

Application for Massachusetts All-Payer Claims 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 apcd.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 All-Payer Claims Database data.
2. After reviewing the Fee Schedule, if you have any questions about the application or data fees, contact apcd.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:	Evaluating temporal trends in breast reconstruction and effects of reimbursement on breast reconstruction and associated procedures
IRBNet Number:	1848373
Organization Requesting Data (Recipient):	The Brigham and Women's Hospital, Inc.
Organization Website:	https://www.brighamandwomens.org/
Authorized Signatory for Organization:	John Shearer, JD, MHA
Title:	Sr. Agreement Associate Mass General Brigham – Research Management
E-Mail Address:	jeshearer@partners.org
Telephone Number:	857-282-1676
Address, City/Town, State, Zip Code:	399 Revolution Drive, Somerville, MA 02145
Data Custodian: (individual responsible for organizing, storing, and archiving Data)	Justin Broyles, MD
Title:	Assistant Professor, Harvard Medical School; Associate Surgeon, Brigham and Women's Hospital
E-Mail Address:	jbroyles@bwh.harvard.edu
Telephone Number:	617-525-7955
Address, City/Town, State, Zip Code:	45 Francis St., Boston, MA 02115
Primary Investigator (Applicant): (individual responsible for the research team using the Data)	Justin Broyles, MD
Title:	Assistant Professor, Harvard Medical School; Associate Surgeon, Brigham and Women's Hospital
E-Mail Address:	jbroyles@bwh.harvard.edu
Telephone Number:	617-525-7955
Address, City/Town, State, Zip Code:	45 Francis St., Boston, MA 02115
Names of Co-Investigators:	Colby Hyland, AB; Goutam Gadiraju, BS
E-Mail Addresses of Co-Investigators:	colby_hyland@hms.harvard.edu; ggadiraju@hms.harvard.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]

- | | | |
|--|--|---------------------------------------|
| <input 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 checked="" 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) | |

[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.

Breast cancer is one of the most common malignancies in women, and 281,550 cases of invasive breast cancer are expected in the United States in 2021.¹ Reconstruction following surgery for breast cancer is increasingly more common, due to increasing collaboration among surgical oncologists and plastic surgeons as well as improved psychosocial outcomes in patients.² In addition, insurance companies are mandated to cover breast reconstruction following mastectomy as of the Women's Health and Cancer Right's Act of 1998. However, there are significant disparities in receipt of breast reconstruction.³ Moreover, there are disparities and variability with regard to the receipt of different types of breast reconstruction, such as implant-based versus autologous reconstruction.⁴ One previously explored explanation for these disparities is variation in reimbursement patterns for different procedures, elucidated using the Massachusetts all-payer claims database.⁵

Over time, breast reconstruction and its associated procedures have undergone much innovation. Several such innovations include: use of biologic or synthetic meshes and matrices with breast implants; tissue expansion; pre-pectoral versus sub-pectoral implant placement; nipple reconstructive procedures, such as tattooing, grafting, and tissue reconstruction; nerve coaptation; use of adjunct technologies, such as indocyanine green angiography or oximeters. In addition, there has been greater optimization of procedures associated with breast reconstruction and consequences of treatment for breast cancer, such as fat grafting and revision surgeries, and innovation in lymphedema treatment, such as debulking, lymphovenous bypass grafting, and lymph node transfer. As our healthcare system moves increasingly toward cost-effective and value-based care, much less is known regarding the specific trends, disparities, and reimbursement differences regarding these procedures.

Given that disparities and differences exist both in receipt of and type of breast reconstruction, we hypothesize that disparities will also exist in these practices and procedures associated with breast reconstruction as well as plastic surgical treatment of lymphedema. We therefore aim to use reimbursement data from the CHIA to assess 1) general trends of breast reconstruction and lymphedema procedures, 2) reimbursement differences to providers and hospitals, 3) disparities and/or differences in care associated with geography and socioeconomic census data, and 4) price variation among payers. Through this, we hope to better elucidate possible drivers to practice variation and disparities in care. We also hope to gain a better understanding of innovative practice adoption among providers and contribute to a more transparent understanding of healthcare delivery.

References

1. Breastcancer.org. U.S. Breast Cancer Statistics. *Breastcancer.org* (2021).
2. Gill, P. S. *et al.* A 10-year retrospective review of 758 DIEP flaps for breast reconstruction. *Plast. Reconstr. Surg.* **113**, 1153–1160 (2004).
3. Soni, S. E., Lee, M. C. & Gwede, C. K. Disparities in Use and Access to Postmastectomy Breast Reconstruction Among African American Women: A Targeted Review of the Literature. *Cancer Control* **24**, 1073274817729053 (2017).
4. Restrepo, D. J. *et al.* Disparities in Access to Autologous Breast Reconstruction. *Medicina (Kaunas)*. **56**, (2020).
5. Panchal, H. *et al.* Impact of Physician Payments on Microvascular Breast Reconstruction: An All-Payer Claim Database Analysis. *Plast. Reconstr. Surg.* **145**, 333–339 (2020).

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.*]
 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.*

We hope to elucidate trends in practice variation and procedural differences, which may better characterize medically underserved areas in Massachusetts needing future intervention. Identifying gaps in certain services will be a crucial first step for healthcare initiatives that promote equity. We also hope to better understand drivers of practice variation, such as reimbursement differences, which may help providers and hospitals better understand disparities in receipt of certain procedures.

VI. DATASETS REQUESTED

The Massachusetts All-Payer Claims Database is comprised of medical, pharmacy, and dental claims and information from the member eligibility, provider, and product files that are collected from health insurance payers licensed to operate in the Commonwealth of Massachusetts. This information encompasses public and private payers as well as data from insured and self-insured plans. APCD data are refreshed and updated annually and made available to approved data users in Release Versions that contain five calendar years of data and three months of run-out. For more information about APCD Release Versions, including available years of data and a full list of elements in the release 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 future years of data that will become available in a subsequent release. Projects that 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 requests are subject to the Data Use Agreement, will require payment of fees for additional Data for Non-Government Entities, 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. Select Release Version and years of data requested (Release Versions and years not listed are not available).

- | | |
|--|--|
| <input type="checkbox"/> Release Version 8.0 | <input checked="" type="checkbox"/> Release Version 10.0 |
| <input type="checkbox"/> 2014 | <input checked="" type="checkbox"/> 2016 |
| <input type="checkbox"/> 2015 | <input checked="" type="checkbox"/> 2017 |
| <input type="checkbox"/> 2016 | <input checked="" type="checkbox"/> 2018 |
| <input type="checkbox"/> 2017 | <input checked="" type="checkbox"/> 2019 |
| <input type="checkbox"/> 2018 | <input checked="" type="checkbox"/> 2020 |

3. Specify below the data files requested for this Project, and provide your justification for requesting *each* file.

<input checked="" type="checkbox"/> Medical Claims
Describe how your research objectives require Medical Claims data: Medical Claims data will be used to identify our primary patient population of interest: women who underwent breast reconstruction and/or treatment for lymphedema. Sociodemographic, clinical variables, diagnostic codes, and reimbursements will also be obtained from this data.
<input checked="" type="checkbox"/> Pharmacy Claims
Describe how your research objectives require Pharmacy Claims data: This file contains data on prescription data, which will enable us to elucidate important trends in prescription drug use during hospital stays and following discharge for breast reconstruction and lymphedema patients.
<input type="checkbox"/> Dental Claims
Describe how your research objectives require Dental Claims data: Click here to enter text.
<input checked="" type="checkbox"/> Member Eligibility
Describe how your research objectives require Member Eligibility data: This data will enable us to better understand the effect of insurance status (insured vs. uninsured) and type of insurance on breast reconstruction procedures and lymphedema treatment procedures.
<input type="checkbox"/> Provider
Describe how your research objectives require Provider data: Click here to enter text.
<input checked="" type="checkbox"/> Product
Describe how your research objectives require Product data: Data within this file will enable us to conduct a thorough analysis of insurance type on breast reconstruction procedures and lymphedema treatment procedurs, as it contains data on benefits, deductibles, and insurance models.

VII. DATA ENHANCEMENTS REQUESTED

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

All-Payer Claims Database data is released in Limited Data Sets (LDS). All Organizations 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 additional elements), please refer to [release layouts, data dictionaries](#) and similar documentation included on CHIA’s website.

1. Specify below which enhancements you are requesting in addition to the “Core” LDS, provide your justification for requesting each enhancement.

a. Geographic Subdivisions

The geographic subdivisions listed below are available for Massachusetts residents and providers only. Select one of the following options.

<input type="checkbox"/> 3-Digit Zip Codes (standard)	<input checked="" type="checkbox"/> 5-Digit Zip Codes***
<p>***If requested, provide justification for requesting 5-Digit Zip Code. Refer to specifics in your methodology: 5-Digit zip codes will enable us to more accurately link zip codes to census data using HUD crosswalk files, in order to determine differential service areas of certain procedures (i.e. underserved, low-income, under-resourced areas vs. adequately served and/or high-income areas)</p>	

b. Date Resolution

Select one option from the following options.

<input type="checkbox"/> Year (YYYY) (Standard)	<input type="checkbox"/> Month (YYYYMM) ***	<input checked="" type="checkbox"/> Day (YYYYMMDD) *** [for selected data elements only]
<p>*** If requested, provide justification for requesting Month or Day. Refer to specifics in your methodology: Breast reconstruction and lymphedema treatment, including revisions, often happen within days or weeks of one another within a patient’s cancer care treatment. As such, resolution of dates to the day will be important for this analysis.</p>		

c. National Provider Identifier (NPI)

Select one of the following options.

<input checked="" type="checkbox"/> Encrypted National Provider Identifiers (standard)	<input type="checkbox"/> Decrypted National Provider Identifiers***
<p>*** If requested, provide justification for requesting decrypted National Provider Identifier(s). Refer to specifics in your methodology: Click here to enter text.</p>	

VIII. MEDICAID (MASSHEALTH) DATA

1. Please indicate whether you are seeking Medicaid Data:

- Yes
 No

2. Federal law (42 USC 1396a(a)7) restricts the use of individually identifiable data of Medicaid recipients to uses that are ***directly connected to the administration of the Medicaid program***. If you are requesting MassHealth Data, please describe, in the space below, why your use of the Data meets this requirement. *Your description should focus on how the results of your project could be used by the Executive Office of Health and Human Services in connection with the administering the MassHealth program.* Requests for MassHealth Data will be forwarded to MassHealth for a determination as to whether the proposed use of the Data is directly connected to the administration of the MassHealth program. CHIA cannot release MassHealth Data without approval from MassHealth. This may introduce significant delays in the receipt of MassHealth Data.

We would need access to Medicaid data in order to compare reimbursements between private and public insurers. In addition, we hope to elucidate any disparities in breast reconstruction and lymphedema treatment care. Excluding patients with Medicaid insurance would potentially bias results and may not accurately reflect underserved patient populations.

3. Organizations approved to receive Medicaid Data will be required to execute a [Medicaid Acknowledgment of Conditions](#). MassHealth may impose additional requirements on applicants for Medicaid Data as necessary to ensure compliance with federal laws and regulations regarding Medicaid.

IX. 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 cross-reference CHIA data to publicly available Health Resources and Services Administration (HRSA) datasets that detail Medically Underserved Areas/Populations (MUA) by zip code. We will use HUD USPS Zip Code Crosswalk files to convert census tracts to 5 digit zip does if necessary.

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.

For any zip codes and MUA census tracts that do not correspond exactly, we will select the zip code that pertains to the largest proportion of the MUA population as outlined by the US Department of Housing and Urban Development (HUD).

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.

Source: <https://data.hrsa.gov/tools/shortage-area/mua-find>

Variables: MUA/PID, Service Area Name, Designation Type, Primary State Name, County, Index of Medical Underservice Score, Rural Status, Designation Date, Designation Status, Update Date, Discipline

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

For any medically underserved areas with a patient population less than 11, we will not report information so as to protect the identity of individuals.

X. 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, we intend to disseminate results in professional journals, as well as abstracts, posters, and oral presentations at professional research conferences. We will explicitly outline in our research methodology that results less than 11 will not be presented or published. Any cells that would contain that data will be masked.

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.

Our results will be disseminated through journals accessible 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 level of geographical analysis will be city/town, as we plan to compare rural vs. urban settings, although we will not explicitly state the names of cities or towns. We will not report data at the zip-code level. Zip codes will be used for linkage analysis as stated above, with MUA aggregated for analysis. Maps will be considered only if results exceed the a total of 11 for any given area.

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?

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.

XI. APPLICANT QUALIFICATIONS

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

All researchers are familiar with using highly sensitive protected health information.

Justin M. Broyles, MD is an Assistant Professor at Harvard Medical School and adjunct faculty at Harvard Business School. His research focus explores the intersections between clinical outcomes, cost, and patient satisfaction. He has led previous research studies using publically available CMS data to determine value in episode based surgical payments.

Colby J. Hyland, AB has previously worked with internal claims and hospital reimbursement data as part of ongoing value-based care initiatives. He also also conducted analyses using publicly available CMS/Medicaid Data to determine cost-effectiveness and value of hospital-based procedures in breast cancer care.

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.)

XII. 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 #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 or 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]

XIII. 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:	John Shearer, JD, MHA
Title:	Senior Agreement Associate, Mass General Brigham
Date:	April 15, 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.