

## EXHIBIT A

ACADEMIC INSTITUTION:

PRIMARY INVESTIGATOR:

PROJECT SHORT NAME:

PROJECT START DATE:

## RESEARCH PROPOSAL

Please read the following and be aware of how these HCCI policies may impact your study.

Data Constraints: Commercial health care claims data are submitted to the Health Care Cost Institute (HCCI) by health insurance carriers. Limited use versions of the data are available through application to HCCI. **The data are available for use in academic and public policy research designed to improve the general public's understanding of health care cost drivers and to offer focus and direction to policy makers, regulators, analysts, consumers, and other specific stakeholders.** The data may not be used for commercial or competitive purposes and there are other constraints you need to note incorporated into the data license agreement. Exploratory projects are designed for feasibility studies and data exploration. No publications of any type are allowed by researchers with an exploratory data license.

### 1. SHORT DESCRIPTION AND TITLE OF PROJECT (Research Projects, Dissertation Projects, Exploratory Projects)

A. Short Title (~10 words)	
B. Short Description (Please describe your project in 100 words or less)	

### 2. REQUEST FOR STUDENT-USE DATASET (Educational Projects)

To request a student-use dataset, please have a representative of your university email HCCI at [data@healthcostinstitute.org](mailto:data@healthcostinstitute.org). Note that use of the student dataset requires tracking of faculty, students, and uses of the dataset for reporting to HCCI for record-keeping purposes.

**3. PROJECT PARTICIPANTS: PRINCIPAL INVESTIGATOR, COLLABORATORS, AND RESEARCH STAFF (Research Projects, Dissertation Projects, Exploratory Projects)**

List the names of all staff on the project, including contractors, who will participate in the research project at any stage of the project. Please add boxes as needed for additional project members. Please attach curriculum vitae or resume for all listed project participants. In the box below, fill in name, project role (e.g., Principle Investigator), title, affiliation, and email address for each team member.

#### 4. RESEARCH PROTOCOL (Research Projects, Dissertation Projects)

Please provide a summary of your research protocol, responding to each of the sections outlined below. The research protocol outlines a strong research design, which clearly states the objectives and the significance of the study, and provides a credible, straightforward argument for the importance of the project.

- A. *HCCI projects are defined by a key research question(s) investigated through a set of testable hypotheses. Please clearly state the research question(s), key metrics to be developed, and hypotheses to be tested. (Maximum 4,000 characters.)*

*B. Summary of background and prior research. Please include citations to any previous work project participants have done relevant to this proposal. The researchers must demonstrate their expertise and experience to conduct and complete the study. (Maximum 2,000 characters.)*

*C. New contribution this research will provide. (Maximum 2,000 characters.)*

*D. Research design and methodology. (Maximum 4,000 characters.)*

*E. Statement of why HCCI data is required for this research. (Maximum 2,000 characters.)*

*F. Intended completion date and dissemination plans. Please clearly describe timeline for project, intended research products to be created (i.e., presentations, manuscripts), and anticipated venues for the research products. (Maximum 2,000 characters.)*

**5. RESEARCH PROTOCOL (Exploratory Projects)**

- A. *Please describe in as much detail as possible what your team will be looking at in the data. If this changes you are required to update HCCI in writing. (Maximum 2,000 characters.)*

- B. *Please describe the goals and timeline of the exploratory project. (Maximum 2,000 characters.)*

## EXHIBIT B

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### DATA REQUEST

(Research Projects, Dissertation Projects, Exploratory Projects)

Recipient is requesting access to a Data Set based on the following criteria below. Recipient will complete the information requested in this Exhibit B.

#### 1. DATA REQUIRED: CHOOSE ONE OPTION FROM EACH SECTION

SECTION 1: CALENDAR YEARS	2008-2012	YES	NO
	2009-2013	YES	NO
	2010-2014	YES	NO
	2011-2015	YES	NO
	2012-2016*	YES	NO
	OTHER** (PLEASE DESCRIBE):	YES	NO
SECTION 2: DATA VIEWS	STANDARD 1 (PLEASE CHECK ONE):	YES	NO
	STANDARD 2 (PLEASE CHECK ONE):	YES	NO

\* 2012-2015 data available now, 2016 data forthcoming.

\*\* Requests for non-standard data views (including non-standard years of data) must be submitted to HCCI in writing and will be subject to additional terms and conditions as well as additional fees.



## 2. DATA MERGES.

*Please be aware that HCCI needs to review any merges on the dataset before they can be performed. HCCI requires the encryption of provider IDs (NPIs), which will be performed by HCCI's vendor at cost to the research team. (Maximum 2,000 characters.)*

Do you plan to merge on additional, non-HCCI datasets to the HCCI data (Please check one)?	YES	NO
If yes, list the datasets you would like to merge at the provider/hospital/pharmacy/facility level (PLEASE DESCRIBE):		
If yes, list the dataset you would like to merge by geography/area (PLEASE DESCRIBE):		

## EXHIBIT C

ACADEMIC INSTITUTION:

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### PARTICIPANT AGREEMENT

(Research Projects, Dissertation Projects, Exploratory Projects)

**Please have Exhibit C completed separately by each team member listed in Exhibit A**

HCCI may amend this Exhibit from time to time by providing Recipient with written notice.

#### 1. ACKNOWLEDGMENT OF PERSONNEL

I, the undersigned, acknowledge, agree, represent and warrant to the following:

1. Health Care Cost Institute ("HCCI") has agreed to a Data License Agreement dated \_\_\_\_\_, 20\_\_ (the "Agreement") with [Research Institution] (the "Recipient") pursuant to which I will be granted access to Data (as defined in the Agreement), and that I have been provided with a copy of, and have read and understand, the Agreement.
2. I am an employee, faculty, student, fellow, resident or research associate at the Recipient, or a collaborator with one of the foregoing, and I require access to the Data, Derivative Information, and Confidential Information for the Purposes (as defined in the Agreement).
3. My affiliation with the Recipient meets each of the following conditions: (i) I am under the supervision and control of the Recipient with respect to the Research (as defined in the Agreement); (ii) I work via networks or in offices or facilities controlled by the Recipient or a collaborating research institution; (iii) I access the Data through the Recipient's systems only; (iv) I am participating in and conducting the Research solely in my capacity as an employee, faculty, student, fellow, resident or research associate of the Recipient, or collaborator with one of the foregoing; and (v) I am not an employee of a health insurance company, nor am I acting on behalf of or in collaboration with, directly or indirectly, any insurer or other commercial entity.
4. I will not use the Data, Derivative Information, or Confidential Information in any manner, except as necessary for the Purposes. I will not use or access any Data outside the United States. I will not disclose the Data or any part thereof to any person or entity for any reason, including without limitation, (i) publishing, (ii) quoting or reproducing for advertising, promotional or public relations purposes, or (iii) reproducing or placing in any data retrieval systems. I will comply with all terms and conditions set forth in the Agreement relating to use of Data,

Derivative Information and Confidential Information, including without limitation the HCCI Policies and Procedures set forth in Exhibit B of the Agreement.

5. Any documents or materials I prepare, which contain information derived from any part of the Data shall be conspicuously marked with confidential and/or proprietary notices substantially similar to those notices contained in the original source documents provided by HCCI. Further, I will not publish or otherwise disclose any information or materials, which contain information derived from any part of the Data in violation of the terms and conditions of the Agreement, including without limitation Section 3.

6. Excluding any representations and warranties explicitly made in Section 7 of the Agreement, HCCI makes no representations or warranties, express or implied, in connection with the Data including without limitation the implied conditions and warranties relating to merchantability and fitness for a particular purpose.

7. All Data is confidential and proprietary and shall be and remain HCCI's property and nothing contained herein shall be construed as granting to me any right, title or interest in or to the Data. I will not disclose the Data, the source of the Data, or the existence of the Agreement or this acknowledgement form to any individual or entity.

8. All Data, and copies thereof in my possession or control, must be promptly returned upon HCCI's request or destroyed. I will not retain any copies of any Data for any purpose.

9. I will not (i) reproduce any of the Data, (ii) attempt to reverse engineer, disassemble or decompile any prototypes, software or other embodiment of the Data in an effort to obtain the identities of persons, payors, or providers, (iii) use the Data or any part thereof for any purpose other than the Research described in Section 2 above, or (iv) use the Data for any commercial purpose; (v) act as consultant or independent contractor to any third party while participating in the Research without prior written disclosure to and approval by HCCI; (ix) make the Data available for access with or by "data mash-up" or automated linkage technologies; (x) link the Data with other data or add other sources of data to the Data at the individual, member, or patient level without pre-approval from HCCI; (xi) re-identify, or attempt to re-identify, or allow to be re-identified, any relative(s), family or household member(s) of any individual within the Data; or (xii) link any of the 16 facial or direct identifiers set forth in 45 C.F.R. Section 164.514(b)(2) with the Data.

9.1 I agree that HCCI has discretion to terminate my participation under the Agreement at any time should HCCI determine that a conflict of interest exists with my participation.

9.2 I agree to comply with any limits, qualifications, conditions, and restrictions set forth in the statistical de-identification determination associated with the Data, as may be communicated by HCCI to Recipient from time to time.

10. I will immediately notify HCCI if my affiliation with Recipient is terminated or otherwise ceases. In the event my affiliation with Recipient is terminated or otherwise ceases, I will not use or access the Data after the effective date of such termination until a new Research Program Agreement is executed by another approved institution with which I am affiliated.

11. Access to the Data Enclave will be subject to the terms and conditions in the Data Enclave Addendum, attached to the Agreement as Exhibit C. I acknowledge and agree that the National Opinion Research Center ("NORC") is a third party beneficiary with respect to the Data Enclave Addendum with the right to enforce such terms and conditions directly against me.

12. I will alert HCCI staff of activities related to dissemination of my research using HCCI data, in the event that it is accepted for publication in a journal or other venue, used in an external presentation, or otherwise shared with others besides my research team. I will make a reasonable effort to contact HCCI two weeks prior to the date of any such dissemination.

## **2. CONFLICTS OF INTEREST DISCLOSURE**

HCCI generally follows the American Economic Association Disclosure Policy and requires researchers and all personnel, as defined in the research license agreement, to disclose potential conflicts of interest and financial arrangements.

Disclosures: During the term of the Data License Agreement, each researcher and all personnel, as defined in the research license agreement, including any additions to researchers and personnel, shall inform HCCI of any material changes to the statements made herein. A misstatement, either now or at a subsequent time during the term of this agreement, or failure to disclose any material change during the term of the Data License Agreement shall constitute a breach of the research license agreement and be grounds for immediate termination of the agreement by HCCI or the data contractor. Additionally, HCCI may immediately terminate the Data License Agreement at any time if a conflict of interest or improper financial arrangement is discovered, whether disclosed by the researcher or not. Moreover, if HCCI reasonably believes that the appearance or potential appearance of a conflict of interest exists, (defined as "any engagement, undertaking, relationship, or position with or financial support from an *"interested party"*(defined as any individual, group, or organization that has a financial, ideological, or political stake related to the research)), HCCI may immediately terminate the Data License Agreement.

Please address the following questions and incorporate as part of your application, do not leave any field blank:

1. *State any actual or anticipated sources of financial support for the proposed research. If none exists, that fact should be stated.*

2. *Identify all interested parties from whom you have received significant financial support, summing to at least \$10,000 in the past three years, in the form of consultant fees, retainers, grants and the like. The disclosure requirement also includes in-kind support, such as providing access to data. If the support in question comes with a non-disclosure obligation, that fact should be stated, along with as much information as the obligation permits. If there are no such sources of funds, that fact should be stated explicitly. An “interested” party is any individual, group, or organization that has a financial, ideological, or political stake related to the article.*

3. *Describe any paid or unpaid positions as officer, director, or board member of relevant non-profit organizations or profit-making entities. A “relevant” organization is one whose policy positions, goals, or financial interests relate to the article.*

4. *Disclose if another party had the right to review the paper prior to its circulation.*

### **3. DATA SECURITY**

All Personnel will maintain and abide by the following data security procedures at all times while participating in the Research:

1. Only Personnel who have completed and signed the Participant Agreement, received formal authorization by HCCI and the Recipient, and completed the NORC online training modules described in Exhibit C of the Data License Agreement will access the Data Enclave (each defined hereinafter as a “User”).
2. Users will only access the Data Enclave through a private, password-secured network. Users will not access the Data Enclave via a public network (e.g., public Wi-Fi).
3. All computers or other devices used to access the Data Enclave or that contain Confidential Information related to the Research will be password protected and locked when unattended. All Personnel will ensure that security software (anti-virus and anti-spyware) is installed and remains up-to-date at all times on all computers or other devices used to access the Data Enclave or conduct the approved Research. Personnel will furthermore access the Data Enclave through the Recipient’s systems only and conduct the Research via networks, computers, or other devices administered by the Recipient institution or a collaborating research institution.
4. Users will not share their password, PIN, or RSA token used for accessing the Data Enclave. Users will not share user accounts with other Personnel.

5. Users will not permit non-Personnel to view material in the Data Enclave or to view or possess any other Confidential Information related to the approved Research.
6. Unless expressly permitted by HCCI in writing, neither the HCCI Data nor any Derivative Information containing Data will reside outside the Data Enclave.
7. No output in any form that is derived from the Data may be downloaded from the Data Enclave unless it satisfies the terms of the Data License Agreement.
8. All printed or electronic copies of research products or preliminary results exported from the Data Enclave will be kept in a locked room accessible only to Personnel.
9. Personnel will not attempt to capture, store or share any images, files or information accessed within the Data Enclave using any form of magnetic storage, screen capture software or devices (including any type of image recording device), screen sharing software or devices.
10. The research team will notify both HCCI and NORC as soon as possible if a member of Personnel will no longer participate in the Research so that access to the Data Enclave for the member of Personnel can be terminated, if applicable.

Any security issues related to the above requirements will be reported as soon as possible to both HCCI and NORC.

AGREED AND ACKNOWLEDGED AS OF \_\_\_\_\_.  
[insert date mm/dd/yyyy]

\_\_\_\_\_  
Signature

\_\_\_\_\_  
[Print name]

## EXHIBIT D

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## DEFAULT MASKING RULES

These rules are the default masking rules to be used for reporting results per calendar year. Exceptions will be considered on a case by case basis.

### 1. Overriding Rules:

- a. No analysis at the individual health plan level
- b. No reporting of health plan market shares based on the Data provided by HCCI and its authorized data custodian
- c. No identifiable profiling of providers
- d. Must follow HIPAA rules for reporting
  - i. <http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm/#top>
- e. Must have a minimum of 5 unique providers in any group/category being reported<sup>1</sup>

### 2. Additional Rules

- a. No reporting of results at a level that could reasonably be used to infer results that would violate any of the above rules. Examples include, but are not limited to, reporting results by a set provider characteristics for small cell sizes such that the combinations of characteristics could be used to identify a patient or provider, or if reporting minimum or maximum values over a range of providers.
- b. Results will go through an exception process and researchers must receive explicit approval for results reporting diagnosis codes (e.g. ICD-9 or ICD-10 codes), at a level below Metropolitan Statistical Area (MSA), reporting in markets dominated by 1 HCCI data contributor (i.e. an HHI > 7,000), or reporting on a rare DRG or procedure (CPT code),.

### 3. Guidelines for Reporting at the **National Level**

- a. If at Current Procedural Terminology (CPT) code level
  - i. Minimum number of claims –200
- b. Diagnosis-Related Group (DRG)
  - i. Minimum number of claims –100
- c. If at the National Drug Code (NDC) level
  - i. Minimum number of claims – 800
- d. If reporting at the level of therapeutic class as determined by the American Hospital Formulary Service (AHFS), the following rules apply:

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<sup>1</sup> A single provider is any entity that sets prices for itself and/or sets the prices of others. Therefore, all locations of a pharmacy chain constitute a single provider. Unfortunately, we have encrypted provider IDs and these may be locational rather than entity based.



- i. If reporting on a single drug or class that contains a single drug, must have 800 claims
  - ii. If reporting on a tier of therapeutic class, for which there exists a lower more granular tier below the class that is being reported, then reporting can be done regardless of number of claims.
- e. If prescription is also a procedure, such as a medical device
  - i. Minimum number of claims – 200
- 4. Guidelines for Reporting at the **Sub-National Level** - depend on market concentration<sup>2</sup>
  - a. The Herfindahl-Hirschman Index (HHI) is used to determine how likely the data would reveal company specific information. HCCI's data contractor has calculated HHIs for states, metropolitan statistical areas (MSAs), and other geographic units. Researchers will need to consult with HCCI to determine appropriate limits on public reporting.
  - b. **Non-concentrated markets** (HHI < 4,150, at least three data contributors, and no one insurer represents more than 45% of market)
    - i. Procedure Based Reporting
      - 1. Can be at the CPT level
        - a. Minimum number of claims – 200
    - ii. Diagnosis Based Reporting
      - 1. Can be at DRG level
        - a. Minimum number of claims – 100
  - c. **Somewhat concentrated markets** (HHI < 5,200 and > 4,150; at a minimum two data contributors, and no one insurer represents more than 60% of the market)
    - i. Procedure Based Reporting
      - 1. If at the five-digit CPT code level, minimum number of claims - 500
        - a. If at the three-digit CPT code level, minimum number of claims – 200
    - ii. Diagnosis Based Reporting
      - 1. Can be at DRG code level
        - a. Minimum number of claims – 200
  - d. **Highly concentrated markets** (HHI > 5,200 and < 7,000; at least two data contributors, and one insurer represents more than 60% of the market)
    - i. Procedure Based Reporting
      - 1. If at the five-digit CPT code level, minimum number of claims - 1,500
      - 2. If at the three-digit CPT code level, minimum number of claims – 500
    - ii. Diagnosis Based Reporting

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<sup>2</sup> The Herfindahl-Hirschman Index is a commonly used index for market share. In this context it is defined as each of HCCI's contributors share of membership in a geographic area squared and summed. The index is bounded between 10,000 (when just one data contributor has the entire market) and 0 (a purely competitive market with an infinite number of data contributors). For example, in a state with two data contributors, one with 60% of the market and the other with 40%, the HHI would be  $3,600 + 1,600$ , or 5,200.

- a. Can be at DRG code level, minimum number of claims – 400
- 5. Guidelines for Reporting Prescription Drug Prices at the Sub-national Level
  - a. Must again have more than 5 providers
    - i. If HHI < 7,000, a minimum of 4,000 prescription claims are required
    - ii. If HHI >7,000, researcher must seek approval to report
    - iii. If geographic area does not have adequate number of providers or claims, it must be expanded to meet these minimums
- 6. Guidelines for Reporting on Episodes of Care
  - a. General rules from section 1 apply
- 7. Researchers will work with HCCI, as needed, in developing reporting tools, such as heat maps and other graphics, that utilize ranges for prices to depict data or analytic results.

\* HCCI may amend this Exhibit from time to time by providing Recipient with written notice.