Commonwealth of Massachusetts
Center for Health Information & Analysis (CHIA)
Non-Governmental Application for Case Mix 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 schedule 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:	Robert W. Yeh, MD, MSc, MBA
Title:	Director, The Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology
Organization:	Beth Israel Deaconess Medical Center
Project Title:	Long-Term Resource Utilization, Readmissions, and Outcomes after Acute Myocardial Infarction or Percutaneous Coronary Intervention
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Names of Co-Investigators:	Eric Secemsky, MD; Dan Kramer, MD; Yun Wang, PhD
Email Addresses of Co-Investigators:	esecemsky@mgh.harvard.edu; dkramer@bidmc.harvard.edu; yunwang@hsph.harvard.edu
Original Data Request Submission Date:	6/22/2016
Dates Data Request Revised:	
Project Objectives (240 character limit)	Our goal is to determine the frequency and clinical impact of out-of-hospital events after AMI or PCI, the burden of resources allocated to the management of these patients, and whether confounding factors such as medication use and compliance contribute to these future events.
Project Research Questions (if applicable) or Business Use Case(s):	The current proposal has 4 main aims: 1. Explore short- and long-term readmission rates, indications for readmission, and outcomes among patients in Massachusetts who have either been admitted for AMI or have undergone PCI. 2. Determine the utilization of outpatient resources, such as non-invasive testing and cardiac rehabilitation services, for the ambulatory management of AMI and PCI patients. 3. Investigate whether medication compliance, including use of antiplatelet agents and statins, and use of high risk medications, such as oral anticoagulants, contribute to the risk of post-discharge events following AMI or PCI.

	4. Analyze whether inclusion of longitudinal patient data can improve risk models for the prediction of out-of-hospital events, including readmission and death, following hospitalization for either AMI or PCI.

II. PROJECT SUMMARY

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

Acute myocardial infarction (AMI) is a frequent cause of disability[1] and a leading cause of death in the United States[2]. Primary percutaneous coronary intervention (PCI) is the widely accepted treatment for patients presenting with AMI[3], and with nearly 600,000 PCIs performed in 2010[4], is the most commonly conducted cardiovascular procedure in the United States. For patients with AMI who have not undergone PCI, there is a higher risk of subsequent cardiovascular events and death[5], as well as a larger burden of resource utilization[6]. In addition, between 7-10% of PCIs are associated with procedural complications, including recurrent ischemia[7] and bleeding[8]. The risk for ischemia and bleeding can persist for years following AMI or PCI and is associated with significant morbidity and mortality[9,10]. Yet most published literature exploring predictors of adverse outcomes associated with AMI or PCI have been limited to events occurring while in-hospital or shortly following discharge[11,12]. As such, there is a need to determine the frequency and clinical impact of out-of-hospital events after AMI or PCI, the burden of resources allocated to the management of these patients, and whether other confounding factors, including use of high-risk medications and compliance with medical therapies, contribute to the development of future events.

To accomplish the study aims, we propose to use the Massachusetts Center for Health Information and Analysis (CHIA) All-Payer Claims Database (APCD) and Case Mix Database, which will allow us to identify all patients who have either been hospitalized with an acute myocardial infarction or undergone a percutaneous coronary intervention in Massachusetts and provide us with the associated inpatient and longitudinal ambulatory claims data. The MA APCD includes data on coverage and services for the vast majority of Massachusetts residents with public or private insurance. It includes data from both health insurance carriers and third party administrators. From the APCD, we will specifically be requesting medical, prescription, member eligibility, and provider files between 2010 and 2014. The Case Mix Database contains an inpatient discharge database spanning the years 1998-2014, an outpatient observation database spanning the years 2002-2014, and an emergency department database spanning the years 2000-2014. We will be requesting those claims pertaining to patients with a hospitalization for AMI or PCI, with a focus on the years of 2010 through 2014 in order to link inpatient and outpatient claims data between the APCD and Case Mix Databases.

References:

1. Murray CJ, Vos T, Lozano R, et al. Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet. 2012;380(9859):2197-2223.

2. Moran AE, Forouzanfar MH, Roth GA, et al. The global burden of ischemic heart disease in 1990 and 2010: the Global Burden of Disease 2010 study. Circulation. 2014;129(14):1493-1501.

3. Keeley EC, Hillis LD. Primary PCI for myocardial infarction with ST-segment elevation. The New England journal of medicine. 2007;356(1):47-54.

4. Chan PS, Patel MR, Klein LW, et al. Appropriateness of percutaneous coronary intervention. Jama. 2011;306(1):53-61.

5. A clinical trial comparing primary coronary angioplasty with tissue plasminogen activator for acute myocardial

infarction. The Global Use of Strategies to Open Occluded Coronary Arteries in Acute Coronary Syndromes (GUSTO IIb) Angioplasty Substudy Investigators. The New England journal of medicine. 1997;336(23):1621-1628.

6. Aasa M, Henriksson M, Dellborg M, et al. Cost and health outcome of primary percutaneous coronary intervention versus thrombolysis in acute ST-segment elevation myocardial infarction-Results of the Swedish Early Decision reperfusion Study (SWEDES) trial. American heart journal. 2010;160(2):322-328.

7. Cantor WJ, Tcheng JE, Blankenship JC, et al. Temporal spectrum of ischemic complications with percutaneous coronary intervention: the ESPRIT experience. The Journal of invasive cardiology. 2004;16(9):475-481.

8. Kazi DS, Leong TK, Chang TI, Solomon MD, Hlatky MA, Go AS. Association of spontaneous bleeding and myocardial infarction with long-term mortality after percutaneous coronary intervention. Journal of the American College of Cardiology. 2015;65(14):1411-1420.

9. Secemsky EA, Matteau A, Yeh RW, et al. Comparison of Short- and Long-Term Cardiac Mortality in Early Versus Late Stent Thrombosis (from Pooled PROTECT Trials). The American journal of cardiology. 2015;115(12):1678-1684.

10. Genereux P, Giustino G, Witzenbichler B, et al. Incidence, Predictors, and Impact of Post-Discharge Bleeding After Percutaneous Coronary Intervention. Journal of the American College of Cardiology. 2015;66(9):1036-1045.

11. Marso SP, Amin AP, House JA, et al. Association between use of bleeding avoidance strategies and risk of periprocedural bleeding among patients undergoing percutaneous coronary intervention. Jama. 2010;303(21):2156-2164.

12. Peterson ED, Dai D, DeLong ER, et al. Contemporary mortality risk prediction for percutaneous coronary intervention: results from 588,398 procedures in the National Cardiovascular Data Registry. Journal of the American College of Cardiology. 2010;55(18):1923-1932.

III. FILES REQUESTED

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

CASE MIX	Levels 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 **PLEASE PROVIDE JUSTIFICATION BELOW FOR REQUESTING THE CHOSEN LEVEL:** Level 5 data (admission date, discharge date, and significant procedures) is needed to examine treatment utilization patterns for patients presenting with AMI or undergoing PCI.	1998 – 2014 Available (limited data 1989-1997) 2010-2014
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 **PLEASE PROVIDE JUSTIFICATION BELOW FOR REQUESTING THE**	2002 – 2014 Available 2010-2014

	CHOSEN LEVEL: Level 5 data (admission date, discharge date, and significant procedures) is needed in order to explore short- and long-term readmission rates, indications for readmission, and outcomes among patients who have experienced AMI or undergone PCI.	
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 ☒Level 5 – Date(s) of Admission; Discharge; Significant Procedures ☐Level 6 – Date of Birth; Medical Record Number; Billing Number **PLEASE PROVIDE JUSTIFICATION BELOW FOR REQUESTING THE CHOSEN LEVEL:** Level 5 data (admission date, discharge date, and significant procedures) is needed in order to explore short- and long-term readmission rates, indications for readmission, and outcomes among patients who have experienced AMI or undergone PCI.	2000 – 2014 Available 2010-2014

IV. FEE INFORMATION

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

☐ Single Use
☐ Limited Multiple Use
☒ 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.

V. REQUESTS PURSUANT TO 957 CMR 5.04 (Researchers, Payers, Providers, and Provider Organizations)
Please complete only if you are requesting Level 1 (de-identified) Case Mix.

Please describe how you will use such data for the purposes of lowering total medical expenses, coordinating care, benchmarking, quality analysis or other administrative research purposes.

VI. ALL OTHER REQUESTS - PURPOSE AND INTENDED USE

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

Acute myocardial infarction (AMI) is a frequent cause of disability and a leading cause of death in the United States. Primary percutaneous coronary intervention (PCI) is the widely accepted treatment for patients presenting with AMI, and with nearly 600,000 PCIs performed in 2010, is the most commonly conducted cardiovascular procedure in the United States. For patients with AMI who have not undergone PCI, there is a higher risk of subsequent cardiovascular events and death, as well as a larger burden of resource utilization. In addition, between 7-10% of PCIs are associated with procedural complications, including recurrent ischemia and bleeding. The risk for ischemia and bleeding can persist for years following AMI or PCI and is associated with significant morbidity and mortality. The results of the proposed research will be intended for publication in academic medical journals, and will be used to improve scientific understanding of factors which influence outcomes for PCI patients.

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.

4.

VII. APPLICANT QUALIFICATIONS

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

Dr. Robert W. Yeh is the Director of the Richard and Susan Smith Center for Outcomes Research in Cardiology at the Beth Israel Deaconess Medical Center, and Assistant Professor of Medicine at Harvard Medical School. His area of investigation focuses on evaluating cardiovascular devices and therapies in both clinical trials and observational studies, with an emphasis on understanding methods to improve the value of novel technologies as they are used in clinical practice. He serves as the Medical Director of Trial Design for the Harvard Clinical Research Institute. His clinical area of expertise is in interventional cardiology, with an emphasis in coronary chronic total occlusion intervention.

Dr. Eric Secemsky, MD, MSc is a cardiologist and research fellow at Massachusetts General Hospital and the Smith Center for Outcomes Research in Cardiology. Dr. Secemsky holds an MS in Epidemiology from the Harvard School of Public Health. His interest is in comparative effectiveness research of therapies related to percutaneous coronary interventions, including use of peri-procedural and long-term anticoagulants. In addition, has served as the Assistant Director of Trial Design at the Harvard Clinical Research Institute since 2014, where he has been involved in the design and analysis of both large and small-scale clinical trials. Dr. Secemsky has been published widely in top-tier journals and presented his original investigations nationally.

Yun Wang, PhD, is the statistician at the Smith Center for Outcomes Research and the Harvard School of Public Health. Dr. Wang has over 20 years of experience in analyzing Medicare claims data, having been the principal statistician involved with the creation of the Medicare 30-day mortality and readmissions metrics.

Dr. Daniel Kramer is a cardiologist and researcher at Beth Israel Deaconess Medical Center and the Smith Center for Outcomes Research in Cardiology. His research focuses on cardiovascular outcomes and health services, specifically investigating policy, performance, and ethical questions surrounding medical devices.

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.)

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, 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 that algorithm 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.

IX. 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.

The results of the proposed research will be intended for publication in academic medical journals, and will be used to improve scientific understanding of factors which influence outcomes for AMI and PCI patients.

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 findings will be only disseminated through peer-reviewed journals and national conferences.

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.

X. 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.

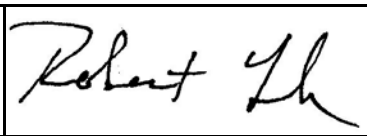
XIII. ASSURANCES

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.

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 practices to protect CHIA data in a manner consistent with the requirements of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Data Recipients must promptly notify CHIA of any unauthorized use or disclosure of CHIA data.

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:	
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Original Application Submission Date:	6/22/2016
Dates Application Revised:	