

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

This application 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 and Case Mix 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:	Susan K. Parsons, MD, MRP
Title:	Professor of Medicine and Pediatrics at Tufts University School of Medicine; Medical Director, Reid R. Sacco Adolescent and Young Adult Program for Cancer and Hereditary Blood Diseases
Organization:	Tufts Medical Center
Project Title:	Cost Effectiveness of Novel Oncolytics in Newly Diagnosed Hodgkin Lymphoma: External Validation Study using APCD
Date of Application:	July 28, 2014
Project Objectives (240 character limit)	Evaluate patterns of healthcare utilization and components of cost among patients with Hodgkin Lymphoma and determine cost modifiers and variability in spending by socio-demographic, clinical, and payer characteristics.
Project Research Questions (if applicable)	1. 2. 3.

I. PROJECT SUMMARY

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

While the majority of patients with Hodgkin Lymphoma (HL) have high rates of treatment success, a subset of patients still experience treatment failure, requiring salvage therapy and, often, hematopoietic cell transplantation (HSCT). Moreover, although cured of their disease, many HL survivors have substantially elevated mortality rates in the decades following treatment due to second cancers and end organ damage. Thus, the major challenge in the development of modern therapies is to optimize the balance between maintaining excellent disease control and minimizing treatment-related burden. Improved risk stratification methods, the addition of novel targeted approaches to radiation therapy, and incorporation of a novel oncolytic into the backbone of chemotherapy are all under evaluation to attain this balance. The cost effectiveness of a novel oncolytic is being examined in two ongoing Phase III trials—one for adults and another for children and adolescent. Our study team is leading the cost effectiveness for the latter study. The purpose of our APCD data request is to facilitate an analysis of

cost of standard therapy in the real world. The APCD data will allow us to delineate cost components during the initial treatment period and estimates of cost due to treatment failure, requiring salvage chemotherapy and possibly, HSCT. We will be collecting units of healthcare utilization in the clinical trial. We propose to assign population-level cost estimates to this healthcare utilization, using the APCD. We will also look at modifiers of cost and variability in spending by socio-demographic characteristics, comorbidity, and insurance. Population-level estimates of healthcare utilization, costs, and associated patterns of care are currently not available for children, adolescent, and adult HL patients. The project is being funded by the Leukemia & Lymphoma Society. We are not subject to any contractual conditions on publication or dissemination of findings.

II. FILES REQUESTED

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

ALL PAYER CLAIMS DATABASE	Level 1 ¹ or 2 ²	Single or Multiple Use	Year(s) Of Data Requested Current Yrs. Available 2009 - 2012
<input checked="" type="checkbox"/> Medical Claims	<input type="checkbox"/> Level 1 ³ <input checked="" type="checkbox"/> Level 2	Single	<input checked="" type="checkbox"/> 2009 <input checked="" type="checkbox"/> 2010 <input checked="" type="checkbox"/> 2011 <input type="checkbox"/> 2012
<input checked="" type="checkbox"/> Pharmacy Claims	<input checked="" type="checkbox"/> Level 2	Single	<input checked="" type="checkbox"/> 2009 <input checked="" type="checkbox"/> 2010 <input checked="" type="checkbox"/> 2011 <input type="checkbox"/> 2012
<input type="checkbox"/> Dental Claims <input checked="" type="checkbox"/> Member Eligibility <input checked="" type="checkbox"/> Provider <input type="checkbox"/> Product	<input type="checkbox"/> Level 2 <input checked="" type="checkbox"/> Level 2 <input checked="" type="checkbox"/> Level 2 <input type="checkbox"/> Level 2	Select... Single Single Select...	<input checked="" type="checkbox"/> 2009 <input checked="" type="checkbox"/> 2010 <input checked="" type="checkbox"/> 2011 <input type="checkbox"/> 2012

CASEMIX	Level 1 - 6	Fiscal Years Requested
Inpatient Discharge	<input type="checkbox"/> Level 1 – No Identifiable Data Elements <input type="checkbox"/> Level 2 – Unique Physician Number (UPN) <input type="checkbox"/> Level 3 – Unique Health Information Number (UHIN) <input type="checkbox"/> Level 4 – UHIN and UPN <input type="checkbox"/> Level 5 – Date(s) of Admission; Discharge; Significant Procedures <input type="checkbox"/> Level 6 – Date of Birth; Medical Record Number; Billing Number	<u>1998-2013 Available</u> (limited data 1989-1997)
Outpatient Observation	<input type="checkbox"/> Level 1 – No Identifiable Data Elements	<u>2002-2012 Available</u> (2013 available 8/1/14)

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.

³ Please note that Level 1 APCD data is not available as of 4/30/2014. This is scheduled to be available later in 2014.

	<input type="checkbox"/> Level 2 – Unique Physician Number (UPN) <input type="checkbox"/> Level 3 – Unique Health Information Number (UHIN) <input type="checkbox"/> Level 4 – UHIN and UPN <input type="checkbox"/> Level 5 – Date(s) of Admission; Discharge; Significant Procedures <input type="checkbox"/> Level 6 – Date of Birth; Medical Record Number; Billing Number	
Emergency Department	<input type="checkbox"/> Level 1 – No Identifiable Data Elements <input type="checkbox"/> Level 2 – Unique Physician Number (UPN) <input type="checkbox"/> Level 3 – Unique Health Information Number (UHIN) <input type="checkbox"/> Level 4 – UHIN and UPN; Stated Reason for Visit <input type="checkbox"/> Level 5 – Date(s) of Admission; Discharge; Significant Procedures <input type="checkbox"/> Level 6 – Date of Birth; Medical Record Number; Billing Number	2000-2012 Available (2013 available 9/1/14)

III. FEE INFORMATION

Please consult the fee schedules for APCD ([Administrative Bulletin 13-11](#)) and Case Mix data ([Administrative Bulletin 13-09](#)) and select from the following options:

APCD Applicants Only

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

Case Mix Applicants Only

- 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.

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 [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.

National data suggest that approximately 1/4 of adults and 1/3 of children/adolescents with HL are insured by Medicaid. Including the Medicaid claims in the APCD allows us to capture overall cost and cost components of healthcare utilization in this critical population. Excluding this population from the analysis would result in biased estimates. Moreover, inclusion of these claims will allow us to analyze cost modifiers and variability in spending by socio-demographic characteristics and payer status.

VI. REQUESTS PURSUANT TO 957 CMR 5.04

If you are a payer, provider, provider organization or researcher seeking access to Level 1 (de-identified) data, 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. Please provide this information below.

N/A

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		

VIII. PURPOSE AND INTENDED USE

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

This database analysis and the ongoing cost effectiveness analysis of the inclusion of a novel oncolytic in

the treatment of HL will provide stakeholders—patients and their families, physicians, payers, and policy makers-- with the much needed information about overall costs and benefits of alternative treatment approaches. The focus of this cost comparison will be the initial years following diagnosis.

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.

IX. APPLICANT QUALIFICATIONS

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

Dr. Parsons, a board certified pediatric hematologist/oncologist, specializes in the treatment of children, adolescents, and young adults with hematologic malignancies, including HL. She is also formally trained in health economics and has spent her career analyzing the financial and functional consequences of cancer care. To conduct the proposed analyses she has assembled a project team including experts in hematologic malignancies and survivorship, in addition to health economists with expertise in the analysis of administrative claims data.

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.)

X. 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. Please be specific in describing vwhich data elements will be linked to outside datasets and how this will be accomplished.

N/A

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

N/A

XI. 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.

Results of the analyses will be published in journals or discussed at conferences or meetings.

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.

The results of our analysis will be available publicly in the form of publications in journals or at conferences and meetings.

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

XII. 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:	

7. 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

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

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

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