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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. Organiations 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 Appliciaton 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

Project Title:	Racial and ethnic disparities in labor after cesarean ending in cesarean birth
IRBNet Number:	1867506-1
Organization Requesting Data (Recipient):	University of Massachusetts Amherst, School of Public Health and Health Sciences, Department of Health Promotion and Policy
Organization Website:	https://www.umass.edu/sphhs/
Authorized Signatory for Organization:	**Jennifer A. Donais**
Title:	Assistant Vice Chancellor for Research and Engagement, Compliance & Support Services, Office of Research Compliance
E-Mail Address:	jadonais@research.umass.edu
Telephone Number:	413-545-5986
Address, City/Town, State, Zip Code:	100 Venture Way, Room 230, Hadley, MA 01035
Data Custodian: **(individual responsible for organizing, storing, and archiving Data)**	**Joseph Pasquini**
Title:	Director of Information Technology
E-Mail Address:	jpasquini@umass.edu
Telephone Number:	413-545-2949
Address, City/Town, State, Zip Code:	209 Arnold House University of Massachusetts Amherst 715 North Pleasant Street Amherst, MA 01003
Primary Investigator (Applicant): **(individual responsible for the research team using the Data)**	**Laura B. Attanasio, PhD**
Title:	Assistant Professor of Health Policy and Management
E-Mail Address:	lattanasio@umass.edu
Telephone Number:	413-545-4480
Address, City/Town, State, Zip Code:	329 Arnold House University of Massachusetts Amherst 715 North Pleasant Street Amherst, MA 01003
Names of Co-Investigators:	Brittany Ranchoff
E-Mail Addresses of Co-Investigators:	branchoff@umass.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)

> The CHIA data request is to obtain the Pregnancy to Early Life Longitudinal Data System for use in a research project (described below).

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 specific aims of this study are: (1) To characterize racial/ethnic variation in birth mode and indications for cesarean among women with a prior cesarean birth, and (2) To determine the relationship between birth mode and maternal morbidity among women with a prior cesearan birth, and whether this relationship varies by race/ethnicity using the Pregnancy to Early Life Longitudinal Data System (PELL).

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**: Applicantions 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.

The attached research methodology is from the IRB protocol approved by MDPH.

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.*

> Addressing the persistently high rates of severe maternal morbidity among women of color is an urgent public health priority. Of the 3.8 million U.S. births each year, nearly a third occur via cesarean delivery, which is a risk factor for severe maternal morbidity. The consistently high cesarean rate over time has resulted in a large number of women giving birth who have had a prior cesarean. Black women have higher rates of primary cesarean than do White women, resulting in Black women being disproportionately represented among births to women with a prior cesarean. Indications associated with primary cesarean delivery also differ by race. Women who have had a prior cesarean birth can either have a planned repeat cesarean or have labor after cesarean (LAC), with the goal of having a vaginal birth after cesarean (VBAC). LAC has potential benefits for women by allowing them to avoid major abdominal surgery and potential complications, as well as avoiding an increased risk of abnormal placental implantation on the uterine wall in future pregnancies, which increases risk for postpartum hemorrhage and preterm birth. Maternal morbidity is lowest with a

vaginal birth, but higher with an unplanned cesarean compared to a planned cesarean. Therefore, women most likely to have a VBAC are considered the best candidates for LAC.

There are racial and ethnic disparities in LAC utilization and success, but these disparities are poorly understood. It is well-documented that Black women are more likely to have LAC compared to White women, but less likely to have a VBAC among those with LAC, even after accounting for medical risk factors. Latina women have a similar or lower likelihood of LAC compared to White women, but are less likely to have a VBAC among those with LAC. Given the persistently high rates of maternal morbidity among racial and ethnic minority women, there is a critical need to better understand the causes and consequences of the lower rate of VBAC success for Black and Latina women who have LAC.

Our long-term goal is to improve the quality of perinatal care in for women of color with a prior cesarean in order to reduce disparities in severe maternal morbidity. The specific objective of this study is to elucidate the mechanisms underlying racial and ethnic disparities in repeat cesarean deliveries following LAC.

This study will provide a better understanding of the causes and consequences of the lower of VBAC successes for Black and Latina women who have LAC. The benefit for society is to improve the quality of perinatal care for women of color with a prior cesarean in order to reduce disparities in severe maternal morbidity.
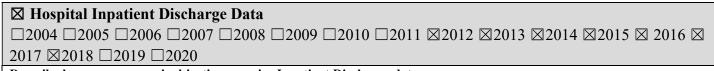
VI.   DATASETS REQUESTED

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: We will be using the Pregnancy to Early Life Longitudinal Data System (PELL), which is the birth and fetal death files are linked to the hospital discharge records of mother's delivery and child's birth comprise the core of the data set. We will be using the information from the hospital discharge records and birth certificate for women meeting our inclusion criteria. Without these, we would be unable to answer the research questions. We will use the PELL ID to merge and sort the data.

☐ **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: Click here to enter text.
☐ **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: Click here to enter text.

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 5-digit Zip Code is a covariate to control for geographic factors. We have requested from the PELL Data System the following variables: county of maternal residence, zip code of maternal residence, and census tract of maternal residence.			

Demographic Data

Selcect _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: We are using the PELL Data System race/ethnicity variable. This is an independent variable and will be used in all areas of this study. Racial inequities are a key focus of the study.	

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: Admission date and discharge date will be used for data manipulation. It will be used in combination with other variables to determine time in hospital before delivery, before discharge, etc. We will also use new delivery date to determine length of time in hospital prior to delivery. For procedure dates, we will be using this for data manipulation to determine the length of time in hospital prior to cesarean delivery. The variables will be used to verify labor after cesarean and to create dependent variables (indication for cesarean and maternal morbidity). Understanding the indications for cesarean delivery and maternal morbidity in labor after cesarean ending in cesarean by race/ethnicity is the goal of this research. In addition, procedures from child hospital discharge will be used for data manipulation to identify congential anomalies for exclusion criteria.		

Practioner 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: The PELL Data System contains an equivalent variable that allows an analyst to track a patient over time. We will use the unique HDUID, KIDUID, uniquemomid, and MOMUID for data manipulation and merge data in combination with the birth certificate and hospital discharge data. This is the PELL unique delivery identifier.	

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.

> We will be using the PELL Data system, which is a linked data set comprised of CHIA Case Mix data sets and Massachusetts Department of Public Health owned data sets (i.e., birth certificate data). We will be using the Hospital Discharge Moms Delivery and the Hospital Discharge Kids Delivery Data Sets in combination with the birth certificate data. We will be using the admission and discharge information, diagnosis codes, and procedure codes for the analysis. Admission and discharge dates will be used for data manipulation. It will be used in combination with other requested variables to determine time in hospital before delivery, before discharge, etc. We will also use new delivery date to determine length of time in hospital prior to delivery. Procedure dates will be used for data manipulation to determin the length of time in hospital prior to cesarean delivery. Additionally, the variables will be used to verify labor after cesarean and to create dependent variables (indication for cesarean and maternal morbidity). Understanding the indications for cesarean delivery and maternal morbidity in labor after cesarean ending in cesarean by race/ethnicity is the goal of this research. Additionally, procedures and diagnosis codes from the kids hospitals discharge will be used for data manipulation to identify congential anomalies for exclusion criteria.

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.

> We will be using the PELL Data system linkage variables to link each dataset. These variables include HDUID, KIDUID, uniquemomid, and MOMUID. These will be used for data manipulation and merge data in combination with the birth certificate and hospital discharge data. All these variables are the PELL unique delivery identifier.

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.

> See the attached document of the requested PELL Data System variables for the hospital discharge and birth certificate data.

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

> This research does not include intervention with living human subjects. This projects uses de-identified secondary data. The project uses secondary data from births in Massachusetts collected and maintained by the Massachusetts Department of Public Health. Data will be coded by linking a unique study identification number created by PELL. Analysis will be performed using the coded data. The only risk is the breach of confidentiality since we will be using the PELL. The study team will take every precaution to ensure that participant confidentiality is maintained. All electronic study data will be kept in password-protected computer files and hard copy data will be stored in a locked environment that is accessible only to the study team members. We will promptly communicate any reportable events to the IRB as soon as possible, but no later than five weekdays. Only aggregate data without personal idetnifiers will be included when presenting results or submitting manuscripts for publication.

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.

> Following the data analysis, we will publish the results of our studies related to all aims in peer-reviewed scientific journals will also be disseminated at academic and policy conferences, and through other dissemination strategies discussed in the proposal. All information shared will be deidentified. We do not

anticipate having cell sizes of patients less than 11 as groups of this size would not permit proper statistical analysis.

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.

Following the data analysis, we will publish the results of our studies related to all aims in peer-reviewed scientific jounrals will also be disseminated at academic and policy conferences, and through other dissemination strategies discussed in the proposal. All information will be deidentified.

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?

Geographic factors will be included as a covariate and will not be presenting data based on geographic level. No maps will be presented. Only aggregate data without personal identifiers will be included when resenting results or submitting manuscripts for publication.

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. Laura Attanasio is a researcher in the field of maternity care quality and patient-centered maternity care. Her research on maternity care has been published in high-impact general journals as well as women's health journals. She currently has 37 peer-reviewed publications. Dr. Attanasio has a current R03 examining decision making about labor after cesarean; the cohort data used in this grant has hospital discharge data from childbirth hospitalizations and birth certificate data linked to survey responses over time. Dr. Attanasio has published several papers that made extensive use of the hospital discharge data. Additionally, Dr. Attanasio used New York hospital data from HCUP in a completed grant-funded study examining the association between hospital percentage of midwife-attended births and obstetric procedure utilization.

Brittany Ranchoff, MPH, is a PhD student in the Health Policy and Management program at UMass Amherst. She has experience working with vital statistics data and a variety of survey data sources, including the National Ambulatory Medical Care Survey and the Listening to Mothers in California survey.

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:	**Massachusetts Green High Performance Computing Center Inc.**
Company Website	https://www.mghpcc.org/
Contact Person:	**Joe Pasquini**
Title:	IT Manager, UMass School of Public Health and Health Sciences
E-mail Address:	jpasquini@umass.edu
Address, City/Town, State, Zip Code:	100 Bigalow St, Holyoke, MA 01040
Telephone Number:	413-552-4900
Term of Contract:	Open-ended

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

Data storage and analysis will be done on the SPHHS computer node which is disconnected from the Internet, is not a cloud based storage solution, and has all the correct compensating controls, including but not limited to: Firewall, secure login, public/private key accounts, encryption for storage, and during transfer through a secure SSH/VPN connection.

This SPHHS compute node is a highly secure partition of the C3DDB, which is a secured portion of the MGHPCC. The SPHHS compute node is itself not connected to the internet, and draws resources from the C3DDB when required. The legal structure of the MGHPCC is such that a Business Associate Agreement (BAA; attached) has been signed between UMass SPHHS and the MGHPCC to ensure that this SPHHS compute node is adequately protected for sensitive health data.

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.

See attached Data Management Plan.

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)	DocuSigned by: *Jennifer A Donais* C11EAC603946499...
Printed Name:	Jennifer A. Donais
Title:	Assistant Vice Chancellor for Research & Engagement, Compliance & Support Services, Office of Research Compliance
Date:	3/16/2022

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.**==

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Data Management Plan for Use of CHIA Data
[Attach to Data Application]

I. INSTRUCTIONS

Any Recipients, contractors, or agents receiving CHIA Data ("Data") must complete and execute this Data Management Plan. Certain CHIA Data includes Protected Health Information ("PHI" as defined under the Health Insurance Portability and Accountability Act [HIPAA] and its implementing regulations) and all CHIA Data contains elements that may be used to identify an individual. The Data Management Plan(s) will be incorporated within the Data Use Agreement that must be executed prior to receipt of the Data. You may wish to refer to the Data Use Agreement as you complete this Data Management Plan. This Data Management Plan should be completed by the Chief Information Security Officer, Chief Privacy Officer, legal counsel or another officer with sufficient knowledge of the Agency or Organization's data privacy and security practices and who has authority to bind the Agency or Organization.

NOTE: This Data Management Plan is confidential and will not become a part of the public record.

II. GENERAL INFORMATION

Project Title: (as it appears on Data Application)	Racial and ethnic disparities in labor after cesarean ending in cesarean birth
Primary Investigator: (as it appears on Data Application)	Laura Attanasio
Organization Requesting CHIA Data (Recipient): (as it appears on Data Application)	University of Massachusetts Amherst, School of Public Health and Health Sciences, Department of Health Promotion and Policy
Organization Holding CHIA Data under this Data Management Plan: (this entity must be either the Recipient or listed as an Agent/Contractor for the Recipient on the Data Application)	University of Massachusetts - Amherst with system administration by Tech Square, Inc.

III. CERTIFICATIONS

The undersigned certifies and agrees as follows:

- The Data will be **encrypted at rest on storage media (backup tapes, local hard drives, network storage, et al) with at least AES-256 standard or stronger**.
- The Data will **be encrypted in transit consistent with the approved method(s) described in this Data Management plan at section V.3-b**.
- Anti-malware software or service is active on any server or endpoint containing or accessing the Data or other controls mitigating malware infection and propagation are in place.
- If a Covered Entity or Business Associate under HIPAA, the Agency or Organization is in full compliance with the privacy and security requirements of HIPAA; trains all staff who access PHI on the requirements of HIPAA; and has Business Associate Agreements with all non-employees who access PHI.
- The Agency or Organization has policies and procedures in place to address:

     o The sharing, transmission and distribution of PHI
     o The physical removal, transport and transmission of PHI
     o The physical possession and storage of PHI
     o The destruction of PHI upon the completion of its use
     o Confidentiality agreements with all individuals, including contractors, who will access PHI
     o Agreements governing the use and disclosure of PHI with all non-employees who will access PHI

IV. RESPONSIBLE PARTIES

Please identify the following individuals within your Agency or Organization:

1. The individual responsible for organizing, storing and archiving the Data. This individual is the Custodian of the CHIA Data required under Article XI of the Data Use Agreement.

Name:	Joseph Pasphini
Agency/Organization:	UMass Amherst School of Public Health and Health Sciences
Title:	Director of Information Technology
Phone:	413-545-2949
Address, City/Town, State, Zip Code:	209 Arnold House, 715 North Pleasant St. Amherst, MA 01003
Email:	jpasquini@umass.edu
Reports to (name and title):	Christopher Greenfield, Associate Dean of Administration and Finance

2. The individual(s) responsible for the research team using the Data, including ensuring each individual (i) has a signed confidentiality agreement, (ii) accesses and uses only the minimal Data necessary to achieve the research purpose, (iii) accesses the Data only on a secured server according to Applicant's policies. This individual is also responsible for maintaining the access log required under Article II, Section 5 of the Data Use Agreement.

Name:	Laura Attanasio
Agency/Organization:	UMass Amherst School of Public Health and Health Sciences
Title:	Assistant Professor
Phone:	413-545-4480
Address, City/Town, State, Zip Code:	715 North Pleasant St. Amherst, MA 01003
Email:	lattanasio@umass.edu
Reports to (name and title):	Elizabeth Bertone-Johnson, Chair, Department of Health Promotion and Policy

3. The individual responsible for notifying CHIA of any breach of the Data Use Agreement or this Data Management Plan.

Name:	Laura Attanasio
Agency/Organization:	UMass Amherst School of Public Health and Health Sciences
Title:	Assistant Professor
Phone:	413-545-4480
Address, City/Town, State, Zip Code:	715 North Pleasant St. Amherst, MA 01003
Email:	lattanasio@umass.edu
Reports to (name and title):	Elizabeth Bertone-Johnson, Chair, Department of Health Promotion and Policy

4. The individual responsible for ensuring the Data is destroyed upon termination of the Data Use Agreement, completing the Data Destruction Form and providing that Form to CHIA.

Name:	Laura Attanasio
Agency/Organization:	UMass Amherst School of Public Health and Health Sciences
Title:	Assistant Professor
Phone:	413-545-4480
Address, City/Town, State, Zip Code:	715 North Pleasant St. Amherst, MA 01003
Email:	lattanasio@umass.edu
Reports to (name and title):	Elizabeth Bertone-Johnson, Chair, Department of Health Promotion and Policy

V. DATA SECURITY AND INTEGRITY

Agents or contractors that will have access to or store the CHIA Data at a location other than the Recipient's location, or in an off-site server and/or database, must complete a separate Data Management Plan.

1. *Physical Location of the Data*:

   a. Please provide the delivery address for the Data, as well as the full address, including building and floor, of each location where Data will be delivered and stored.

Delivery:

Organization: UMass Amherst School of Public Health and Health Sciences, Department of Health Promotion nd Policy			
Street Address: Arnold House 329, 715 North Pleasant St.	City: Amherst	State: MA	01003
Office Telephone *(Include Area Code)*: 413-545-4480			

Storage:

Organization: Massachusetts Green High Performance Computing Center			
Street Address: 100 Bigelow St.	City: Holyoke	State: MA	ZIP Code: 01040
Office Telephone *(Include Area Code)*: 413-545-2040			

   b. Will the Data be stored by the third party on a system in the cloud (reachable via the Internet)?
   ☐ Yes   ☒ No

      i. If you answered yes to (b): Has this Cloud Service Provider passed a FedRAMP 3PAO assessment *for the specific cloud system* which will host the data*?*
      ☐ Yes   ☐ No

    ii. If you answered yes to (b): What is the name of the provider *and* the FedRAMP level the specific cloud system hosting the data is operating at?

> Click here to enter text.

2. *Data Privacy Training and Awareness:*

    a. Has every individual who will access the Data received training on the proper handling of protected health information and/or personal data within the last year?
    ☒ Yes   ☐ No

3. *Encryption of Data*:

    a. Will all CHIA Data at rest be encrypted on storage media (backup tapes, local hard drives, network storage, et al) with **encryption at least AES-256 or stronger.** *All recipients of CHIA Data must encrypt data at rest a Data Management Plan indicating otherwise <u>will not</u> be approved and returned for revisions.*
    ☒ Yes   ☐ No

    b. Will CHIA Data be transmitted by your Agency or Organization over the Internet?
    ☐ Yes   ☒ No

    If you answered yes to (b): which of the following if any are used when transmitting data over the internet? If selecting *other* please describe the method in space provided below.
    ☐ SSL (meets or exceeds TLS 1.1 or TLS 1.2)   ☐ SFTP   ☐ other

> Click here to enter text.

4. *Information Security:*

    a. Does your Agency or Organization have published information security policies which are followed and accessible to all staff accessing or handling CHIA Data?
    ☒ Yes   ☐ No

    b. Has every individual who will access the CHIA Data received cyber security awareness training in the last year?
    ☒ Yes   ☐ No

    c. Has your Agency or Organization experienced a breach of PHI or Personally Identifiable Information in the last seven (7) years?
    ☐ Yes   ☒ No

        i. *If you answered yes to (c): how was the breach resolved and what steps were taken to prevent a recurrence?*

> Click here to enter text.

5. *Technical and Physical Controls:*

a. Are all the user accounts that log on to any machine (server or endpoint) that accesses the Data uniquely assigned to individual users (i.e., the user accounts are not shared)?
☒ Yes ☐ No

b. Is an audit log maintained of all user log-on attempts to the system hosting the CHIA Data?
☒ Yes ☐ No

c. What is the minimum password length and character complexity (uppercase, lowercase, numeric, and special characters) required for new passwords on the user accounts logging on to the system accessing the CHIA Data?

All accounts have a strict password requirement that includes passwords between 10 and 16 characters, including characters from three of four categories (uppercase, lowercase, digits, special characters), cannot contain NetID (forwards or backwards), and not the same as previous five passwords.

d. Describe any additional authentication technical security controls you employ to defend the system against unauthorized logon, e.g. maximum failed login attempts, lockout period, etc.:

SSH tunneling to connect to the SPHHS cluster expires after a period without activity.

e. Do you run a current version of a commercial off-the-shelf anti-virus or anti-malware product on the systems that will host or access the CHIA Data?
☒ Yes ☐ No

If you answered no to (e), please provide details within your response in question (g) regarding additional controls implemented to prevent malware infection and propagation.

f. If the CHIA Data will be on a server or network accessible storage drive, then check all the security features present in the room containing CHIA Data:
   i. ☒ Recorded video
   ii. ☒ Access log of all individuals entering the room
   iii. ☒ Secure server rack
   iv. ☒ Access control limiting access only to authorized individuals

g. What additional specific physical or technical safeguards (not mentioned in prior answers) will be used to *mitigate* the risk of unauthorized access to CHIA Data?

The Mass Green High Performance Compute Center (MGHPCC) facilities are monitored 24/7 by cameras, as well as a front desk security guard. The front door is key card locked and visitors need to be buzzed in then sign in at the front desk, take a security badge and wait for their sponsor (person they are visiting in the facility). Key locked elevator as well. Hardware security is handled by physical cages, RFID door locks, as well as cameras to all sensitive locations.

h. When was the last information security risk assessment performed in your Agency or Organization? Who conducted it?

Last security risk assessment was done in September 2018 by Compass IT Compliance.

i.   When was the last IT audit performed in your Agency or Organization? Who conducted it?

> The last IT audit was done in September of 2018 by Compass IT Compliance.

VI. DATA DESTRUCTION

The Recipient attests that the CHIA Data and all copies of the CHIA Data used by the Applicant or its employees, contractors, or agents will be destroyed upon Project Completion or termination of the Data Use Agreement. All data destruction must conform to the requirements of M.G.L. c. 93I and to the Data Use Agreement. Please specify below the technical measures you will use to meet these requirements.

> Upon the completion of the project, we will destroy the backup copy of the data stored on the encrypted hard drive as well as the data stored on the SPHHS cluster. The backup copy of the data will be destroyed using the UMass Hard Drive and Magnetic Tape Destruction policy, which provides a service that is designed to comply with HIPAA regulations. This is done by filling out the online Surplus Equipment Disposal form and following the direction and policies for the destruction of the drive. The UMass Policy for Hard Drive & Magnetic Tape Destruction does not include cluster supported drives, and as such The School of Public Health & Health Sciences has created our own procedure based on best practice for deleting data on a drive. The official policy is still in draft. In an emergency we can destroy the encryption key and key slot rendering the data unencryptable and thus completely inaccessible.
>
> For a planned destruction we'll do the above and also overwrite the entire partition with garbage data a few times to ensure its complete destruction.

VII. ATTESTATION

By submitting this Data Management Plan, the Agency or 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 Agency or 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 its agents.

By signature below, I attest: (1) to the accuracy of the information provided herein (2) that the Agency or Organization agrees to hold and/or access CHIA Data at all times in compliance with all provisions of this Data Management Plan and the Data Use Agreement; and (3) to my authority to bind the Agency or Organization undersigned as an authorized signatory of the Agency or Organization.

Signature: (Authorized Signatory for Agency or Organization holding CHIA Data)	DocuSigned by: *Jennifer A Donais* C11EAC003940499...
Printed Name:	**Jennifer A. Donais**
Title:	Assistant Vice Chancellor for Research & Engagement, Compliance & Support Services, Office of Research Compliance
Agency or Organization Holding CHIA Data:	University of Massachusetts Amherst
Date:	3/16/2022