Application for Massachusetts Case Mix and Charge Data (Non-Government) [Exhibit A – Data Application]

I.   INSTRUCTIONS

This form is required for all Applicants, Agencies, or Organizations, hereinafter referred to as "Organization", except Government Agencies as defined in 957 CMR 5.02, requesting protected health information. All Organizations must also complete the Data Management Plan, and attach it to this Application. The Application and the Data Management Plan must be signed by an authorized signatory. This Application and the Data Management Plan will be used by CHIA to determine whether the request meets the criteria for data release, pursuant to 957 CMR 5.00. Please complete the Application documents fully and accurately. Prior to receiving CHIA Data, the Organization must execute CHIA's Data Use Agreement. Organizations may wish to review that document prior to submitting this Application.

Before completing this Application, please review the data request information on CHIA's website:
- Data Availability
- Fee Schedule
- Data Request Process

After reviewing the information on the website and this Application, please contact CHIA at casemix.data@state.ma.us if you have additional questions about how to complete this form.

The Application and all attachments must be uploaded to IRBNet. All Application documents can be found on the CHIA website.

Information submitted as part of the Application may be subject to verification during the review process or during any audit review conducted at CHIA's discretion.

Applications will not be reviewed until the Application and all supporting documents are complete and the required application fee is received.

*A **Fee Remittance Form** with instructions for submitting the application fee is available on the CHIA website. If you are requesting a fee waiver, a copy of the Fee Remittance Form and any supporting documentation must be uploaded to IRBNet. Please be aware that if your research is funded and under that funding you are required to release raw data to the funding source, you may not receive CHIA Data.*

II.   FEE INFORMATION

1. Consult the most current Fee Schedule for Case Mix and Charge Data.

2. After reviewing the Fee Schedule, if you have any questions about the application or data fees, contact casemix.data@state.ma.us.

3. If you believe that you qualify for a fee waiver, complete and submit the Fee Remittance Form and attach it and all required supporting documentation with your application. Refer to the Fee Schedule (effective Feb 1, 2017) for fee waiver criteria.

4. Applications will not be reviewed until the application fee is received.

5. Data for approved Applications will not be released until the payment for the Data is received.

III.   ORGANIZATION & INVESTIGATOR INFORMATION Data

Project Title:	Assessing the association between combined sewer overflow events and gastrointestinal illness in the Merrimack Valley
IRBNet Number:	1868879-1
Organization Requesting Data (Recipient):	Trustees of Boston University, School of Public Health - Department of Environmental Health
Organization Website:	https://www.bu.edu/sph/about/departments/environmental-health/
Authorized Signatory for Organization:	**William Segarra, JD, MPH**
Title:	Director, Industry Contracts and Agreements
E-Mail Address:	segarra@bu.edu
Telephone Number:	617-353-6151
Address, City/Town, State, Zip Code:	25 Buick Street, Suite 200, Boston, MA 02215
Data Custodian: **(individual responsible for organizing, storing, and archiving Data)**	**Beth Haley, MA**
Title:	Doctoral Candidate
E-Mail Address:	bethaley@bu.edu
Telephone Number:	339-227-0030
Address, City/Town, State, Zip Code:	715 Albany Street Boston, MA, 02118
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	**Wendy Heiger Bernays, PhD**
Title:	Clinical Professor
E-Mail Address:	whb@bu.edu
Telephone Number:	781-910-6463
Address, City/Town, State, Zip Code:	715 Albany Street Boston, MA, 02118
Names of Co-Investigators:	Beth Haley, MA (Doctoral Candidate, BUSPH) Jyotsna Jagai, PhD (Senior Research Data Analyst, University of Chicago)
E-Mail Addresses of Co-Investigators:	bethaley@bu.edu jjagai2@bsd.uchicago.edu

IV.   PROJECT INFORMATION

IMPORTANT NOTE: Organization represents that the statements made below as well as in any study or research protocol or project plan, or other documents submitted to CHIA in support of the Data Application are complete and accurate and represent the total use of the CHIA Data requested. Any and all CHIA Data released to the Organization under an approved application may ONLY be used for the express purposes identified in this section by the Organization, and for no other purposes. Use of CHIA Data for other purposes requires a separate Data Application to CHIA written request to CHIA, with approval being subject to CHIA's regulatory restrictions and approval process. Unauthorized use is a material violation of your institution's Data Use Agreement with CHIA.

1. What will be the use of the CHIA Data requested? [Check all that apply]

☒ Epidemiological   ☐ Health planning/resource allocation   ☐Cost trends

☒ Longitudinal Research   ☐ Quality of care assessment   ☐ Rate setting
☐ Reference tool   ☒ Research studies   ☐ Severity index tool (or other derived input)
☐ Surveillance   ☒ Student research   ☐ Utilization review of resources
☐ Inclusion in a product   ☐ Other (describe in box below)

Click here to enter text.

2. Provide an abstract or brief summary of the specific purpose and objectives of your Project. This description should include the research questions and/or hypotheses the Project will attempt to address, or describe the intended product or report that will be derived from the requested data and how this product will be used. Include a brief summary of the pertinent literature with citations, if applicable.

The primary goal of this project is to improve our understanding of health outcomes associated with untreated sewage released during combined sewer overflow (CSO) activations in a river system used as a drinking water source. We propose to use the Merrimack River, located in New Hampshire and northern Massachusetts, as a model CSO-impaired river system. We will evaluate the relationship between CSO activations and acute gastrointestinal illness (AGI) in Massachusetts communities that source their drinking water from the Merrimack River and communities with a different drinking water source from 2014 to 2019. We will also evaluate the relationship between heavy precipitation and AGI to determine which predictor (CSO activations or precipitation) has a stronger association with AGI in communities with a CSO-impaired drinking water source. *We hypothesize that cases of AGI will be associated with upstream CSO activations*, after controlling for confounding factors, only among communities that source their drinking water exclusively from the Merrimack River. We also expect to find that among communities with a CSO-impacted drinking water source, CSO activations will be a stronger predictor of AGI than heavy ($\geq 90^{th}$ or $\geq 95^{th}$ percentile) or extreme ($\geq 99^{th}$ percentile) precipitation.

The results of these analyses will be published in the scientific literature and shared by the authors in the study region through partnerships with local community groups and municipal and state governments.

Microbial contamination of drinking water due to poor source water quality, insufficient treatment, and water distribution network failures can cause illness among drinking water consumers in the United States[1,2]. Rainfall is an important driver of drinking water-associated GI illness, especially for surface water sources[3,4]. The majority of epidemiological studies investigating the relationship between GI illness and heavy rainfall found a significant but lagged relationship between precipitation events and increased GI illness with a lag period ranging from 1 day to 6 weeks[5–12]. CSO activations—which are also driven by heavy rainfall—are significant sources of pathogens[13–16]. Only a few studies have directly assessed the health impacts or risks associated with CSO activations. Of the three retrospective time series analyses investigating the relationship between CSO or sewage bypass events and GI illness through drinking water exposure, two suggest that sewage discharge events are associated with GI illness in systems where drinking water is sourced from the affected water body[17,18]. One of these studies, led by co-investigator Dr. Jyotsna Jagai, found a 13% increase in the expected rate of emergency room visits due to gastrointestinal illness among all age groups following 99th percentile rainfall in the Lower Merrimack region from 2003 to 2007[18]. The proposed research will address sources of potential exposure misclassification in the Jagai 2015 study by incorporating CSO event data (instead of rainfall as a proxy), town drinking water source, and the geospatial relationship of CSO events and drinking water intakes into our analysis.

1.   Messner M, Shaw S, Regli S, Rotert K, Blank V, Soller J. An approach for developing a national estimate of waterborne disease due to drinking water and a national estimate model application. *J Water Health*. 2006;4 Suppl 2:201-240. doi:10.2166/wh.2006.024

2.   Reynolds KA, Mena KD, Gerba CP. Risk of waterborne illness via drinking water in the United States. *Rev Environ Contam Toxicol*. 2008;192:117-158. doi:10.1007/978-0-387-71724-1_4

3.   Guzman Herrador BR, de Blasio BF, MacDonald E, et al. Analytical studies assessing the association between extreme precipitation or temperature and drinking water-related waterborne infections: a review. *Environ Health*. 2015;14:29. doi:10.1186/s12940-015-0014-y

4.   Curriero FC, Patz JA, Rose JB, Lele S. The association between extreme precipitation and waterborne disease outbreaks in the United States, 1948-1994. *Am J Public Health*. 2001;91(8):1194-1199. doi:10.2105/ajph.91.8.1194

5.   Tornevi A, Axelsson G, Forsberg B. Association between precipitation upstream of a drinking water utility and nurse advice calls relating to acute gastrointestinal illnesses. *PLoS One*. 2013;8(7):e69918. doi:10.1371/journal.pone.0069918

6.   De Roos AJ, Kondo MC, Robinson LF, et al. Heavy precipitation, drinking water source, and acute gastrointestinal illness in Philadelphia, 2015-2017. *PLoS One*. 2020;15(2). doi:10.1371/journal.pone.0229258

7.   Drayna P, McLellan SL, Simpson P, Li SH, Gorelick MH. Association between rainfall and pediatric emergency department visits for acute gastrointestinal illness. *Environ Health Perspect*. 2010;118(10):1439-1443. doi:10.1289/ehp.0901671

8.   Bush KF, O'Neill MS, Li S, et al. Associations between extreme precipitation and gastrointestinal-related hospital admissions in Chennai, India. *Environ Health Perspect*. 2014;122(3):249-254. doi:10.1289/ehp.1306807

9.   Lin S, Sun M, Fitzgerald E, Hwang SA. Did summer weather factors affect gastrointestinal infection hospitalizations in New York State? *Sci Total Environ*. 2016;550:38-44. doi:10.1016/j.scitotenv.2015.12.153
10.   Gleason JA, Fagliano JA. Effect of drinking water source on associations between gastrointestinal illness and heavy rainfall in New Jersey. *PLoS One*. 2017;12(3):e0173794. doi:10.1371/journal.pone.0173794
11.   Chhetri BK, Takaro TK, Balshaw R, et al. Associations between extreme precipitation and acute gastro-intestinal illness due to cryptosporidiosis and giardiasis in an urban Canadian drinking water system (1997-2009). *J Water Health*. 2017;15(6):898-907. doi:10.2166/wh.2017.100
12.   Lai H, Hales S, Woodward A, et al. Effects of heavy rainfall on waterborne disease hospitalizations among young children in wet and dry areas of New Zealand. *Environment International*. 2020;145:106136. doi:10.1016/j.envint.2020.106136
13.   Rechenburg A, Koch Ch, Claßen Th, Kistemann Th. Impact of sewage treatment plants and combined sewer overflow basins on the microbiological quality of surface water. *Water Science and Technology*. 2006;54(3):95-99. doi:10.2166/wst.2006.454
14.   Donovan E, Unice K, Roberts JD, Harris M, Finley B. Risk of gastrointestinal disease associated with exposure to pathogens in the water of the Lower Passaic River. *Appl Environ Microbiol*. 2008;74(4):994-1003. doi:10.1128/AEM.00601-07
15.   Hata A, Katayama H, Kojima K, et al. Effects of rainfall events on the occurrence and detection efficiency of viruses in river water impacted by combined sewer overflows. *Science of The Total Environment*. 2014;468-469:757-763. doi:10.1016/j.scitotenv.2013.08.093
16.   Arnone RD, Walling JP, Arnone (corresponding RD, Walling JP. Evaluating Cryptosporidium and Giardia concentrations in combined sewer overflow. *Journal of Water and Health*. Published online 2006:157-165.
17.   Redman RL, Nenn CA, Eastwood D, Gorelick MH. Pediatric emergency department visits for diarrheal illness increased after release of undertreated sewage. *Pediatrics*. 2007;120(6):e1472-1475. doi:10.1542/peds.2007-0283
18.   Jagai JS, Li Q, Wang S, Messier KP, Wade TJ, Hilborn ED. Extreme Precipitation and Emergency Room Visits for Gastrointestinal Illness in Areas with and without Combined Sewer Systems: An Analysis of Massachusetts Data, 2003-2007. *Environ Health Perspect*. 2015;123(9):873-879. doi:10.1289/ehp.1408971

3. Has an Institutional Review Board (IRB) reviewed your Project?

☒ Yes [*If yes, a copy of the approval letter and protocol <u>must</u> be included with the Application package on IRBNet.*]

☐ No, this Project is not human subject research and does not require IRB review.

4. **Research Methodology**: Applications must include either the IRB protocol or a written description of the Project methodology (typically 1-2 pages), which should state the Project objectives and/or identify relevant research questions. This document must be included with the Application package on IRBNet and must provide sufficient detail to allow CHIA to understand how the Data will be used to meet objectives or address research questions.

V.   PUBLIC INTEREST

1. Briefly explain why completing this Project is in the public interest. Use quantitative indicators of public health importance where possible, for example, numbers of deaths or incident cases; age-adjusted, age-specific, or crude rates; or years of potential life lost. *Uses that serve the public interest under CHIA regulations include, but are not limited to: health cost and utilization analysis to formulate public policy; studies that promote improvement in population health, health care quality or access; and health planning tied to evaluation or improvement of Massachusetts state government initiatives.*

By completing this project, we will answer key questions that are important for community members and leaders in the Merrimack River watershed as well as for initiatives by Massachusetts state government (Energy and Environmental Affairs). The Merrimack River is a primary drinking water source for over 550,000 people living downstream of combined sewer outfalls, including a number of Environmental Justice communities. A 2015 study in Massachusetts found a 13% increase in the expected rate of emergency room visits due to gastrointestinal illness (incident cases) among all age groups following 99th percentile rainfall in the Lower Merrimack region from 2003 to 2007[18], raising concerns about how CSO activations may impact health through drinking water contamination. The proposed project will expand upon this study by addressing sources of potential exposure misclassification in the 2015 study, using data on CSO events instead of a proxy (99th percentile rainfall), and assessing the relationship between AGI and CSO activations in more recent years to see if the association is robust over time. The results of this study will be used to promote improvement in population health and water quality in the Merrimack region.

Over 700 communities in the United States have combined sewer systems, especially in the Northeast and Midwest where climate change may exacerbate CSO activations. Although there is a well-established association between rainfall and pathogen-associated illness such as gastroenteritis in the United States, the link between CSO activations and adverse health outcomes is less understood. The results of this study will inform the scientific literature on the health implications of CSO activations beyond the Merrimack River region.

VI.   DATASETS REQUESTED

The Massachusetts Case Mix ("Case Mix") are comprised of Hospital Inpatient Discharge, Emergency Department and Outpatient Hospital Observation Stay Data collected from Massachusetts' acute care hospitals, and satellite emergency facilities. Case Mix Data are updated each fiscal year (October 1 – September 30) and made available to approved data users. For more information about Case Mix Data, including a full list of available elements in the datasets please refer to release layouts, data dictionaries and similar documentation included on CHIA's website.

Data requests are typically fulfilled on a one time basis, however; certain Projects may require years of data not yet available. Applicants who anticipate a need for future years of data may request to be considered for a subscription. Approved subscriptions will receive, upon request, the same data files and data elements included in the initial release annually or as available. Please note that approved subscription request will be subject to the Data Use Agreement, will require payment of fees for additional Data, and subject to the limitation that the Data can be used only in support of the approved Project.

1. Please indicate below whether this is a one-time request, or if the described Project will require a subscription.

☒ One-Time   Request   **OR**   ☐ Subscription

2. Specify below the dataset(s) and year(s) of data requested for this Project, and your justification for requesting *each* dataset. Data prior to 2004 is not available.

☒ **Hospital Inpatient Discharge Data**
☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☐2012 ☐2013 ☒2014 ☒2015 ☒ 2016 ☒ 2017 ☒2018 ☒2019 ☐2020
Describe how your research objectives require Inpatient Discharge data: The outcome of interest for this project is emergency department (ED) visits for acute gastrointestinal illness (AGI). Because ED visits that result in an inpatient discharge do not appear in the Outpatient Emergency Department Database, we require access to Inpatient Discharge data to capture all cases of AGI that entered the hospital system through the ED.
☒ **Outpatient Hospital Observation Stay Data**
☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☐2012 ☐2013 ☒2014 ☒2015 ☒ 2016 ☒ 2017 ☒2018 ☒2019 ☐2020
Describe how your research objectives require Outpatient Hospital Observation Stay data: The outcome of interest for this project is emergency department (ED) visits for acute gastrointestinal illness (AGI). Because ED visits that result in an observation stay do not appear in the Outpatient Emergency Department Database, we require access to Outpatient Hospital Observation Stay data to capture all cases of AGI that entered the hospital system through the ED.
☒ **Emergency Department Data**
☐2004 ☐2005 ☐2006 ☐2007 ☐2008 ☐2009 ☐2010 ☐2011 ☐2012 ☐2013 ☒2014 ☒2015 ☒ 2016 ☒ 2017 ☒2018 ☒2019 ☐2020
Describe how your research objectives require Emergency Department data: The outcome of interest for this project is emergency department (ED) visits for acute gastrointestinal illness (AGI), so the research objectives require that we access ED data.

VII.   DATA ENHANCEMENTS REQUESTED

State and federal privacy laws limit the release and use of Data to the minimum amount of data needed to accomplish a specific Project objective.

Case Mix Data are released in Limited Data Sets (LDS). All applicants receive the "Core" LDS, but may also request the data enhancements listed below for inclusion in their analyses. Requests for enhancements will be reviewed by CHIA to determine whether each represents the minimum data necessary to complete the specific Project objective.

For a full list of elements in the release (i.e., the "Core" elements and enhancements), please refer to release layouts, data dictionaries and similar documentation included on CHIA's website.

Please note that CHIA Case Mix Data contain reports produced using proprietary computer software created, owned, and licensed by the 3M Company. All Copyrights in and to the 3M APR^{TM} Software, and to the 3M APR^{TM} DRG classification system(s) (including the selection, coordination and arrangement of all codes) are owned by 3M. All rights reserved.

1. Specify below which enhancements you are requesting in addition to the "Core" LDS. CHIA will use this information to determine what Level of data is needed for pre-FY 2015 data requests.

Geographic Subdivisions

State, five-digit zip code, and 3-digit code are available for patients residing in CT, MA, ME, NH, RI, VT, and NY. City or Town of residence is available for residents of MA only. States outside of this region will be coded as XX ("Other").

Select *one* of the following options:

☐ 3-Digit Zip Code (Standard)	☒ 3-Digit Zip Code & City/Town ***	☐ 5-Digit Zip Code ***	☐ 5-Digit Zip Code & City/Town ***
***If requested, provide justification for requesting 5-Digit Zip Code or City/Town. Refer to specifics in your methodology: The town of residence will be our chief means for assigning exposure to AGI cases. The objective of this study is to assess whether the association between upstream CSO activations and AGI differs depending on primary community drinking water source (Merrimack River or other drinking water source) over the study period. Community-level exposure status will be assigned based on drinking water source. The Merrimack River is the primary drinking water source for four Massachusetts communities. Eight communities adjacent to the Merrimack River in Massachusetts that do not rely on the river as a drinking water source at any point in the year will be selected as the Unexposed Group. Individual-level data from CHIA on emergency room (ER) visits for gastrointestinal illness will be aggregated to determine community-level counts of AGI. Town of residence is important data for this study because it will be used to calculate the daily total number of AGI cases per 100,000 people for each exposure group throughout the study period.			

Demographic Data

Select *one* of the following options:

☒ Not Requested (Standard)	☐ Race & Ethnicity***
** If requested, provide justification for requesting Race and Ethnicity. Refer to specifics in your methodology: Click here to enter text.	

Date Resolution

Select *one* of the following options for dates of admissions, discharges, and significant procedures.

☐ Year (YYYY)(Standard)	☐ Month (YYYYMM) ***	☒ Day (YYYYMMDD)***

***If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology:
We are requesting the dates of admissions so that we can calculate the daily number of ED visits for AGI as the outcome of interest and assign exposure (either CSO occurrence or precipitation total) on a daily basis. This level of temporal resolution allows us to evaluate different lag periods (e.g., 4, 8, 15, or 28 days) based on the existing literature within the distributed lag nonlinear model framework that we proposed for the statistical analysis.

Practitioner Identifiers (UPN)
Select _one_ of the following options.

☒ Not Requested (Standard)	☐ Hashed ID ***	☐ Board of Registration in Medicine Number(BORIM) ***

 ***If requested, provide justification for requesting Hashed ID or BORIM Number. Refer to specifics in your methodology:
Click here to enter text.

Unique Health Information Number (UHIN)
Select _one_ of the following options.

☒ Not Requested (Standard)	☐ UHIN Requested ***

*** If requested, provide justification for requesting UHIN. Refer to specifics in your methodology:
Click here to enter text.

Hashed Mother's Social Security Number
Select _one_ of the following options:

☒ Not Requested (Standard)	☐ Hashed Mother's SSN Requested ***

*** If requested, provide justification for requesting Hashed Mother's SSN. Refer to specifics in your methodology:
Click here to enter text.

VIII.   DATA LINKAGE

Data linkage involves combining CHIA Data with other data to create a more extensive database for analysis. Data linkage is typically used to link multiple events or characteristics within one database that refer to a single person within CHIA Data.

1. Do you intend to link or merge CHIA Data to other data?
     ☒ Yes
     ☐ No linkage or merger with any other data will occur

2. If yes, please indicate below the types of data to which CHIA Data will be linked. [Check all that apply]
     ☐ Individual Patient Level Data (e.g. disease registries, death data)
     ☐ Individual Provider Level Data (e.g., American Medical Association Physician Masterfile)
     ☐ Individual Facility Level Data (e.g., American Hospital Association data)
     ☒ Aggregate Data (e.g., Census data)
     ☐ Other (please describe):

3. If yes, describe the dataset(s) to which the CHIA Data will be linked, indicate which CHIA Data elements will be linked and the purpose for each linkage.

Aggregate data:
- Census data will be used to determine population of each town so that cases of AGI for each exposure group can be standardized by total population.
- The spatial relationship of the towns to CSO outfalls will be used to determine exposure in the case of CSO activations; precipitation levels will also be assigned at the town level.
- Details on daily CSO activations (location, occurrence (count), and discharge volume (continuous)) and precipitation (total volume (continuous) and heavy precipitation (binary)) will be linked to the dataset by date

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4. If yes, for each proposed linkage above, please describe your method or selected algorithm (e.g., deterministic or probabilistic) for linking each dataset. If you intend to develop a unique algorithm, please describe how it will link each dataset.

Linkage will be executed deterministically by town of residence and date of visit. Census and spatial data will be linked to cumulative CHIA health data by town of residence. CSO activation and precipitation data will be linked to cumulative CHIA health data by date of visit.

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5. If yes, attach or provide below a complete listing of the variables from <u>all sources</u> to be included in the final linked analytic file.

Variables in linked analytic file:
- Date (January 1, 2014 – December 31, 2019)
- Daily cases of AGI for each town in the exposed group
- Daily cases of AGI for each town in the unexposed group
- Total daily cases of AGI among the exposed group
- Total daily cases of AGI among the unexposed group
- Population of each town in the exposed group
- Population of each town in the unexposed group

- Total population of the exposed group
- Total population of the unexposed group
- Total daily cases of AGI among the exposed group per 100,000 people
- Total daily cases of AGI among the unexposed group per 100,000 people
- Number of daily upstream CSO activations for each town in the study
- Total number of daily upstream CSO activations for each exposure group
- Total daily upstream CSO discharge volume for each exposure group
- Total daily precipitation for each exposure group
- Daily extreme precipitation (Y/N)

6. If yes, please identify the specific steps you will take to prevent the identification of individual patients in the linked dataset.

Data will only be linked in aggregate form. We do not have individual-level information that would be needed to identify individual patients.

IX.   PUBLICATION / DISSEMINATION / RE-RELEASE

1. Do you anticipate that the results of your analysis will be published or made publically available? If so, how do you intend to disseminate the results of the study (e.g.; publication in professional journal, poster presentation, newsletter, web page, seminar, conference, statistical tabulation)? Any and all publication of CHIA Data must comply with CHIA's cell size suppression policy, as set forth in the Data Use Agreement. Please explain how you will ensure that any publications *will not disclose a cell less than 11*, and percentages or other mathematical formulas that result in the display of a cell less than 11.

We anticipate that the results of this analysis will be shared publicly in a variety of ways. We plan to publish the results in a peer-reviewed scientific journal and to present on the study at scientific conferences via oral or poster presentations. Ms. Haley will also present the findings of this study as part of her dissertation defense and possibly in departmental seminars prior to her defense. The research team has built close relationships with relevant community groups in the Merrimack River Valley who are increasingly focused on addressing water quality issues. The research team will share our results with local community groups and municipal and state governments through presentations of findings and through non-technical summaries of the results.

We do not anticipate that there will be challenges complying with CHIA's cell size suppression policy because any descriptive statistics done at the town level (the smallest geographic unit) would be aggregated to a full year; for example, we might decide to include a table with annual totals of ED visits for AGI by town, but expect that each cell would have far more than 11 cases of AGI. However, we will ensure that our team will follow the policy by requiring that the Data Custodian, Ms. Haley, approves all materials for publication. If there is a scenario in which there are fewer than 11 cases in a cell, no specific value will be included in the table; a placeholder such as "< 11" will be added to the cell instead.

2. Describe your plans to use or otherwise disclose CHIA Data, or any Data derived or extracted from such Data, in any paper, report, website, statistical tabulation, seminar, or other setting that is not disseminated to the public.

We do not currently have any plans to use the CHIA data in any papers, reports, or presentations that are not disseminated to the public.

3. What will be the lowest geographical level of analysis of data you expect to present for publication or presentation (e.g., state level, city/town level, zip code level, etc.)? Will maps be presented? If so, what methods will be used to ensure that individuals cannot be identified?

The lowest geographical level of analysis of data presented in a publication or presentation will be city/town level. Maps will likely be included, but only to show the spatial relationship of the towns included in the analysis and CSO outfall locations. None of the CHIA data will be shown in the maps.

4. Will you be using CHIA Data for consulting purposes?
  ☐ Yes
  ☒ No

5. Will you be selling standard report products using CHIA Data?
  ☐ Yes
  ☒ No

6. Will you be selling a software product using CHIA Data?
  ☐ Yes
  ☒ No

7. Will you be using CHIA Data as in input to develop a product (i.e., severity index took, risk adjustment tool, reference tool, etc.)
  ☐ Yes
  ☒ No

8. Will you be reselling CHIA Data in any format not noted above?
  ☐ Yes
  ☒ No

If yes, in what format will you be reselling CHIA Data?

Click here to enter text.

9. If you have answered "yes" to questions 5, 6, 7 or 8, please provide the name and a description of the products, software, services, or tools.

Click here to enter text.

10. If you have answered "yes" to questions 5, 6, 7 or 8, what is the fee you will charge for such products, software, services or tools?

Click here to enter text.

X.   APPLICANT QUALIFICATIONS

1. Describe your previous experience using hospital data. This question should be answered by the primary investigator and any co-investigators who will be using the Data.

Dr. Heiger-Bernays has worked with complex research data sets (cancer and non-cancer outcomes, environmental conditions) in the US and globally (Ogoniland, Nigeria). She has also had extensive experience in working with personal data that are protected as well as where privacy concerns exist. Both Dr. Heiger-Bernays and Ms. Haley work closely with colleagues who are currently working with large electronic medical records data, should any questions arise.

Ms. Haley does not currently have any experience using hospital data. Since September of 2020, she has been part of a research team at Boston University that works with identifiable COVID-19 case and death data. As a result of this experience and her training, she is familiar with the importance of patient privacy and data management processes when working with health data. Ms. Haley has experience working with the other datasets included in this project (CSO, precipitation, US Census, and spatial data). Dr. Jagai will mentor Ms. Haley directly on the use of CHIA data.

Dr. Jagai has worked extensively with hospital data, including with CHIA data. She has used these data for various health analyses associating hospitalizations with environmental factors. In particular, she has focused on hospitalizations for gastrointestinal illnesses. Her previous work has looked at seasonal patterns of hospitalizations in association with streamflow, concentrated animal feeding operations, overall environmental quality, and aggregated water quality. She has been working with hospitalization data for over 15 years.

2. **Resumes/CVs**: When submitting your Application package on IRBNet, include résumés or curricula vitae of the principal investigator and co-investigators. (These attachments will not be posted on the internet.)

XI.   USE OF AGENTS AND/OR CONTRACTORS

By signing this Application, the Organization assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors. The Organization must have a written agreement with the agent of contractor limiting the use of CHIA Data to the use approved under this Application as well as the privacy and security standards set forth in the Data Use Agreement. CHIA Data may not be shared with any third party without prior written consent from CHIA, or an amendment to this Application. CHIA may audit any entity with access to CHIA Data.

Provide the following information for **all** agents and contractors who will have access to the CHIA Data. [*Add agents or contractors as needed.*]

AGENT/CONTRACTOR #1 INFORMATION	
Company Name:	Click here to enter text.
Company Website	Click here to enter text.
Contact Person:	Click here to enter text.
Title:	Click here to enter text.
E-mail Address:	Click here to enter text.
Address, City/Town, State, Zip Code:	Click here to enter text.
Telephone Number:	Click here to enter text.
Term of Contract:	Click here to enter text.

1. Describe the tasks and products assigned to the agent or contractor for this Project and their qualifications for completing the tasks.

Click here to enter text.

2. Describe the Organization's oversight and monitoring of the activities and actions of the agent or contractor for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or contractor has access.

Click here to enter text.

3. Will the agent or contractor have access to and store the CHIA Data at a location other than the Organization's location, off-site server and/or database?

☐ Yes
☐ No

4. If yes, a separate Data Management Plan **must** be completed by the agent or contractor.

AGENT/CONTRACTOR #2 INFORMATION	
Company Name:	Click here to enter text.
Company Website	Click here to enter text.
Contact Person:	Click here to enter text.
Title:	Click here to enter text.
E-mail Address:	Click here to enter text.
Address, City/Town, State, Zip Code:	Click here to enter text.
Telephone Number:	Click here to enter text.
Term of Contract:	Click here to enter text.

1. Describe the tasks and products assigned to the agent or contractor for this Project and their qualifications for completing the tasks.

Click here to enter text.

2. Describe the Organization's oversight and monitoring of the activities and actions of the agent or contractor for this Project, including how the Organization will ensure the security of the CHIA Data to which the agent or contractor has access.

Click here to enter text.

3. Will the agent or contractor have access to and store the CHIA Data at a location other than the Organization's location, off-site server and/or database?

☐ Yes
☐ No

4. If yes, a separate Data Management Plan **must** be completed by the agent or contractor.

[INSERT A NEW SECTION FOR ADDITIONAL AGENTS/CONTRACTORS AS NEEDED]

XII.   ATTESTATION

By submitting this Application, the Organization attests that it is aware of its data use, privacy and security obligations imposed by state and federal law *and* confirms that it is compliant with such use, privacy and security standards. The Organization further agrees and understands that it is solely responsible for any breaches or unauthorized access, disclosure or use of CHIA Data, including, but not limited to, any breach or unauthorized access, disclosure or use by any third party to which it grants access.

Organizations approved to receive CHIA Data will be provided with Data following the payment of applicable fees and upon the execution of a Data Use Agreement requiring the Organization to adhere to processes and procedures designed to prevent unauthorized access, disclosure or use of data.

By my signature below, I attest: (1) to the accuracy of the information provided herein; (2) this research is not funded by a source requiring the release of raw data to that source; (3) that the requested Data is the minimum necessary to accomplish the purposes described herein; (4) that the Organization will meet the data privacy and security requirements described in this Application and supporting documents, and will ensure that any third party with access to the Data meets the data use, privacy and security requirements; and (5) to my authority to bind the Organization.

Signature: (Authorized Signatory for Organization)	
Printed Name:	**William Segarra, JD, MPH**
Title:	Director, Industry Contracts and Agreements
Date:	Click here to enter text.

Attachments:
A completed Application must have the following documents attached to the Application or uploaded separately to IRBNet:
☐ 1. IRB approval letter and protocol (if applicable), or research methodology (if protocol is not attached)
☐ 2. Data Management Plan (including one for each agent or contractor that will have access to or store the CHIA Data at a location other than the Organization's location, off-site server and/or database);
☐ 3. CVs of Investigators (upload to IRBNet)

APPLICATIONS WILL NOT BE REVIEWED UNTIL THEY ARE COMPLETE, INCLUDING ALL ATTACHMENTS.