

Commonwealth of Massachusetts
Center for Health Information & Analysis (CHIA)
Non-Governmental Application for Case Mix Data

This form is required by all Applicants, except Government Agencies as defined in 957 CMR 5.02. All Applicants must also complete the Data Management Plan, attached to this Application. The Application and the Data Management Plan must be signed by an authorized signatory of the organization. This Application and the Data Management Plan will be used by CHIA to determine if your organization may receive CHIA data. 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 organization must execute the Data Use Agreement. You may wish to review that document as you complete these forms.

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.

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

I. GENERAL INFORMATION

APPLICANT INFORMATION	
Applicant Name:	Chrysalynne D. Schmults MD, MSCE
Title:	Associate Professor of Dermatology, Harvard Medical School Director, Brigham and Women's Mohs and Dermatologic Surgery Center Director, Dana Farber High-Risk Skin Cancer Clinic
Organization:	Brigham and Women's Hospital Department of Dermatology
Project Title:	Skin Cancer Expenditure and Equity Analysis
IRBNet ID:	pkaria
Mailing Address:	Brigham and Women's Faulkner Hospital Mohs and Dermatologic Surgery Center 1153 Centre Street, Suite 4349 Jamaica Plain, MA 02130
Telephone Number:	617-983-4626
Email Address:	cschmults@partners.org
Names of Co-Investigators:	Emily Stamell Ruiz, MD Pritesh Karia, MPH Frederick Morgan, BSPH
Email Addresses of Co-Investigators:	esruiz@partners.org pkaria@partners.org fmorgan@partners.org
Original Data Request Submission Date:	06/02/2016
Dates Data Request Revised:	N/A
Project Objectives (240 character limit):	Estimate occurrence, treatment, and cost of care for skin cancer in Massachusetts. The cost of skin cancer diagnosis and treatment will be tabulated based on money paid by insurers. Patients will be stratified by skin cancer tumor type (squamous cell carcinoma, basal cell carcinoma, melanoma, or skin neoplasm of uncertain behavior), demographics (age, race, ethnicity, gender, and other) and type of private insurer.

Project Research Questions (if applicable):	<p>1. What is the overall cost of various treatments for cutaneous skin cancers to private insurances?</p> <p>2. What factors are associated with disparities in care delivered and cost?</p> <p>3. How can we use this information to optimize both the treatment of cutaneous skin cancers and the cost of healthcare?</p>

II. PUBLIC INTEREST & PROJECT SUMMARY

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

Skin cancer is the most commonly diagnosed cancer in the United States with over 3,750,000 new cases estimated to occur each year. An estimated \$1.4 billion is spent on skin cancer each year in the Medicare population alone. Yet almost nothing is known about how the money is spent or whether disparities exist in care received. Comprehensive cost-assessment and identification of any disparities in care are vitally needed for policy makers and healthcare administrators to make optimal decisions about how best to serve this very large patient population.

The purpose of this research study is to estimate the occurrence, treatment, and cost of care for skin cancer in the United States state-by-state utilizing All Payer Claims Databases of healthcare expenditures in states with these systems, and via data from the Center for Medicare and Medicaid Services in all 50 states.

This study will be the first to evaluate how money is spent on skin cancer and whether care inequities are present. Skin cancer health inequities in relation to socioeconomic status and race/ethnicity will be examined by linking area-based data derived from the APCD (such as zip code) with the United States Census Bureau data in order to create a socioeconomic metric. The results will provide comprehensive data regarding the economic impact of skin cancer and will provide patients, physicians, healthcare administrators, and policy makers with information they need to optimize skin cancer prevention and control efforts.

2. Has an Institutional Review Board (IRB) reviewed your project?

- Yes, a copy of the approval letter and protocol must be **attached** to this Application
- No, this project is not human subject research and does not require IRB review.

3. If your project has not been reviewed by an IRB, please **attach** a brief (1-2 page) description of your project including the methodology, objectives, and research questions.

III. DATA FILES REQUESTED *[Applicants seeking 2015 data only should skip to Question 2]*

1. FY 2004 – 2014 Data: Please indicate the Case Mix files from which you seek data, the Level(s), the year(s) of data requested, and your justification for requesting each file. Please refer to the Case Mix Data Specifications for details of the file contents.

CASE MIX FILES	Levels 1 – 6	Years Available 2004 - 2014
Inpatient Discharge	<input type="checkbox"/> Level 1 – 3 Digit Zip Code	Year(s) of Data Requested:

	<input type="checkbox"/> Level 2 – Unique Physician Number (UPN) + 5 Digit Zip Code <input type="checkbox"/> Level 3 – Unique Health Information Number (UHIN) <input type="checkbox"/> Level 4 – UHIN and UPN <input checked="" type="checkbox"/> Level 5 – Date(s) of Admission; Discharge; Significant Procedures <input type="checkbox"/> Level 6 – Date of Birth; Medical Record Number; Billing Number PLEASE PROVIDE JUSTIFICATION BELOW FOR REQUESTING THE CHOSEN LEVEL: Level 5 Inpatient Discharge information is essential for tracking patient treatment over time	2010-2014
Outpatient Observation	<input type="checkbox"/> Level 1 – 3 Digit Zip Code <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 checked="" type="checkbox"/> Level 5 – Date(s) of Admission; Discharge; Significant Procedures <input type="checkbox"/> Level 6 – Date of Birth; Medical Record Number; Billing Number PLEASE PROVIDE JUSTIFICATION BELOW FOR REQUESTING THE CHOSEN LEVEL: Level 5 Outpatient Discharge information is essential for tracking patient treatment over time	Year(s) of Data Requested: 2010-2014
Emergency Department	<input type="checkbox"/> Level 1 – 3 Digit Zip Code <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 PLEASE PROVIDE JUSTIFICATION BELOW FOR REQUESTING THE CHOSEN LEVEL:	Year(s) of Data Requested:

2. FY 2015 Data: Beginning with fiscal year 2015, Massachusetts Acute Care Hospital and Case Mix and Charge Data (collectively Case Mix Data) are released in **Limited Data Set (LDS) files**. Please refer to the Case Mix Data Specifications for details of the file contents.

Please indicate the Case Mix files from which you seek data, the year(s) of data requested, and your justification for requesting each file.

CASE MIX LIMITED DATA SET FILES	Year(s) Of Data Requested Current Yrs. Available <input type="checkbox"/> 2015
<input type="checkbox"/> Inpatient Discharge	Please describe how your research objectives require Inpatient Discharge data:
<input type="checkbox"/> Outpatient Observation	Please describe how your research objectives require Outpatient Observation data:
<input type="checkbox"/> Emergency Department	Please describe how your research objectives require Emergency Department data:

Sections IV-IX must be completed by all Applicants requesting 2015 data. Applications that only include requests for prior years of data can skip to Section X.

IV. GEOGRAPHIC DETAIL

Please choose one of the following geographic options for MA residents:

<input type="checkbox"/> 3 Digit Zip Code (Standard)	<input type="checkbox"/> 3 Digit Zip Code & City/Municipality ***	<input type="checkbox"/> 5 Digit Zip Code ***	<input type="checkbox"/> 5 Digit Zip Code & City/Municipality ***
***Please provide justification for the chosen level of geographic detail if requesting something other than 3-Digit Zip Code only. Refer to specifics in your methodology:			

V. DEMOGRAPHIC DETAIL

Please choose one of the following demographic options:

<input type="checkbox"/> Not Requested (Standard)	<input type="checkbox"/> Race & Ethnicity***
*** If requested please, provide justification for requesting Race and Ethnicity. Refer to specifics in your methodology:	

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VI. DATE DETAIL

Please choose one option from the following options for dates:

<input type="checkbox"/> Year (YYYY)(Standard)	<input type="checkbox"/> Month (YYYYMM) ***	<input type="checkbox"/> Day (YYYYMMDD)***
<p>***Please provide justification for the chosen level of date detail if requesting Month or Day. Refer to specifics in your methodology:</p>		

VII. PHYSICIAN IDENTIFICATION NUMBERS (UPN)

Please choose one of the following options for Provider Identifier(s):

<input type="checkbox"/> Not Requested (Standard)	<input type="checkbox"/> Hashed ID ***	<input type="checkbox"/> Board of Registration in Medicine # (BORIM) ***
<p>***If requested please, provide justification for requesting Hashed ID or BORIM #. Refer to specifics in your methodology:</p>		

VIII. HASHED UNIQUE HEALTH IDENTIFICATION NUMBER (UHIN)

Please choose one of the following:

<input type="checkbox"/> Not Requested (Standard)	<input type="checkbox"/> UHIN Requested ***
<p>*** If requested please, provide justification for requesting UHIN. Refer to specifics in your methodology:</p>	

IX. HASHED MOTHER'S SOCIAL SECURITY NUMBER

Please choose one of the following:

<input type="checkbox"/> Not Requested (Standard)	<input type="checkbox"/> Hashed Mother's SSN Requested ***
<p>*** If requested please, provide justification for requesting Hashed Mother's SSN. Refer to specifics in your methodology:</p>	

X. 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, please indicate below the types of database to which CHIA Data be linked. [Check all that apply]

- Individual Patient Level Data (e.g. disease registries, death data)
- Individual Provider Level Data (e.g., American Medical Association Physician Masterfile)
- Individual Facility Level Data level (e.g., American Hospital Association data)
- Aggregate Data (e.g., Census data)
- Other (please describe):

3. 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(s):

Zip codes from the APCD will be linked to US Census bureau data. Variables in the US Census Bureau data such as median household income and race/ethnicity will be used as proxy variables to create a socioeconomic metric.

4. 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.

An algorithm has not been developed yet. However, we plan to work with a biostatistician to see if our desired goals are achievable.

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

Only aggregate US census data will be used. This data cannot be linked to individual patients. The linked data will be stored and handled with the same level of security as the APCD files.

XI. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Describe your plans to publish or otherwise disclose CHIA Data, or any data derived or extracted from such CHIA Data, in any paper, report, website, statistical tabulation, seminar, conference, or other setting. All publication of CHIA Data must comply with CHIA's cell size suppression policy, as set forth in the Data Use Agreement. Please explain how you will ensure that any publications will not display a cell less than 11, and no percentages or other mathematical formulas will be used if they result in the display of a cell less than 11.

Aggregate data resulting from this analysis will be compiled and presented at national dermatology meetings and published in peer-reviewed journals. No patient-level data will be disclosed.

2. Do you anticipate that the results of your analysis will be published and/or publically available to any interested party? Please describe how an interested party will obtain your analysis and, if applicable, the amount of the fee, that the third party must pay.

The results will be made publicly available via peer-reviewed journals. Article reprints will be available for free upon request.

3. Will you use CHIA Data for consulting purposes?

- Yes
- No

4. Will you be selling standard report products using CHIA Data?

- Yes
- No

5. Will you be selling a software product using CHIA Data?

- Yes
- No

6. Will you be reselling CHIA Data in any format?

- Yes
- No

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

N/A

7. If you have answered “yes” to questions 4, 5 or 6, please describe the types of products, services or studies.

N/A

8. If you have answered “yes” to questions 4, 5, or 6, what is the fee you will charge for such products, services or studies?

N/A

XII. APPLICANT QUALIFICATIONS

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

Principal Investigator: Chrysalyn D. Schmults MD, MSCE

Dr. Schmults directs the Mohs and Dermatologic Surgery Center at Brigham and Women’s Hospital and founded the High-Risk Skin Cancer Clinic at Dana-Farber/Brigham and Women’s Cancer Center. In these roles, she has made several innovations in clinical care. She is one of the foremost experts on non-melanoma skin cancer specifically cutaneous squamous cell carcinoma. She is the first dermatologist to serve as principal investigator on an investigational chemotherapy trial at Dana-Farber Cancer Institute. She developed the Brigham and Women’s staging system for cutaneous squamous cell carcinoma and will be directing the American Joint Committee on Cancer’s 8th edition workgroup for cutaneous squamous cell carcinoma staging. She has also conducted broader-based cost-effectiveness research including a current study of cost effectiveness of sentinel lymph node biopsy in thin melanomas and a prior cost comparison of infection control techniques in skin cancer surgery.

Co-Investigator: Emily Stamell, MD

Dr. Stamell is a Procedural Dermatology fellow at the Mohs and Dermatologic Surgery Center, Brigham and Women’s Hospital. She will be starting a two-year Master of Public Health (MPH) program in Clinical Effectiveness at Harvard School of Public Health in the Summer of 2014. She has extensive training in conducting skin cancer research.

Study Manager: Pritesh S. Karia, MPH

Mr. Karia is responsible for developing data collection systems-from surveys to electronic medical record databases- for a wide range of projects focusing on staging, prognosis, and treatment of cutaneous squamous cell carcinoma and other non-melanoma skin cancers at the Mohs and Dermatologic Surgery Center, Brigham and Women’s Hospital. In addition, Mr. Karia ensures compliance with institutional research policies, trains research staff on data collection and data entry, and conducts statistical analysis of study data.

Research Assistant: Frederick Morgan, BSPH

Mr. Morgan is a full-time Brigham and Women’s Hospital employee. He has experience analyzing hospital reimbursement data to assess the cost of skin cancer. Additionally, he assists with data collection and ensures compliance with institutional research policies.

2. **Attach** résumés or curricula vitae of the Applicant/principal investigator, and co-investigators. (These attachments will not be posted on the internet.)

XIII. USE OF AGENTS AND/OR CONTRACTORS

Please note: by signing this Application, the Organization assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors.

Third-Party Vendors. Provide the following information for all agents and contractors who will work with the CHIA Data.

Company Name:	There are no third party vendors or agents involved in this project
Contact Person:	
Title:	
Address:	
Telephone Number:	
E-mail Address:	
Organization Website:	

1. Will the agent have access to the CHIA Data at a location other than your location, your off-site server and/or your database?

- Yes, a separate Data Management Plan must be completed by each agent who will store CHIA Data
- No

2. Describe the tasks and products assigned to this agent for this project; their qualifications for completing the tasks; and the Organization’s oversight of the agent, including how the Organization will ensure the security of the CHIA Data to which the agent has access.

N/A

XIV. FEE INFORMATION

Please consult the fee schedules for Case Mix Data and select from the following options:

- Single Use
- Limited Multiple Use
- Multiple Use

Are you requesting a fee waiver?

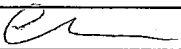
- Yes
 No

If yes, please refer to the [Application Fee Remittance Form](#) and submit a letter stating the basis for your request (if required). 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.

By submitting this Application, the Data Applicant 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 Data Applicant 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.

Applicants requesting data from CHIA will be provided with data following the execution of a Data Use Agreement that requires the Data Applicant to adhere to processes and procedures aimed at preventing unauthorized access, disclosure or use of data.

By my signature below, I attest to: (1) the accuracy of the information provided herein; (2) that the requested data is the minimum necessary to accomplish the purposes described herein; (3) the Data Applicant will meet the data privacy and security requirements describe 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 organization seeking CHIA Data for the purposes described herein.

Signature: (Authorized Agent)	
Printed Name :	
Title:	
Applicant's Signature:	
Name:	Chrysalynne Schmults, MD, MSCE
Title:	Associate Professor of Dermatology, Harvard Medical School Director, Brigham and Women's Mohs and Dermatologic Surgery Center Director, Dana Farber High-Risk Skin Cancer Clinic
Original Data Request Submission Date:	6/02/2016
Dates Data Request Revised:	

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

1. IRB approval letter or summary of project (if applicable)
 2. Resumes of Applicant and co-investigators
 3. Data Management Plan (for each institution that will store CHIA Data)