difficult to interpret and apply. Some of the laws present differing consent requirements, and federal agency guidance is limited. For instance, HIPAA presents interpretive challenges. Data holders (i.e., sources), especially state agencies, must be cognizant of potential penalties for improper disclosure. To avoid penalties for noncompliance, it is important for the receiving organization to identify its legal authority for obtaining data along with a clear justification for disclosing the data. It should be noted that we were able to surmount the HIPAA issues. In contrast, the FERPA and WIC barriers proved insurmountable.

Many MDHHS programs use similar processes for disclosing data the Registry needed, including Medicaid. For those programs, a DUA could be used to develop one consent form covering each of them. The DUA "provides a clear picture of what the purpose is for the data and identifies the legal issues to be resolved, and helps to get agency buy-in." One strategy to facilitate data sharing arrangements would be to use the DUA as early as possible. Even so, certain specific programs have more stringent consent requirements that may need to be addressed separately, especially WIC and school districts.

Aside from the specifics of the legal issues, one observer depicted the political environment in which agency decisions are being made. In an era of general distrust, "Government needs to protect its reputation. Public trust is a key issue. Unlawful data disclosures undermine trust in government." For these reasons, the legal review will most likely be slow and cautious, though we hope this Handbook will reassure agencies and their attorneys about the legal validity of similar data requests.

Policy recommendations

One evident policy change beyond the scope of this Handbook is the need to update federal and state privacy laws to accommodate public health data needs. The update should involve a more flexible consent process allowing sharing of data for public health purposes. In our interviews, respondents specifically mentioned barriers to obtaining data from the WIC and Medicaid programs. Federal guidance on disclosure and consent for public health purposes would also facilitate the process.

A similar problem exists for obtaining data from school districts. We are well aware that schools must carefully protect access to data, and that FERPA creates barriers to disclosure. At the same time, school districts need to understand the importance of assisting the Registry in obtaining lists of students potentially at risk for lead exposure given the Registry's key role in connecting them to services. Federal guidance would perhaps encourage school districts to be more amenable to public health data requests.

At the state level, MDHHS's default policy should be to disclose information to a public health authority, such as the Flint Registry, unless there is a compelling reason not to, rather than starting from a neutral position in assessing the request. Policy guidance from the MDHHS Administrator to facilitate data sharing would almost certainly streamline the consent process.

Practice recommendations

Our respondents raised several practice suggestions for the Registry to consider, many of which the Registry has already incorporated. The practice recommendations largely address the Registry's internal challenges.

- Conduct outreach in a way that supports groups with lower literacy and makes clear the benefits available.
- Consider ongoing outreach to enrollees throughout the enrollment and service delivery processes.
- Examine what support service providers need to better process Registry referrals, what services enrollees are actually receiving, and why enrollees are not receiving or pursuing the referrals.
- Improve marketing to explain why data are being requested, how the referral process works, and what the limits are to receiving services.
- Be transparent about the time it takes to complete the enrollment and service referral processes and the Registry's limits in whether and how services will be provided.
- Word of mouth is the best recruitment strategy.

Taken together, these recommendations are designed to increase enrollment, build trust, and make sure the Registry meets the community's needs.

Maxine and her family, Flint Registry Community Ambassadors.

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[2] *Id.* at 17-19.

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[4] *Id.* at 24.

[5] *Flint Registry,* CDC, https://www.cdc.gov/nceh/lead/programs/flint-registry.htm (last visited Nov. 2, 2021).

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[8] Flint Registry Project Narrative (June 22, 2017), on file with authors. *See also* Flint Water Advisory Task Force—Final Report, *supra* note 6, at 32.

[9] Flint Water Advisory Task Force—Final Report, *supra* note 6, at 21.

[10] *Id.* at Appendix V, Detailed Timeline, p. 23-26.

[11] The Greater Flint Health Coalition is a non-profit collective impact organization that convenes and leads collaborative, multisector efforts to improve health among Flint residents. Greater Flint Health Coalition, https://gfhc.org/about/ (last visited Nov. 2, 2021).

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[36] 18 U.S.C. § 2721, Mich. Comp. Laws §§ 257.208c, 28.298. Note that the applicable laws distinguish between personal information (PI) and "highly restricted personal information" (HRPI), which is a subset of PI. PI includes information such as driver identification number, name, address (but not zip code), and telephone number, while HRPI refers to more sensitive information such as an individual's photograph, social security number, and medical or disability information. 18 U.S.C. § 2725(3)-(4), Mich. Comp. Laws §§ 257.40b, 28.291a(a)-(b). Although federal law allows both PI and HRPI to be disclosed under the governmental agency exception described above, Michigan law is more restrictive on disclosure of HRPI. 18 U.S.C. § 2721, Mich. Comp. Laws §§ 257.208c, § 28.298. The Flint Registry did not need or request HRPI.

[37] 18 U.S.C. § 2721, Mich. Comp. Laws §§ 257.208c, 28.298.

[38] 18 U.S.C. § 2721(b)(5), Mich. Comp. Laws §§ 257.208c(3)(e), 28.298(3)(e). Federal law generally prohibits disclosing data for "bulk distribution for surveys, marketing or solicitations" absent express consent from each individual to whom the information pertains. However, it appears this limitation may not apply to surveys, marketing, or solicitations carried out by or on behalf of governmental agencies if the activity is integral to a governmental function. *See, e.g.,* Downing v. Globe Direct LLC, 682 F.3d 18, 23-24 (1st Cir. 2012).

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[105]Information related to mental health, alcohol or drug use, sexual attitudes or practices, and genetic information are examples of sensitive information. *Certificate of Confidentiality (CoC) FAQs – What is meant by sensitive information,* CDC, https://www.cdc.gov/os/integrity/confidentiality/faq_confidentiality.htm##q6 (last visited Nov. 2, 2021).

[106]A certificate of confidentiality *shall* be issued for research which is wholly or partially federally funded, and *may* be issued for research which does not receive federal funding. 42 U.S.C. § 241(d)(1)(A). For information on the Certificate of Confidentiality Application Process, *see Certificate of Confidentiality (CoC) FAQs,* CDC, https://www.cdc.gov/os/integrity/confidentiality/faq_confidentiality.htm (last visited Nov. 2, 2021).

[107]Public Health Service Act § 308(d), 42 U.S.C. § 242m. See *Assurances of Confidentiality,* CDC, https://www.cdc.gov/os/integrity/confidentiality/index.htm (last visited Nov. 2, 2021).

[108]42 U.S.C. § 242m; *Assurances of Confidentiality, supra* note 107.

[109]*Electronic Transactions Act,* Uniform Law Commission, https://www.uniformlaws.org/committees/community-home?CommunityKey=2c04b76c-2b7d-4399-977e-d5876ba7e034 (last visited Nov. 2, 2021).

[110]Mich. Comp. Laws § 450.831 et seq.

[111]Preamble to the Uniform Electronic Transactions Act, Pub. Act 305 of 2000, codified at Mich. Comp. Laws § 450.831.

[112]Mich. Comp. Laws § 450.832(g).

[113]Mich. Comp. Laws §§ 450.837, 450.841, 450.843, 450.844.

[114]Mich. Comp. Laws §§ 450.835(2), 450.838.

[115]Mich. Comp. Laws § 450.835(2).

[116]Mich. Comp. Laws § 450.838.

[117]15 U.S.C. § 7001(a).

[118]15 U.S.C. § 7001(b), (c).

[119]15 U.S.C. § 7001(d)(1), (e).

[120]HHS Office of Civil Rights, *Would business associate contracts in electronic form satisfy HIPAA,* U.S. Dept. of Health & Human Servs., hhs.gov (Dec. 19, 2002), https://www.hhs.gov/hipaa/for-professionals/faq/247/are-business-associate-contracts-in-electronic-form-acceptable/index.html.

[121]*See, e.g., IRB Application Process,* University of Michigan Research Ethics & Compliance, https://research-compliance.umich.edu/irb-application-process (last visited Nov. 23, 2021); *Activities Requiring Review,* Michigan State University Office of Regulatory Affairs, https://hrpp.msu.edu/help/required/index.html (last visited Nov. 23, 2021).

IX. Appendices

Appendix A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the General Counsel
Public Health Division
CDC/ATSDR Branch
1600 Clifton Road, N.E., MS D53
Atlanta Georgia 30333
(404) 639-7200

September 25, 2017

Nicole Jones, M.S. Ph.D.
Director, Flint Lead Exposure Registry
Assistant Professor, MSU-Hurley Children's Hospital Pediatric Public Health Initiative
Michigan State University College of Human Medicine
200 East 1st Street
Flint, Michigan 48502

Re: Grant of Authority pursuant to HIPAA

Dear Dr. Jones:

This letter serves as verification of a grant of authority from the Centers for Disease Control and Prevention (CDC), for you to conduct the public health activities described here, acting as a public health authority pursuant to the Standards for Privacy of Individually Identifiable Health Information promulgated under the Health Insurance Portability and Accountability Act (HIPAA) [45 CFR Parts 160 and 164)]. Under this rule, covered entities may disclose, without individual authorization, protected health information to public health authorities *". . . authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions . . . ."* The definition of a public health authority includes *". . . an individual or entity acting under a grant of authority from or contract with such public agency . . . ."*

Michigan State University (MSU), Hurley Children's Hospital Pediatric Public Health Initiative is acting under grant with the CDC to conduct CDC-RFA-EH17-1704, *Lead Exposure Registry of Flint Residents-Michigan*, which is authorized by Section 2203(b) of Public Law 114-322, the Water Infrastructure Improvements for the Nation (WIIN) Act of 2016; 42 U.S.C. Section 300j-27(b). The CDC grants this authority to Michigan State University, Hurley Children's Hospital Pediatric Public Health Initiative for purposes of this project. Further, the CDC considers this to be a public health surveillance and intervention activity for which disclosure of protected health information by covered entities is authorized by 45 CFR § 164.512(b) of the Privacy Rule.

If you have questions or concerns about this grant of authority, please contact Stephanie Davis, Project Officer at sgd8@cdc.gov.

Sincerely,

[redacted]

Kenya S. Ford
Senior Attorney
Office of the General Counsel
Public Health Division
CDC/ATSDR Branch

cc: Stephanie Davis

The Network for Public Health Law

Ideas. Experience. Practical answers.

Checklist of Factual Information Needed to Address Proposed Data Collection, Access and Sharing to Improve the Health of Communities

Attorneys and privacy officers provide advice to public health agencies and other organizations on an array of questions about collecting, accessing, and sharing information. Questions may involve oral, written or electronic data. Responses must consider whether a public health agency or other organization has the legal authority to collect, access, or share information, and if so, what are the conditions and limitations for data sharing. In addition to legal considerations, policy and ethical concerns may be relevant. In some situations - for example, threats of communicable disease or environmental hazards – a public health agency might face competing interests of protecting individual privacy, protecting the public's health, and avoiding stigma of communities or individuals. Certain factual information about the data to be shared and the circumstances and conditions for sharing is needed to evaluate proposed data sharing. The checklist below is intended to assist public health practitioners and advocates and community organizations in providing relevant factual information to resolve questions about proposed data collection, access and sharing.

What?

What is the purpose of the data request? What do you want to do with the data?

What data do you need to accomplish your goal? Identify data source(s), data type(s) and data elements.

From whom?

From whom might you obtain these data? Identify each data provider.

With whom?

With whom do you want to share these data? Identify each data recipient.

Why?

Why are you sharing these data with these partners? What is the connection between these data and what you want to accomplish? Ensure that the stated purpose is consistent with the described proposed use.

How Much?
How much data do you need to accomplish your goal? Will de-identified information or a limited data set (that includes demographics but not personal information) serve the purpose?

Conditions?
Under what terms or conditions, if any, was this information provided to you? Acceptable uses and linkages of the information?

How? Where?
How will the information be transferred/shared/stored?

Protections?
What privacy and security measures are in place to protect information during transfer, storage, use and disposal?

And then what?
Retention, reuse, further sharing, disposal of the data?

Assurance?
Audits or other mechanisms to monitor proper receipt, storage, access and use?

Accountability?
What are the terms of data use and means to enforce for violations?

Tool available to download at:
https://www.networkforphl.org/resources_collection/2019/09/30/400/tool_checklist_of_information_needed_to_address_proposed_data_collection_access_and_sharing

Supporters

This document was developed by Denise Chrysler, J.D., Director, at the Network for Public Health Law – Mid-States Region. The Network for Public Health Law provides information and technical assistance on issues related to public health. The legal information and assistance provided in this document does not constitute legal advice or legal representation. For legal advice, please consult specific legal counsel.

October 2019

Appendix C

MICHIGAN STATE
UNIVERSITY

May 21, 2018

Michigan Department of State
Commercial Services Section
7064 Crowner Drive
Lansing, MI 48918
Email: ListSales@michigan.gov

College of Human Medicine

Division of Public Health

200 East 1st Street
Flint, MI 48502

810-600-5601
Fax: 810-600-5609
publichealth.msu.edu

Dear List Sales Department:

This is a request for a list of information from the Michigan Department of State records maintained under the Michigan Vehicle Code, Mich. Comp. Laws § 257.201 et seq., and under Mich. Comp. Laws § 28.291 et seq., pertaining to State Personal Identification Cards.

This request is submitted by the Michigan State University, Hurley Children's Hospital Pediatric Public Health Initiative (MSU-Hurley), for the purpose of implementing the Flint Lead Exposure Registry (Registry), which is operated under a grant of public health authority from the Centers for Disease Control and Prevention (CDC). The Flint Lead Exposure Registry is authorized by the Water Infrastructure Improvements for the Nation (WIIN) Act for the purpose of "collect[ing] data on the lead exposure of residents of [Flint] on a voluntary basis." Pub. L. No. 114-322, § 2203(b) (2016) (codified at 42 U.S.C. § 300j-27(b)). As a public health authority, the Registry is conducting public health surveillance, outreach, education, and referral for services.

Disclosure of lists of information from Department of State records to federal, state, or local governmental agencies for use in carrying out the agency's functions, or to a private person or entity acting on behalf of a governmental agency in carrying out its functions, is permitted under Mich. Comp. Laws §§ 257.232(1) and 28.300(1). See also Mich. Comp. Laws §§ 257.208c(3)(a) and 28.298(3)(a) (permitting disclosure of individual records to governmental agencies). The CDC's Grant of Authority to MSU-Hurley states that MSU-Hurley shall be treated as a public agency and public health authority for the purpose of implementing the Flint Lead Exposure Registry. See Letter from CDC/ATSDR Branch to MSU-Hurley, dated September 25, 2017 (enclosed).

As Director of the Flint Lead Exposure Registry, I am requesting a list of the following data from the records of all operator's license or personal identification card holders residing in zip codes 48501-48507, 48532, and 48529.

- Name
- Birthdate
- Address
- Phone Number
- Gender

This data is requested one time (not on a recurring basis) and will be used to carry out the functions of the Flint Lead Exposure Registry operating pursuant to the CDC's Grant of Authority. For example, the data will be used to compile and/or confirm the accuracy of contact information for Flint residents who may have been exposed to lead in their drinking water, which will in turn be used to conduct community outreach to inform individuals of their potential eligibility to enroll in the Registry, which is a public health surveillance and intervention activity.

The Registry will work with the following third party vendors to perform the public health activities described above:

- Hurley Medical Center (HMC)—will serve as the Registry data coordinating center. In this role HMC will be involved in all aspects of the Registry process, compiling and/or confirming data accuracy, and deploying the Registry outreach activity.
- Epic Systems (ES)—will supporting HMC in adaptation of HMC's Epic software platform.
- Nordic Consulting—will perform programming for custom features in HMC's Epic software.

I understand that this request must include the signature of someone who is authorized to enter into agreements on behalf of MSU, however, to determine the appropriate signatory, we must understand the fee for requested data. When we are able to provide an estimate of the cost of the data request, we can obtain the necessary signature. If you could provide a cost estimate that would be very helpful.

Please contact me at 810-[redacted]icole.Jones@hc.msu.edu, if you have any questions about this request. Thank you in advance for your assistance.

Sincerely,

Nicole Jones, M.S. Ph.D.
Director, Flint Lead Exposure Registry
Assistant Professor, MSU-Hurley Children's Hospital Pediatric Public Health Initiative
Michigan State University College of Human Medicine
200 East 1st Street
Flint, Michigan 48502

Pending Signature of Authorized Representative, Michigan State University (pending information on costs)

Enclosure
Letter from Kenya S. Ford, Senior Attorney, CDC/ATSDR Branch, to Nicole Jones, M.S. Ph.D., Director, Flint Lead Registry, Re: Grant of Authority pursuant to HIPAA (September 25, 2017).

Appendix D

OFFICIAL DATA REQUEST FROM
DR. MONA HANNA-ATTISHA, PRINCIPAL INVESTIGATOR FLINT REGISTRY
MAY 15, 2018

The Flint Registry project under the oversight of Dr. Mona Hanna-Attisha requests access to student directory information from Flint Community Shools for students who were potentially exposed to the Flint Water System from April 25, 2014 - October 15, 2015. The aim of the Flint Registry is to connect persons exposed to lead contaminated water from the Flint Water System to community services that may help lessen the negative impact of this exposure.

The data requested will be used to identify individuals who may be eligible, based upon potential exposure to lead contaminated water at home or school, to participate in the Flint Registry. Individuals identified as potentially eligible will be contacted and invited to participate in the Registry. Participation is completely voluntary. Because of its importance for Flint residents, the CDC has funded the Flint Registry under the Public Health Service Act and granted it public health authority to support this work. The Registry is asking for this data to actively enroll and screen as many families as possible. By sharing this data, Flint Community Schools are able to fulfil their obligation to find as many students as possible who may need additional education support.

We request the following data:

Student Directory Information that is not subject to FERPA including: student's name; address; telephone listing; electronic mail address; date and place of birth; grade level; enrollment status; dates of attendance; and the most recent educational agency or institution attended

Current contact information is requested for students who lived or went to school at an address served by the Flint Water System for the 2014-2015, 2015-2016 school years. This includes students with home addresses served by the Flint Water System for the 2014-2015, 2015-2016 school years or who attended a school served by the Flint Water System for the 2014-2015, 2015-2016 school years.

Purpose of the request:

De-identified information or a limited data set will not serve the intended purpose. Identifying data are required for accurate tracking and contact with individuals who are potentially eligible to participate in the Flint Registry. Name, address and phone numbers will be used for contacting potential participants. Date and place of birth birth are required for identification of potential duplicate records because multiple methods will be used to locate families. Additional data will be used to keep up to date records on family location.

These data will be handled in a manner appropriate to protect the confidentiality of individuals. The Flint Registry handles data according to the specifications of the Flint Registry Data Management Plan, a document reviewed by the CDC and other data experts, which describes the processes of data protection, including physical and virtual access, backup and storage of Flint Registry data. Only Flint Registry personnel will have access to view the data requested from Flint Community Schools, and they will do so only for recruitment, enrollment, and communication required in conducting Registry tasks. All Flint Registry personnel receive certified training in the protection of participants in human subject research, compliance with HIPAA data standards, and training in data confidentiality.

As one part of the Flint Registry process, individuals who agree to participate will be asked to give their permission (consent) to share data with service providers. Consent to share these data is voluntary. Consent to share these data may be revoked at any time for any reason. In addition, they will be asked separately to give permission to be potentially contacted in the future regarding research studies for which they may be eligible to participate.

Aggregate (de-identified) data related to Flint Registry demographics, protocol metrics, and/or outcomes will be shared with participants and the community of Flint via information posted at FlintRegistry.org. However, these data will be aggregated and will not include any individual level data.

OFFICIAL DATA REQUEST FROM
DR. MONA HANNA-ATTISHA, PRINCIPAL INVESTIGATOR FLINT REGISTRY
MAY 17, 2018

The Flint Registry project under the oversight of Dr. Mona Hanna-Attisha requests access to student directory information from Genesee Intermediate School District for students who were potentially exposed to the Flint Water System from April 25, 2014 - October 15, 2015. The aim of the Flint Registry is to connect persons exposed to lead contaminated water from the Flint Water System to community services that may help lessen the negative impact of this exposure.

The data requested will be used to identify individuals who may be eligible, based upon potential exposure to lead contaminated water at home or school, to participate in the Flint Registry. Individuals identified as potentially eligible will be contacted and invited to participate in the Registry. Participation is completely voluntary. Because of its importance for Flint residents, the CDC has funded the Flint Registry under the Public Health Service Act and granted it public health authority to support this work. The Registry is asking for this data to actively enroll and screen as many families as possible. By sharing this data, GISD is able to fulfil its obligation to find as many students as possible who may need additional education support.

We request the following data:

Student Directory Information that is not subject to FERPA including: student's name; address; telephone listing; electronic mail address; date and place of birth; grade level; enrollment status; dates of attendance; and the most recent educational agency or institution attended

Current contact information is requested for students who lived or went to school at an address served by the Flint Water System for the 2014-2015, 2015-2016 school years. This includes students with home addresses served by the Flint Water System for the 2014-2015, 2015-2016 school years or who attended a school served by the Flint Water System for the 2014-2015, 2015-2016 school years.

Purpose of the request:

De-identified information or a limited data set will not serve the intended purpose. Identifying data are required for accurate tracking and contact with individuals who are potentially eligible to participate in the Flint Registry. Name, address and phone numbers will be used for contacting potential participants. Date and place of birth birth are required for identification of potential duplicate records because multiple methods will be used to locate families. Additional data will be used to keep up to date records on family location.

These data will be handled in a manner appropriate to protect the confidentiality of individuals. The Flint Registry handles data according to the specifications of the Flint Registry Data Management Plan, a document reviewed by the CDC and other data experts, which describes the processes of data protection, including physical and virtual access, backup and storage of Flint Registry data. Only Flint Registry personnel will have access to view the data requested from GISD, and they will do so only for recruitment, enrollment, and communication required in conducting Registry tasks. All Flint Registry personnel receive certified training in the protection of participants in human subject research, compliance with HIPAA data standards, and training in data confidentiality.

As one part of the Flint Registry process, individuals who agree to participate will be asked to give their permission (consent) to share data with service providers. Consent to share these data is voluntary. Consent to share these data may be revoked at any time for any reason. In addition, they will be asked separately to give permission to be potentially contacted in the future regarding research studies for which they may be eligible to participate.

Aggregate (de-identified) data related to Flint Registry demographics, protocol metrics, and/or outcomes will be shared with participants and the community of Flint via information posted at FlintRegistry.org. However, these data will be aggregated and will not include any individual level data.

OFFICIAL DATA REQUEST FROM
DR. MONA HANNA-ATTISHA, PRINCIPAL INVESTIGATOR FLINT REGISTRY
JUNE 12, 2018

The Flint Registry project under the oversight of Dr. Mona Hanna-Attisha requests access to student directory information from Genesee Intermediate School District for students who were potentially exposed to the Flint Water System during April 25, 2014 - October 15, 2015. This request is based on FERPA's health or safety emergency exception to consent. (34 CFR §99.31(a)(10) and 34 CFR §99.36). Lead is a known neurotoxin that has been associated with reduction in intellectual abilities, learning deficits, and neurobehavioral disorders in children. Lead is long-acting; it can stay in the body for years with long-term consequences that continue after the exposure has ended. It is crucial that testing and support services be provided to children as soon as possible to reduce the long-term consequences from exposure.

The aim of the Flint Registry is to connect persons exposed to lead contaminated water from the Flint Water System to services that may lessen the negative impact of this exposure. The Registry is especially interested in serving schoolchildren because the potential long-acting consequences of lead exposure places these students in continuing threat to their compromised educational health and safety.

The data requested will be used to identify individuals who may be eligible, based upon potential exposure to lead contaminated water at home or school, to participate in the Flint Registry. Individuals identified as potentially eligible will be contacted and invited to participate in the Registry. Participation is completely voluntary. Because of its importance for Flint residents, the CDC has funded the Flint Registry under the Public Health Service Act and granted it public health authority to support this work. The Registry is asking for this data to actively enroll and screen as many families as possible. By sharing this data, GISD is able to fulfil its obligation to find as many students as possible who may be experiencing a continuing threat to healthy developmental as a result of lead-exposure, and who may need additional education support.

We request the following data:

Student Directory Information that is not subject to FERPA including: student's name; address; telephone listing; electronic mail address; date and place of birth; grade level; enrollment status; dates of attendance; and the most recent educational agency or institution attended.

Current contact information is requested for students who lived or went to school at an address served by the Flint Water System for the 2014-2015, 2015-2016 school years. This includes students with home addresses served by the Flint Water System for the 2014-2015, 2015-2016 school years or who attended a school served by the Flint Water System for the 2014-2015, 2015-2016 school years.

Purpose of the request:

De-identified information or a limited data set will not serve the intended purpose. Identifying data are required for accurate tracking and contact with individuals who are potentially eligible to participate in the Flint Registry. Name, address and phone numbers will be used for contacting potential participants. Date and place of birth birth are required for identification of potential duplicate records because multiple methods will be used to locate families. Additional data will be used to keep up to date records on family location.

These data will be handled in a manner appropriate to protect the confidentiality of individuals. The Flint Registry handles data according to the specifications of the Flint Registry Data Management Plan, a document reviewed by the CDC and other data experts, which describes the processes of data protection, including physical and virtual access, backup and storage of Flint Registry data. Only Flint Registry personnel will have access to view the data requested from GISD, and they will do so only for recruitment, enrollment, and communication required in conducting Registry tasks. All Flint Registry personnel receive certified training in the protection of participants in human subject research, compliance with HIPAA data standards, and training in data confidentiality.

As one part of the Flint Registry process, individuals who agree to participate will be asked to give their permission (consent) to share data with service providers. Consent to share these data is voluntary. Consent to share these data may be revoked at any time for any reason. In addition, they will be asked separately to give permission to be potentially contacted in the future regarding research studies for which they may be eligible to participate.

Aggregate (de-identified) data related to Flint Registry demographics, protocol metrics, and/or outcomes will be shared with participants and the community of Flint via information posted at FlintRegistry.org. However, these data will be aggregated and will not include any individual level data.

Consideration for Disclosure:

Request of this information is made in view of the significant and continuing threat to the health or safety of students

exposed to lead-contaminated water from the Flint Water System. While exposure to the lead contaminated water occurred in 2014-2016, significant health consequences continue, including consequenes to learning. It is critical that as many individuals as possible be notified of the Registry to help ensure they obtain services to reduce the impact of lead. Disclosing the requested information to the Registry is necessary to provide the greatest level of support and assistance to protect the health of the GISD students.

Appendix E

MDHHS Database Matrix

Database	Basis for identifiable data without consent	Basis for identifiable data with consent	Consent requirements	Analysis
Medicaid				
Centers for Medicare & Medicaid Services	Data made available under a data use agreement for research, policy development and other purposes. Must comply with CMS privacy and security requirements and data release policies.	N/A	N/A	It is recommended that the Flint Registry not pursue obtaining data through federal CMS for logistical reasons.
Michigan Medicaid Program	HIPAA allows sharing of protected health information for public health purposes; Medicaid regulations do not. Medicaid regulations would allow disclosure of non-consented data if the Flint Registry was providing services to Medicaid beneficiaries.	Data may be available with the consent of the individual for purposes set out in consent form.	If data disclosure does not meet a HIPAA exception to consent, then a HIPAA compliant authorization is required. No compound authorization will be accepted by MDHHS. Medicaid regulations do not provide specific requirements or form that a consent must satisfy.	MDHHS is concerned that if it provides non-consented data to the Flint Registry, there is a risk that the Flint Registry might use it for purposes that do not meet public health requirements, especially should the CDC grant of public health authority end. MDHHS could provide Medicaid data to the Flint Registry for purposes set out in the consent. MDHHS would require a HIPAA-compliant consent. MDHHS believes that HIPAA precludes a compound authorization, which would mean that the consent for disclosure of Medicaid data would need to have its own form or section.
Michigan Disease Surveillance System (MDSS)	Data might be obtainable under a public health exception, but it would require the local health officer or the director of MDHHS to determine that disclosure of MDSS data to the Flint Registry would be required for the protection of public health.	Data may only be disclosed with the consent of the individual or the individual's guardian.	Written consent as part of a general consent form that explicitly states that access to MDSS records is being granted by the individual to the Flint Registry.	MDHHS could provide MDSS data to the Flint Registry if provided with well-defined data elements and as long as the consent requirements are met. MDHHS is concerned about a parent giving consent for disclosure of an STD report, since minors have certain consent and privacy rights should they seek diagnosis or treatment for an STD. MDHHS wants HIV/AIDS information excluded because of enhanced protections and sensitivity. Even if this data may be obtained without consent, it may be easiest to use a consent form.

Database	Basis for identifiable data without consent	Basis for identifiable data with consent	Consent requirements	Analysis
Vital Records				
Vital Events Records	The Public Health Code permits MDHHS to disclose identifiable information from its system of vital statistics to federal, state, local, and other public and private agencies for "administrative and statistical purposes" upon terms prescribed by MDHHS. The Flint Registry might seek identifiable data under an exception for "statistical purposes" and for research purposes, albeit not human subjects research.	For records that are more restricted under law, such as birth records, MDHHS would require consent from particular individuals that specifies the exact records to which they are consenting to be provided to the Flint Registry.	Written consent as part of a general consent form.	For more restrictive records, such as birth records, MDHHS would require consent from particular individuals that specifies the exact records to which they are consenting to be provided to the Flint Registry. MDHHS has expressed a need to determine the exact data elements sought by the Flint Registry as well as the format in which they would be received. MDHHS has suggested that it would be easiest to transfer only certain data elements related to particular records, rather than an original copy of a record.
Birth Defects Registry	Data might be obtainable without consent under two circumstances: First, MDHHS may disclose birth defects registry information for a study or research project. These rules require review by a scientific advisory panel, review and approval by the Department's IRB, and approval by the Director. Informed consent would be required unless the IRB found that standards were met to waive consent. The researcher would be prohibited from contacting the registrant or family unless MDHHS sends a notice about the study and the parent, guardian, or registrant affirmatively agrees to participate in the project. Secondly, MDHHS' director may authorize information from the birth defects registry to be used by an authorized agent of the department to offer medical and other support services to the registrant. The department may contact the parent, parents, or legal guardian or registrant, if an adult, who is identified in the birth defects registry to offer referral to medical and other support services as appropriate.	Data from the birth defects registry may be disclosed with the consent of the individual or the individual's guardian, but the requirements for obtaining consent are restrictive.	Consent signed by the individual Witnessed by an employee or authorized agent of MDHHS Presentation of suitable identification or signature notarized by a notary public or magistrate In the case of parents or guardians acting on behalf of a child or ward, a certified birth certificate, for parents, or a certified copy of the court order appointing the guardian, must be presented.	Birth defects registry data is not available with only a general consent and has additional requirements which may be challenging logistically. The Flint Registry should consider consulting with program staff to see how they've addressed this challenge in the past. MDHHS is reluctant to consider the consent exception for "study or research projects." These terms are not defined in Michigan law. The Flint Registry would need to make a case that it falls within the definition of a study. Per MDHHS, any birth defects registry data request would be reviewed by an IRB even if it is not considered research.

Database	Basis for identifiable data without consent	Basis for identifiable data with consent	Consent requirements	Analysis
Cancer Registry	MDHHS may disclose cancer registry information for a study or research project. These rules require review by a scientific advisory panel, review and approval by the Department's IRB, and approval by the Director. Informed consent would be required unless the IRB found that standards were met to waive consent. The researcher would be prohibited from contacting the registrant or family unless MDHHS sends a notice about the study and the parent, guardian, or registrant affirmatively agrees to participate in the project.	Data from the cancer registry may be disclosed with the consent of the individual or the individual's guardian, but the requirements for obtaining consent are restrictive.	Consent signed by the individual Witnessed by an employee or authorized agent of MDHHS Presentation of suitable identification or signature notarized by a notary public or magistrate In the case of parents or guardians acting on behalf of a child or ward, a certified birth certificate, for parents, or a certified copy of the court order appointing the guardian, must be presented.	Cancer registry data is not available with only a general consent and has additional requirements which may be challenging logistically. Because the consent form would not meet the process requirements under the Cancer Registry rules, this should not be included in the consent form. If this data were obtained through the exception for study or research purposes, the Flint Registry would need to consider how to ensure limits on the use of data to permitted uses. A DUA or MOU could be a possible solution. This category of data may lend itself better to a secondary data release (i.e., the Flint Registry later requests specific data for a specific study, rather than obtaining through "general" process). This would require: 1. A justification for why the Flint Registry is a study. 2. Clear delineation between what data is being requested for the current study versus what may be requested later for future studies.
Michigan Care Improvement Registry (MCIR)	Data might be obtainable without consent under two circumstances: First, the Flint Registry could become a registered MCIR user. This would require a written agreement that includes the terms and conditions of obtaining information, the information that may be obtained, and how the users will maintain confidentiality of the information. Second, the Flint Registry could become an authorized representative of a study or research project reviewed by the scientific advisory panel and approved by MDHHS' director.	Data may be disclosed to the individual to whom the information pertains or the individual's legal representative or others, per the written request of the individual, but the requirements for obtaining consent are restrictive.	Consent signed by the individual Witnessed by an employee or authorized agent of MDHHS Presentation of suitable identification or signature notarized by a notary public or magistrate	Due to the restrictive requirements for obtaining consent and reluctance to classify the Flint Registry as a study under the rule, the Flint Registry should pursue becoming a MCIR authorized user. As part of its user agreement with the Flint Registry, MDHHS would require that the Flint Registry obtain consent for the data release, and that such consent could be included in a general consent form that covers other data. The user agreement would set up user rights so the Flint Registry can only access data requested for specific inviduals consistent with the consent. This would give the Flint Registry direct access to MCIR interface.

Database	Basis for identifiable data without consent	Basis for identifiable data with consent	Consent requirements	Analysis
Childhood Lead Poisoning Prevention Program (CLPPP)	A public health exception allows MDHHS to release confidential CLPPP information without consent if necessary for the purpose of public health activities designed to prevent lead poisoning within a community.	Data may be disclosed with consent.	Written consent as part of a general consent form.	MDHHS could provide information to the Flint Registry via the public health exception under the CDC's grant of public health authority. MDHHS states that a written consent should be obtained. No particular form is required, and consent can be included in a general consent form that includes release of other data. The Flint Registry's use of nonconsented data must be limited to public health purposes. A withdrawal of CDC's authority would end the Flint Registry's ability to obtain additional CLPPP information via the public health exception. Since consent requirements are not restrictive, getting consent from individuals for CLPPP data should be pursued.
Lead Safe Home Program (LSH)	MDHHS suggests that an agreement between the Flint Registry and MDHHS may be used to disclose LSH information to the Flint Registry in lieu of consent. Additionally, under a public health exception it might be possible to obtain LSH program data from Genesee County Health Department or health care providers, though this may be logistically difficult.	N/A	N/A	As a condition of sharing LSH program data, MDHHS would require a continuing agreement that the Flint Registry exempt such data from the Freedom of Information Act and not re-disclose such data in identifiable form.
Women, Infants, and Children (WIC)	MDHHS may disclose WIC information to public organizations for use in the administration of their programs that serve persons eligible for the WIC Program. The public organization may use the information: • to establish the eligibility of WIC applicants or participants for the programs that the organization administers; • to conduct outreach to WIC applicants and participants for such programs; • to enhance the health, education, or well-being of WIC applicants or participants who are currently enrolled in such programs. Several prerequisites might make this provision impractical.	WIC participants may sign a consent form that authorizes the disclosure and specifies the parties to which the information may be disclosed.	Written consent as part of a general consent form. The individual must be notified that signing the consent form is not a condition of eligibility for the WIC program and refusing to sign will not impact their participation in the WIC program.	Disclosure without consent has to be approved by the USDA local office. This is a procedural hurdle, so it would be easier to obtain consent. MDHHS could provide WIC data to the Flint Registry if WIC participants sign a general consent form. MDHHS would require the consent form to state, "Signing to release information to the Flint Registry is not a condition of any MDHHS program eligibility; refusing to sign will not impact participation in said programs." MDHHS cautions that even with a release, information may be contained in its records concerning family members or other individuals that the consent might not cover.

Appendix F

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 MDHHS-DataRequests@michigan.gov within the Bureau of Information Management.
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 **Flint Registry Recruitment**		
Request Number (include number from MDHHS-5614, Request for Data)		
Data Recipient **Mona Hanna-Attisha**		
Organization **Michigan State University, College of Human Medicine**		
Address **200 East 1st Street**		
City **Flint**	State **MI**	Zip Code **48502**
Phone Number **53**	Email Address **hannamon@msu.edu**	

In accordance with this agreement, data are provided to the Data Recipient by the Michigan Department of Health and Human Services (MDHHS), **Bureau of Family Health Services/Division of Immunization, Michigan Department of Health and Human Services/Medical Services Administration, Bureau of Epidemiology and Population Health/Division of Environmental Health** 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.

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])

Michigan Care Improvement Registry (MCIR) **Michigan Medicaid Program (Medicaid)** **Michigan Childhood Lead Poisoning Prevention Program (CLPPP)-SEE ATTACHED**
Identify the MDHHS program sponsor(s) for the Requested Data. A sponsor is needed for each area providing data. **Division of Immmunization (MCIR)**
Sponsor **Tina Scott**
Title/Program **Section Manager, Assessment and Local Support, MCIR**

Phone Number	Email Address
517 [redacted]	**scottt1@michigan.gov**

Identify the MDHHS program sponsor(s) for the Requested Data. A sponsor is needed for each area providing data. **Medical Services Administration (Medicaid)**
Sponsor **Erin Emerson**
Title/Program **Chief of Staff to the Medicaid Director/Medicaid**

Phone Number	Email Address
517	**emersone@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). **Data are requested for the purpose of identifying potentially eligible individuals, based upon exposure to lead contaminated water at home or school, to participate in the Flint Registry. A primary goal of the Flint Registry is to connect lead exposed individuals to existing services to ameliorate the harmful effects of lead exposure. Because of its importance for Flint residents, the Flint Registry was granted public health authority by the CDC under the Public Health Service Act to support this work.**
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.

Data are requested to facilitate public health intervention. Data will be used to identify potentially eligible individuals based upon exposure to lead contaminated water at home or school,to participate in the Flint Registry. Potentially eligible individuals will be identified using data provided by the MDHHS, from the MCIR, Medicaid and CLPPP programs, and from zip codes of interest. Addresses will be geocoded by MSU to identify potential registrants.

A Flint Registry invitation letter, with opt-out option, will be mailed to identified persons. If no opt-out is received after the first mailed invitation, individuals will receive follow up invitations as follows: after a 2-week wait period, a second attempt mailed invitation letter and a phone call invitation; and finally a mailed final reminder invitation. Attempts to invite participants by mail or phone will be discontinued immediately, when an individual opts-out or declines participation. Participation is completely voluntary, and may be rescinded at any time.

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.
A list of data elements described in the attachment will be requested from MCIR, Medicaid, and CLPPP for all living persons residing in zip codes 48501-48507, 48532, and 48529, between 4/25/2014 to 6/1/2018. We request that Dr. Kevin Dombkowski access the State data warehouse to obtain these data. See item 3d.

   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)
   See attached document.
   Note:BLL level will be used to prioritize the order in which potential participants are contacted for recruitment.High, medium, not detected BBLs would be prioritzed, respectively.

   b. Specify if the data requested is identifiable, de-identified, or a limited data set as defined by HIPAA.
   Data is identifiable.

   c. Specify the medium requested (e.g., electronic, hard copy, etc.).
   Electronic

   d. Specify the method of data transfer from MDHHS to Data Recipient.

	MCIR, Medicaid and CLPPP data will be acquired under the direction of Dr. Kevin Dombkowski through existing secure VPN connections with the MDHHS data warehouse and other systems. In collaboration with Dr. Dombkowski, an MDHHS MCIR epidemiologist will query archived MCIR address history data for children meeting the Flint Registry eligibility criteria. MDHHS / MCIR will provide Dr. Dombkowski a file containing MCIR ID and historical addresses for the persons identified. These data will be transferred to Dr. Dombkowski using a secure file transfer protocol such as the University of Michigan Health System MiShare utility or the DCH-File Transfer Application. Dr. Dombkowski will subsequently obtain the current primary and stacked responsible party information for the MCIR IDs provided. MCIR, Medicaid, and CLPPP datasets will be merged and formatted by Dr. Dombkowski as required for transfer and loading into the Flint Registry database. All datasets prepared by Dr. Dombkowski will be transferred to MDHHS using a secure file transfer protocol such as the University of Michigan Health System MiShare utility or the DCH-File Transfer Application. MDHHS will subsequently transfer the prepared datasets to the Flint Registry by using a secure file transfer protocol or by using an encrypted, password protected USB drive. Passwords will be communicated directly to data recipient (not by email).
e.	Specify how the data will be stored and protected (e.g., encryption, password protected). **Data delivered to MSU will be stored in a password protected file on an encrypted server at the MSU Biomedical Research Informatics Core (BRIC). BRIC currently serves as a FISMA compliant data coordinating center for an other CDC-funded study. Data will be imported and merged into a password protected REDCap database hosted by MSU-BRIC as part of a larger list of potentially eligible individuals. Access to data in REDCap is protected by user-specific passwords and PI-designated permission levels. Any processing of data prior to importing into REDCap(i.e. geocoding, reformatting) will take place in encrypted, password protected environments.** **Data from REDCap will be securely transferred to Hurley via a direct linkage into Epic software. Epic software at Hurley will be used to manage recruitment activities for potentially eligible individuals. REDCap will be used to administer surveys.**
f.	Specify how access to the data will be managed. **Access to the MDHHS data delivered to MSU and stored at BRIC will be restricted to only those individuals listed below. These individuals will receive certified human subjects research training, and data security and confidentially training.**
g.	Specify with name and title of all whom will have access to the data.

Flint Registry personnel: Mona Hanna-Attisha, Principal Investigator; Nicole Jones, Director; Marty Crawford, Assistant Director; Alice Barnett, Coordinator; Royce Stephens, Interviewer Supervisor; Imari Smith, Kiaya Geohagan, Shanitha Harris – Interviewers; Stephanie Bahorski, Child Survey Manager; To Be Named, additional data collectors; To be named, Data Manager; Rick Sadler, Geographer; Khalid Ibrahim, MSU-BRIC data manager; Michael Szidel, MSU-BRIC developer; and Jon Babbage, MSU-BRIC information systems administrator.

University of Michigan, Child Health Evaluation and Research (CHEAR)Center: Kevin Dombkowski, Research Professor; and Hannah Jary, programmer/analyst.

Hurley Medical Center (HMC) Flint Registry data coordinating center personnel and related subcontractors: Renee Link, HMC Director of Enterprise Data Analytics; Morgan Kelly, Application Integration Specialist; Jessica Coyne,Report Writer and Data Change Agent; Sheldon Jackson, Systems Engineer; Patric Wallace, Applications Analyst; Steve Mass, HIM Analyst; Branden Bryan, Epic Systems Technical Support.Clayton Mckinny, Epic Corporation Interface TS; and Joseph Grathoff, Hurley Epic Interface Analyst.

h. Specify whether the data will be destroyed after it is no longer needed.

Data of individuals identified as potentially eligible based on geo-coding and transferred to REDCap and Epic will be available to Flint Registry personnel (with permission to access subject-level data) for the life of the Flint Registry.

MDHHS data provided by U of M CHEAR via secure file transfer system and stored in an encrypted, password protected file at MSU BRIC will be destroyed after the CDC funding period is complete (estimated, July 2021).

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.)

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.)

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.)

   MSU will use these data to contact individuals to 1) determine their eligibility and 2) for those who agree, to obtain their consent to participate in the Flint Registry Project.

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;

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.

In accordance with Public Act 540 of the Public Acts of 1996, amended in 2006 as Act 91, and codified as MCL 333.9201 et. seq. of the Michigan Public Health Code, the MDHHS has established the Michigan Care Improvement Registry to record and to access information regarding administered immunizations and other health related data. Access to MCIR and MCIR data is permitted only under Part 92 of the Public Health Code and applicable administrative rules. Administrative Rule 325.162 allows MDHHS to grant access to MCIR data only upon receipt and acceptance of a written agreement between the user and MDHHS that stipulates the terms and conditions of obtaining the information, including the data elements and how the user will maintain confidentiality of MCIR information. MDHHS may revoke a user's access privileges if the user violates this Agreement. A user may be a person or organization that is authorized by the Department. Rule 325.161. This Agreement serves as the MCIR user agreement and stipulates the terms and conditions of obtaining the information.

The MDHHS may cancel this agreement with proper notice.

The unauthorized use or disclosure of confidential information is punishable by imprisonment or fine or both under state and federal laws specific to the data released.

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) **Anne C. DiSante, CLP**	Title **Associate Director, MSU Technologies**
Signature of Responsible Data Recipient	Date March 3, 2019

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) **Tina Scott**	Title **Section MaDivision of Immmunization (MCIR)**
Signature of Responsible MDHHS Sponsor	Date
Name of Responsible MDHHS Sponsor (Type or Print) **Erin Emerson**	Title **Chief of Staff to the Medicaid Director/Me**
Signature of Responsible MDHHS Sponsor	Date

MDHHS RESPONSIBLE PARTY SIGNATURE

Project Title **Flint Registry Recruitment**	
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.	

Appendix G

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:

- 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.
- Spell out all acronyms when initially referenced.
- Complete and submit to MDHHS-DataRequests@michigan.gov within the Bureau of Information Management.
- 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.
- This application is not an agreement until authorized by the Chief Compliance Officer and all signatures have been affixed.

Project Title Flint Registry		
Request Number (include number from MDHHS-5614, Request for Data)		
Data Recipient Mona Hanna-Attisha, MPH, MD		
Organization Michigan State University, College of Human Medicine		
Address 200 East 1st Street		
City Flint	State MI	Zip Code 48502
Phone Number 353	Email Address hannamon@msu.edu	

In accordance with this agreement, data are provided to the Data Recipient by the Michigan Department of Health and Human Services (MDHHS), 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), to the extent applicable as described in more detail below, and all other applicable public health, research, and confidentiality laws.

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])

Medicaid Medical Services Administration; Michigan Childhood Lead Poisoning Prevention Program (CLPPP), Division of Environmental Health; Vital Records, Division of Vital Records and Health Statistics; Lead Safe Home Program. Information requested in the section BELOW did not fit within allowable space. Refer to supplemental documentation "Appendix B: DUA Outcomes-Section 1 Continuation_11.09"

Identify the MDHHS program sponsor(s) for the Requested Data. A sponsor is needed for each area providing data. Medical Services Administration	
Sponsor Erin Emerson	
Title/Program St.Off.Admin,Off.Strategic Prtnshps and Medicaid Admin.Services,Medicaid	
Phone Number 517 [redacted]	Email Address EmersonE@michigan.gov
Identify the MDHHS program sponsor(s) for the Requested Data. A sponsor is needed for each area providing data. Division of Environmental Health	
Sponsor Carin Speidel	
Title/Program State Administrative Manager, Healthy Homes Section	
Phone Number 517	Email Address SpeidelC@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).

General information for all program data: Michigan State University has been funded by the CDC, beginning August 1, 2017, to establish and implement the Flint Registry (FR), under the Public Health Service Act, 42 U.S.C. § 300j-27, as a lead exposure registry to collect data on the lead exposure of residents of a Flint on a voluntary basis.

As relevant to MDHHS HIPAA covered components: To support this important work, on September 25, 2017, CDC issued a grant of authority to MSU, to act as a public health authority, pursuant to HIPAA, to collect and receive health information, without individual authorization under HIPAA to conduct public health activities including public health surveillance, public health investigations, and public health interventions. A primary goal of the FR is to identify individuals on the Flint water system who may have been exposed to lead contaminated water and connect these individuals to existing services to ameliorate the harmful effects of lead exposure.

Data requested pursuant to this agreement are separate from any data MDHHS may provide to the FR pursuant to consents obtained by the FR.

Data will only be requested on those qualifying individuals who consent to participate in the registry. In the event that an individual withdraws consent to participate in the registry, no further data on that individual will be provided under this agreement and data requests under this agreement will be amended to omit any such individual.

At this time, the data being provided pursuant to this agreement are not intended to be used for "research" as defined by 45 CFR 46, the Common Rule.

Details of each individual program are attached in Appendix A and data elements are attached as Appendix C for all current data sources. The parties agree that data sources or elements may be added or subtracted from Appendix A and C from time to time as necessary to reflect data that are currently being shared. Changes may be required based on a change in status of the FR as a public health authority, a change in law, or a change in approach by either the FR or MDHHS.

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.

Program data provided by the MDHHS from Medicaid, CLPPP, Vital Records, and Lead Safe Home are requested to facilitate evaluation of Medicaid recipient outcomes and the FR public health intervention.

Preventative service outcomes and process metrics data will be used to evaluate the impact of the FR referral of participants to programs of potential eligibility. The focus of these measures will be to reflect the degree to which the FR and associated operations support efforts to optimize recommended service utilization.

Persons eligible to join the FR are those who lived, worked, attended school, or regularly visited the City of Flint from April 25, 2014 to October 15, 2015. This includes those who were prenatal during this time period. A FR invitation letter is texted, emailed, or mailed by USPS to potentially eligible persons or their parent/guardian. About 10 days after the invitation is sent, individuals receive a phone call from FR staff. FR interviewers periodically repeat attempts to reach persons by phone for whom outreach has been unsuccessful. In some cases, a reminder letter is texted, emailed, or mailed by USPS to persons who are difficult to reach by phone. Attempts to invite or remind participants by text, email, mail or phone will be discontinued immediately, when an individual declines participation. Participation is completely voluntary, and may be revoked at any time.

Data of FR participants provided by the MDHHS to the FR will be linked with FR data, and analyzed for the purposes described in Section 2.1.

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.
   Date Overview Description
   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)
      Please see attached document entitled "Appendix C, FR Requested Outcomes Data Elements for FR access by PHA".
   b. Specify if the data requested is identifiable, de-identified, or a limited data set as defined by HIPAA.
      Data are identifiable. Published or shared data will adhere to the Safe Harbor method of deidentification (exclusion of 18 key variables).
   c. Specify the medium requested (e.g., electronic, hard copy, etc.).
      Electronic
   d. Specify the method of data transfer from MDHHS to Data Recipient.

On a regular basis (e.g. quarterly), the FR will send a data file to the University of Michigan Child Health Evaluation and Research Center (UM-CHEAR) to request MDHHS outcomes data of FR participants. The FR-MDHHS PHA Outcomes Data Request file will comprise participant name, FR identification number (FRID), DOB, gender, and enrollment date. Data will be acquired by the UM-CHEAR working on behalf of the MDHHS, using existing secure VPN connections with the MDHHS data warehouse and other systems (e.g. MCIR). MDHHS will make every effort to provide a response in a timely basis, but response time will depend on availability of staff.

Per data deposit and dissemination agreement between Michigan State University and the University of Michigan, datasets acquired by UM-CHEAR will be transferred to the Flint Registry's secure virtual data enclave within the University of Michigan's Inter-University Consortium for Political and Social Research (ICPSR).

Login access will be validated directly with the ICPSR via established security protocols allowing only named Flint Registry employees and specified UM-CHEAR/ICPSR staff.

UM-CHEAR on behalf of MDHHS will provide outcomes data for the file of requested participants to the FR via the ICPSR on a regular basis (e.g. quarterly).

e. Specify how the data will be stored and protected (e.g., encryption, password protected).
Data delivered to FR will be stored in a password protected file on the Spartan 365, MSU's enterprise instance of Outlook 365. Microsoft's Enterprise Agreement for Spartan 365 provides compliance with the Family Educational Rights and Privacy Act (FERPA) and Health Insurance Portability and Accountability Act (HIPAA). This means student and health information are protected and onshore data storage is ensured.
As part of MSU's Spartan 365 agreement, Microsoft will not mine individual data and will only access that data for troubleshooting needs or malware prevention. Spartan 365 customer data belong to the customer, and the customer can export its data at any time. Backups to the data will be stored at the FR on an encrypted, password protected USB drive maintained in a locked drawer. Processing of data will take place in encrypted, password protected environments.

As a member of the Inter-university Consortium for Political and Social Research (ICPSR), the FR may store its data in the secure data enclave established for ICPSR members to manipulate and analyze data in a protected environment.

f. Specify how access to the data will be managed.
Access to MDHHS data delivered to the FR will be restricted to only those individuals listed below. These individuals will receive certified human subjects research training, and data security and confidentially training.

g. Specify with name and title of all whom will have access to the data.
FR personnel: Mona Hanna-Attisha, Principal Investigator;
Nicole Jones, Director; Marty Crawford, Director for External Data Sources; Jacqueline Dannis, Data Manager; to be named, data collectors; Rick Sadler, Geographer; to be named, MSU-BRIC data manager, developer, and system administrator.

University of Michigan, Child Health Evaluation and Research (CHEAR) Center: Kevin Dombkowski, Research Professor; Hannah Peng, Senior Statistician; Lisa Cohn, Senior Database Analyst/Programmer; Pooja Patel, Data Analyst.

University of Michigan, Inter-University Consortium for Political and Social Research (ICPSR): Trent Alexander, Associate Director ICPSR; Ambyr Amen-Ra, Project Manager; to be named, ICPSR Data Curator.

h. Specify whether the data will be destroyed after it is no longer needed.

See Appendix A for details on how data will be handled when no longer needed or if circumstances change.

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.)

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.)

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.)

   Exception: FR participants WHO GAVE CONSENT to have their information shared with service providers and/or to be contacted in the future by the FR for potential research studies may have their data shared or be contacted, respectively.

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;

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.

The MDHHS may cancel this agreement with proper notice.

The unauthorized use or disclosure of confidential information is punishable by imprisonment or fine or both under state and federal laws specific to the data released.

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) Richard W. Chylla, Ph.D., CLP, RTTP	Title Executive Director, MSU Technologies
Signature of Responsible Data Recipient Richard W. Chylla, PhD, CLP, RTTP Digitally signed by Richard W. Chylla, PhD, CLP, RTTP Date: 2021.07.09 16:50:21 -04'00'	Date July 9, 2021

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) Dr. Joneigh Khaldun	Title Chief Medical Executive
Signature of Responsible MDHHS Sponsor [redacted]	Date 8/2/2021
Name of Responsible MDHHS Sponsor (Type or Print)	Title
Signature of Responsible MDHHS Sponsor	Date

MDHHS RESPONSIBLE PARTY SIGNATURE

Project Title	
Request Number (include number from MDHHS-5614, Request for Data)	
Name of MDHHS Chief Compliance Officer	
Signature of MDHHS Chief Compliance Officer Cynthia Green-Edwards, MDHHS Chief Compliance Officer	Date Digitally signed by Cynthia Green-Edwards, MDHHS Chief Compliance Officer Date: 2021.07.20 12:50:02 -04'00'
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.	

Section I: Data Sources

Medicaid: Medicaid data held by MDHHS are covered both by Medicaid confidentiality regulations as well as HIPAA. Under MDHHS's hybrid entity designation, Medicaid is a HIPAA covered component of MDHHS.

Medicaid data are requested for purposes directly connected to administration of the Medicaid State Plan See 45 CFR 164.512.

Medicaid data may be provided under HIPAA to the Flint Registry (FR) pursuant to 45 CFR 164.512(b)(1)(i) because the FR is currently designated as a public health authority. Any change to the status of the FR as a public health authority shall be reported to MDHHS as soon as practicable, but in no event later than two weeks after a change, in order to determine what, if any, changes to this agreement and data retention may be required. See Section II below, Data Retention and Destruction requirements.

Data will be used to evaluate the impact of participation in the FR on Medicaid beneficiaries in the following areas: effectiveness of FR referrals to increase Medicaid enrollment of those not previously enrolled; Medicaid recipient enrollment in additional state and local services related to mental and physical support for individuals impacted by the Flint Water Crisis; changes in utilization of health services, changes in health outcomes associated with services, and changes in lead exposure. The FR's use of Medicaid data not only supports administration of the State Plan, it furthers important public health objectives. These include improvement in health outcomes of Flint's population, including Medicaid recipients, through identification of the nature and scope of lead's impact, increased enrollment in Medicaid and services intended to mitigate the harmful impact of lead exposure, and evaluation of the effectiveness of the FR as a public health intervention to improve population-level outcomes.

Lead Safe Home: Under MDHHS's hybrid entity designation, the Lead Safe Home program is NOT a HIPAA covered component of MDHHS. Data held by the Lead Safe Home program may be confidential if it leads to the identifcation of an individual protected under R 325.9086. However, MDHHS may share data protected under this rule "if necessary for the purpose of public health activities designed to prevent or mitigate lead poisoning within a community." R 325.9086(2)(f). Given the FR role as a public health authority as described in this DUA and appendecies, the data are being shared for this purpose.

Lead Safe Home data are requested to examine the effectiveness of Flint Registry referrals to the Lead Safe Home program. The FR will compare the data of individuals who were referred and enrolled in the Lead Safe Home program to individuals who were referred and did not enroll in the Lead Safe Home program.

Childhood Lead Poisoning and Prevention Program (CLPPP): Under MDHHS's hybrid entity designation, CLPPP is NOT a HIPAA covered component of MDHHS. Data held by the CLPPP program is confidential if it leads to the identifcation of an individual protected under R 325.9086. However, MDHHS may share data protected under this rule "if necessary for the purpose of public health activities designed to prevent or mitigate lead poisoning within a community." R 325.9086(2)(f). Given the FR role as a public health authority as described in this DUA and appendicies, the data are being shared for this purpose.

CLPPP data are requested to examine one of the FR's stated goals, specifically to reduce lead poisoning in the community. The FR will compare blood lead levels of participants before and after enrollment in the Registry.

Vital Records: Under MDHHS's hybrid entity designation, Vital Records is NOT a HIPAA covered component of MDHHS. Vital records data requested are being shared pursuant to MCL 333.2883(2), which allows MDHHS to provide data to "federal, state, local, and other public or private agencies for statistical or administrative purposes on the terms or conditions prescribed by" MDHHS. Consistent with MCL 333.2883(2), the records provided from the Vital Records program may only be used "for the purpose for which" it was requested, as outlined in this agreement.

Vital Records data are requested for FR participants to statistically evaluate FR survey data to assess congruence between self-reported data and vital records data, as a measure of data quality. Vital Records data will also be used to look at health outcomes of individuals who were enrolled in the FR.

Section II: Data Retention and Destruction Requirements

MDHHS program data provided by the MDHHS to the FR will generally be available for the duration of the FR to FR personnel with permission to access subject-level data.

Because the potential value of these data and the data they may produce by analysis cannot be determined in advance of the FR's end date, the following steps will be followed to determine the final disposition of these data.

First, the FR will notify the MDHHS when the FR ceases to operate and/or when the FR's grant of PHA is recinded.

Second, the FR leadership and To-Be-Named MDHHS designees will meet to determine the final disposition of these data. This plan applies to data received by the FR from the MDHHS under this agreement, and does not apply to

program data provided to the FR as a function of FR participants' consent. Data obtained with participant consent will remain property of the FR.

If the parties cannot agree as to the disposition of the data, MDHHS shall make the final determination as to the appropriate final disposition of the data.

If data provided to the FR, absent participant consent, is to be destroyed, the FR leadership agrees to complete the Affidavit of Destruction of Data form provided by MDHHS.

Ongoing, daily management of FR data is described in the FR Data Management Plan, which is maintained as specified by the funding requirements of the Centers for Disease Control and Prevention.

APPENDIX B to DATA USE AND NON-DISCLOSURE AGREEMENT CONCERNING PROTECTED HEALTH INFORMATION OR OTHER CONFIDENTIAL INFORMATION
Michigan Department of Health and Human Services

Identify the MDHHS program sponsor(s) for the Requested Data. A sponsor is needed for each area providing data.

MDHHS Program: Division of Environmental Health
Sponsor: Dan Albright
Title/Program: Data Analyst, CLPPP
Phone Num[redacted]791
Email Address: AlbrightD@michigan.gov

MDHHS Program: Division for Vital Records and Health Statistics
Sponsor: Jeffrey Duncan
Title/Program: State Office Administrator, Division for Vital Records and Health Statistics
Phone Num[redacted]677
Email Address: DuncanJ11@michigan.gov

MDHHS Program: Medical Services Administration
Sponsor: Erin Emerson
Title/Program: St.Off.Admin, Off.Strategic Prtnshps and Medicaid Admin.Services, Medicaid
Phone Num[redacted]72
Email Address: EmersonE@michigan.gov

MDHHS Program: Division of Environmental Health
Sponsor: Carin Speidel
Title/Program: State Administrative Manager, Healthy Homes Section
Phone Num[redacted]819
Email Address: SpeidelC@michigan.gov

APPENDIX C: Flint Registry Outcome Metrics Data Acquisition Framework (updated 6-2-2021)

<table>
<tr><td colspan="3">Data requested for time period of April 1, 2013, to today's date
(I.e. one year prior to the start of the Flint water crisis to current date)</td></tr>
<tr><th>Preventive Services Outcomes / Process Metrics</th><th>Records requested</th><th>Data Source</th></tr>
<tr><td>Medicaid ID# **
Not provided to Flint Registry. Used internally by Kevin Dombkowski, working on behalf of MDHHS, to match individuals across MDHHS programs.</td><td></td><td rowspan="3">Medicaid claims and encounters</td></tr>
<tr><td>Name
Address
Date of Birth
Gender</td><td>All persons enrolled in the FR, for the purpose of linking an individual's MDHHS data to his/her FR data</td></tr>
<tr><td>All claims data

Example Domains of Interest:
Well child / well visits, Maternal care, infant care, Chronic disease management (e.g., asthma, sickle cell, etc.), Emergency Department use for primary care, ambulatory sensitive conditions, outpatient, ED, inpatient, pharmacy, durable medical equipment, Missed opportunities for vaccination, Missed opportunities for follow up CLPPP testing Adult annual physical, HEDIS measures (aka preventative services), Physical and mental health diagnosis codes in claims, mental health measures, adhd, odd, ocd, etc., adult lead/trauma exposure sequalae, kin issues, fertility issues, miscarriage</td><td>All persons enrolled in the FR</td></tr>
</table>

June 2021

Name Address Date of Birth Gender mother's SSN (for use as matching variable) WIC status during pregnancy (will not include records from WIC), smoking during pregnancy, alcohol during pregnancy, other risk factors, birthweight, gestational age, maternal morbidity, abnormal conditions of newborn, congenital anomalies of newborn, breast feeding initiated / planned Plurality Previous children born alive now living Previous children born alive now dead Previous children born dead Last fetal death year Last fetal death month Last fetal death day Mothers birth year Mothers birth month Mothers birthday Mothers mailing street address Mothers Mailing city Mothers mailing state Mothers mailing zip	All persons enrolled in the Flint Registry	**Vital Records**

June 2021

Name Address Date of Birth Gender	Persons enrolled in the Flint Registry, for the purpose of linking an individual's MDHHS data to his/her FR data	**CLPPP**
Specimen Date- Date the blood sample was taken Sample type- Capillary or venous, or unknown PB result PB result text Note: BLL values reportable **prior to Nov 2017**: Low <5, medium (5<15 mg/dl), high (15 < 45 mg/dl), and very high (>45 mg/dl BLL values reportable **after Oct 2017**: not detected, low (ND<5 mg/dl), medium (5<15), high (15<45) and very high (>45)	All persons enrolled in the FR	
Name Date of Birth Gender General description: participation in LSH program; extent of renovation Requested elements from data dictionary: Address Application Date Application Status If denied, Denial Reason If waiver needed, criteria waived reason Assessment Type Investigation type Investigation activity type Hazard type Project Start Date Project End Date Project Details: Abatement Clearance Date	All persons enrolled in the Flint Registry	**Lead Safe Home**

Note: zip codes of residence in the city of Flint: 48501 - 48507, 48532, and 48529

June 2021

Flint Registry-MDHHS Management of Consents

Management of Participants for MDHHS outcomes data shared with the Flint Registry by PHA

1. Management of participants
    a. Each FR participant is assigned a study identifier: Flint Registry ID (FRID).
    b. Consent (Yes/No) to participate in the Registry and Date of Consent are collected separately for adult and child participants.
    c. Consent to participate data are stored in the Flint Registry's REDCap and Epic data systems.
    d. When a participant withdraws his/her consent to participate in the FR, the Date of withdraw and mode of communication are documented in the REDCap and Epic data systems
2. Request for outcomes data for current FR participants (e.g. quarterly schedule)
    a. On a quarterly basis, FR will create a current participants file
        i. Queries to create the current participants file will EXCLUDE participants who are no longer participating in the FR (i.e., the file will exclude participants who have withdrawn consent to participate). Exclusion will use date_of_ withdraw and mode_of_communication variables (= null)
    b. Each record will comprise name, dob, gender.
    c. The FR will send to UM-CHEAR a file of current participants

Appendix H

Flint Registry/Adult Consent Form

This is the consent version that can be completed and signed in-person.

Adult consent to enroll

The next section asks about your decision to participate in the Registry and is called the consent. The consent section must be completed by the adult who is enrolling in the Registry or by the adult's official legal representative.

Are you completing this on behalf of someone else?

☐ Yes

☐ No

If Yes, what is your relationship to the adult who is enrolling in the Flint Registry:

☐ I am currently his/her Durable Power of Attorney

☐ I am currently his/her Legal Guardian

About the Flint Registry

The goals of the Registry are to connect people to services, to document the health effects of the Flint water crisis, and to promote wellness and recovery. The Flint Registry is for adults and children exposed to the Flint Water System from April 25, 2014 - October 15, 2015.

The Registry is sponsored by the Centers for Disease Control and Prevention and led by a Flint-based team at Michigan State University (MSU). MSU works with many groups in the community including the City of Flint, Greater Flint Health Coalition, educators, clinicians, community-based organizations, and most importantly, residents of Flint, to make sure the Registry reflects the needs of the community.

Participating in the Flint Registry is voluntary. If you decide not to enroll in the Registry, you will not lose any rights or benefits that you would otherwise get. Please take your time to make your choice about participating. If you have questions, at any time, please contact Flint Registry staff by phone at 833-GO-FLINT or email at flintregistry@hc.msu.edu.

Here are some frequently asked questions about the Flint Registry. More information is also available at FlintRegistry.org

Flint Registry/Adult Consent Form

This is the consent version that can be completed and signed in-person.

What will happen if I join the Flint Registry?

✓ **Step 1-Complete your Survey**

If you choose to enroll, you will be asked to fill out a survey. This survey will include questions about your background, health, and exposure to Flint water. You can choose one of these ways to complete your survey: online, over the phone, at the Flint Registry office, or by filling out and mailing back a paper copy of the survey. After completing the survey, you will be mailed a thank you check.

✓ **Step 2-Get Referred**

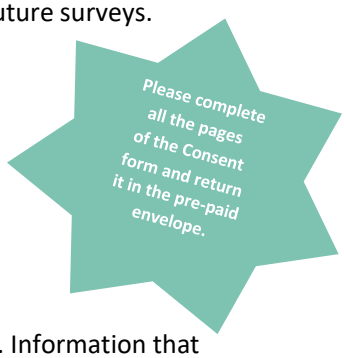
If you agree to be referred to services, the Flint Registry team will share your information and connect you to community services you may be eligible for. These services may include medical insurance, nutrition support, and home lead identification and fixing.

✓ **Step 3 - Complete your follow-up survey**

About one year after completing your first survey, you will be asked to fill out a follow-up survey**.**

✓ **Step 4 - Future Surveys**

The Registry may continue to be funded and to contact you about future surveys.



Can I stop participating in the Registry if I change my mind?

Yes. You can decide to leave the Registry at any time.

How does the Registry use, protect, and share information?

Any information gathered by the Registry about you will be kept confidential. Information that identifies you will not be shared without your consent unless we are required by law to disclose information.

In rare cases, we may be required to reveal confidential information related to safety. We are required to report suspected cases of child abuse, or if you tell us you are planning to cause serious harm to yourself or others, or if we reasonably believe you are a threat to yourself or others.

Flint Registry/Adult Consent Form

This is the consent version that can be completed and signed in-person.

Information will be kept in a secure database at MSU and Hurley Medical Center. The databases will only be available to Registry staff and the Registry's contractors.

We will do our best to make sure that the personal information gathered for this study is kept private. We have taken multiple steps to protect your information by using password protected systems with physically secured servers. All Flint Registry workers are required to receive training in ways to keep information secure.

Information from the Registry will be made available to Flint residents and community members in the form of group reports. Your name will not be connected with your answers. Information may be shared with researchers and be published or presented at professional meetings, but there will be no information that identifies you, like your name or your birthdate. Unless you agree, your name and contact information will not be shared with anyone.

What are the benefits of participating in the Registry?

You may personally benefit from your participation if Registry staff are able to refer you to services. Other people may benefit because information collected in the Flint Registry may help us understand how lead exposure affects health.

What are the possible risks of participating?

The possible risks of participating are that some of the survey questions may remind you of your feelings or issues you faced during the water crisis. The Registry will provide information on community resources to help with your feelings.

If you have questions, please contact us at FlintRegistry@hc.msu.edu or call 833-GO-FLINT.

Join the Registry

Based on the information provided, would you like to join the Registry?

- ☐ Yes. Please enroll me in the Flint Registry.
- ☐ No. Do NOT enroll me in the Flint Registry.

Adult Consent InPerson 2021-02-16V06 2021-02-16V06

Flint Registry/Adult Consent Form

This is the consent version that can be completed and signed in-person.

There are additional decisions to make about participating in the Registry:

Decision 1: Let the Registry help you access resources

The Registry's survey will ask questions about your health, household information, and exposure to lead. Using your answers, the Registry will help identify the services in the community that you may be eligible for.

Do you choose to "give permission" or to "NOT give permission" for the Registry to share your survey information with service providers to help enroll you in programs and services?

- ☐ Yes. I give my permission for the Flint Registry to share my information with service providers.
- ☐ No. I do NOT give my permission for the Flint Registry to share my information with service providers.

Decision 2: Allow the Flint Registry to contact you about other projects

Research on the water crisis is important to further our understanding of how to help children and adults exposed to lead and similar crises. Do you choose to "give permission" or to "NOT give permission" for the Registry to contact you in the future to learn about other projects?

- ☐ **Yes.** I give my permission for the Flint Registry to contact me in the future about participating in other projects.
- ☐ **No.** I do NOT give my permission for the Flint Registry to contact me about participating in other projects.

MDHHS Consent Decision: Allow the Michigan Department of Health and Human Services (MDHHS) to provide some of your program information to the Flint Registry

The Registry would like to obtain information about your health and well-being from your MDHHS records for the following programs: Michigan Care Improvement Registry (MCIR), Childhood Lead Poisoning Prevention Program (CLPPP), Vital Records, Women Infants and Children (WIC), and Lead Safe Home. **Giving permission to MDHHS to share your information is voluntary and refusing does not affect your eligibility for any MDHHS programs or services.**

Flint Registry/Adult Consent Form

This is the consent version that can be completed and signed in-person.

With your permission, we can link this information with other information in the Registry to help us to better understand the impact of lead-exposure on your health and to understand how using services from the State of Michigan may have affected your health. Your permission to allow MDHHS to provide some of your information to the Flint Registry ends when the Registry ends, unless you choose to withdraw your permission in writing before that time.

- ☐ **Yes.** I give my permission for the MDHHS to provide my information from MCIR, CLPPP, Vital Records, WIC, and Lead Safe Home to the Flint Registry.
- ☐ **No.** I do NOT give my permission for the MDHHS to provide my information from MCIR, CLPPP, Vital Records, WIC, and Lead Safe Home to the Flint Registry.

Medicaid Consent Decision: Allow the Michigan Department of Health and Human Services (MDHHS) to provide some of your HIPAA-protected health information to the Flint Registry

The Registry would like to obtain information about your health and well-being from your Medicaid records held by the MDHHS. Medicaid records are governed by the Health Information Portability and Accountability Act (HIPAA). **Giving permission to MDHHS to share your Medicaid information is voluntary and refusing does not affect your eligibility for any MDHHS programs or services.**

With your permission, we can link this information with other information in the Registry to help us to better understand the impact of lead-exposure on your health and to understand how using Medicaid services from the State of Michigan may have affected your health. Your permission to allow MDHHS to provide some of your Medicaid information to the Flint Registry ends when the Registry ends, unless you choose to withdraw your permission in writing before that time. Any information gathered by the Registry about you will be kept confidential. Information that identifies you will not be shared without your consent unless we are required by law to disclose information. If we are required by law to disclose information, it is possible that this information will no longer be protected under HIPAA.

Flint Registry/Adult Consent Form

This is the consent version that can be completed and signed in-person.

You may request a copy of your decision, or you may change your decision to share data at any time by submitting a Request to Withdraw form. The form may be found at FlintRegistry.org, or you may ask for a copy to be mailed by calling the Registry at 833-GO-FLINT (833-463-5468).

☐ **Yes.** I give my permission for the MDHHS to provide my Medicaid information to the Flint Registry.

☐ **No.** I do NOT give my permission for the MDHHS to provide my Medicaid information to the Flint Registry.

What is your relationship to the person enrolling in the Flint Registry: (check one)?

☐ Self

☐ I am currently his/her Durable Power of Attorney

☐ I am currently his/her Legal Guardian and am responsible to act on behalf of him/her in matters of care or custody.

Participant information and signature

Please print information below:

_____

First Name Middle Initial Last Name

_____

Date of Birth

_____

Address

_____

City State Zip Code

Signature _____Date_____

Adult Consent InPerson 2021-02-16V06 2021-02-16V06

Flint Registry/Adult Consent Form

This is the consent version that can be completed and signed in-person.

Adult MDHHS and Medicaid Consent

The next section asks about your decision to participate in the Registry and is called the consent. The consent section must be completed by the adult who is enrolling in the Registry or by the adult's official legal representative.

Are you completing this on behalf of someone else?

☐**Yes**

☐**No**

If Yes, what is your relationship to the adult who is enrolling in the Flint Registry:

☐ I am currently his/her Durable Power of Attorney

☐ I am currently his/her Legal Guardian

MDHHS Consent Decision: Allow the Michigan Department of Health and Human Services (MDHHS) to provide some of your program information to the Flint Registry

The Registry would like to obtain information about your health and well-being from your MDHHS records for the following programs: Michigan Care Improvement Registry (MCIR), Childhood Lead Poisoning Prevention Program (CLPPP), Vital Records, Women Infants and Children (WIC), and Lead Safe Home. **Giving permission to MDHHS to share your information is voluntary and refusing does not affect your eligibility for any MDHHS programs or services.**

With your permission, we can link this information with other information in the Registry to help us to better understand the impact of lead-exposure on your health and to understand how using services from the State of Michigan may have affected your health. Your permission to allow MDHHS to provide some of your information to the Flint Registry ends when the Registry ends, unless you choose to withdraw your permission in writing before that time.

☐ **Yes.** I give my permission for the MDHHS to provide my information from MCIR, CLPPP, Vital Records, WIC, and Lead Safe Home to the Flint Registry.

☐ **No.** I do NOT give my permission for the MDHHS to provide my information from MCIR, CLPPP, Vital Records, WIC, and Lead Safe Home to the Flint Registry.

Flint Registry/Adult Consent Form

This is the consent version that can be completed and signed in-person.

Medicaid Consent Decision: Allow the Michigan Department of Health and Human Services (MDHHS) to provide some of your HIPAA-protected health information to the Flint Registry

The Registry would like to obtain information about your health and well-being from your Medicaid records held by the MDHHS. Medicaid records are governed by the Health Information Portability and Accountability Act (HIPAA). **Giving permission to MDHHS to share your Medicaid information is voluntary and refusing does not affect your eligibility for any MDHHS programs or services.**

With your permission, we can link this information with other information in the Registry to help us to better understand the impact of lead-exposure on your health and to understand how using Medicaid services from the State of Michigan may have affected your health. Your permission to allow MDHHS to provide some of your Medicaid information to the Flint Registry ends when the Registry ends, unless you choose to withdraw your permission in writing before that time. Any information gathered by the Registry about you will be kept confidential. Information that identifies you will not be shared without your consent unless we are required by law to disclose information. If we are required by law to disclose information, it is possible that this information will no longer be protected under HIPAA.

You may request a copy of your decision, or you may change your decision to share data at any time by submitting a Request to Withdraw form. The form may be found at FlintRegistry.org, or you may ask for a copy to be mailed by calling the Registry at 833-GO-FLINT (833-463-5468).

☐ **Yes.** I give my permission for the MDHHS to provide my Medicaid information to the Flint Registry.

☐ **No.** I do NOT give my permission for the MDHHS to provide my Medicaid information to the Flint Registry.

What is your relationship to the person enrolling in the Flint Registry? (check one)

☐ Self

☐ I am currently his/her Durable Power of Attorney

☐ I am currently his/her Legal Guardian and am responsible to act on behalf of him/her in matters of care or custody.

Flint Registry/Adult Consent Form

This is the consent version that can be completed and signed in-person.

Participant information and signature

Please print information below:

_____

First Name Middle Initial Last Name

_____

Date of Birth

_____

Address

_____

City State Zip Code

Signature _____Date_____

Appendix I

Flint Registry/Child Consent Form

This is the consent version that can be completed and signed in-person.

Consent to enroll your Child

The next section asks about your decision to participate in the Registry and is called the consent. The consent section must be completed by your child's parent or legal guardian.

About the Flint Registry

The goals of the Registry are to connect people to services, to document the health effects of the Flint water crisis, and to promote wellness and recovery. The Flint Registry is for adults and children exposed to the Flint Water System from April 25, 2014 - October 15, 2015.

The Registry is sponsored by the Centers for Disease Control and Prevention and led by a Flint-based team at Michigan State University (MSU). MSU works with many groups in the community including the City of Flint, Greater Flint Health Coalition, educators, clinicians, community-based organizations, and most importantly, residents of Flint, to make sure the Registry reflects the needs of the community.

Participating in the Registry is voluntary. If you decide not to enroll your child in the Registry, you will not lose any rights or benefits that you would otherwise get. Please take your time to make your choice about participating. If you have questions, at any time, please contact Registry staff by phone at 833-GO-FLINT or email at flintregistry@hc.msu.edu.

Here are some frequently asked questions about the Flint Registry. More information is also available at FlintRegistry.org

What will happen if I join the Flint Registry?

✓ **Step 1-Complete your Survey**

If you choose to enroll your child, you will be asked to fill out a survey. This survey will include questions about your child's background, health, development and exposure to Flint water. You will need to complete a separate survey for each child. The child survey will take about 45 minutes to complete for each child. You can choose one of these ways to complete your child's survey: online, over the phone, at the Flint Registry office, or by filling out and mailing back a paper copy of the survey. After completing the survey, you will be mailed a thank you check for each child's survey.

Flint Registry/Child Consent Form

This is the consent version that can be completed and signed in-person.

✓ **Step 2-Get Referred**

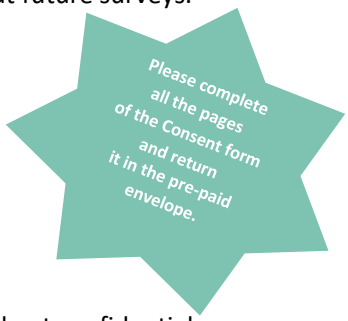
If you agree to be referred to services, the Flint Registry team will share your information and connect you to community services your child may be eligible for. These services may include medical insurance, nutrition support, early learning support for children, and home lead identification and fixing.

✓ **Step 3 - Complete your follow-up survey**

About one year after completing your first survey, you will be asked to fill out a follow-up survey for your child.

✓ **Step 4 - Future Surveys**

The Registry may continue to be funded and to contact you about future surveys.



Can I stop participating in the Registry if I change my mind?

Yes. You can decide to leave the Registry at any time.

How does the Registry use, protect, and share information?

Any information gathered by the Registry about you, or your child will be kept confidential. Information that identifies you or your child will not be shared without your consent unless we are required by law to disclose information.

In rare cases, we may be required to reveal confidential information related to safety. We are required to report suspected cases of child abuse, or if you tell us you are planning to cause serious harm to yourself or others, or if we reasonably believe you are a threat to yourself or others.

Information will be kept in a secure database at MSU and Hurley Medical Center. The databases will only be available to Registry staff and the Registry's contractors.

We will do our best to make sure that the personal information gathered for this study is kept private. We have taken multiple steps to protect your information by using password protected systems with physically secured servers. All Flint Registry workers are required to receive training in ways to keep information secure.

Flint Registry/Child Consent Form

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Information from the Registry will be made available to Flint residents and community members in the form of group reports. Your child's name will not be connected with your answers. Information may be shared with researchers and be published or presented at professional meetings, but there will be no information that identifies you or your child, like your name or your birthdate. Unless you agree, your name and contact information will not be shared with anyone.

What are the benefits of participating in the Registry?

You and your child may personally benefit from your participation if Registry staff are able to refer you to services for you and your child. Other people may benefit because information collected in the Flint Registry may help us understand how lead exposure affects health.

What are the possible risks of participating?

The possible risks of participating are that some of the survey questions may remind you of your feelings or issues you faced during the water crisis. You may learn that your child is showing signs of delay or other health concerns, which may be stressful to you. The Registry will provide information on community resources to help with your feelings and to help your child, if delays or health concerns are identified.

If you have questions, please contact us at FlintRegistry@hc.msu.edu or call 833-GO-FLINT.

Join the Registry

Based on the information provided, would you like your child to join the Registry?

- ☐ **Yes.** Please enroll my child in the Registry.
- ☐ **No.** Do NOT enroll my child in the Registry.

There are additional decisions to make about participating in the Registry

Decision 1: Let the Registry help you access resources

The Registry's survey will ask questions about you and/or your child's health, household information, and exposure to lead. Using your answers, the Registry will help identify the services in the community that your child may be eligible for.

Flint Registry/Child Consent Form

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Do you choose to "give permission" or to "NOT give permission" for the Flint Registry to share your survey information with service providers to help enroll your child in programs and services? This may include making a referral to Genesee Health System's Neurodevelopmental Center of Excellence.

☐ **Yes.** I give my permission for the Registry to share my information with service providers.

☐ **No.** I do NOT give my permission for the Registry to share my information with service providers.

Decision 2: Allow the Flint Registry to contact you about other projects

Research on the water crisis is important to further our understanding of how to help children and adults exposed to lead and similar crises. Do you choose to "give permission" or to "NOT give permission" for the Flint Registry to contact you in the future to learn about other projects?

☐ **Yes.** I give my permission for the Registry to contact me in the future about participating in other projects.

☐ **No.** I do NOT give my permission for the Registry to contact me about participating in other projects.

MDHHS Consent Decision: Allow the Michigan Department of Health and Human Services (MDHHS) to provide some of your child's program information to the Flint Registry

The Registry would like to obtain information about your child's health and well-being from MDHHS program records. MDHHS birth certificate records and program records provide information about your child's birth and participation in services such as WIC, the Lead Safe Home Program, the Michigan Care Improvement Registry (MCIR), and the Childhood Lead Poisoning Prevention Program (CLPPP). **Giving permission is voluntary and refusing does not affect you or your child's eligibility for any MDHHS programs or services.**

Flint Registry/Child Consent Form

This is the consent version that can be completed and signed in-person.

With your permission, we can link this information with other information in the Registry to help us to better understand the impact of lead on your child's health and to understand how using services from the State of Michigan may have affected the health of your family. Your permission to allow MDHHS to provide some of your child's information to the Flint Registry ends when the Registry ends, unless you choose to withdraw your permission before that time.

☐ **Yes.** I give my permission for the MDHHS to provide my child's information from MCIR, CLPPP, Vital Records, WIC, and Lead Safe Home to the Flint Registry.

☐ **No.** I do NOT give my permission for the MDHHS to provide my child's information from MCIR, CLPPP, Vital Records, WIC, and Lead Safe Home to the Flint Registry.

Medicaid Consent Decision: Allow the Michigan Department of Health and Human Services (MDHHS) to provide some of your child's HIPAA-protected health information to the Flint Registry

The Registry would like to obtain information about your child's health and well-being from Medicaid records held by the MDHHS. Medicaid records are governed by the Health Information Portability and Accountability Act (HIPAA). **Giving permission to MDHHS to share your Medicaid information is voluntary and refusing does not affect your eligibility for any MDHHS programs or services.**

With your permission, we can link this information with other information in the Registry to help us to better understand the impact of lead-exposure on your health and to understand how using Medicaid services from the State of Michigan may have affected your child's health. Your permission to allow MDHHS to provide some of your child's Medicaid information to the Flint Registry ends when the Registry ends, unless you choose to withdraw your permission in writing before that time. Any information gathered by the Registry about your child will be kept confidential. Information that identifies you or your child will not be shared without your consent unless we are required by law to disclose information. If we are required by law to disclose information, it is possible that this information will no longer be protected under HIPAA.

You may request a copy of your decision, or you may change your decision to share data at any time by submitting a Request to Withdraw form. The form may be found at FlintRegistry.org, or you may ask for a copy to be mailed by calling the Registry at 833-GO-FLINT (833-463-5468).

Flint Registry/Child Consent Form

This is the consent version that can be completed and signed in-person.

Consent to enroll your Child

The next section asks about your decision to participate in the Registry and is called the consent. The consent section must be completed by your child's parent or legal guardian.

About the Flint Registry

The goals of the Registry are to connect people to services, to document the health effects of the Flint water crisis, and to promote wellness and recovery. The Flint Registry is for adults and children exposed to the Flint Water System from April 25, 2014 - October 15, 2015.

The Registry is sponsored by the Centers for Disease Control and Prevention and led by a Flint-based team at Michigan State University (MSU). MSU works with many groups in the community including the City of Flint, Greater Flint Health Coalition, educators, clinicians, community-based organizations, and most importantly, residents of Flint, to make sure the Registry reflects the needs of the community.

Participating in the Registry is voluntary. If you decide not to enroll your child in the Registry, you will not lose any rights or benefits that you would otherwise get. Please take your time to make your choice about participating. If you have questions, at any time, please contact Registry staff by phone at 833-GO-FLINT or email at flintregistry@hc.msu.edu.

Here are some frequently asked questions about the Flint Registry. More information is also available at FlintRegistry.org

What will happen if I join the Flint Registry?

✓ **Step 1-Complete your Survey**

If you choose to enroll your child, you will be asked to fill out a survey. This survey will include questions about your child's background, health, development and exposure to Flint water. You will need to complete a separate survey for each child. The child survey will take about 45 minutes to complete for each child. You can choose one of these ways to complete your child's survey: online, over the phone, at the Flint Registry office, or by filling out and mailing back a paper copy of the survey. After completing the survey, you will be mailed a thank you check for each child's survey.

Flint Registry/Child Consent Form

This is the consent version that can be completed and signed in-person.

Child MDHHS and Medicaid Consent

The next section asks about your decision to participate in the Registry and is called the consent. The consent section must be completed by your child's parent or legal guardian.

MDHHS Consent Decision: Allow the Michigan Department of Health and Human Services (MDHHS) to provide some of your child's program information to the Flint Registry

The Registry would like to obtain information about your child's health and well-being from MDHHS program records. MDHHS birth certificate records and program records provide information about your child's birth and participation in services such as WIC, the Lead Safe Home Program, the Michigan Care Improvement Registry (MCIR), and the Childhood Lead Poisoning Prevention Program (CLPPP). **Giving permission is voluntary and refusing does not affect you or your child's eligibility for any MDHHS programs or services.**

With your permission, we can link this information with other information in the Registry to help us to better understand the impact of lead on your child's health and to understand how using services from the State of Michigan may have affected the health of your family. Your permission to allow MDHHS to provide some of your child's information to the Flint Registry ends when the Registry ends, unless you choose to withdraw your permission before that time.

☐ **Yes.** I give my permission for the MDHHS to provide my child's information from MCIR, CLPPP, Vital Records, WIC, and Lead Safe Home to the Flint Registry.

☐ **No.** I do NOT give my permission for the MDHHS to provide my child's information from MCIR, CLPPP, Vital Records, WIC, and Lead Safe Home to the Flint Registry

Flint Registry/Child Consent Form

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Medicaid Consent Decision: Allow the Michigan Department of Health and Human Services (MDHHS) to provide some of your child's HIPAA-protected health information to the Flint Registry

The Registry would like to obtain information about your child's health and well-being from Medicaid records held by the MDHHS. Medicaid records are governed by the Health Information Portability and Accountability Act (HIPAA). **Giving permission to MDHHS to share your Medicaid information is voluntary and refusing does not affect your eligibility for any MDHHS programs or services.**

With your permission, we can link this information with other information in the Registry to help us to better understand the impact of lead-exposure on your health and to understand how using Medicaid services from the State of Michigan may have affected your child's health. Your permission to allow MDHHS to provide some of your child's Medicaid information to the Flint Registry ends when the Registry ends, unless you choose to withdraw your permission in writing before that time. Any information gathered by the Registry about your child will be kept confidential. Information that identifies you or your child will not be shared without your consent unless we are required by law to disclose information. If we are required by law to disclose information, it is possible that this information will no longer be protected under HIPAA.

You may request a copy of your decision, or you may change your decision to share data at any time by submitting a Request to Withdraw form. The form may be found at FlintRegistry.org, or you may ask for a copy to be mailed by calling the Registry at 833-GO-FLINT (833-463-5468).

☐ **Yes.** I give my permission for the MDHHS to provide my child's Medicaid information to the Flint Registry.

☐ **No.** I do NOT give my permission for the MDHHS to provide my child's Medicaid information to the Flint Registry.

Flint Registry/Child Consent Form

This is the consent version that can be completed and signed in-person.

Child information

_____

First Name Middle Initial Last Name

_____

Date of Birth

Parent/legal guardian information and signature

Please print your information below (NOT your child's information):

_____

Parent/Guardian First Name Middle Initial Last Name

_____

Parent/Guardian Date of Birth

_____

Address

_____

City State Zip Code

Parent/Guardian Signature _____Date_____