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

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

I. GENERAL INFORMATION

APPLICANT INFORMATION	
Applicant Name:	Roy H Perlis, MD MSc
Title:	Director of MGH Psychiatry Center for Experimental Drugs and Diagnostics (CEDD); Associate Professor at Harvard Medical School
Organization:	Massachusetts General Hospital
Project Title:	Medication adverse effect burden scores to stratify risk for hospital readmission
Date of Application:	10/30/13
Project Objectives (240 character limit)	To validate a set of risk prediction models based on medication adverse effects. These models can be used for quality-improvement initiatives to identify individuals most likely to benefit from targeted interventions.
Project Research Questions	1. How common are hospital admissions or readmissions for fall, delirium, and other potential neurologic and psychiatric adverse events? 2. What sociodemographic and clinical features are most strongly associated with these admissions or readmissions? 3. How strongly are predicted medication adverse effects associated with these admissions or readmissions, after accounting for the predictors identified in question #2? 4. How well do prediction models using sociodemographic and clinical features, as well as medication adverse effect scores, stratify risk for admissions or readmissions?

Please indicate if you are a Researcher, Payer, Provider or Provider Organization and you are seeking data pursuant to 957 CMR 5.04 (De-Identified Data) or 957 CMR 5.05 (Direct Patient Identifiers for Treatment or Coordination of Care).

◉ Researcher ○ Payer ○ Provider / Provider Organization	○ 957 CMR 5.04 (De-identified Data) ○ 957 CMR 5.05 (Direct Patient Identifiers)

All other requests are subject to 957 CMR 5.06.

II. PROJECT SUMMARY

Briefly describe the purpose of your project and how you will use the CHIA data?

An important contributor to preventable health care costs is medication adverse effects[1], particularly among older patient populations exposed to multiple medications with overlapping adverse effect profiles. Among these, the consequences of fall can be substantial[2,3] – for example, falls represent the leading cause of death caused by injury among elderly patients[4], and a major contributor to placement in long-term care facilities[5]. A means of identifying individuals at particularly high risk for these outcomes solely based upon clinical risk factors could allow for targeted interventions aimed at reducing risk, which may otherwise be too costly to apply in unselected patient populations[5].

To date, the majority of such prediction rules require assessment of patients by a skilled clinician[3,6-8] or use of a specialized device[9] , and focus on relatively small or specific subgroups[3]. Multiple prior studies have investigated overall anticholinergic adverse effect burden[10-12], but these models do not account for other cognitive effects, such as excessive sedation, which may not be associated with anticholinergic mechanisms.

The aim of the present study will be to validate the use of drug burden scores for stratifying risk for hospital admissions and emergency department visits for fall-related injuries. Individual sociodemographic and clinical features will be examined for association with falls, along with aggregate measures of medication adverse effects which have been developed by the investigators. Risk models developed based on data from one New England hospital will be further examined in this uniquely important data set.

1. Bates DW, Spell N, Cullen DJ, et al. The costs of adverse drug events in hospitalized patients. Adverse Drug Events Prevention Study Group. JAMA 1997;277:307-11.
2. Bohl AA, Phelan EA, Fishman PA, Harris JR. How are the costs of care for medical falls distributed? The costs of medical falls by component of cost, timing, and injury severity. The Gerontologist 2012;52:664-75.
3. da Costa BR, Rutjes AW, Mendy A, Freund-Heritage R, Vieira ER. Can falls risk prediction tools correctly identify fall-prone elderly rehabilitation inpatients? A systematic review and meta-analysis. PLoS One 2012;7:e41061.
4. Preventing falls among older adults. 2007. (Accessed September 1, 2013, 2013, at http://www.cdc.gov/ncipc/duip/preventadultfalls.htm.)
5. Health Quality O. Prevention of falls and fall-related injuries in community-dwelling seniors: an evidence-based analysis. Ontario health technology assessment series 2008;8:1-78.
6. Nystrom A, Hellstrom K. Fall risk six weeks from onset of stroke and the ability of the Prediction of Falls in Rehabilitation Settings Tool and motor function to predict falls. Clinical rehabilitation 2013;27:473-9.
7. Baetens T, De Kegel A, Calders P, Vanderstraeten G, Cambier D. Prediction of falling among stroke patients in rehabilitation. Journal of rehabilitation medicine : official journal of the UEMS European Board of Physical and Rehabilitation Medicine 2011;43:876-83.
8. Ryan JJ, McCloy C, Rundquist P, Srinivasan V, Laird R. Fall risk assessment among older adults with mild Alzheimer disease. Journal of geriatric physical therapy 2011;34:19-27.
9. Sterke CS, van Beeck EF, Looman CW, Kressig RW, van der Cammen TJ. An electronic walkway can predict short-term fall risk in nursing home residents with dementia. Gait & posture 2012;36:95-101.
10. Duran CE, Azermai M, Vander Stichele RH. Systematic review of anticholinergic risk scales in older adults. Eur J Clin Pharmacol 2013;69:1485-96.
11. Pasina L, Djade CD, Lucca U, et al. Association of anticholinergic burden with cognitive and functional status in a cohort of hospitalized elderly: comparison of the anticholinergic cognitive burden scale and anticholinergic risk scale: results from the REPOSI study. Drugs Aging 2013;30:103-12.
12. Mangoni AA, van Munster BC, Woodman RJ, de Rooij SE. Measures of Anticholinergic Drug Exposure, Serum Anticholinergic Activity, and All-cause Postdischarge Mortality in Older Hospitalized Patients with Hip Fractures. Am J Geriatr Psychiatry 2013;21:785-93.

III. FILES REQUESTED

Please indicate the databases from which you seek data, the Level(s) and Year(s) of data sought.

DATABASE	Level 1[1] or 2[2]	Single or Multiple Use	Year(s) Of Data Requested Current Yrs. Available 2009 - 2011
☑ Medical Claims	☑ Level 1 ☑ Level 2	Single	☑ 2009 ☑ 2010 ☑ 2011
☐ Pharmacy Claims	☑ Level 1 ☑ Level 2	Single	☑ 2009 ☑ 2010 ☑ 2011
☐ Dental Claims	☐ Level 2	Select...	☐ 2009 ☐ 2010 ☐ 2011
☐ Member Eligibility	☑ Level 2	Single	☑ 2009 ☑ 2010 ☑ 2011
☐ Provider	☐ Level 2	Select...	☐ 2009 ☐ 2010 ☐ 2011
☐ Product	☐ Level 2	Select...	☐ 2009 ☐ 2010 ☐ 2011

CASEMIX	Level 1 - 6	Fiscal Years Requested
Inpatient Discharge	☐ Level 1 – No Identifiable Data Elements ☐ Level 2 – Unique Physician Number (UPN) ☐ Level 3 – Unique Health Information Number (UHIN) ☐ Level 4 – UHIN and UPN ☐ Level 5 – Date(s) of Admission; Discharge; Significant Procedures ☐ Level 6 – Date of Birth; Medical Record Number; Billing Number	1998-2012 Available (limited data available 1989-1997)
Outpatient Observation	☐ Level 1 – No Identifiable Data Elements ☐ Level 2 – Unique Physician Number (UPN) ☐ Level 3 – Unique Health Information Number (UHIN) ☐ Level 4 – UHIN and UPN ☐ Level 5 – Date(s) of Admission; Discharge; Significant Procedures ☐ Level 6 – Date of Birth; Medical Record Number; Billing Number	2002-2011 Available

[1] Level 1 Data: De-identified data containing information that does not identify an individual patient and with respect to which there is no reasonable basis to believe the data can be used to identify an individual patient. This data is de-identified using standards and methods required by HIPAA.

[2] Level 2 (and above) Data: Includes those data elements that pose a risk of re-identification of an individual patient.

Emergency Department	☐ Level 1 – No Identifiable Data Elements ☐ Level 2 – Unique Physician Number (UPN) ☐ Level 3 – Unique Health Information Number (UHIN) ☐ Level 4 – UHIN and UPN; Stated Reason for Visit ☐ Level 5 – Date(s) of Admission; Discharge; Significant Procedures ☐ Level 6 – Date of Birth; Medical Record Number; Billing Number	2000-2011 Available

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. MEDICAID DATA

Federal law (42 USC 1396a(a)7) restricts the use of individually identifiable data of Medicaid recipients to uses that benefit 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 benefits the administration of the Medicaid program.

Validation of a tool developed to stratify risk for outcomes precipitated by medication adverse effects will allow targeted interventions to reduce those risks. This will benefit the administration of the Medicaid program through the potential reduction of health care costs and the increase precision in targeting patient populations (within the Medicaid program) that are more vulnerable to medication adverse effects and consequences of these adverse effects.

VI. MEDICARE DATA

Medicare data may be disseminated to state agencies and/or entities conducting research projects that are directed and partially funded by the state if such research projects would allow for a Privacy Board or an IRB to make the findings listed at 45 CFR 164.512(i)(2)(ii) if the anticipated data recipient were to apply for the data from CMS directly. If you are requesting Medicare data, please explain how your research project is directed and partially funded by the state and describe in detail why your proposed project meets the criteria set forth in 45 CFR 164.512(i)(2)(ii). Applicants must describe how they will use the data and inform CHIA where the data will be housed. CHIA must be informed if the data has been physically moved, transmitted, or disclosed.

N/A

VII. DIRECT PATIENT IDENTIFIERS[3]

State and federal privacy laws may require the consent of Data Subjects prior to the release of any Direct Patient Identifiers. If you are requesting data that includes Direct Patient Identifiers, please provide documentation of patient consent or your basis for asserting that patient consent is not required.

[3] Direct Patient Identifiers. Personal information, such as name, social security number, and date of birth, that uniquely identifies an individual or that can be combined with other readily available information to uniquely identify an individual.

VII. REQUESTS PURSUANT TO 957 CMR 5.04

Payers, providers, provider organizations and researchers seeking access to Level 1 (de-identified) data are required to describe how they will use such data for the purposes of lowering total medical expenses, coordinating care, benchmarking, quality analysis or other administrative research purposes. Please provide this information below.

Hospital admissions precipitated by medication adverse effects are a major preventable contributor to health care costs. The identification of tools to stratify risk for these outcomes will enable the development of targeted interventions to reduce these risks, in two distinct ways. First, by identifying high-risk populations, it will allow for interventions to be applied in the patient populations most likely to benefit from them, with the greatest opportunity to reduce costs and improve outcomes. Second, because these models rely on aggregate measures of risk associated with medications, they may facilitate the development of specific interventions aimed at addressing medication adverse effects. However, a critical next step to enable clinical dissemination is refining and validating these models outside of a single academic health system.

IX. 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	all	age >=40 years
Pharmacy Claims	all	age >=40 years
Dental Claims		
Membership Eligibility	all	age >=40 years
Provider		
Product		

X. PURPOSE AND INTENDED USE

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

As mentioned previously, hospital admissions precipitated by medication adverse effects are a major preventable contributor to health care costs. Identifying tools that can stratify risk for those outcomes is within public interest because they may facilitate the development of interventions and prevent greater cost to the public.

2. **Attach** a brief (1-2 pages) description of your research methodology. (This description will not be posted on the internet.) Please see attached document "Methods for APCD data request."

3. Has your project received approval from your organization's Institutional Review Board (IRB)?

☑ 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.

XI. APPLICANT QUALIFICATIONS

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

Dr. Roy Perlis is Director of the Center for Experimental Drugs and Diagnostics in the Department of Psychiatry and the Center for Human Genetic Research at Massachusetts General Hospital, and Associate Professor of Psychiatry at Harvard Medical School. His research over the past decade is focused on the identification of outcome predictors in medicine, and specifically on the development of clinical and biological risk stratification measures. He has particular expertise in the use of large-scale clinical data sets, including claims data and electronic health records, for pharmacovigilance studies. As a geneticist, Dr. Perlis also has deep experience in safeguarding sensitive clinical data sets.

Mr. Victor Castro is Corporate Team Lead of the Phenotyping Center at Partner HealthCare Research Information Systems. His research work includes extracting and validating clinical, sociodemographic and behavioral phenotypes from electronic health records using novel statistical, epidemiological and visualization methods. Mr. Castro has particular expertise in a number of software tools for mining large clinical datasets, including the i2b2 framework, Microsoft SQL Server, R and JavaScript.

2. Attach résumés or curriculum 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.)

XII. DATA LINKAGE AND FURTHER DATA ABSTRACTION

1. Does your project require linking the CHIA Data to another dataset? YES ☐ NO ☑

2. If yes, will the CHIA Data be linked to other patient level data or with aggregate data (e.g. Census data)?

   Patient Level Data ☐ Aggregate Data ☐

3. If yes, please identify all linkages proposed and explain the reasons(s) that the linkage is necessary to accomplish the purpose of the project.

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

XIII. 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, or similar document.

Study results may be published or presented. Any data published from this study will be done in aggregate form. No patient identifiers will be included in any form of publication.

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.

Yes, the results will be published and made available to any interested party, free of charge, via PubMed Central.

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

N/A

XIV. 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:	N/A
Contact Person:	
Title:	
Address:	
Telephone Number:	
E-mail Address:	
Organization Website:	

1. Will the agent/contractor have access to the data at a location other than your location or in an off-site server and/or database? YES ☐ NO ☐

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

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

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