

**Commonwealth of Massachusetts
Center for Health Information & Analysis (CHIA)
Non-Government Application for MA APCD Limited Data Set**

This form is required by all Applicants, except Government Agencies as defined in [957 CMR 5.02](#). All Applicants must also complete the Data Management Plan, attached to this Application. The Application and the [Data Management](#) Plan must be signed by an authorized signatory of the organization. This Application and the Data Management Plan will be used by CHIA to determine if your organization may receive CHIA data. Please be sure the documents are completed fully and accurately. You may wish to consult the Evaluation Guide that CHIA will use to review your documents. Prior to receiving CHIA Data, the organization must execute the [Data Use Agreement](#). You may wish to review that document as you complete these forms. This application should be completed by the Primary Investigator, and must be signed by a party with authority to bind the organization seeking CHIA Data for the purposes described herein.

NOTE: In order for your Application to be processed, you must submit the required application fee. Please consult the fee schedules for MA APCD data for the appropriate fee amount. A [remittance](#) form with instructions for submitting the application fee is available on the CHIA website.

All attachments must be uploaded to IRBNet with your Application. All applications documents can be found on the [CHIA website](#) in Word and/or PDF format.

I. GENERAL INFORMATION

APPLICANT INFORMATION	
Applicant Name: (Primary Investigator)	Cecilia Lee, MD
Title:	Assistant Professor
Organization:	University of Washington, Seattle
Project Title:	The association between diabetic retinopathy and other ocular or systemic conditions
Mailing Address:	HMC 359608, 325 9 th Ave, Seattle, WA 98104
Telephone Number:	206-685-4705
Email Address:	Leecs2@uw.edu
Names of Co-Investigators:	Aaron Lee, MD
Email Addresses of Co-Investigators:	leeay@uw.edu
Original Data Applicant Submission Date:	
Dates Data Application Revised:	
Project Objectives (240 character limit):	To evaluate the association between the severity of diabetic retinopathy and other ocular or systemic conditions using MA All-payers Claims Database
Project Research Questions (if applicable) or Business Use Case(s):	<p>1. Is there an association between the severity of diabetic retinopathy and age-related macular degeneration?</p> <p>2. Are patients who had vitrectomy surgery for proliferative diabetic retinopathy at increased risk for the following events: Myocardial infarction,</p>

	<p>dialysis, stroke, hospitalization, and mortality in a health care setting?</p> <p>3. Are patients who had pan-retinal photocoagulation for proliferative diabetic retinopathy at increased risk for the following events: Myocardial infarction, dialysis, stroke, hospitalization, and mortality in a health care setting?</p> <p>4. Are patients who had intravitreal vascular-endothelial growth factor inhibitor for diabetic macular edema at increased risk for the following events: Myocardial infarction, dialysis, stroke, hospitalization, and mortality in a health care setting?</p>
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II. PUBLIC INTEREST & PROJECT SUMMARY

1. Briefly explain why completing your project is in the public interest.

All our study questions have direct public health implications since we are interested in finding out whether diabetic retinopathy is associated with other morbidity and mortality in a health care setting. No prospective clinical trial will be able to find an answer to these questions since this will require a large sample size with long follow up.

We plan to publish all our findings in peer-reviewed journals, thus any important results will be shared with the public.

2. Has an Institutional Review Board (IRB) reviewed your project?

- Yes, a copy of the approval letter and protocol must be **attached** to this Application
- No, this project is not human subject research and does not require IRB review.

3. If your project has not been reviewed by an IRB, please **attach** a brief (1-2 page) description of your project including the methodology, objectives, and research questions.

III. DATA FILES REQUESTED

1. Please indicate the MA APCD databases from which you seek data, the year(s) of data requested, and your justification for requesting each file. Please refer to the [MA APCD Release 5.0 Data Specifications](#) for details of the file contents.

<p>MA ALL-PAYER CLAIMS DATABASE FILES</p>	<p>Year(s) Of Data Requested Current Yrs. Available</p> <p><input checked="" type="checkbox"/> 2011 <input checked="" type="checkbox"/> 2012 <input checked="" type="checkbox"/> 2013 <input checked="" type="checkbox"/> 2014 <input checked="" type="checkbox"/> 2015</p>
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<input checked="" type="checkbox"/> Medical Claims	Please describe how your research objectives require Medical Claims data: We are doing medical research regarding treatment outcomes, medical claims is necessary to perform the work. We are requesting Data from the currently available years: 2011-2015.
<input checked="" type="checkbox"/> Pharmacy Claims	Please describe how your research objectives require Pharmacy Claims data: A significant portion of patients with diabetic retinopathy and age-related macular degeneration receives vascular endothelial growth factor inhibitor. We want to be able to find those patients who are undergoing treatment for these conditions.
<input type="checkbox"/> Dental Claims	Please describe how your research objectives require Dental Claims data:
<input type="checkbox"/> Member Eligibility	Please describe how your research objectives require Member Eligibility data:
<input type="checkbox"/> Provider	Please describe how your research objectives require Provider data:
<input type="checkbox"/> Product	Please describe how your research objectives require Product data:

IV. GEOGRAPHIC DETAIL

Please choose one of the following geographic options for MA residents. For releases with 5 digit zip code, CHIA will apply a substance abuse filter which will remove all claims that include a substance abuse diagnosis.

<input type="checkbox"/> 3 Digit Zip Code (MA) (standard)	<input checked="" type="checkbox"/> 5 Digit Zip Code (MA)***
<p>***Please provide justification for requesting 5 digit zip code. Refer to specifics in your methodology:</p> <p>We would like 5 zip codes because one of the variables that can affect the patients’ clinical outcome is access to care and we will use the distance information from their usual hospitals or physicians.</p>	

V. DATE DETAIL

Please choose one option from the following options for dates:

<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, please provide justification for requesting Month or Day. Refer to specifics in your methodology:</p> <p>We will be selecting patients who had a surgery for diabetic retinopathy. Having detailed date information will help us analyze the</p>		

temporal relationship between the eye surgery and additional outcomes of interest.
 Also time dependent survival analysis regarding various outcomes will be performed using cox regression (which will require dates).

VI. NATIONAL PROVIDER IDENTIFIER (NPI)

Please choose one of the following options for National Provider Identifier(s):

<input type="checkbox"/> Encrypted National Provider Identifier(s) (standard)	<input checked="" type="checkbox"/> Unencrypted National Provider Identifier(s)***
<p>*** If requested please, provide justification for requesting unencrypted National Provider Identifier(s). Refer to specifics in your methodology: In order to associate outcomes with provider type/level of specialty we plan to link unencrypted NPI with CMS NPI Registry data and/or AMA physician master file date. This will allow us, for example, to determine if health outcomes vary when patients seek care at smaller community hospitals compared to large specialty hospitals such as Massachusetts Eye and Ear.</p>	

VII. MEDICAID DATA

Please indicate here whether you are seeking Medicaid Data:

- Yes
- No

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 Medicaid data from Level 2 or above, please describe, in the space below, why your use of the data meets this requirement. Requests for Medicaid 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 Medicaid program.

VIII. DATA LINKAGE AND FURTHER DATA ABSTRACTION

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

1. Do you intend to link or merge CHIA Data to other datasets?

- Yes
- No linkage or merger with any other database will occur

2. If yes, please indicate below the types of database to which CHIA Data 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 level (e.g., American Hospital Association data)
- Aggregate Data (e.g., Census data)
- Other (please describe):

3. If yes, describe the data base(s) to which the CHIA Data will be linked, which CHIA data elements will be linked; and the purpose for the linkage(s):

Driving distance to provider will be extrapolated with ZIP Code GPS coordinate using Open Street Map

Unencrypted NPI will be linked with CMS NPI data and/or AMA physician master file data to determine provider level of specialty/expertise.

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.

Driving distance - Probabilistic

Linkage of unencrypted NPI to CMS NPI data -Deterministic

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

Driving distance - Open Street map travel distance calculations are based on census ZIP code area centroids which is fuzzy matching routine rather than exact matching to patient address and analysis of distance will be aggregated.

All linked and merged data will be aggregated and not reported at patient level and will utilized cell suppression.

XI. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Describe your plans to publish or otherwise disclose CHIA Data, or any data derived or extracted from such CHIA Data, in any paper, report, website, statistical tabulation, seminar, conference, or other setting. 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 display a cell less than 11, and no percentages or other mathematical formulas will be used if they result in the display of a cell less than 11.

We plan to publish our findings in peer-reviewed journals and during appropriate research conferences.

2. Do you anticipate that the results of your analysis will be published and/or publically available to any interested party? Please describe how an interested party will obtain your analysis and, if applicable, the amount of the fee, that the third party must pay.

The results will be available through our publications.

3. Will you use CHIA Data for consulting purposes?

- Yes
- No

4. Will you be selling standard report products using CHIA Data?

- Yes
- No

5. Will you be selling a software product using CHIA Data?

- Yes
- No

6. Will you be reselling CHIA Data in any format?

- Yes
- No

If yes, in what format will you be reselling CHIA Data (e.g., as a standalone product, incorporated with a software product, with a subscription, etc.)?

7. If you have answered “yes” to questions 4, 5 or 6, please describe the types of products, services or studies.

8. If you have answered “yes” to questions 4, 5, or 6, what is the fee you will charge for such products, services or studies?

X. APPLICANT QUALIFICATIONS

1. Describe your qualifications (and the qualifications of your co-investigators) to perform the research described.

Dr. Aaron Lee and Cecilia Lee are both clinician-scientists and have been working on outcome research using large datasets for several years. Dr. A. Lee has a Masters of Science in Clinical Investigations and has published more than

12 peer-reviewed publications using similar datasets in ophthalmology.

Dr. C. Lee is currently obtaining a Masters of Science in epidemiology and received NEI K23 funding to pursue clinical research interests.

Our team is composed of Dr. C. Lee (PI), A. Lee(co-investigator), L. Ding (statistician), and Ian Luttrell (research coordinator) and has clinical and statistical expertise to perform the study.

2. **Attach** résumés or curricula vitae of the Applicant/principal investigator, and co-investigators. (These attachments will not be posted on the internet.)

XI. USE OF AGENTS AND/OR CONTRACTORS

Please note: 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.

Third-Party Vendors. Provide the following information for all agents and contractors who will work with the CHIA Data.

Company Name:	
Contact Person:	
Title:	
Address:	
Telephone Number:	
E-mail Address:	
Organization Website:	

1. Will the agent have access to the CHIA Data at a location other than your location, your off-site server and/or your database?

- Yes, a separate Data Management Plan **must** be completed by each agent who will store CHIA Data
- No

2. Describe the tasks and products assigned to this agent for this project; their qualifications for completing the tasks; and the Organization’s oversight of the agent, including how the Organization will ensure the security of the CHIA Data to which the agent has access.

XII. FEE INFORMATION

Please consult the [fee schedules](#) for MA APCD Data and select from the following options:

- Researcher
- Others (Single Use)
- Others (Multiple Use)

Are you requesting a fee waiver?

- Yes
- No

If yes, please refer to the [Application Fee Remittance Form](#) and submit a letter stating the basis for your request (if required). Please refer to the [fee schedule](#) for qualifications for receiving a fee waiver. If you are requesting a waiver based on the financial hardship provision, please provide documentation of your financial situation. Please note that non-profit status alone isn't sufficient to qualify for a fee waiver.

By submitting this Application, the Data Applicant attests that it is aware of its data use, privacy and security obligations imposed by state and federal law *and* is compliant with such use, privacy and security standards. The Data Applicant further agrees and understands that it is solely responsible for any breaches or unauthorized access, disclosure or use of any CHIA Data provided in connection with an approved Application, including, but not limited to, any breach or unauthorized access, disclosure or use by its agents.

Applicants requesting data from CHIA will be provided with data following the execution of a Data Use Agreement that requires the Data Applicant to adhere to processes and procedures aimed at preventing unauthorized access, disclosure or use of data.

By my signature below, I attest to: (1) the accuracy of the information provided herein; (2) that the requested data is the minimum necessary to accomplish the purposes described herein; (3) the Data Applicant will meet the data privacy and security requirements describe 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 (4) my authority to bind the organization seeking CHIA Data for the purposes described herein.

Signature: (Authorized Agent)	
Printed Name :	Dr. Russell Van Gelder
Title:	Professor and Chair
Signature: (Applicant/Primary Investigator)	
Name:	Dr. Cecilia Lee
Title:	Assistant Professor
Original Data Request Submission Date:	
Dates Data Request Revised:	

Attachments. Please indicate below which documents have been attached to the Application and uploaded to IRBNet:

- 1. IRB approval letter or summary of project (if applicable)
- 2. Resumes of Applicant and co-investigators
- 3. Data Management Plan (for each institution that will store CHIA Data)