

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

Project Title:	Differences in uptake of highly effective contraceptive methods offered immediately postpartum in Massachusetts, 2017-2021
IRBNet Number:	1919057-1
Organization Requesting Data (Recipient):	Tufts Medical Center, Department of Obstetrics and Gynecology
Organization Website:	https://www.tuftsmedicalcenter.org/
Authorized Signatory for Organization:	Dr. Erika Werner
Title:	Physician-in-Chief and Chair, Obstetrics and Gynecology
E-Mail Address:	ewerner@tuftsmedicalcenter.org Assistant: India Taylor, itaylor@tuftsmedicalcenter.org
Telephone Number:	6176362382
Address, City/Town, State, Zip Code:	800 Washington St., Box 22, Boston, MA 02111
Data Custodian: (individual responsible for organizing, storing, and archiving Data)	Dr. Megan Evans
Title:	Director for Residency Program, Assistant Professor, Obstetrics and Gynecology
E-Mail Address:	mevans2@tuftsmedicalcenter.org
Telephone Number:	6176362229
Address, City/Town, State, Zip Code:	800 Washington St., Box 22, Boston, MA, 02111
Primary Investigator (Applicant): (individual responsible for the research team using the Data)	Dr. Megan Evans
Title:	Director for Residency Program, Assistant Professor, Obstetrics and Gynecology
E-Mail Address:	mevans2@tuftsmedicalcenter.org
Telephone Number:	6176362229
Address, City/Town, State, Zip Code:	800 Washington St., Box 22, Boston, MA, 02111
Names of Co-Investigators:	Dr. Preetha Nandi, Dr. Erika Werner, Devika Lekshmi, Alysa St. Charles
E-Mail Addresses of Co-Investigators:	pnandi@tuftsmedicalcenter.org
	astcharles1@tuftsmedicalcenter.org
	ewerner@tuftsmedicalcenter.org
	dlekshmi@tuftsmedicalcenter.org

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]

- | | | |
|---|--|---|
| <input checked="" type="checkbox"/> Epidemiological | <input type="checkbox"/> Health planning/resource allocation | <input type="checkbox"/> Cost trends |
| <input type="checkbox"/> Longitudinal Research | <input type="checkbox"/> Quality of care assessment | <input type="checkbox"/> Rate setting |
| <input type="checkbox"/> Reference tool | <input checked="" type="checkbox"/> Research studies | <input type="checkbox"/> Severity index tool (or other derived input) |
| <input type="checkbox"/> Surveillance | <input type="checkbox"/> Student research | <input type="checkbox"/> Utilization review of resources |
| <input type="checkbox"/> Inclusion in a product | <input type="checkbox"/> Other (describe in box 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.

Highly effective contraception, including reversible methods such as intrauterine devices (IUDs) or contraceptive implants, as well as sterilization (i.e. permanent contraception), is widely used among women ages 15 to 44 years; however there are many barriers that prevent birthing patients from receiving these desired methods in the postpartum period (1). Specifically, approximately 75% of patients who desire an IUD postpartum do not receive it, and only 39-57% of patients who want postpartum sterilization undergo the procedure (2, 3). Multiple individual, provider and system-level barriers exist in accessing these contraceptive methods, which have been well described in the literature (2, 4). Providing these services in an inpatient setting prior to the discharge of birthing patients who desire these methods can have significant individual health and public health implications, including the potential to reduce short-interval pregnancy, unintended pregnancy, and the associated maternal and fetal morbidity (1, 5). Delays in or inability to access these services were likely impacted by the COVID19 pandemic (6). Additionally, the pandemic likely indirectly impacted use of highly effective contraception immediately postpartum due to fewer antenatal appointments, logistical barriers, hospital policies for elective procedures, and expedited discharges (6, 7).

Massachusetts (MA) has robust policy and reimbursement guidelines in place that allow for provision of highly effective contraception during delivery admissions, which can mitigate these access issues. However, uptake of these services across state hospitals has not been previously studied. This study aims:

- 1) To examine uptake among Massachusetts birthing patients of highly effective contraception used in the immediate postpartum period, including post-placental IUD, contraceptive implant or sterilization procedures
- 2) To identify differences in these contraceptive methods by race, insurance status, and hospital setting (academic versus non-academic institutions)
- 3) To interpret the findings of differential use of these contraceptive methods with respect to the COVID19 pandemic
- 4) To share our research findings with community and health care stakeholders to inform policies to improve access to these methods prior to discharge from delivery admissions

This study will be a cross-sectional study with the primary outcome of immediate postpartum long-acting reversible contraceptive (LARC) and sterilization rates (individual as well as composite outcomes). The co-variables of interest include self-reported race, age, insurance status, and type of hospital. Our research group plans to share our findings with community stakeholders such as Partners in Contraceptive Choice and Knowledge (PICCK, an HHS-funded program in MA), Perinatal-Neonatal Quality Improvement Network (PNQIN) of MA, and other relevant groups. Our findings will be used to inform efforts in improving patient and provider access to and knowledge of the use of these highly effective contraception methods in the postpartum period, including highlighting implementation strategies in specific communities in MA. We aim to publish this work in a medical journal to contribute to the growing body of evidence in the scientific literature.

(A list of references is available at the end of the Application.)

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

Yes [If yes, a copy of the approval letter and protocol must be included with the Application package on IRBNet.] - our institution's (Tufts Medical Center) Health Science Research IRB has reviewed our request for IRB exemption and an approval letter has been included 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.

This study will be a cross-sectional study evaluating immediate postpartum LARC and sterilization rates (our individual as well as composite outcome variables) by co-variables of self-reported race, age, insurance status (private or public), and type of hospital (academic or community). Other co-variables of interest include parity (i.e. number of prior births), gestational age at delivery, and type of delivery (cesarean or vaginal). For this analysis, we will request the de-identified Case Mix Dataset for the inpatient claims data between 2017 and 2021. Our team will identify all patients who had a delivery in an MA hospital during this time period, and ascertain those patients who received one of the contraceptive procedures of interest (i.e. immediate postpartum IUD, implant, or sterilization) during their delivery admission. These procedures will be identified by unique procedure codes. These rates will be stratified by discharge year, 2017 through 2021. ANOVA and Chi-square tests will be conducted for numerical and categorical co-variables, respectively, to evaluate associations between co-variables of interest and our primary outcome variables. We plan to evaluate the potential influence of the COVID19 pandemic by analyzing these trends by discharge year and make qualitative inferences on changes in trends in our outcomes. Of note, these data analyses will not be linked to individual COVID19 diagnoses or regional COVID19 outbreaks; we plan to interpret our findings within a lens of the COVID19 pandemic and known institutional and state policy changes to make general recommendations for service delivery improvement. Statistical analyses will be conducted by our team data analysts with an alpha level of 0.05 using Stata software.

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.*

The implications of this study highlight current trends and potential disparities in uptake of highly effective contraception in the immediate postpartum period, thereby offering opportunities for policy and service delivery transformation for these services in MA. There is currently limited literature that quantifies the unmet need in immediate postpartum contraception, that is, the phenomenon that patients are not receiving the contraception that they desire in this critical period in a birthing patient's health and livelihood. Specifically, approximately 40% of patients do not present for their postpartum visit, a healthcare encounter where most postpartum contraception is offered (2). Furthermore, approximately one in five women report that they are not using their preferred method of contraception (8). Resultantly, patients unable to access postpartum contraception are at risk of short-interval pregnancy, unintended pregnancy, and/or associated health risks such as preterm birth, low birth weight, and severe maternal morbidity (5, 9). There are many factors that contribute to this discrepancy in provision of this preventive service, including patient-level, provider-level and system-level barriers. By measuring uptake of these services in Massachusetts, our research will inform ways that hospitals, communities and the Commonwealth can improve access and optimize uptake of highly effective contraception in an inpatient setting that can mediate some of these barriers and better meet individual family planning goals in a patient-centered fashion.

This research will additionally help elucidate underlying disparities in accessing postpartum contraception in MA. Multiple studies nationally demonstrate that there are significant racial and ethnic differences in access to and uptake of postpartum contraception. In one study, Black women were 27% less likely to receive any type of birth control in the postpartum period, and 36% less likely to receive a highly effective method compared to White women (10). Other studies have demonstrated that ethnic minorities and those with lower socioeconomic status are less likely to receive high-quality counseling from providers (11, 12). Furthermore, the COVID19 pandemic may have exacerbated some of these trends for certain patient populations who face multiple social determinants of health. The findings of this research will contribute to health disparities research regarding the unmet need for desired contraceptive methods particularly among marginalized populations.

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 2021

Describe how your research objectives require Inpatient Discharge data:

The provision of immediate postpartum LARC methods or sterilization prior to discharge requires verifying procedure codes from inpatient delivery admissions. To clarify, this study will not be evaluating the provision of these procedures in the outpatient setting, but rather attempt to capture trends of providing these contraceptive methods prior to a patient being discharged from the hospital. This subsector of patients who receive these contraceptive methods in an inpatient setting will help fill the gap in knowledge of patient uptake, acceptability and access to these methods during this time period.

Outpatient Hospital Observation Stay Data

2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016
 2017 2018 2019 2020 2021

Describe how your research objectives require Outpatient Hospital Observation Stay data:

We seek to quantify rates of our primary outcome during inpatient stays for a delivery; however, some institutions may bill for an immediate postpartum IUD or implant insertion through a separate observation stay admission. Additionally, some patients may receive this method in the setting of a previable preterm delivery, a delivery of an intra-uterine fetal demise, or after an induced abortion - these are patients we wish to include in our data analyses to be complete. These admissions may be coded as an observation stay as opposed to an inpatient admission as they may not stay in the hospital more than one night. We request this data to thoroughly evaluate the provision of these services in a hospital stay following a delivery, and the few patients who may be included in the observation stay dataset are critical to include in our analyses.

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™ Software, and to the 3M APR™ 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:

<input checked="" type="checkbox"/> 3-Digit Zip Code (Standard)	<input type="checkbox"/> 3-Digit Zip Code & City/Town ***	<input type="checkbox"/> 5-Digit Zip Code ***	<input type="checkbox"/> 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:			
Click here to enter text.			

Demographic Data

Select one of the following options:

<input type="checkbox"/> Not Requested (Standard)	<input checked="" type="checkbox"/> Race & Ethnicity***
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**** If requested, provide justification for requesting Race and Ethnicity. Refer to specifics in your methodology:**

As aforementioned in our methods, we will be using self-identified race as a co-variate to evaluate trends among various populations in uptake of highly effective contraception. This will highlight existing or changing differences between racial and ethnic groups in provision of these services, which has previously been described in the literature. Evaluating these differences during this time period will inform potential policy changes to improve access to these services by marginalized populations in MA.

Date Resolution

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

<input type="checkbox"/> Year (YYYY)(Standard)	<input checked="" type="checkbox"/> Month (YYYYMM) ***	<input type="checkbox"/> Day (YYYYMMDD)***
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*****If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology:**

We wish to evaluate rates of uptake of these procedures over a five year period with a slightly finer level of granularity in order to measure trends of our outcome variable over time. That is, there may be fluctuation over the course of a 12-month period with uptake of these contraceptive services (as there is also seasonal fluctuation in birth rates, for example) (10). This level of detail to the discharge and procedure data will also allow us to contextualize our findings with the wax and wane of the COVID19 pandemic. We will not be associating the outcome data with individual COVID19 diagnoses. Our interpretation of the trends of postpartum contraception use would be too broad to conduct on a year-by-year basis.

Practitioner Identifiers (UPN)

Select one of the following options.

<input checked="" type="checkbox"/> Not Requested (Standard)	<input type="checkbox"/> Hashed ID ***	<input type="checkbox"/> Board of Registration in Medicine Number(BORIM) ***
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*****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.

<input checked="" type="checkbox"/> Not Requested (Standard)	<input type="checkbox"/> UHIN Requested ***
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***** 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:

<input checked="" type="checkbox"/> Not Requested (Standard)	<input type="checkbox"/> Hashed Mother's SSN Requested ***
<p>*** If requested, provide justification for requesting Hashed Mother's SSN. Refer to specifics in your methodology: Click here to enter text.</p>	

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.

N/A

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.

N/A

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

N/A

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

N/A

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.

Yes, our team hopes to share our findings in a multi-faceted approach to reach the scientific community as well as community stakeholders. We aim to publish our findings in a high-impact professional journal in women's health, such as *Obstetrics and Gynecology*, *American Journal of Obstetrics and Gynecology*, or *Contraception*. We additionally plan to share our findings through a collated report or presentation with collaborators that conduct work in maternal health and health equity across the state, such as PNQIN and PICCK. Through our methodology and planned data analyses, our research team will ensure to comply with CHIA's cell suppression policy and will not publish any cell less than 11. No published tables or figures would include this information and will not disrupt the integrity of our shared findings.

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.

As stated above, we plan to share our findings through a report or presentation with community stakeholders. We do not intend to publish this information on any website.

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?

We will be coding institutions at which the primary outcome procedures were performed as "academic" or "community" hospital settings. We will not be using zip code or city/town level data. For these two qualifiers, we expect that this binary co-variate will obscure identifiability of individuals who received any of the procedures of interest.

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 tool, 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?

N/A

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.

N/A

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?

N/A

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.

The PI and co-PIs on this application all have extensive experience working with hospital data. These investigators have conducted epidemiologic as well as cohort studies at the hospital, local, state and national levels. All co-investigators on this project have led and participated in projects in translational clinical research as well as public health research through each of their respective Masters programs. Two investigators, Dr. Evans and Dr. Werner, are faculty leadership at Tufts Medical Center (Residency Program Director and Chair of the Department of Obstetrics and Gynecology, respectively), and support multiple projects by learners in the department. Please refer to each investigator’s CV for specific details on projects they have conducted using hospital data.

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.*]

No contractors will be included in this application.

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.

N/A

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.

N/A

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.

N/A

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.

N/A

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:	
Printed Name:	Megan Evans, MD, MPH
Title:	Director for Residency Program, Assistant Professor, Obstetrics and Gynecology
Date:	8/1/22

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.