Commonwealth of Massachusetts
Center for Health Information & Analysis (CHIA)
Non-Government APCD Request for Data

This form is to be used by all applicants, except Government Agencies, as defined in 957 CMR 5.02.

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

I. GENERAL INFORMATION

APPLICANT INFORMATION	
Applicant Name:	Nathaniel Rickles
Title:	Associate Professor of Pharmacy Practice & Administration
Organization:	Northeastern University School of Pharmacy
Project Title:	Exploring Factors Affecting Medication Adherence Trajectories
Mailing Address:	218 TF, 140 The Fenway
Telephone Number:	(617) 373-7721
Email Address:	n.rickles@neu.edu
Names of Co-Investigators:	
Email Addresses of Co-Investigators:	
Original Data Request Submission Date:	March 10, 2015
Dates Data Request Revised:	
Project Objectives (240 character limit)	To determine the most significant factors affecting the time to initial medication non-adherence after starting a new chronic medication. To develop an explanatory model for factors affecting the time to initial medication non-adherence after starting a new chronic medication.
Project Research Questions (if applicable)	1. What is the average length of time to first and second consecutive points of non-adherence across different chronic medications? 2. What patient demographic and clinical characteristics, drug, pharmacy, prescriber, insurer, geographic and other factors affect the length of time to the first and second consecutive points of medication non-adherence associated with the start of a new medication across multiple chronic conditions? 3. What are the most significant factors predicting the length of time to the first and second consecutive points of medication non-adherence associated with the start

	of a new medication across multiple chronic conditions?

II. PROJECT SUMMARY

Briefly describe the purpose of your project and how you will use the requested CHIA data to accomplish your purpose.

The purpose of the present project is to examine the factors associated with length of time to first and second consecutive points of medication non-adherence after starting a new chronic medication. It has been well described that initial medication adherence is critical to establishing a chronic pattern of medication adherence after starting a new medication. Individuals who become non-adherent during the initial months of therapy are more likely to remain non-adherent during later stages of therapy. There are no known explorations about the factors that affect the time course to initial medication non-adherence. Through such a longitudinal exploration using CHIA pharmacy data, we aim to identify potential intervention targets for a subsequent study to reduce initial medication non-adherence and promote sustained optimal medication adherence.

III. FILES REQUESTED

Please indicate the databases from which you seek data, and the year(s) of data requested.

ALL PAYER CLAIMS DATABASE	Single or Multiple Use	Year(s) Of Data Requested Current Yrs. Available 2009 – 2013
☐Medical Claims	☐Single Use ☐Multiple Use	☐2009 ☐2010 ☐2011 ☐2012 ☐2013
☒Pharmacy Claims	☐Single Use ☒Multiple Use	☐2009 ☐2010 ☒2011 ☒2012 ☒2013
☐Dental Claims	☐Single Use ☐Multiple Use	☐2009 ☐2010 ☐2011 ☐2012 ☐2013
☒Member Eligibility	☒Single Use ☒Multiple Use	☐2009 ☐2010 ☒2011 ☒2012 ☒2013
☒Provider	☐Single Use ☒Multiple Use	☐2009 ☐2010 ☒2011 ☒2012 ☒2013
☐Product	☐Single Use ☐Multiple Use	☐2009 ☐2010 ☐2011 ☐2012 ☐2013

IV. REQUESTED DATA ELEMENTS [APCD Only]

State and federal privacy laws limit the use of individually identifiable data to the minimum amount of data needed to accomplish a specific project objective. Please use the APCD Data Specification Workbook to identify which data elements you would like to request and attach this document to your application.

V. FEE INFORMATION

Please consult the fee schedules for APCD data) and Case Mix data, available at http://chiamass.gov/regulations/#957_5, and select from the following options:

APCD Applicants Only

☒ Academic Researcher
☐ Others (Single Use)
☐ Others (Multiple Use)

Are you requesting a fee waiver?

☐ Yes
☒ No

If yes, please submit a letter stating the basis for your request. 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.

VI. MEDICAID DATA [APCD Only]

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 with the administration of the Medicaid program. If you are requesting Medicaid data from Level 2 or above, please describe in detail why your use of the data meets this requirement. Applications requesting 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. MassHealth may impose additional requirements on applicants for Medicaid data as necessary to ensure compliance with federal laws and regulations regarding Medicaid.

> The proposal is focused on improving medication adherence which is a critical goal of the administration of an efficient and less costly Medicaid program. The achievement of this goal will also help reduce Medicaid healthcare costs (hospitalizations, ER visits, etc.).

VII. FILTERS

If you are requesting APCD elements from Level 2 or above, describe any filters you are requesting to use in order to limit your request to the minimum set of records necessary to complete your project. (For example, you may only need individuals whose age is less than 21, claims for hospital services only, or only claims from small group projects.)

APCD FILE	DATA ELEMENT(S) FOR WHICH FILTERS ARE REQUESTED	RANGE OF VALUES REQUESTED
Medical Claims		
Pharmacy Claims		
Dental Claims		
Membership Eligibility		

Provider		
Product		

IX. PURPOSE AND INTENDED USE

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

> Medication non-adherence is associated with several negative patient outcomes including poor clinical outcomes, greater morbidity and mortality. In addition, medication non-adherence costs the United States over an estimated $290 billion annually in direct and indirect costs. There is great need to characterize medication adherence trajectories (in particular initial medication non-adherence) so we might identify additional targets for subsequent intervention.

2. **Attach** a brief (1-2 pages) description of your research methodology. (This description will not be posted on the internet.)

3. Has your project received approval from your organization's Institutional Review Board (IRB)? Please note that CHIA will not review your application until IRB documentation has been received (if applicable).
   - ☐ Yes, and a copy of the approval letter is attached to this application.
   - ☒ No, the IRB will review the project on _____.
   - ☐ No, this project is not subject to IRB review.
   - ☐ No, my organization does not have an IRB.

X. APPLICANT QUALIFICATIONS

1. Describe your qualifications to perform the research described or accomplish the intended use of CHIA data.

> I am both a clinical pharmacy doctorate and a PhD in the social and administrative sciences providing the analytic training to design and evaluate medication use data. In particular, I have done prior research in medication adherence.

2. Attach résumés or curricula vitae of the applicant/principal investigator, key contributors, and of all individuals who will have access to the data. (These attachments will not be posted on the internet.)

XI. 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, will the CHIA Data be linked or merged to other individual patient level data (e.g. disease registries, death data), individual provider level data (e.g., American Medical Association Physician Masterfile) , facility level (e.g., American Hospital Association data) or with aggregate data (e.g., Census data)? [check all that apply]
   - ☐ Individual Patient Level Data

What is the purpose of the linkage:

What databases are involved, who owns the data and which specific data elements will be used for linkage:

☐ Individual Provider Level Data

What is the purpose of the linkage:

What databases are involved, who owns the data and which specific data elements will be used for linkage:

☐ Individual Facility Level Data

What is the purpose of the linkage:

What databases are involved, who owns the data and which specific data elements will be used for linkage:

☐ Aggregate Data

What is the purpose of the linkage:

What databases are involved, who owns the data and which specific data elements will be used for linkage:

3. 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 .

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

5. If yes, and the data mentioned above is not in the public domain, please attach a letter of agreement or other appropriate documentation on restrictions of use from the data owner corroborating that they agree to have you initiate linkage of their data with CHIA data and include the data owner's website.

XII. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Describe your plans to publish or otherwise disclose CHIA Data, or any data derived or extracted from such data, in any paper, report, website, statistical tabulation, seminar, conference, or other setting.

We do plan to publish the data in a pharmacy or health services research journal. We are only interested in publishing data in the aggregate form and not to identify any individual or organization. We also plan to present data at scientific meetings such as the American Pharmacists Association, AcademyHealth, and/or the American Public Health Association.

2. Will the results of your analysis be publicly available to any interested party? Please describe how an interested party will obtain your analysis and, if applicable, the amount of the fee.

Our analysis will be made available to the public in the form of a published manuscript or presented data at a professional meeting. There will be no other effort to disseminate information to separate entities and no collection of any fees.

3. Will you use the data for consulting purposes?

☐ Yes
☐ No

4. Will you be selling standard report products using the data?

☐ Yes
☐ No

5. Will you be selling a software product using the data?

☐ Yes
☐ No

6. Will you be reselling the data?

☐ Yes
☐ No

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

7. If you have answered "yes" to questions 3, 4 or 5, please describe the types of products, services or studies.

XIII. USE OF AGENTS AND/OR 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:	

8. Will the agent/contractor have access to the data at a location other than your location, your off-site server and/or your database?

   ☐ Yes
   ☐ No

   If yes, please provide information about the agent/contractor's data management practices, policies and procedures in your Data Management Plan.

9. Describe the tasks and products assigned to this agent or contractor for this project.

10. Describe the qualifications of this agent or contractor to perform such tasks or deliver such products.

11. Describe your oversight and monitoring of the activity and actions of this agent or subcontractor.

XIV. ASSURANCES

Applicants requesting and receiving data from CHIA pursuant to 957 CMR 5.00 ("Data Recipients") will be provided with data following the execution of a data use agreement that requires the Data Recipient to adhere to processes and procedures aimed at preventing unauthorized access, disclosure or use of data, as detailed in the DUA and the applicant's CHIA-approved Data Management Plan.

Data Recipients are further subject to the requirements and restrictions contained in applicable state and federal laws protecting privacy and data security, and will be required to adopt and implement policies and procedures designed to protect CHIA data in a manner consistent with the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

By my signature below, I attest to: (1) the accuracy of the information provided herein; (2) my organization's ability to meet CHIA's minimum data security requirements; and (3) my authority to bind the organization seeking CHIA data for the purposes described herein.

Signature:	
Printed Name:	Nathaniel M. Rickles, Pharm.D., Ph.D.
Title	Asscociate Professor of Pharmacy Practice & Administration
Original Data Request Submission Date:	
Dates Data Request Revised:	