Commonwealth of Massachusetts Center for Health Information & Analysis (CHIA) Government Agency Application for MA APCD Data [Exhibit A: Data Application]

This Application is to be used by agencies, departments or authorities of the Commonwealth of Massachusetts, as well as agencies and departments of the United States of America ("Government Agencies"). Data requests from other states, as well as other political subdivisions of the Commonwealth of Massachusetts must use the Non-Government Agency Application. The Application must be signed by an authorized signatory of the Agency. This Application will be used by CHIA to determine if your Agency may receive the CHIA data requested. 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 Agency 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 Agency seeking CHIA Data for the purposes described herein.

All attachments must be uploaded to IRBNet with your Application. All applications documents can be found on the <u>CHIA website</u> in Word and/or PDF format.

I. GENERAL INFORMATION

APPLICANT INFORMATION		
Applicant Name:	Rosa Rodriguez-Monguio, PhD, MS	
(Primary Investigator)		
Title:	Associate Professor	
Government Agency Requesting Data:	Univesity of Massachusetts, Amherst	
(Recipient)		
Project Title:	Evaluation of Effectiveness & Cost-Effectiveness of Drug Courts	
IRBNet ID:		
Address, City/Town, Zip Code	715 North Pleasant St. 322 Arnold House	
Telephone Number:	413-545-7427	
Email Address:	rmonguio@schoolph.umass.edu	
Names of Co-Investigators:	Gina M Vincent, Ph.D.	
	Associate Professor of Psychiatry (Psychology)	
	University of Massachusetts Medical School (UMMS)	
	Ira K. Packer, Ph.D., ABPP (Forensic)	
	Clinical Professor of Psychiatry, UMMS	
	Dara Drawbridge, Ph.D.	
	Research Postdoctoral Fellow, UMMS	
Email Addresses of Co-Investigators:	Ira.Packer@umassmed.edu	
Original Request Submission Date:	February 1 st , 2017	
Dates Request Revised:	August 9, 2017	
Project Objectives (240 character limit)	In response to the Legislature requirement for a drug court evaluation the	
	Trial Court enlisted the Massachusetts (MA) Center of Excellence for Specialty	
	Courts at the University of Massachusetts Medical School (UMMS) to conduct	
	an evaluation of the drug courts. The objectives of this study are to assess the	
	effectiveness of the drug courts on adult probationers (cases) reducing	

	recidivism and substance abuse relapse rates compared to matched cohort r probationers in conventional courts (controls) and to evaluate the cost-effectiveness of the drug court intervention compared to a matched control-
	group of non-drug court probationers.
Project Research Questions (if applicable)	This study will answer the following questions:
	1. Are drug court probationers less likely than similar individuals placed on
	traditional probation to reoffend and to relapse?
	2. Are drug court services a cost-effective intervention compared to
	traditional courts to reduce recidivism and relapse?

II. PUBLIC PURPOSE & PROJECT SUMMARY

1. Briefly identify the public purpose(s) for which CHIA data are sought and how you will use the requested data to accomplish your public purpose(s).

In order to properly evaluate the effectiveness and cost-effectiveness of the Drug Court, as required by Chapter 165 of the Acts of 2014, researchers at UMass and UMMS need access to various data elements relating to Drug Court Probationers and matched cohort of probationers in the conventional courts that CHIA possesses. More specifically, we are requesting access to the APCD administrative claims data contained in the medical and pharmaceutical claims files along with eligibility, product and provider files. As part of the cost-effectiveness analysis, researchers at UMass and UMMS will assess and compare health care services utilization and cost (i.e., charges and paid amount) of probationers in both cohorts (cases and controls) for all health care services provided to probationers across levels of care along with pharmaceuticals. Our hypothesis is that probationers in the drug court will use less health care services and pharmaceuticals and thus, will incur in lower overall cost than probationers in the conventional courts. In addition, we hypothesize that probationers in the drug court will use less inpatient and emergency department care than probationers in the conventional court leading to lower cost of provision of care. Given the demographics of probationers, in particular the proportion of probationers relaying on public health coverage (e.g. MassHealth) study findings has the potential to inform the health and economic burden on health care services funded by the Commonwealth of Massachusetts.

 2. Has an Institutional Review Board (IRB) reviewed your project? 	ion package on IRBNet.
3. Do you plan to use CHIA data to identify individuals? If so, please describe your justification the research methodology. (See Section II.4 below) ☐ Yes ☑ No	on or research need clearly

4. **Research Methodology**: Applicants must provide 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. Applications that do not include this methodology statement cannot be reviewed or approved.

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 <u>each</u> file. Please refer to the <u>MA APCD Release Data Specifications</u> for details of the file contents.

MA ALL-PAYER CLAIMS DATABASE	Year(s) Of Data Requested Current Yrs. Available ☑ 2011 ☑ 2012 ☑ 2013 ☑ 2014 ☑ 2015
Medical Claims ☑ Level 2 ☐ Level 3	Please describe how your research objectives require Medical Claims data: Medical claims data are requested to compare health care services utilization and cost of probationers to conduct the cost-effectiveness analysis
Pharmacy Claims ☑ Level 2 ☐ Level 3	Please describe how your research objectives require Pharmacy Claims data: Pharmacy claims data are requested to compare health care services utilization and cost of probationers to conduct the cost-effectiveness analysis
Dental Claims ☐ Level 2 ☐ Level 3	Please describe how your research objectives require Dental Claims data:
Member Eligibility ☑ Level 2 ☐ Level 3	Please describe how your research objectives require Member Eligibility data: Member elegibility data are requested to assess socio-demographic of probationers. Member eleigibility demographics will be also used as control variables in the analysis.
Provider ⊠ Level 2 □ Level 3	Please describe how your research objectives require Provider data: Provider claims data are requested to compare health care services utilization and cost of services provided to probationers by level of care and specialty of the provider including values for provider specialty codes. Provider data will be used also as control variables in the analysis.
Product ⊠ Level 2 □ Level 3	Please describe how your research objectives require Product data: We are requesting product data to assess member enrollment/ elegibility. We are requesting product plan data to assess the type of insurance/payer applied to the claim line.
Benefit Plan¹ ☐ Level 3	Please describe how your research objectives require Benefit Plan data:
MassHealth Enhanced Eligibility File ² ☐ Level 3	Please describe how your research objectives require MassHealth Enhanced Eligibility data:

IV. REQUESTED DATA ELEMENTS

1. 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. CHIA requires Applicants to justify individually identifiable elements in order to conform tothese privacy laws. Please use the <u>APCD Government Data Specification Workbook</u> (Excel) to identify which data elements you are requesting and **attach** this document to your Application. Further, please provide justifications for any individually identifiable elements where it is required, as indicated in the APCD Data Specification Workbook.

¹ Benefit Plan file data has only been submitted starting in October 2013 and contains only Level 3 elements.

² MassHealth Enhanced Eligibility has only been submitted starting in 2012 and contains only Level 3 elements.

V. SUBSTANCE ABUSE RECORDS

1. Are you requesting substance abuse records subject to 42 CFR Part 2? Understanding the limitations under federal law (42 CFR Part 2) for the release of substance abuse data, if the Agency is requesting such data, we request that the Agency cite its authority under 42 CFR Part 2 that allows the release.
☑ Yes (Written authority pursuant to 42 CFR Part 2 provided by Agency's legal counsel must be attached)☐ No
VI. MEDICAID DATA
 1. Please indicate 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.
We are requesting level 2 (i.e., de-identified) Medicaid data. Given the demographics of our study population, more specifically the percentage of study participants covered by MassHealth, we are requesting MassHealth data. We are requesting MassHealth data to assess health care services provided and to estimate cost of provision of care to the Medicaid state program. The cost-effectiveness analysis may illuminate resources utilization and cost and well as potential savings to MassHealth for the cohort of probationers in the drug court compared to probationers in the conventional courts.
Government agencies approved to receive Medicaid data will be required to execute an Addendum [available on CHIA website and in the IRBNet document library] to CHIA's standard data use agreement, containing terms and conditions required by CHIA's data sharing agreement with MassHealth. MassHealth may impose additional requirements on applicants for Medicaid data as necessary to ensure compliance with federal laws and regulations regarding Medicaid.
VII. MEDICARE DATA
 1.Please indicate whether you are seeking Medicare Data:
Medicare data may only 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 CER 164 512(i)(2)(ii) ("Waiver Requirements") if the anticipated data recipient were to apply for the

Medicare data may only 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) ("Waiver Requirements") if the anticipated data recipient were to apply for the data from CMS directly. Please **attach** the IRB or Privacy Board waiver letter. If the Applicant does not have a waiver letter, CHIA may be able to determine that the research project meets the Waiver Requirements. Please answer the following questions and provide any additional information that may be helpful in making this determination:

2. The Agency has a plan, and will abide by the plan, to protect all Protected Health Information (PHI) (as defined under HIPAA) from use or disclosure not expressly permitted under this Application:

⊠ Yes
\square No
3. The Agency will destroy all PHI at the earliest opportunity, consistent with the executed Data Use Agreement with CHIA: ☑ Yes ☐ No
 4. The Agency will not disclose any PHI to any individual not authorized or legally required to use the PHI: ☑ Yes ☐ No
5. The Applicant cannot conduct the research without access to the PHI requested: ☐ Yes ☐ No
6. Briefly describe how you will use the Medicare data in the space below:
We are requesting level 2 (i.e., de-identified) Medicare data. Given the demographics of our study population, more specifically the percentage of study participants covered by Medicare as well as dual elegible (Medicare/Medicaid) study participants, we are requesting Medicare data. We are requesting Medicare data to assess health care sorvices provided

participants, we are requesting Medicare data. We are requesting Medicare data to assess health care services provided and to estimate cost of provision of care to the Medicare federal program. The cost-effectiveness analysis may illuminate resources utilization and cost and well as potential savings to Medicare for the cohort of probationers in the drug court compared to probationers in the conventional courts.

7. The Agency must inform CHIA of the location where the data will be stored and may not move the data to any other location without first informing CHIA.

All Addresses (where Medicare data will be stored):

Organization: University of Massachusetts, Amherst			
Street Address:715 Arnold House	City:Amherst	State: MA	ZIP Code: 01003
Office Telephone (Include Area Code): 413-545-7427			

Organization: University of Massachusetts Medical School, Chang Bldg			
Street Address: 222 Maple Ave	City: Shrewsbury	State: MA	ZIP Code: 01545
Office Telephone (Include Area Code): (508) 856-8727			

8. Applicants seeking Medicare data must complete a Medicare Request Form available on the CHIA website and in the IRBNet document library. Applicants approved to receive Medicare data will be required to execute an <u>Addendum</u> to CHIA's standard Data Use Agreement, containing terms and conditions required by CHIA's Data Use Agreement with CMS.

VIII. DATA LINKAGE AND FURTHER DATA ABSTRACTION

Note: Data linkage involves combining CHIA data with other databases 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.

\boxtimes	Yes, CHIA data will be linked or merged with individual patient level data
	If yes, will CHIA data be merged or linked using individually identifiable elements?
	⊠ Yes
	□ No
	Yes, CHIA data will be linked or merged with aggregate data
	No linkage or merger with any other database will occur

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

2. 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:

To analyze data pertaining to participants in the specialty Drug Court program, compared to matched cohort of non-drug court probationers, in order to evaluate the effectiveness and cost-effectiveness of the Drug Court program and to identify resources and opportunities available for improving the program outcomes, the Massachusetts Trial Court will put probationers' identifiers and randomized research IDs on a password-protected and encrypted flash drive to be hand delivered to the appropriate data parties at CHIA. CHIA will link the available case-level data by using the identifiers provided by the Trial Court to create analytic files that will include available record level data elements set forth on APCD data files as requested above and the random ID as an identifier. CHIA will not include any personal identifiers in the data files that will provide to researchers at UMass.

3. If yes, please describe the method or selected algorithm (e.g. deterministic or probabilistic) that will be used for linking each data set for each proposed linkage:

CHIA will perform the data linkages using the identifiers provided by the Trial Court to create APCD analytic files. CHIA will provide de-identified APCD data files to UMass researchers using the random ID provided by the Trial Court as an identifier. Researchers at UMass will merge de-identified data files from CHIA and store the merged file on a password protected folder on the password protected and encrypted server in the School of Public Health and Health Sciences.

4. If yes, please describe how your project methodology will prevent the identification of individuals in the linked dataset.

The linked dataset will not include any individual identifier. The linked dataset will only include random ID provided by the Trial Court as an identifier.

5. Once the linkage/merge is made, what non-MA APCD data elements will appear in the new linked file?

Once the linkage/merge is made the random ID provided by the Trial Court as an identifier will be included in the APCD dataset.

X. APPLICANT QUALIFICATIONS

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

Associate professor Rosa Rodriguez-Monguio, PhD, MS is a health economist and an established researcher with extensive experience in the areas pertinent to this study. She has served as PI or co-PI in several state and federal grants and have a prolific record of peer-reviewed publications for each project.

Dr. Rodriguez-Monguio has extensive competency in data analytics and experience collecting, triangulating and conducting large retrospective analysis using medical and administrative claims datasets including most relevant to this application APCD data (2009-2013). Two peer-reviewe publications using APCD data are currently in progress.

Dr. Rodriguez-Monguio's research focus on economic evaluation of health care services and pharmaceuticals and outcomes research. Through her research, Dr. Rodriguez-Monguio advances and applies a variety of quantitative methods to study access to health care services and pharmaceuticals and costs. Dr. Rodriguez-Monguio's research aim is to improve patient-level outcomes and contain healthcare cost. Her current studies assess drug utilization and safety (opioids, antipsychotics, antibiotics, antidiabetic drugs), cost-effectiveness of community-based interventions to reduce drug use and abuse and drug cost and the effect of generic drugs market entry.

Gina Vincent, Ph.D. is an Associate Professor of Psychiatry at UMass Medical School. She has a Ph.D. in Experimental Psychology with a specialization in forensic psychology. She has conducted many grant-funded studies of the outcomes of implementation of evidence-based practices in the justice system. She is currently the PI of the Drug Court Evaluation being conducted by the Center of Excellence for Specialty Courts (COE) at UMMS.

Dara Drawbridge, Ph.D. is a Research Postdoctoral Fellow of the COE at UMMS. She has a Ph.D. in Criminal Justice and has coordinated multiple justice-related and recidivism studies. Dr. Drawbridge has been coordinating much of the data collection for the COE's Drug Court Evaluation.

Ira K. Packer, Ph.D., Clinical Professor of Psychiatry, is the Director of the Massachusetts Center of Excellence for Specialty Courts (CoE). Through its contract with the Trial Court, the CoE is tasked with conducting this study of the effectiveness and cost-effectiveness of Drug Courts. Dr. Packer has extensive experience working with courts and State Agencies (including serving as Assistant Commissioner of Mental Health). In addition, he has conducted research and published on a variety of issues related to the interface between the legal system and individuals with mental health and substance abuse problems.

2. <u>Resumes/CVs</u>: Please include with your application package on IRBNet résumés or curricula vitae of the Applicant/principal investigator, and co-investigators. (These attachments will not be posted on the internet.)

Resumes for Drs. Rodriguez-Monguio, Gina Vincent, Ira Packer, and Dara Drawbridge are attached.

XI. USE OF AGENTS AND/OR CONTRACTORS

Please Note: by signing this Application, the Agency assumes all responsibility for the use, security and maintenance of the CHIA data by its Agents, including but not limited to contractors.

Provide the following information for all agents and contractors who will have access to the CHIA data. *Add agents or contractors as needed.*

Address, City/Town, Zip Code	715 North Pleasant St
Telephone Number:	413-545-7427
E-mail Address:	rmonguio@schoolph.umass.edu
Organization Website:	https://www.umass.edu/sphhs/person/faculty/rosa-rodriguez-monguio
1.Will the agent or contractor has site server and/or database?☐ Yes☒ No	ave access to or store the CHIA Data at a location other than the Applicant's location, off-
	cts assigned to this agent for this project; their qualifications for completing the tasks; ne agent, including how the Agency will ensure the security of the data to which the
Company Name:	
Contact Person:	
Title:	
Address, City/Town, Zip Code	
Telephone Number:	
E-mail Address:	
Organization Website:	
1.Will the agent or contractor has site server and/or database?☐ Yes☐ No	ave access to or store the CHIA Data at a location other than the Applicant's location, off-
	cts assigned to this agent for this project; their qualifications for completing the tasks; ne agent, including how the Agency will ensure the security of the data to which the

University of Massachusetts, Amherst

Rosa Rodriguez-Monguio, PhD, MS

Associate Professor

XII. DATA SECURITY, TRANSMISSION AND STORAGE

Company Name:

Contact Person:

Title:

All Recipients of CHIA data, including third parties, must comply with the privacy and security standards set forth under 45 CFR § 164.530(c) and any applicable federal or state privacy law, implementing regulation or executive order. In furtherance of this objective, please provide the following information.

1. All Addresses where data will be stored:

and passwords;

Organization: University	of Massachusetts, Amherst			
Street Address: 715 North Pleasant St		City: Amherst	State: MA	ZIP Code: 01003
Office Telephone (Inclu	ıde Area Code): 413-545-7427			
	cy of Massachusetts Medical So		1	1
Street Address: 222 Ma		City: shrewsbury	State: MA	ZIP Code: 01545
Office Telephone (Inclu	ide Area Code): (508) 856-872	7		
Agency will use: ☐ VPN ☑ Secure FTP ☐ Encrypted email deliv	data will be transmitted between ery system and identify why this method me	,, ,,		
-	between UMASS investigator Dr and encrypted UMMS FTP site - N	_	the coinvestiga	ator Dr. Vincent at
encryption requirements	s statement, you are attesting to a construct the state of the state o	of at least 128 bits in trans	sit.	ing data transfer
 ☑ The data will I ☑ Access to the accounts and ☑ Access to the ☑ Any data incluice ☑ Data must be data can be referention required ☐ Data with the study ☐ Data with one of the study ☐ Other 	d on a network drive - I attest that be stored in project specific folde data will be restricted to authorize passwords; data will be restricted by limiting ided in the network backup will be segregated from other Agency data moved from Agency computers a direments. Please identify which will be kept on media which will covill be stored in a logical contained data or project; OR will be stored in a database that continued in the project data will not be stored or pro	r; zed personnel by requiring folder access to authorize se encrypted with a key ler ata to ensure that at the co and/or destroyed consiste option(s) the Agency will ontain no other data; OR er on electronic media, suc ontains no other data. specify why you deem the	computer logated personnel or ngth of at least onclusion of the nt with privacy use to segregate has a partition	on with unique user nly; 256 bits. e study or project all y, security and record te the data: n or folder solely for
B. For Data store	d on the local hard drive of a com	nputer - I attest that the fo	ollowing require	ements will be met:

Access will be restricted to authorized personnel by requiring computer log-on with unique user accounts

When not in use, the computer will be stored in a locked container or locked room to which access is restricted to authorized personnel;
☐ For this study/project data will not be stored on a local hard drive or a computer.
C. For data on paper documents - I ensure that the following requirements will be met:
\square The data will be stored in a secure area only accessible by authorized personnel;
☐ When not in use, the data will be stored in locked container or locked room with access limited to authorized personnel;
□ For this study/project data will not be reduced to or stored in paper form.
D. For data that is being stored on a CD/DVD/Flash Drive - I attest that the following requirements will be met:
\square The data will not be transported out of a secure area only accessible by authorized personnel;
☐ The data will be encrypted with a key length of at least 256 bits;
☐ When not in use, the data will be stored in a locked cabinet or locked room to which access is restricted to authorized personnel.
☐ For this study/project data will not be stored on CD/DVD/Flash Drive

XIII. ATTESTATION

By submitting this Application, the Agency 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 Agency 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.

Government Agencies requesting data from CHIA will be provided with data following the execution of a Data Use Agreement, or pursuant to a specific data sharing agreement, that requires the Agency to adhere to processes and procedures aimed at preventing unauthorized access, disclosure or use of data.

By my signature below, I attest (1) to the accuracy of the information provided herein; (2) that the requested data is the minimum necessary to accomplish the purposes described herein; (3) the Agency 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, (4) my authority to bind the Agency seeking CHIA data for the purposes described herein.

Signature: (Authorized Agent)	Rose Cuangino
Printed Name:	Rosa Rodriguez-Monguio, PhD, MS
Title:	Associate Professor
Government Agency:	University of Massachusetts, Amherst
Original Request Submission Date:	February 1 st , 2016
Dates Request Revised:	August 9, 2017

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

\boxtimes	1. IRB approval letter and protocol (if applicable)
\boxtimes	2. 1-2 page Research Methodology
X	3. Resumes of Applicant and co-investigators
	4. Agency's legal counsel opinion re: requested 42 CFR Part 2 data
	5. Medicare data IRB or privacy board waiver letter
\boxtimes	6. APCD Data Specification Workbook with all requested individually identifiable elements justified