Oregon Health Authority

All Payer All Claims Application for Limited or Custom Data Files
APAC-3

OHA DRTS: 5031_Variation_in_Cardiovascular_Healthcare_Value

This application is used in conjunction with the APAC-2 submitted. If any corrections to information submitted on the APAC-2 are required, please note the changes below (as relevant) and in the email to which this application will be attached.

PROJECT INFORMATION

Project Title: Variation in Cardiovascular Healthcare Value

Principal Investigator: Vinay Kini, MD, MS

Title of Principal Investigator: Assistant Professor of Medicine

Organization: University of Colorado School of Medicine

Address: 12631 E. 17th Ave, Academic Office One

City: Aurora State: CO Zip Code: 80212

Telephone: 267-975-3617

Email: vinay.kini@ucdenver.edu

Application Date: 3/20/19

SECTION 1: PROJECT STAFF

1.1 Project Staff: Please list any staff in addition to the principal investigator who will have direct access to the data. This must include any contractors or other third-parties with access to the data.

Name Bridget Mosley Role Data Analyst
Email bridget.mosley@ucdenver.edu

Name Role
Email

Name Role
Email

Name Role
Email

Name Role
Email

Attach additional sheets as needed.

1.2 Technical Staff: Please list any additional staff who will be maintaining the data file(s) or otherwise assisting in the transfer or receipt of the data files. Files will not be transferred to anyone who is not listed on this application as either project staff or technical staff.

Name Role
Email

Name Role
Email

SECTION 2: PROJECT SUMMARY

2.1 Project Purpose: Briefly describe the purpose of the project and how it meets the APAC use as research, public health surveillance activities or health care operations. A more detailed project description including background, methodology and analytic plan that supports the APAC data options and data elements selected for your project may be submitted with this application.

Health care value is defined as patient health outcomes achieved relative to the total costs of care. Achieving high-value healthcare has been proposed as a unifying goal for improving care delivery. Overuse of cardiovascular tests and treatments can be harmful and leads to high costs, whereas underuse can lead to significant health disparities and worsen patient outcomes. If we can understand the factors that lead to overuse and underuse, we can develop standardized processes to ensure that patients who are most likely to benefit from therapies have access to them, and those who are unlikely to benefit can move quickly to other treatment approaches most suited to their needs and preferences. Thus, it is imperative that we gain a better understanding of variation in cardiovascular healthcare value across hospitals and healthcare systems.

2.2 Research Questions: What are the key research questions or hypotheses of the project? If this project is research and has been approved by an Institutional Review Board (IRB), the research questions must align with the IRB approval documentation.

This project has 3 Aims:
1. Among adults in the state of Oregon, describe variation in healthcare value across a spectrum of common cardiovascular hospitalizations (such as heart failure, heart attack, stroke, and arrhythmia), and determine patient-, payer-, and provider-level effects on cardiovascular healthcare value.
2. Understand the impact of different diagnostic tests and treatments (such as stress tests and stent placements) on cardiovascular healthcare value among the conditions described in Aim 1.
3. Describe the prevalence of low-value cardiovascular healthcare services (i.e., tests and treatments that provide no benefit to patients but contribute to healthcare costs) across common outpatient procedures such as cardiac testing prior to low-risk surgeries, and unnecessary imaging tests after pacemaker implantation.

2.3 Products or Reports: Describe the intended product or report that will be derived from the requested data and how this product will be used.

Our audience includes clinicians who provide care to patients with cardiac disease in the state, healthcare administrators and researchers seeking to understand how to achieve high-value healthcare, and patients seeking out high-value cardiovascular healthcare services. We plan on publishing our results in academic medical journals such as the Journal of the American College of Cardiology and the Journal of the American Heart Association.

2.4 Project Timeline: What is the timeline for the project?

a. Anticipated Start Date: 6/1/19
b. Anticipated Publication/Release Date: 6/1/21
c. Anticipated End Date: 6/1/22

2.5 Data files may not be released or reused beyond the terms of the data use agreement resulting from this application regardless of funding source or other obligations of the Principal Investigator, organization or research team.

- [x] I understand this limitation and agree that data files or work products will not be shared at less than an aggregated, de-identified level.
- [ ] I understand this limitation and request approval to share data files or work products at a potentially re-identifiable level as follows:

SECTION 3: DATA REQUEST

3.1 Purpose of the Data Request:

a. Listed below are the purposes for which OHA may share APAC data. Please choose the category in which your project falls (***choose only one***).

- [x] Research (refer to 45 CFR 164.501 for definition)
- [ ] Public health activities (refer to 45 CFR 164.512(b) for definition)
- [ ] Health care operations (refer to 45 CFR 164.501 for definition)

  Covered entity? [ ] Yes [ ] No

  (refer to 45 CFR 160.103 for definitions related to covered entities)
- [ ] Treatment of patient by health care provider (refer to 45 CFR 164.506 (c)(2) for definition)

  Covered entity? [ ] Yes [ ] No
- [ ] Payment activities performed by covered entity or health care provider (refer to 45 CFR 164.506 (c)(3) for definition)

  Covered entity? [ ] Yes [ ] No
- [ ] Work done on OHA's behalf by a Business Associate (refer to 45 CFR 160.103 for definition).

b. Describe how the project falls into the category chosen above.

Our project falls under research because we aim to describe variation in use of cardiovascular healthcare services and costs, and understand how patient-, payer-, and hospital effects affect variation. Our main goal is to advance understanding of the field of healthcare value, and we plan on publishing our results in academic medical journals.

3.2 Direct identifiers. What level of data identifiers are you requesting (***choose only one***)? Reference the Data Elements Workbook for the categorization of data elements.

- [ ] De-identified (as outlined in 45 CFR 164.514(e)) protected health information
- [x] Limited, potentially re-identifiable data elements
- [ ] Restricted direct identifiers (member name, address, date of birth, etc.) *Please note:* Direct identifiers are only released under special circumstances that comply with HIPAA requirements, and will require specific approvals, such as Institutional Review Board (IRB) approval, patient consent and/or review by the Department of Justice.

3.3 Human Subjects Research: Institutional Review Board (IRB) protocol and approval are required for most research requests for limited data elements and are mandatory for research requests for restricted data elements. Not obtaining IRB approval or waiver in advance may delay approval of the data request. **Also, if the research questions reported in 2.2 of this application do not match the submission and IRB approval received, the application will be denied.**

a. Does your project have IRB approval for human subjects research?

☒ Yes ☐ Not applicable (project is not research on human subjects)

If yes, include the IRB application and approval memo with the submission of the APAC-3 and complete parts b-e below.

☑ IRB application and approval memo are attached.

b. Describe how this application is within the authority of the approving IRB.

All research activities (data storage, analysis, and release of results) will occur at the University of Colorado Denver. The PI and data analyst are members of UCD's Outcomes Research Center, which operates under UCD's School of Medicine. All research projects with a primary investigator at UCD are required to gain approval (or exemption) from COMIRB (The Colorado Multiple Institutional Review Board - an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the University of Colorado Denver and its affiliates).

c. Describe why the project could not be practicably conducted without a waiver of individual authorization (a waiver of individual authorization is provided by the IRB in cases in which the researcher does not need written authorization from participants to use their PHI):

This study involves analysis of de-identified billing claims of over 100,000 patients. Given this large sample size, and the fact that we will not have any direct contact with patients, we believe the research could not practicably be carried out without the waiver.

d. On what date does the IRB approval expire? 9/1/19

SECTION 4: DATA ELEMENTS

Refer to the APAC Data Dictionary for detailed information about the data elements. OHA will only provide the minimum necessary data required for the project as represented in the research questions, protocol and IRB approval. In compliance with HIPAA regulations, you will only receive data elements that are adequately justified.

4.1 Data Element Workbook: Complete the Data Element Workbook. Complete the data request options and the data elements worksheets.

☑ Data Element Workbook completed and attached, including justifications for each element requested

4.2 Minimum Necessary Requirement: Please explain why the requested APAC options and data elements are the minimum necessary required for the project. The justification should be specific to this project and more than 'potential confounding variable'. Attach additional sheets as needed.

1. We are NOT requesting sensitive patient identifiable information (i.e., DOB or zip code). However we ARE requesting dates of service. We need these to identify when patients received cardiac tests or treatments because time to treatment may affect patient health outcomes under study. As an example, cardiology guidelines recommend that some patients receive implantable defibrillators 40 days after a large heart attack. Patients with a significant delay (e.g., 80 days or 160 days) may have worsened health outcomes. Thus, time to treatment (based on dates of service) will be needed to assess our outcomes under study.

2. We are requesting de-identified provider information. One of our goals is to analyze variation in healthcare value at the hospital level. For example, we may find that patients who receive care for a heart attack at "Hospital A" achieve better outcomes relative to costs (higher healthcare value) relative to "Hospital B." We would like to identify which tests and treatments Hospital A uses to treat heart attack patients. To do this, we will need de-identified ("dummy variables") for healthcare providers (both hospitals and practices). We are NOT seeking identifiable provider information such as hospital or provider names.

3. We are requesting only diagnosis and procedure codes for common cardiovascular conditions. These include diagnoses such as heart failure, hypertension, and coronary artery disease and procedures such as coronary stenting and pacemaker implantation. We seek to describe variation in healthcare value across these common cardiovascular conditions and have requested only the minimum data elements to do this. We are NOT requesting any data elements that fall outside of cardiovascular healthcare.

SECTION 5: DATA MANAGEMENT & SECURITY

5.1 Data Reporting: APAC data or findings may not be disclosed in a way that can be used to re-identify an individual. Data with small numbers – defined as values of 30 or less (n≤30) or subpopulations of 50 or fewer individuals (n≤50) – cannot be displayed in findings or outputs derived from APAC data. Please describe the techniques you will use to prevent re-identification when findings or outputs result in small numbers or subgroups (e.g. aggregation, cell suppression, generalization, or perturbation).

All data analysis will take place on secure servers at the University of Colorado Denver's Outcomes Research Center. If any subgroup analyses have data with small numbers, we will use both aggregation and cell suppression to prevent re-identification. Results from these small numbers will be aggregated on the variable of interest (i.e., proportion with hypertension), and we will use cell suppression on any potential re-identifiable data elements such as dates of service.

5.2 Data Linkage: OHA seeks to ensure that APAC data cannot be re-identified if it is linked or combined with data from other sources. Requesters are strongly encouraged to consult with Health Analytics about linking APAC data with other data prior to submitting a data request. OHA prefers to conduct APAC data linking in-house and share only encrypted identifiers with data requesters

a. Does this project require linking to another data source?

☐ Yes ☒ No

If yes, please complete parts b-d below.

b. At what level will data be linked?

☐ Aggregate ☐ Facility ☐ Person

c. If required to link

☐ Authorized to provide data for linking at OHA

☐ Not authorized to provide data for linking at OHA

☐ Unknown

d. Describe and justify all necessary linkages, including the key fields in each data set, how they will be linked, the software proposed to perform the linkage and why it is necessary.

e. Describe in detail the steps will you take to prevent re-identification of linked data.

5.3 Data Security:

☑ a. Attach a detailed description of your plans to manage access to the APAC data, personnel safeguards, technical and physical safeguards and administrative safeguards. Please describe and ensure the following:

- Designation of a single individual as the custodian of APAC data, either the Principal Investigator or staff listed in Section 1 of this

application, who is responsible for oversight of APAC data including reporting any breaches to OHA and ensuring the data are properly destroyed upon project completion

- A security risk management plan applicable to APAC data
- Compliance with HIPAA and the HITECH Act
- Ensure that all parties accessing APAC data are listed on the data use agreement and agree to the same terms and conditions for securing and protecting APAC data
- Procedures to restrict APAC data access to only those individuals listed on the data use agreement
- Ensure training for personnel on how to properly manage protected health information and electronic health information has occurred
- Signed agreements for organizational security and privacy policies
- User account controls i.e., password protections, maximum failed login attempts, lockout periods after idle time, user audit logs, etc.
- Electronic device protections i.e., anti-virus or anti-malware software, firewalls, and network encryption
- Procedures for restricting remote access to APAC data
- Procedures for storing hard copy data
- Protection of derivatives of APAC data at the identifiable level
- If applicable, procedures for handling direct identifiers, including storing identifiers separately from other APAC data
- Procedure for identifying, reporting and remedying any data breach

b. Record level or derivative data that can be reidentified must be destroyed within 30 days of the end of the data use agreement, in a manner that renders it unusable, unreadable, or indecipherable. What are your plans for destruction of the dataset and any potentially identifiable elements of the data once the data use agreement has expired?

The data will be housed in a directory that is only accessibly by the PI and an analyst active in the research protocol. If a researcher ends their participation in the project their access to the directory will be terminated. Upon completion of the project, the data files and backups located on the server are destroyed per protocol. Standardized procedures are used to dispose of equipment, with additional measures in place to delete sensitive data (Examples: Hard disk scrubbers, physical destruction of equipment).

SECTION 6: COST OF DATA

6.1 COST OF DATA:

If you are requesting **only data elements marked with an x** in the limited column in the APAC data elements worksheet, calculate the cost using the table below. Payment must be received before the data will be provided. An invoice is available to facilitate payment if requested.

If you are requesting **any data elements not marked with an x** in the limited column in the APAC Data Dictionary, an invoice will be sent after OHA approves the request. The invoice must be paid before the APAC team will provide the approved data.

	Payers			
	All Payers	**Only Commercial Medicare**	**Only Commercial Insurance**	**Only OEBB/PEBB**
Claims Data:				
All Medical and pharmacy claims	☐$3,000	☐$1,000	☐$1,000	☐$1,000
All medical claims (no pharmacy)	☐$1,500	☐$500	☐$500	☐$500
All pharmacy claims (no medical)	☐$1,500	☐$500	☐$500	☐$500
Only hospital inpatient claims	☐$375	☐$125	☐$125	☐$125
Only emergency department claims	☐$375	☐$125	☐$125	☐$125
Only ambulatory surgery claims	☐$375	☐$125	☐$125	☐$125
Only outpatient claims	☐$375	☐$125	☐$125	☐$125
Enrollment data				
Billed premium data				
Provider data				
a. Total each column				
b. Sum across column totals				
c. Number of years of data				
d. Multiply rows b and c				
e. OHA Production Cost				$560
f. Add rows d and e for Total				

SECTION 7: CHECKLIST AND SIGNATURE

7.1 Checklist: Please indicate that the following are completed:

- ☑ I acknowledge that payment will not be refunded if OHA fulfills the data request, but the receiving entity does not have the capability to import or analyze the data
- ☑ All questions are answered completely
- ☑ Data Element Workbook is attached to email or printed application (data options and data element worksheets completed)
- ☑ IRB approval memo is attached to email or printed application, if applicable
- ☑ Data privacy and security policies for the requesting organization, and any third-party organizations are attached to the email or printed application

7.2 Signature: The individual signing below has the authority to complete this application and sign on behalf of the organization identified in Section 1. By signing below, the individual attests that all information contained within this data Request Application is true and correct.

Signature Vinay Kini Digitally signed by Vinay Kini Date: 2019.04.12 12:54:01 -06'00' Date

Printed name Vinay Kini

Title MD, Assistant Professor

Return the completed form with required attachments to APAC.Admin@state.or.us.

Completed forms may also be printed and mailed to:

APAC Program Manager
Office of Health Analytics
421 SW Oak St., Suite 850 – APAC
Portland, OR 97204

Attachment: Data Privacy and Security Policies and Procedures

The ACCORDS Data Analysis Center. Established in 2014, the Adult and Child Consortium for Outcomes Research and Delivery Science (ACCORDS) at the University of Colorado Denver has supported multiple federally-funded research projects via the Data Analysis Center (DAC), a high-security server platform. The Oregon APAC will be stored and analyzed on this server. Copying and transfer of data from the server to other media is prohibited.

System Security. The hardware at the core of the DAC is located in a high-security server center at the University of Colorado Anschutz Medical Campus. The system is managed by a team of full-time systems analysts with advanced training in system/network security, and who have established multiple layers of physical and cyber security and system monitoring, in accordance with the standards established by the 2002 Federal Information Security Management Act (FISMA) and the 2009 Health Information and Technology for Economic and Clinical Health Act (HITECH). The main levels of security are fourfold and include machine physical security at the IT facility at which the servers are housed, additional physical security of the server machines within the highly restricted server containment room, electronic server security (firewalls, passwords, encryption) restricting electronic access to the machines, and directory/file access controls restricting access to the datasets only to those users with adequate security clearance.

Privacy Protection. "Strong" password protection (alpha/numerical/symbolic characters) is used at the server and web portal levels for all transactions that provide access to sensitive subject data. Passwords are managed under a set of machine rules requiring all users to change their password every 90 days. Protected health information (PHI) data access will be limited to the project's principal investigator (Dr. Kini), a project programmer, and the server information technology systems architect on an as-needed basis. Prior to receiving PHI access, all study personnel must demonstrate annual completion of Health Information Portability and Accountability Act (HIPAA) training. File access on the servers is monitored by electronic logs that capture each user's logins, file manipulations, and keystroke entries. Remote electronic access to servers will be limited to the project team using Secure Shell (SSH2) and private networking with a limited subset of approved IP addresses. The server itself resides behind an industry-standard firewall. Data queries and reports produced via web interfaces will be conducted using secure web connections with SSL certificates that provide a minimum of 1024-bit encryption.

System Computational Ability. Servers at DAC are customized to each individual research project. For the proposed research, the candidate has already secured a 12-core Xeon CPU with 96GB RAM and 4TB SSD. The computational speed exceeds typical desktop benchmarks three-fold. Software packages including SAS 9.3 (Cary, NC) and STATA 13 (College Station, TX) are maintained on this system, permitting a vast array of statistical analyses. The PI will access the server and conduct all planned analyses from his office via a secure private network connection.

Data Access, Reporting and Publication. Access to the data will be limited to the PI (Kini) and a trained analyst at ACCORDS who will function under the security and system rules and regulations attached. Required courses in IT and HIPAA, data, security, policies and best practices will be completed and routinely updated by the PI and data analyst. The PI (Kini) will notify OHA of any changes of personnel that occur during the study period. Dr. Kini will be personally responsible for tracking the active status of the analyst performing the research. The PI (Kini) will be responsible for ensuring that data reporting and publication will be consistent with the DUA, including notification of OHA if any data breach occurs. The proposed research will be carried out entirely by Dr. Kini and an analyst at ACCORDS under his direct supervision.

Section A: Submission Details

Date of Initial Submission: Aug 16, 2016 Version Date: Mar 5, 2019

Section B: Protocol Information

Protocol Number: **16-1723** PI: **Kini, Vinay U**

Do not enter PI name here it will be added automatically when selected in Section C below

Project Title:

Optimizing Value In Cardiac Procedures Using Administrative Data

Section C: Key Study Personnel

Remove	Last Name	First Name and MI	Dept/Division	Best Contact Phone #	VA Employee	Role
PI	Kini	Vinay U	Medicine/Cardiology	267-975-3617	☐	Principal Investigator
X	Kini	Vinay U	Medicine/Cardiology	267-975-3617	☐	Primary Contact
X					☐	

Add Another Investigator

Add 1 Investigator with the role of PI (and if PI is a student, 1 Investigator with Role of Faculty Mentor). Also add 1 Investigator with the role of Primary Contact. (Maximum of 3 investigators listed in this table). **All** Study Personnel, including any listed above, must be added on the electronic ***Personnel Form*** when the protocol is submitted to COMIRB through eRA(InfoEd).

Contact Information:

1. Is the PI a student or trainee (including resident/fellow), or doing this research to fulfill an educational requirement? ○ Yes ◉ No

2. Best contact for scientific questions?

2a. Name: Vinay Kini

2b. Phone (10 digit #): (267) 975-3617

Section D: Type of Review being Requested

See guidance on choosing the appropriate review type

1. Type of Review being requested:

- ☐ **Full Board**
- ☑ **Expedited** [adds Attachment F]
- ☐ **Exempt or Non-Human Subject Research (including QA/QI/Program Evaluation)**
- ☐ Secondary review (select only if you are requesting COMIRB cede to an outside IRB)

Attachment F has been added (JUMP)

Section E: Funding

1. Do you have funding for this study? (●) Yes ( ) No ( ) Pending (submitted)

a. Select the institution that is the **primary** recipient of this funding.
- If receiving funds through an industry contract, select the local affiliate institution receiving those funds.
- If our local affiliate receives federal funds through a sub-contract from another institution, select 'Other.'

UCD Anschutz Campus

b. Is this study funded by a federal grant? (●) Yes ( ) No

COMIRB must review the grant: [✓] Submitted [ ] Grant is already on file with COMIRB

Include/Upload Grant document with this Submission

c. Funding Sponsor (if DoD funding, please specify which branch of DoD is providing the funding):

NIH/NHLBI

d. Has the institution's Grants and Contracts office set up an account to use these funds? ( ) Yes (●) No

Warning: All incoming funds must be routed through the Office of Grants and Contracts (OGC). You cannot use Foundation/ Gift money for research without setting up an account with OGC.

Section F: Performance Sites

1. Are any of the investigators funding/directing research procedures conducted outside of the USA, or traveling outside of the USA to collect data? [adds Attachment B] ( ) Yes (●) No

Section F(a): Affiliate Performance Sites

Definition of Affiliate ⓘ

2. Indicate VA involvement in this study (must select one) **Note: 'Multi-site' means more than one local UCD-affiliated site**

[ ] VA only study (if yes to any one of these criteria)	[ ] Multi-site involving VA (if yes to any one, **and** no VA-only criteria met)	[✓] Non-VA study
* Funding solely from the VA **OR** * All procedures performed on VA property, recruiting only at the VA, or using only VA equipment/ resources **OR** * All investigators and study personnel working solely on VA time	* Both VA and non-VA funding **OR** * Some procedures performed on VA property, some recruitment at the VA , or using some VA equipment/ resources **OR** * Some investigators and study personnel working on VA time	* No VA funding **AND** * No procedures/recruitment performed on VA property, and not using VA equipment/ resources **AND** * No investigators or study personnel working on VA time

3. Will any of the following Affiliates be utilized as sites for this research (includes data locations and investigator appointments)? ⓘ

Note: at least one of these affiliate institution must be checked 'yes.' UCD should usually be checked 'yes' due to the investigator's faculty appointment.

a. UCD (Downtown Denver Campus) ( ) Yes (●) No

b. UCD (Anschutz Medical Campus) (●) Yes ( ) No

c. University of Colorado Hospital (including the Adult CTRC or an off-campus site) (●) Yes ( ) No

- [✓] UH-Anschutz Inpatient Pavilion(s)
- [ ] Adult CTRC
- [ ] UH-Anschutz Outpatient Pavilion
- [ ] UH satellite location(s)

d. Veteran's Administration Hospital (ECHCS) ( ) Yes (●) No

i) Are any study personnel employed/paid by the VA? (●) Yes ( ) No

Include with this submission the Yellow VA Clearance Letter

e. Denver Health and Hospitals ( ) Yes (●) No

i) Is **any** Investigator **employed** by Denver Health and Hospitals? ◯ Yes ◉ No

f. Children's Hospital Colorado (including the Pediatric CTRC or an off-campus site) ◯ Yes ◉ No

g. Colorado School of Mines ◯ Yes ◉ No

The performance site(s) and review type you have indicated above require that this protocol be submitted through the UCD HSR portal prior to submission to COMIRB. Please make sure this protocol has been submitted through the portal and the appropriate clearance letter has been obtained before submitting to COMIRB; the clearance letter will need to be uploaded with your COMIRB submission. To access the UCD HSR portal, please click here.

Section F(b): Non-Affiliate Performance Sites

Definition of Non-Affiliate ⓘ

4. Does this study involve other Non-Affiliated Sites? ◯ Yes ◉ No

This should be answered 'yes' if the study will involve any other locations other than those indicated in section F(a) above. The other sites may or may not actually be engaged in conducting the research; engagement can be clarified on Attachment A. [adds Attachment A]

Section G: Description of Study

1. Summary in lay terms: Provide a brief statement describing the research project in 8th Grade Language. This section should include the study aims and rationale, and a brief overview of how you will answer the research question (Approximately 1 paragraph)

Rationale: Cardiac procedures are often used in clinical situations that physician groups have rated as "low-value", meaning they provide little or no health benefit to patients. Despite efforts to minimize low-value procedures, rates of low-value procedures remain high, and can lead to high healthcare costs and unnecessary downstream invasive testing. However, classifying procedures as low-value is usually done with medical record review, and therefore often limited to single centers or small sample sizes. As a result, little is known about the rate of low-value procedures, and variation in the use of low-value procedures, across a diverse array of hospitals and health systems.

Our first objective is to determine whether administrative data codes can accurately identify low-value cardiac procedures. To do this, we will compare administrative data codes obtained from the Colorado All-Payer Claims Database to a linked "gold standard" derived from patient charts at the University of Colorado Hospital. Once we have identified the most accurate administrative data codes that identify low-value procedures, we will use these codes to determine the overall rate of, and hospital-level variation in, the use of low-value procedures in the states of Colorado and Oregon, using de-identified claims from the Colorado and Oregon All-Payer Claims Databases. The grant funding for this study applies only to the second objective.

2. Are there special review considerations?

a. Would you like this study reviewed by the Social/Behavioral panel (consider for Downtown Denver Campus protocols, social research, and non-treatment behavioral research)? ◯ Yes ◉ No

b. Is this an Oncology or Cancer Center project? ◯ Yes ◉ No

c. Are drugs or biologics that involve **human gene transfer**, or deliver recombinant DNA to subjects, included in this research? ◯ Yes ◉ No

d. Does the protocol involve administration of radioactive substances to subjects (including PET scans, radiolabeled tracers, radioactive drugs, etc.)? ◯ Yes ◉ No

e. Does the protocol involve research on newborn blood spot? ◯ Yes ◉ No

f. Is there any research being done on fetal or embryonic tissue? ◯ Yes ◉ No

Section H: Human Subjects

1. Age Range of Subjects to be enrolled: Lower Limit: **18** **Years** (inclusive) Upper Limit: **100** **Years** (inclusive)

Enrollment Numbers **Note: the number of subjects needed in #2 and #3 below should be justified in the Data Analysis section of the protocol included with your submission.**

2. Maximum number of subjects the study needs to **consent** at **all** sites (local + non-affiliated sites): **Up to** 200,000

3. a. Maximum number of **local** subjects (i.e., those enrolled at sites under COMIRB purview) that will be **consented**, including screen failures and withdrawals: **Up to** 200,000

   b. Number of **local** subjects (i.e., those enrolled at sites under COMIRB purview) necessary to collect sufficient data to answer the research question: 200,000

   Note: this number will typically be smaller than the number in #3a.

4. Is the enrollment limited on the basis of gender, race, or ethnicity? ○ Yes ◉ No

5. Inclusion Criteria: (Define the characteristics of the population to be included in the study - Must match protocol)

For our first objective, we will review charts on 1000 sequential patients who received stress tests and 1000 sequential patients who received echocardiograms at the University of Colorado Hospital. There are no other specific inclusion criteria.
For our second objective, we will obtain de-identified administrative claims on all patients who received cardiovascular procedures in the states of Colorado and Oregon between 2010 and 2018 (maximum of 198,000 patients). There are no other specific inclusion criteria.

6. Exclusion Criteria: (Define the characteristics of the population(s) to be excluded, such as age < 18, Prisoners, Pregnant women, or decisionally challenged)

All patients in this study will be over the age of 18 years. There are no other exclusion criteria.

Vulnerable Populations:

7. Inclusion of Vulnerable Populations (check all that apply):
   These vulnerable populations **cannot** be enrolled into a study without prior IRB approval. Will any of these populations be enrolled into the study?

   a. Children (under age 18)? [adds Attachment H] ○ Yes ◉ No

   b. Wards of the State (children in custody of the state)? ○ Yes ◉ No

   c. Neonates (Birth to 30 days)? [adds Attachment I] ○ Yes ◉ No

   d. Pregnant Women or Fetuses? [adds Attachment J] ○ Yes ◉ No

      i. Does this study exclude pregnant women from enrollment, **and** counsel women on avoiding pregnancy during the trial, but intend to retain or follow-up women who incidentally become pregnant during the trial? ○ Yes ◉ No

   e. Prisoners or those on probation or alternative sentencing? [adds Attachment K] ○ Yes ◉ No

   f. Decisionally Challenged (adults only)? Check yes also if populations with a high likelihood of decisional impairment will be screened for the study. [adds Attachment L] ○ Yes ◉ No

      i. Cognitively impaired
      ii. Incompetent to consent
      iii. Proxy consent
      iv. Consenting in life threatening situations

Check 'no' for #7(f) if this study involves **only** use of existing data (i.e., retrospective chart review), even if some of the subjects were decisionally challenged when the data were generated.

TARGETED Recruitment

8. Check any of the following populations that are being TARGETED for recruitment:

   ☐ a. Indigent/Uninsured?
   ☐ b. Nursing Home Residents?
   ☐ c. Students of PI or study staff?
   ☐ d. Students to be recruited in their educational setting?

- ☐ e. Employees directly under supervision of the PI or a Co-I?
- ☐ f. People engaged in illegal activities and/or illegal immigrants?
- ☐ g. People with Post Traumatic Stress Disorder (PTSD)?
- ☐ h. People with Traumatic Brain Injury (TBI)?
- ☐ i. Terminally Ill Patients (life expectancy < 6 mos)?
- ☐ j. People with mental illness or learning disabilities?
- ☐ k. Others vulnerable to coercion?

Section I: Procedures

1. Duration of study procedures for each subject: n/a (chart review)
2. Anticipated time to complete all study enrollment: We anticipate chart review will be completed in 6 months.
3. Are all study procedures for local site(s) accurately described in the protocol? ◉ Yes ○ No
4. Does this research involve the delivery of health care, or treatment-oriented procedures? ○ Yes ◉ No
   a. Is there a "usual practice" for what you are studying (e.g., educational techniques, behavioral modification)? ○ Yes ◉ No
5. Are any additional materials used with subjects (questionnaires, interview guides, informational, diaries)? **Not Applicable**

6. Indicate if any of these procedures are relevant to this study:
   a. Is the administration of any drugs, biologics, supplements, or isotopes dictated by the protocol? ⓘ [adds Attachment C] ○ Yes ◉ No
   b. Devices (Including Mobile Medical Applications) ⓘ [adds Attachment D]
      1. Does this study collect **any** data about **any** devices, **or**
      2. Use a diagnostic assay to determine eligibility? ○ Yes ◉ No
   c. Will the internet be used to collect research data? (i.e. Test, Surveys, Chat Rooms, etc.) [adds Attachment G] ○ Yes ◉ No
   d. Will you create a database for future recruitment? [adds Attachment P] ○ Yes ◉ No
   e. Will Genetic Testing be involved with this study? [adds Attachment Q] ○ Yes ◉ No
   f. Will Biological samples such as urine, sputum, or blood be collected for use in **this** study? [adds Attachment R] ○ Yes ◉ No
   g. Will data and/or biological samples be stored (banked) for future unspecified research questions? [adds Attachment S] ○ Yes ◉ No
   h. Are public schools/universities being used as a setting for this research? [adds Attachment T] ○ Yes ◉ No

Section J: Potentials Risks for Subjects

1. Do you view the risk of this study as minimal ? **(Note: The Committee may disagree)** ◉ Yes ○ No
   a. Justify this determination:

This study involves a retrospective chart review, and analysis of de-identified administrative data. No direct contact with patients will be involved.

2. Describe the anticipated risk of the research: (list risks in order of likelihood and magnitude (very common, common, rare but serious))

We will be collecting patient identifiers (name and date of birth) to link data obtained from chart review to administrative data from the Colorado All-Payer Claims Database. The main risk from chart review and collection of PHI is loss of confidentiality, which will be minimized by the procedures outlined below. our use of the secure server at the Adult and Child Consortium for Outcomes Research and

Delivery Science (ACCORDS) at the University of Colorado Denver for data collection, storage, and analysis. The ACCORDS server uses a robust set of security mechanisms including firewalls and audit trails to ensure records are kept secure and confidential.

3. Describe the plan to minimize risk: (use procedures that are standard of care where possible)

First, we will be using the secure server at the Adult and Child Consortium for Outcomes Research and Delivery Science (ACCORDS) at the University of Colorado Denver for data collection, storage, and analysis. The ACCORDS server uses a robust set of security mechanisms including firewalls and audit trails to ensure records are kept secure and confidential. Data access will be limited to the PI and study personnel listed on the study personnel form. PHI will only be used for the goals of the project and will not be reused or disclosed for any purpose. All identifiers will be destroyed with hard disk scrubbing once the project is completed.

4. Is it possible that the research team may uncover certain incidents (e.g., child abuse) or diseases (e.g., tuberculosis) that are reportable to state authorities through interventions/testing required by this protocol? ○ Yes ◉ No

5. Describe the Potential Benefits of this Study:

Low-value cardiac procedures can lead to worsened patient outcomes and high healthcare costs. This research will uncover the burden of low-value testing in the states of Colorado and Oregon, and we anticipate will lead to novel methods of reducing low-value testing so that patients outcomes can be improved.

6. Describe why the risks to subjects are reasonable in relation to the anticipated benefits to participants and/or society, and in relation to the importance of the knowledge that may reasonably be expected to result, thereby falling in favor of performing this study:

a. To Participant:

The main risk to subjects from this retrospective chart review is loss of confidentiality, which we will keep to a minimum as outlined above. There will be no direct benefit to research subjects from this study, as they will not be contacted and our data is retrospective.

b. To Society:

We believe the benefit to society outweighs the small risk of loss of confidentiality of the research subjects. A significant percentage (25-40%) of cardiac procedures are rated as "rarely appropriate" by physician groups, resulting in unnecessary radiation exposure, downstream invasive procedures, and high healthcare costs. We anticipate our research will further define the scope of the problem, and lead to real-world solutions to reduce low-value procedures, thereby improving patient outcomes and decreasing the burden of high healthcare costs on society.

c. Justify the importance of the knowledge gained:

Current efforts to reduce low-value cardiac procedures have not been clearly successful. Our approach to measuring the scope of the problem and (we anticipate) finding real-world solutions is innovative and could make a significant impact on improving patient outcomes while reducing healthcare costs.

Section K: Recruitment Methods

1. Will subjects be recruited to this study? ⓘ **No (Secondary data or sample use only)**

a. Describe how you will find the data, records, or samples of your subjects:

For our first objective, we will review charts of 1000 consecutive patients who received stress tests and 1000 consecutive patients who received echocardiograms at the University of Colorado hospital starting in January 2012. The data obtained from this chart review will be linked to each subject's administrative claims in the Colorado All-Payer Claims Database via their names and dates of birth.

For our second objective, we will be obtaining de-identified administrative claims of all patients in the states of Colorado and Oregon who received cardiac procedures between 2010 and 2018. This data will be obtained from the Colorado and Oregon All-Payer Claims databases.

Section L: Informed Consent

I. Consent Process / Consent Documentation

All studies must either have a **consent process** or **waive consent completely**. Note that studies using deception or a Waiver of Documentation of Consent still have a consent process of some kind. For the next question (1), answer "No" **only** if you are requesting a Full Waiver of Consent for the entire study. Otherwise, answer "Yes" and provide details of the consent process used in this study in the subsequent questions.

1. Does this study have a consent process? ○ Yes ◉ No

2. Is a Waiver of Consent or a Waiver of Documentation of Consent being Requested? [adds Attachment M] ◉ Yes ○ No

Consent cannot be waived if doing research on Newborn Blood Spots

a. Describe which group or portion(s) of the study the waiver pertains to:

The waiver will pertain to the first objective (retrospective chart review of 2000 patients undergoing cardiac testing at the University of Colorado). We do not believe a waiver will be necessary for the second objective, since all administrative claims will be de-identified by the administrators of the Colorado and Oregon All-Payer Claims Databases.

Based on your your answers to above, waiver of consent and/or waiver of documentation of consent is needed. Please complete Attachment M.

Attachment M has been added (JUMP)

Section M: Privacy and Confidentiality during Study Procedures

Privacy - refers to subjects' ability to control others' access to information about themselves

1. Will the PI/Research Team interact with subjects to collect information? ○ Yes ◉ No

2. Could association with the research be considered stigmatizing or damaging to the subjects' financial standing, employability or reputation? (e.g. STD/HIV clinic, Substance Abuse Rehabilitation Center) ○ Yes ◉ No

Confidentiality - refers to the investigator protecting others' access to subject information

3. Check if any of the following Personal Information attributes are being collected/stored for ***research purposes***?

- ☑ Name/Initials
- ☐ Address
- ☐ E-Mail Address
- ☐ Telephone/Fax Number
- ☐ Social Security Number (unless **only** being used for reimbursement or hospital processing)
- ☐ Medical Record/Health Plan/Ascension Number

4. Will personal information elements be stored separately from other research data? ◉ Yes ○ No

5. Will personal information be available to anyone other than research personnel? ○ Yes ◉ No

6. Will any data about an individual, group or institution be considered sensitive? ○ Yes ◉ No

Section N: HIPAA (Health Information Portability and Accessibility Act)

Learn more about HIPAA

1. Do HIPAA regulations apply to this research (i.e. covered entity accessing, using or disclosing identifiable health information [PHI])? ◉ Yes ○ No

2. How are you **accessing** PHI under HIPAA regulations (i.e. what authorizations are in place)?

a. Treatment Relationship (i.e. for clinical purposes) ☐

b. HIPAA (A) Authorization ☐

c. HIPAA Waiver [adds Attachment O] ☑ Attachment O has been added (JUMP)

d. Data Use Agreement ☑

e. Business Associate Agreement ☐

f. HIPAA not needed to access to health information in this study ☐

With whom is this agreement being made?

The Colorado Institute for Value in Healthcare, a non-profit organization that administers the Colorado All-Payer Claims Database.

3. Will PHI be disclosed outside the covered entity? ○ Yes ◉ No
Note: study monitors reviewing study records at our study site is considered a disclosure

4. What authorization(s) is (are) in place for the **use** and/or **disclosure** of the PHI collected? ⓘ

☐ HIPAA (B) Authorization
☐ Data Use Agreement (for disclosure of a limited data set only)
☑ Requesting HIPAA Waiver [adds Attachment O]
☑ Business Associate Agreement (full PHI)

Attachment O has been added (JUMP)

5. Will a signed and dated copy of the HIPAA B form be provided to the subject?

○ Yes; studying is using a stand-alone HIPAA B form
○ **N/A: Combined Consent/HIPAA Document used (*preferred method)**
○ No: Waiver of Consent (or Waiver of Documentation of Consent) precludes HIPAA Authorization
◉ No: Requesting HIPAA Waiver

Make sure that you have requested a HIPAA Waiver (#2c or #4) above

6. The HIPAA rule makes transfer of data within a study complicated. If there will be more than one transfer step of data in this study, you are strongly encouraged to include a flow diagram of the data movements in this research. Click here for a sample flow diagram.

☐ Check here if you are including a flow diagram of data movement with your submission

Section O: Data Management and Security Plan

Electronic Data

1. Will data be stored in ELECTRONIC format? ◉ Yes ○ No

a. Describe the system/application(s) used for the storage, and management of data (e.g. MS Access, Electronic CRF, Red Cap, etc.):

All data will be collected, stored, and analyzed in the secure server of the Adult and Child Consortium for Outcomes Research and Delivery Science (ACCORDS) at the University of Colorado Denver.

b. Describe where the primary data set will be located:

i. Secure Server ◉ Yes ○ No

A. Describe Server

This is a secure server maintained by the Adult and Child Consortium for Outcomes Research and Delivery Science (ACCORDS) at the University of Colorado Denver. ACCORDS researchers store and analyze data for research on this server, which uses a robust set of security mechanisms including firewalls and audit trails to ensure records are kept secure and confidential. Data is accessed via VPN at the University of Colorado Denver to authorized users.

ii. Local Hard Drive ○ Yes ◉ No

iii. REDCap Data Storage ○ Yes ◉ No

iv. Data are transmitted directly to sponsor/funding entity site: ○ Yes ◉ No

c. How will these data be protected?

i. Encrypted ◉ Yes ○ No

ii. Restricted Access ◉ Yes ○ No

A. If Restricted Access, who will have access to the data?

The PI and study personnel (Drs. Ho and Masoudi) will be the only ones with access to the data.

d. Is removal of identifiable data from the department restricted? ◉ Yes ○ No

e. Will **identifiable** data be stored on a mobile device? ○ Yes ◉ No

f. Will additional copies of identifiable data be created? ○ Yes ◉ No

g. Will the system/application be accessible via the internet? ◉ Yes ○ No
(**Please check "no" for REDCap data storage and e-CRF transmission to Sponsor**)

Attachment G is added

Audio/Digital Audio Recordings

2. Will any audio or visual data be collected? ○ Yes ◉ No

Paper Data

3. Will data be stored in Paper Format (**This includes Consent and HIPAA documents**)? ○ Yes ◉ No

Data Destruction Plan

4. Is there a plan to destroy study data? (if yes, select one of the subsequent choices) ◉ Yes ○ No

a. HIPAA Regulations: 7 years after IRB acknowledgement of study closure ◉ Yes ○ No

b. NIH Regulations: >3 years from the date the Financial Status Report is submitted ○ Yes ◉ No

c. FDA Regulations involving **Drugs**: 2 years following the data a marketing application is approved (or per sponsor requirements which may be longer) ○ Yes ◉ No

d. FDA Regulations involving **Devices**: 2 years following the approval for marketing (or per sponsor requirements which may be longer) ○ Yes ◉ No

e. VA regulations: Destruction of VA research data will follow the VA ORD Records Control Schedule (RCS) 10-1, Section 7.6 , Research Investigator files, approved July 2015. ○ Yes ◉ No

f. Children's Hospital Colorado Policy: see CHCO Research Data-Ownership, Use, and Retention Policy ○ Yes ◉ No

g. Other Agency Criteria ○ Yes ◉ No

Section P: Data and Safety Monitoring Plan

Unanticipated Problems (UAP's) require monitoring and reporting

All studies have potential unanticipated problems (at a minimum, breach of confidentiality is a reportable UAP). These include any "unanticipated event" or any "unexpected adverse event that is at least probably related to the research". All UAP's must be reported in accordance with current COMIRB policy using the electronic forms available.

Click here and see #14 for UAP policy

1. Describe who will monitor for unanticipated problems of **local** subjects:

The PI will be responsible for monitoring for breach of confidentiality. Audit trails will be used to monitor for any unauthorized access to data.

2. **PI confirms that all unanticipated problems will be reported to COMIRB within five (5) days (this box must be checked)** ☑

3. Will PI be responsible for ongoing review of **local** adverse events and serious adverse events? (physical or psychological harm to subjects)

N/A (study does not involve physical/psychological harms)

4. To what external entities will **local** adverse events be reported?

a. Sponsor ○ Yes ◉ No

b. Coordinator Center/Lead Site ○ Yes ◉ No

c. FDA ○ Yes ◉ No

d. None ○ Yes ◉ No

e. Other ◉ Yes ○ No

i. Describe other entity:

The Center for Improving Value in Health Care - administrators for the Colorado All-Payer Claims Database.

5. Will periodic global review of safety/adverse events (SAE's and AE's) occur? ○ Yes ○ No ◉ N/A

6. Will any formal interim analyses be performed? ○ Yes ◉ No

7. Are there defined **participant** discontinuation criteria? ○ Yes ◉ No

8. Are there any **overall protocol/study** stopping rules? ○ Yes ◉ No

Section Q: Resources for Conducting Research

COMIRB wants to ensure that the PI has the resources to conduct a safe and compliant study

1. Are there any factors that limit the feasibility of this study? (e.g. limited population, competing resources, other studies, etc.) ○ Yes ◉ No

2. Describe the facilities available for the research:

The research will be carried out in the ACCORDS center at the University of Colorado Denver (Anschutz). ACCORDS is a multidisciplinary center that houses researchers, biostatisticians, and analysts who share a common goal of improving health care value and patient outcomes.

3. Describe the resources available to conduct the research (e.g. Support Staff, Time, Funding, etc.)

The PI has 50% protected time for research, and will be the primary person performing the research. Drs. Ho and Masoudi (co-investigators) have extensive experience in cardiovascular outcomes research and will regularly provide feedback and, as necessary, oversight to ensure the research is carried out responsibly and effectively.

4. What resources are available at performance sites to treat emergencies resulting from study-related procedures (check all that apply)?

- ☑ a. Not Applicable
- ☐ b. Basic Life Support (BLS) trained personnel
- ☐ c. Advanced Cardiac Life Support (ACLS) trained personnel and crash cart
- ☐ d. Emergency supplies to stabilize subject until emergency personnel arrive
- ☐ e. Emergency response team within facility
- ☐ f. Call 9-1-1
- ☐ g. Other

5. Describe the process to ensure that all persons assisting with the research are adequately informed about the protocol and their related duties:

The research involves a retrospective chart review and analysis of administrative data, and will primarily be carried out by the PI. Drs. Ho and Masoudi will be involved in helping direct the research, methods of analysis, and manuscript drafting and critical revisions.

6. Will other medical or psychological resources be required as a consequence of the research?
(Include referral plans for newly identified diagnosis, suicidal ideation or problem behaviors [e.g., EtOH abuse]. Think about possible incidental findings on any imaging studies done for research purposes only.) ○ Yes ◉ No

Section R: Conflict of Interest

1. Have all investigators and coordinators listed on this application completed and submitted a UCD COI disclosure form to the **UCD** COI office? ◉ Yes ○ No
This applies to affiliate investigators even if they have submitted a COI declaration in accordance with their home institutional policy.

2. Are there any Conflict of Interest issues to be disclosed for the investigators or key personnel **that relate to this study**? ○ Yes ◉ No

Section S: Clinical Trials Compliance

1. Clinical Trials (standard definition)

A research study in which one or more human subjects are prospectively assigned *[individually or in clusters]* to one or more interventions *[including behavioral interventions, placebo or other control]*, to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

a) Does this study meet the above definition of a clinical trial? ○ Yes ◉ No

This study is not a clinical trial and therefore does not require posting on clinicaltrials.gov. However, you may wish to optionally post this study on ct.gov. **YOU SHOULD KNOW** that many journals are now requiring that studies be registered on clinicaltrials.gov **before enrolling the first subject**, in order to be accepted for publication (see the International Committee of Medical Journal Editors notice: http://www.icmje.org/publishing_10register.html). With voluntary posting on ct.gov, be aware that:

- The FDA mandatory language about ct.gov posting should **not** appear in the consent form
- Only study methodology needs to be posted; do not post study results (very onerous process)
- Contact the Clinical Research Support Center (303.724.1111) for assistance, training, and guidance on ct.gov issues

Complete attached Fee Billing Form

F Attachment F: Request for Expedited Review

Jump Back

To **Qualify** for expedited review, the research **Must be No More Than Minimal Risk:**

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is not greater than the risk of doing so as part of routine physical examination.

1. Does this project meet the definition of minimal risk? (•) Yes ( ) No

Justify this assessment:

This study involves a retrospective chart review and analysis of a large, de-identified administrative dataset. Thus, the main risk is breach of confidentiality. However, we will take all necessary precautions to minimize this risk, as described above.

2. Does this study involve any of the following:

a. Research Involving Prisoners as subjects: ( ) Yes (•) No

b. Research that includes genetics testing with direct or indirect Identifiers: ( ) Yes (•) No

c. Research involving Major Deception: ( ) Yes (•) No

Major Deception: Mislead subjects about their health status, the researchers, or the research purpose
Minor Deception: Incomplete disclosure of some purpose of the study to avoid biasing results

d. Research involving consent via proxy: ( ) Yes (•) No

e. Research involving emergency waiver of consent: ( ) Yes (•) No

f. Classified Research involving human subjects: ( ) Yes (•) No

g. Requests for non-significant risk determination for devices: ( ) Yes (•) No

h. Prospectively validating greater than minimal risk health care: ( ) Yes (•) No

i. Identification of subjects or their responses will reasonably place them at risk of criminal or civil liability or be damaging to the financial standing, employability, insurability, reputation, or be stigmatizing: ( ) Yes (•) No

This Project Qualifies for Expedited Review.

Attachment F: Expedited Research Categories

Instructions:

If the research does not fit any of the categories below, it **must** be reviewed at Full Board **even** if it is minimal risk.

Check all of the following categories that apply to his research. **More than one** category may be checked

☐ **Category 1**. Clinical Studies of drugs and medical devices ONLY when conditions (a) OR (b) is met.

a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risk associated with the use of the product is not eligible for expedited review.)
b. Research of medical devices for which
   i. an investigational device exemption application (21 CFR Part 812) is not required; OR
   ii. the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ **Category 2**. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a. from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; **OR**
b. from other adults and children considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount may not exceed the LESSER of 50 ml or 3ml per kilogram in an 8 week period and collection may not occur more frequently than 2 times per week.

☐ **Category 3**. Prospective collection of biological specimens for research purposes by noninvasive means.

a. Hair and nails clippings in a non disfiguring manner
b. deciduous teeth at time of exfoliation or if routine patient care indicates need for extraction
c. permanent teeth if routine patient care indicates need for extraction
d. excreta and external secretions (including sweat)
e. uncannulated saliva collection either in an unstimulated fashion or stimulated by chewing gumbase ow wax or applying a dilute citric solution to the tongue
f. placenta removed at delivery
g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
h. supra- and subgingival dental plaque and calculus provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
i. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
j. sputum collected after saline mist nebulization

☐ **Category 4**. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review. Including studies of cleared devices for new indications.)

Examples:

a. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or are an invasion of the subject's privacy.
b. weighing or testing sensory acuity.
c. magnetic resonance imaging.
d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, ultrasound, electroretinography, diagnostic infrared imaging, doppler blood flow, and echocardiography.
e. moderate exercise, muscular strength testing, body composition assessement, and flexibility testing where appropriate given the age, weight and health of the individual.

☒ **Category 5**. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected, solely for non-research purposes (such as medical treatment or diagnosis) (Note: Some research in the category may be exempt from HHS Regulations for the protection of human subjects 45 CFR 46.101(b)(4). This listing refers only to research that is NOT exempt.)

☐ **Category 6**. Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ **Category 7**. Research on individual or group characteristics or behavior (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavioral) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS Regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt)

☐ **§ 46.118** Protocols submitted for review under 45 CFR 46.118 (infrastructure protocols). Research protocols lacking definite plans for involvement of human subjects.

M Attachment M: Waiver of Consent Request

Jump Back

Except as provided below, written documentation of informed consent that embodies all the required elements of informed consent, as described in 45 CFR 46.116 is required for all research subjects. Consent waiver is not an option if the study is subject to FDA Regulations, except for under very select circumstances (contact COMIRB). Consent waiver is not an option if the study is performing research on newborn blood spots.

With sufficient justification, the IRB may approve a consent process that does not include or alters some or all of the elements of informed consent, provided that it finds and documents specific requirements. If requesting an alteration of consent, justify such in accordance with the criteria below established under 45 CFR 46.116(d)(1-4) [**waiver of consent**] or 45 CRF 46.117(c)(1 or 2) [**waiver of documentation of consent**].

For all waivers, the research (or procedures for which the waiver is sought) must involve no more than minimal risk to the subjects.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Notes on study pre-screening:

1) If you are interacting with potential subjects (phone or in person) to screen for eligibility, COMIRB does not consider verifying eligibility criteria listed on the study advertisement to be a research procedure; no waivers are required for such verification. Questioning that goes beyond such verification requires a consent process prior to questioning. Please submit the **pre-screening script** to read to potential subjects and request a waiver of *documentation of consent* using this Attachment. Please see **COMIRB's Guidance on Pre-screening**.

2) For VA research: Using the medical record to pre-screen potential subjects requires full waiver of consent (and waiver of HIPAA).

Note on HIPAA: If this study is subject to HIPAA regulations, you are using the combined consent/HIPAA document, and you are requesting a waiver of consent or waiver of documentation of consent, you will also need to complete Attachment O (Waiver of HIPAA Authorization); Attachment O can be opened by selecting the appropriate box in section N, #5.

Type of Waiver being Requested

Select the type of waiver being requested (more than one may be chosen):

- [x] **Full Waiver of consent (no consent, or consent is altered to omit certain required elements)**
- [ ] **Waiver of Written Documentation (e.g., verbal Consent, information sheet)**

Section A: Waiver or Alteration of Consent

Describe the portion of the project for which consent waiver is requested (e.g., screening phase only, deception, entire study)

Entire study

If requesting a waiver or alteration from the requirements for obtaining informed consent, justify such in accordance with all the criteria established under 45 CFR 46.116(d) (1-4). Waiver of consent is not an option if the study is subject to FDA regulation.

1. Explain why the research (or procedures for which the waiver is sought) poses minimal risk to the subject:

This study involves a retrospective chart review and analysis of a de-identified administrative dataset. We will be collecting patient identifiers (name and DOB), and therefore there will be a small but real risk of breach of confidentiality. We will make every effort to minimize that risk, including collecting, storing, and analyzing all data on the secure server located at the Adult and Child Consortium for Outcomes Research and Delivery Science at the University of Colorado Denver.

2. Explain why the waiver or alteration will not adversely affect the rights and welfare of the subject:

This study involves a retrospective chart review and analysis of a de-identified administrative dataset. Since the research poses minimal risk to the subjects (i.e., loss of confidentiality), a waiver of consent will not adversely affect the rights and welfare of the subjects.

3. Explain why the research could not practicably be carried out without the waiver or alteration *(note: a survey can still provide subjects with elements of consent in writing; see postcard consent template on the COMIRB website).*

Our study involves a retrospective chart review of 2000 patients. Given this large sample size, and the fact that we will not have any direct contact with patients, we believe the research could not practicably be carried out without the waiver.

4. Once subjects have completed the study, will information be given to, or other debriefing be done with the subject? Explain:

No. This is a retrospective chart review with no direct contact with patients.

O Attachment O: HIPAA Waiver

Jump Back

1. Describe the portion of the project for which HIPAA waiver is requested (e.g., screening, entire study)

Entire study

PHI Access and Use

2. List what **health information*** will be **accessed*** under this waiver:

We will be accessing patient charts from the electronic medical record at the University of Colorado Hospital. From patient charts, we will be collecting names, dates of birth, dates of cardiac testing, symptoms which may have prompted testing, sex, race, and comorbid medical conditions.

*** Health information means any clinical data pertaining to health that you are recording for the research (e.g., lab results, mood diary, smoking status, procedure results)**

*** If the research includes looking at medical records or some other form of PHI, this is considered to be *accessing* PHI, regardless of whether this information is being recorded**

3. Check the identifiers that will be viewed with the above health information: **NONE** ☐

☒ Names/Initials	☐ URLs (http://...)
☐ Telephone Numbers	☐ Vehicle identifiers and serial numbers
☐ Fax Numbers	☐ Certificate / license numbers
☐ Electronic mail addresses	☐ Device identifiers and serial numbers
☒ All dates (except year alone*) that are directly related to an individual (date of birth, discharge date, etc.)	☐ Biometric identifiers (including finger and voice prints)
☐ Social Security Numbers	☐ Full Face photographic images and any comparable images
☐ Medical Record numbers	☐ IP address numbers
☐ Health plan beneficiary numbers	☐ Geographic subdivisions smaller than a state
☐ Account Numbers	☐ Any other unique identifying number, characteristic or code

*** For all subjects over 89 years, birth year alone is considered a direct identifier**

4. Which of the above **identifiers and health information** will be **recorded** for the research (OK to say 'all of the above,' or 'none'):

All of the above.

PHI Disclosure

5. Will any of the above health information be **disclosed** with any of the identifiers in #3 above to parties outside of the research institution under this waiver (i.e., without obtaining the subjects' authorization)? ◉ Yes ○ No

a. What **identifiable** health information above **(**with which identifiers) will be disclosed under this waiver (OK to say 'all of the above,' or 'none'), and **to whom** will the PHI be disclosed. Make sure it is the minimum necessary to achieve research aims:

Names and dates of birth will be disclosed to the Center for Improving Value in Health Care, a non-profit organization that was created through state legislation to administer the Colorado All-Payer Claims Database. This is the minimum amount of PHI that is required in order to create a linked data set that combines clinical information obtained from medical records, to the patients' comprehensive administrative billing claims throughout the state of Colorado.

b. Describe your plan to ensure that the recipient(s) will not re-use the PHI for purposes other than this research project, and that the recipient(s) will not disclose the PHI to anyone else except for authorized oversight of this research or as required by law.

The Center for Improving Value in Healthcare was created by state legislation to develop and administer the Colorado All-Payer Claims Database. They are subject to the rules set forth by the Colorado Department of Healthcare Policy and Financing, which includes strict enforcement of HIPAA privacy and security. They are required to only use PHI for the purpose of linking administrative data, for their triple aim of improving health, enhancing quality, and lowering cost. http://www.civhc.org/Home.aspx.

HIPAA Waiver Justification

6. Is it possible or likely that the PHI collected under this waiver will contain information that puts the subject at risk for civil or criminal liability, or that could be damaging to a subject's financial standing, employability, or reputation? ○ Yes ◉ No

7. Will the PHI be used for any purposes other than those described in this protocol, this waiver request, or as required by law? ○ Yes ◉ No

8. Describe the plan to destroy the identifiers as soon as possible, consistent with the conduct of this research and local regulations:

Upon completion of the research, patient identifiers will be destroyed by using the hard disk scrubbers on the ACCORDS server.

9. Will a signed informed consent document be obtained? ○ Yes ◉ No

10. Describe why this research could not be done without this HIPAA waiver:

We have applied for a waiver of consent, as described above.

Note: waiver of consent, or waiver of documentation of consent, when using the combined consent/HIPAA form is an acceptable justification.

11. Describe why this research could not be done without access to, and use of, the PHI listed above:

The collection of PHI in order to link clinical data with administrative data is critical to this study. Our first objective is to determine whether administrative data can be used to identify low-value testing. Since the "gold standard" of identifying low-value testing is clinical data obtained from medical records, this project could not be practicably carried out without this linkage, since there would be no way to compare the two approaches.

IRB Review Fee Billing Form

An IRB Review Fee is charged for initial and annual continuing full board review and initial expedited review of non-federally sponsored research and for research awards administered by affiliated institutions. Full COMIRB Fee Policy

Type of Review Requested:	**Expedited**
Funding Type:	**Federal funding**
Institution Receiving Funding:	University of Colorado (Anschutz Medical Center)

No Payment is required

University Research
UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

Colorado Multiple Institutional Review Board, CB F490
University of Colorado, Anschutz Medical Campus
13001 E. 17th Place, Building 500, Room N3214
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University of Colorado Hospital | Denver Health Medical Center | Colorado Prevention Center | Children's Hospital Colorado | Denver Health and Hospital Authority | VA Eastern Colorado Health Care System (Denver VAMC)

Certificate of Approval

25-Sep-2018

Title:	Optimizing Value In Cardiac Imaging Using Administrative Data
Subject:	COMIRB Protocol 16-1723 Continuing Review
Investigator:	Vinay Kini
Sponsor(s):	None~
Effective Date:	25-Sep-2018
Expedited Category:	5

Submission ID: CRV002-1

SUBMISSION DESCRIPTION:

Study status: data analysis (closed to enrollment of new subjects)

This study is being transitioned to comply with the “2018 Requirements” of the Federal Policy for the Protection of Human Subjects. You are required to comply with the Pre-2018 Requirements until January 21, 2019, except for the requirement for continuing review. Your study has not been given an expiration date. Beginning January 21, 2019 you are required to comply with the 2018 Requirements

You are still required to submit changes to your research for approval prior to implementing those changes. You are still required to report unanticipated problems and serious or continuing noncompliance to COMIRB. When your research is complete you must report the study closure to COMIRB. Your responsibilities as Principal Investigator are posted here: http://www.ucdenver.edu/research/Research%20Administration%20Documents/Responsibilities-of-Investigators.docx

REVIEW DETAILS– Please read carefully:

The following documents have been reviewed by the Chair as part of this approval:

PDF CR Form
Abstract 1
Abstract 2
Application for Protocol Review v 10.3.17
Cover Letter
Personnel Form
Protocol v 8.11.16

COMIRB only stamps the approved versions of consent documents and local advertisements in the top right hand corner. Approved copies of the study documents are available for download via eRA(InfoEd).

If red-line changes were made, the tracked changes and clean versions have been uploaded into eRA (InfoEd). If the PI disagrees with these changes, submit a change form to COMIRB with the revised documents.

Click here to your submission: Submission Page

Study personnel are approved to conduct the research as described in the above documents approved by COMIRB

Information on how to submit changes (amendments) to your study, reports of unanticipated problems, and request for study closure to COMIRB can be found on the COMIRB website
http://www.ucdenver.edu/research/comirb/submissions/Pages/default.aspx

For the duration of this research the investigator must:

- Submit any change in the research design, investigator, and any new or changed study documents (including new/changed consent forms, questionnaires, advertisements, etc.) to COMIRB and receive approval before implementing the changes
- Use only a copy of the COMIRB-approved, stamped Consent and/or Assent Form. The investigator bears the responsibility for obtaining Informed Consent from all subjects as required by COMIRB prior to the start of study procedures. COMIRB REQUIRES that the subject be given a copy of the consent and/or assent form after it is signed.
- Inform COMIRB immediately of any Unanticipated Problems that are unexpected and related to the study in accordance with COMIRB Policies and Procedures.
- Remain actively engaged in the conduct of the research. The investigator must ensure that all enrolled participants are appropriate for the study prior to study procedures beginning.

As part of this review it was determined that for this research:

1. Risks to subjects are minimized.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with, and to the extent required by, §46.116.
5. Informed consent will be appropriately documented in accordance with, and to the extent required by, §46.117.
6. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. Appropriate safeguards are in place to protect potentially vulnerable populations from coercion and undue influence.

Please reply to the email containing this letter, contact the COMIRB Help Desk at COMIRB@ucdenver.edu or call 303-724-1055 if you have questions or concerns.

Sincerely,

UCD Panel A

Please answer each of the following questions about APAC data request options and submit with your APAC data request:

Please indicate the year(s) of data requested	2011	2012	2013	2014	2015	2016	2017
		x	x	x	x	x	x

Do you want out-of-state people included in claims & elligibility data?	Yes	No
		x

Do you want denied claims included?	Yes	No
		x

Do you want orphan claims included?	Yes	No
		x

Do you want self-insured eligibility and claims data included?	Yes	No
		x

Do you want PEBB and OEBB eligibility and claims data included?	Yes	No
		x

Do you want to limit claims by allowed amount?	No	Yes, limit to greater than zero	Yes, limit to greater than or equal to zero
	x		

What payer types do you want?	Commercial	Medicaid	Medicare (commercial only)	CMS Me access.
	x	x	x	

Please answer each of the following questions about APAC data request options and submit with your APAC data request:

What medical claim types do you want?	All medical claims	Inpatient hospital	Emergency department	Outpatient
	x			

Do you want professional services included with the medical claim types?	Yes	No
	x	

Do you want pharmacy claims?	Yes	No
		x

Do you want monthly eligibility data?	Yes	No
	x	

Do you want member demographic data?	Yes	No
	x	

Do you want provider data?	Yes	No
	x	

Do you want billed premium data?	Yes	No
		x

Do you want claims and eligibility data for selected age groups only?	All ages	Exclude people 65 yrs and older	Specify age exclusions:
	x		

Do you want to limit claims and eligibility data by gender?	Include all	Include only female	Include only male

Please answer each of the following questions about APAC data request options and submit with your APAC data request:

	x		

Do you want to limit medical claims data to selected diagnoses?	No	Yes. List diagnosis codes
		x

Do you want to limit pharmacy data to selected NDC codes or therapeutic classes?	No	Yes. List NDC codes or therapeutic classes codes

Are you requesting identifiable data?	No	Zip code	County	Address	Name	Month of birth	Month of death
	x						

dicare (Restricted Available to OHA only)

Ambulatory surgery	Ambulance	Transportation	Hospice	Skilled Nursing Facility

Date of birth	Date of death

Mark requested data elements	Data Element	Description	Justification
	Data Elements Available for Both Medical and Pharmacy Claims		
x	Year or incurred_year	Year of service or eligibility occurred	We need dates of service (day, month, year) because time to treatment may affect patient health outcomes under study (e.g., time between diagnosis of heart failure and first evaluation of cardiac function).
x	YearMonth or incurred_year_and_month	Year and month service or eligibility occurred	
x	incurred_month_start_date	First day of the month the service or eligibility occurred	
	Incurred_cal_quarter	Quarter the service or eligibility occurred	
x	Fromdate or fill date or from_date	Service begin date or pharmacy fill date	
x	Todate or to_date	Service end date	
x	Paydate or paid_date	Payment date	
x	Paid_Month_Start_Date	First day of the month the service was paid	
x	Personkey or MI_Person_key	Unique identifier created for a person across payers and years	We need to identify patients across time (i.e., patient had a heart attack in 2013 and then again in 2016) to measure outcomes and costs
x	hcg or HCG_MR_line	HCG is the lowest level of the vendor health care grouping system	We need to know where services occurred (i.e., in hospital or outpatient settings) to understand whether services provide better healthcare value depending on where they are performed.
	hcg_Version	Version 2010 V 3.0.12	
	hcg_Year	Year associated with HCG version	
	HCG_MR_Line_Desc	Description of HCG MR_LINE	
	HCG_Setting	Highest level of the HCG system. One of five categories	
	HCG_MR_Line_Group	Second level of the HCG system	
	HCG_MR_Line_Code_and_Desc	Over 100 HCG line group categories	

Mark requested data elements	Data Element	Description	Justification
	HCG_MR_Line_Rollup	Third level of the HCG system	
	HCG_MR_Line_Rollup_Desc	61 HCG line group categories	
	MR_Line_Case_Key	Represents and HCG MR line case	
	Cases	HCG measure of unique services; number of inpatient admits	
	Case_source	HCG Source of case counts	
	Case_basis	HCG Type if case	
	Util_Source	HCG Source of utlization counts	
	Util_Basis	HCG description of utilization type	
	MR_Admit_cases_raw	HCG source admit or cases	
	MR_Units_Days_Raw	HCG source units or days	
	PBP_Admits_cases_raw	HCG source Medicare Plan Benefit Package admits or cases	
	PBP_line_code_and_desc	Desciption HCG source Medicare Plan Benefit Package categories	
	qtydisp or quantity or qty or SV_Units	Quantity or count of services delivered; Revenue code count for inpatient hospitalization and CPT count for outpatient services; Quantity of pharmaceutical dispensed	
	Medicareflag	Medicare coverage flag derived from HCG based on plan benefit package line (PBP). PBP is based on CPT/HCPCS, revenue and diagnosis codes.	
	Payer_LOB	Payer line of business from derived from payer reported product code from eligibility data only and not claims data. Orphan claims assigned null.	
	Paytype or payer_type	Payer reported payer type codes from eligibility data only and not from claims data	

Mark requested data elements	Data Element	Description	Justification
	MC001_APAC _Payer_type	Payer reported payer type codes from claims data	
	MC001_APAC _Payer_type_desc and claims payer type	Payer type description	
x	Prod	Payer reported product code from eligibility data only and not claims data	We will measure healthcare value across different payer types (Medicare, Medicaid, and commericial) to examine differences across payer types.
x	APAC_Product_code	Payer reported product code from claims data	
x	agegrp	Five year age groups calculated based on month of date of service	Age is an important descriptive variable, as most cardiovascular conditions become more common in older age
x	Attid or att_prov_key	Vendor created unique identifier for attending, rendering or pharmacy provider based on payer reported unique identifier. Identifier is payer specific and not unique across payers or years	We are requesting de-identified provider information. One of our goals is to analyze variation in healthcare value at the hospital level. For example, we may find that patients who receive care for a heart attack at "Hospital A" achieve better outcomes relative to costs (higher healthcare value) relative to "Hospital B." We would like to identify which tests
x	Attid_encrypt or Att_Prov_ID_encrypted	encrypted ProviderID	
x	ATT_PROV_CW_KEY	Vendor created unique attending provider identifier across payers and years	
x	Billid	APAC assigned billing provider ID	
x	Billid or Bill_Prov_Key	Vendor created unique identifier for billing provider based on payer reported unique identifier. Identifier is payer specific and not unique across payers or	

Mark requested data elements	Data Element	Description	Justification
x	BILL_PROV_CW_KEY	Vendor created unique billing provider identifier across payers and years	and treatments Hospital A uses to treat heart attack patients. To do this, we will need de-identified ("dummy variables") for healthcare providers (both hospitals and practices). We are NOT seeking identifiable provider information such as hospital or provider names. We may not need all of the elements checked in the workbook, but were not sure which ones we would need to accomplish our goals.
x	Billid_taxonomy	National uniform claim committee (NUCC) provider taxonomy for the billing provider; NPI if not reported	
x	Entity or bill_prov_name	Name of the entity that generated the bill for the service. Medical billing provider or pharmacy name. Name is payer specific and not unique across payers or years	
x	Paid or amt_paid	Payment made by payer. Does not include expected copayment, coinsurance and deductible that patient is responsible to pay to the provider	We will need data on costs to measure healthcare value which is defined as outcomes / cost. We will calculate costs both from the payer and member perspective, and therefore will need data elements for both.
x	Copay or amt_copay	Expected Co-payment by the member	
x	Coins or amt_coins	Expected Co-insurance by the member	
x	Deduct or amt_deduct	Expected Deductible by the member	
x	OOP or amt_pat_paid	Expected Patient paid amount. Amount patient paid. Required if co-payment, co-insurance or deductible are missing	
	Data Elements Avaliable Only for Medical Claims		
x	POS	Industry standard place of service code	We need to know where services occurred (i.e., in hospital or outpatient settings) to understand whether services provide better healthcare value depending on where they are performed.

Mark requested data elements	Data Element	Description	Justification
x	Adm_date	Admission date required for inpatient hospitalizations	We need to know specific dates because time to treatment may affect patient health outcomes under study (e.g., time between diagnosis of heart failure and first evaluation of cardiac function.)
x	Dis_date	Discharge date required for inpatient hospitalization	
x	ptstatus or dis_stat	Status for member discharged from the hospital	We need to know and adjust for patients who died during hospitalization.
x	los	length of inpatient hospital stay. Length of stay equals discharge date minus admission date	LOS is important because it is a contributor to healthcare costs and we will adjust for this in our models.
x	ICD version or ICD_10_OR_HIGHER	Specifies the claim ICD version ICD9 or ICD10	
x	dx1 or ICD_DIAG_01_Primary	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	
x	dx1 description or ICD_DIAG_DESC_PRIMARY	Primary diagnosis description	
x	dx2 or ICD_DIAG_02	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	
x	dx3 or ICD_DIAG_03	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	
x	dx4 or ICD_DIAG_04	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	
x	dx5 or ICD_DIAG_05	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	

Mark requested data elements	Data Element	Description	Justification
x	dx6 or ICD_DIAG_06	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	Diagnosis codes are critical to identifying patients hospitalized with cardiac conditions such as heart attack. Codes in non-primary positions will be used to identify comorbid conditions for risk adjustment.
x	dx7 or ICD_DIAG_07	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	
x	dx8 or ICD_DIAG_08	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	
x	dx9 or ICD_DIAG_09	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	
x	dx10 or ICD_DIAG_10	Principal diagnosis. ICD-9 for dates of service before 10/01/2014 and ICD-10 after	
x	px1 or ICD_Proc_01_Principle	The main or principal inpatient surgery ICD code	Knowing which procedures were performed among patients hospitalized with cardiovascular conditions is critical to understanding whether procedures contributed to to high-value healthcare. An example would be placement of a coronary stent in a patient hospitalized with heart attack.
x	px2 or ICD_Proc_02	Inpatient surgery ICD code 2	
x	px3 or ICD_Proc_03	Inpatient surgery ICD code 3	
x	px4 or ICD_Proc_04	Inpatient surgery ICD code 4	
x	px5 or ICD_Proc_05	Inpatient surgery ICD code 5	
x	px6 or ICD_Proc_06	Inpatient surgery ICD code 6	
x	px7 or ICD_Proc_07	Inpatient surgery ICD code 7	
x	px8 or ICD_Proc_08	Inpatient surgery ICD code 8	
x	px9 or ICD_Proc_09	Inpatient surgery ICD code 9	
x	px10 or ICD_Proc_10	Inpatient surgery ICD code 10	
x	poa1	Inpatient present on admission flag for diagnosis 1. Required if diagnosis 1 is populated	POA indictors are important for risk adjustment and for understand whether complications or new diagnoses were made during a patient's hospitalization.
x	poa2	Present on admission flag for diagnosis 2. Required if diagnosis 2 is populated	

Mark requested data elements	Data Element	Description	Justification
x	poa3	Present on admission flag for diagnosis 3. Required if diagnosis 3 is populated	
x	poa4	Present on admission flag for diagnosis 4. Required if diagnosis 4 is populated	
x	poa5	Present on admission flag for diagnosis 5. Required if diagnosis 5 is populated	
x	poa6	Present on admission flag for diagnosis 6. Required if diagnosis 6 is populated	
x	poa7	Present on admission flag for diagnosis 7. Required if diagnosis 7 is populated	
x	poa8	Present on admission flag for diagnosis 8. Required if diagnosis 8 is populated	
x	poa9	Present on admission flag for diagnosis 9. Required if diagnosis 9 is populated	
x	poa10	Present on admission flag for diagnosis 10. Required if diagnosis 10 is populated	
x	proccode or Proc_code	The Current Procedural Terminology (CPT) code or the Healthcare Common Procedure Coding System (HCPCS) code	These procedure codes and modifiers are important in particular to identify diagnostic cardiovascular procedures (such as stress tests) which may contribute to high healthcare value.
x	proc_desc	CPT and HCPCS code descriptions	

Mark requested data elements	Data Element	Description	Justification
x	mod1	CPT or HCPCS modifier with all digits and numeric codes https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-	These procedure codes and modifiers are important in particular to identify diagnostic cardiovascular procedures (such as stress tests) which may contribute to high healthcare value.
x	mod2	CPT or HCPCS modifier with all digits and numeric codes https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-	
x	mod3	CPT or HCPCS modifier with all digits and numeric codes https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-	
x	mod4	CPT or HCPCS modifier with all digits and numeric codes https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-	
x	msdrg	MS DRG is a Medicare grouping system that classifies inpatient hospital services into one of approximately 750 groups.	The MSDRG code is useful in verifying that the primary diagnosis codes are accurate (i.e., to ensure that primary diagnosis of heart attack matches what it on the MSDRG code).
	Data Elements Available Only for Pharmacy Claims		
	Data Elements Available for Member Demographic Data (static except for		
x	personkey or MI_Person_key	Unique identifier created for a person across payers and data years	We need to identify patients across time (i.e., patient had a heart attack in 2013 and then again in 2016) to measure outcomes and costs

Mark requested data elements	Data Element	Description	Justification
x	gender or Mem_gender	Member Gender	All public use variables listed below will be used for descriptive analysis and risk adjustment.
x	YOB	Member year of birth	Age is an important descriptive variable, as most cardiovascular conditions become more common in older age. We would prefer to have age in years based on YOB so we can risk adjust based on age and described median age of the cohort. We do NOT need any more identifiable information than this.
x	agegrp	Five year age groups calculated based on month of eligibility	
x	race or mem_race	Member race reported by payer. Static from latest quarterly data submitted. Race data for 59% of unique people is missing or unknown.	All public use variables listed below will be used for descriptive analysis and risk adjustment.
x	ethn or mem_ethnicity	Member ethnicity reported by payer. Static from latest quarterly data submitted. Ethnicity data for 72% of unique people is missing or unknown.	All public use variables listed below will be used for descriptive analysis and risk adjustment.

Mark requested data elements	Data Element	Description	Justification
x	lang or Mem_language	Primary spoken language; Static from latest quarterly data submitted. Payers report three-character string from ANSI/NISO https://www.loc.gov/standards/iso639-2/php/code_list.php Vendor recodes ANSI/NISO to numeric codes. Language data for 50% of unique persons is missing or uknown.	All public use variables listed below will be used for descriptive analysis and risk adjustment.
x	MSA or Mem_MSA	Member metropolitan statistical area defined by US Census. Static from latest quarterly data submitted	All public use variables listed below will be used for descriptive analysis and risk adjustment.
x	urban	Zip codes grouped into urban and rural identified by OHA. Static from latest quarterly data submitted	All public use variables listed below will be used for descriptive analysis and risk adjustment.
	Data Elements Available for Monthly Member Eligibility Dat		
	Data Elements Available for Provider Data		

Mark requested data elements	Data Element	Description	Justification
x	Prov_CW_Key	Vendor created unique provider identifier across payers	We are requesting de-identified provider information. One of our goals is to analyze variation in healthcare value at the hospital level. For example, we may find that patients who receive care for a heart attack at "Hospital A" achieve better outcomes relative to costs (higher healthcare value) relative to "Hospital B." We would like to identify which tests and treatments Hospital A uses to treat heart attack patients. To do this, we will need de-identified ("dummy variables") for healthcare providers (both hospitals and practices). We are NOT seeking identifiable provider information such as hospital or provider names. We may not need all of the elements checked in the workbook, but were not sure which ones we would need to accomplish our goals.
x	ATT_PROV_CW_KEY	Vendor created unique attending provider identifier across payers	
x	prov_key or ATTID or att_prov_key	Payer specific identifier number for the attending, servicing, or rendering medical or pharmacy provider. Identifier is not unique across payers	
x	spec or Attending_MI_Specialty	Vendor derived provider specialty for attending, servicing or rendering provider	
x	Bill_Prov_ID_encrypted	Encrypted unique identifier for billing provider	

Mark requested data elements	Data Element	Description	Justification
x	Bill_Prov_Name	Name of billing provider	
	Data Elements Available for Billied Premium Data		
	Restricted Access Data Elements that Require Strong Justification and Detailed Data Security and Release Plar		
	Restricted Access Data Elements that Are Never Shared or Rarely Shared,		

Appendix C – Staff checklist and Minimum Necessary Review (MNR) for limited, custom or Business Associate requests

Staff Reviewer: Oliver

Agreement Number: 5031

Purpose

The purpose of the staff checklist for limited, custom or Business Associate requests is to:

1. Assess whether applicant completely and adequately filled out the APAC-3
2. Complete the Minimum Necessary Review to:
    a. Assess whether OHA is disclosing no more than a limited data set
    b. Provide criteria for assessing if the organization's data request is the minimum necessary to accomplish the purposes stated in the application or amendment.

Instructions

Complete all sections. If you check "no" on any question, please detail in the "notes" section why you checked "no" and what applicant must do in order to receive a "yes". If there are tasks in which the applicant receives a "yes", but staff reviewer has concerns, please describe concern in the "notes" section and be sure to pass along that concern to DRC in the DRC review form. For the Minimum Necessary Review, provide the rationale for the response in the "notes" section.

Task	Yes	No	N/A	Notes
Section 1 complete and responses adequate?	X			
Section 2 complete and responses adequate?	X			
Section 3 complete?	X			
Only chose one box in question 3.1?	X			
Only chose one box in question 3.3a?	X			
Adequately justified in 3.3b how project falls into category chosen in question 3.3a?	X			
If IRB review is required for this project, (IRB is required for all research requests or requests for Medicare FFS data) is IRB protocol and approval memo attached? (OHA may use DRC as a "Privacy Board" for Business Associates that don't have an IRB, but need Medicare FFS data. Please talk to Program Manager if this is the case.)	X			
IRB registered with US Department of Human Services, Office of Human Research Protections? (Write IRB number and expiration in "notes")	X			https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-and-fwa-status/index.html

Task	Yes	No	N/A	Notes
				IORG0000433: Colorado Multiple Institutional Review Board (COMIRB).
IRB accredited? (Write accrediting agency in notes)			X	https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-and-fwa-status/index.html
IRB's approval has been verified?	X			
IRB disclosed and mitigated all actual conflicts of interest with the approval research or the IRB has no actual conflicts of interest			X	
If actual conflict of interest exists, is documentation attached?			X	
May DRC rely on IRB's review?	X			
Adequately justified in 3.4b how the project is within the scope of the current IRB approval?	X			
Adequately described in 3.4c why the approving IRB has jurisdiction over this project?	X			
Adequately described in 3.4d why the project could not be conducted without a waiver of individual authorization?	X			
Does IRB have more than 3 months left on the approval memo, as outlined in 3.3e?	X			
Section 4 complete?	X			
Data Element Workbook attached?	X			
Do all requested elements have a year requested, filters applied and justification response in Data Element Workbook?	X			2012-2017.
If requesting a limited data set, does Data Element Workbook align with response in 4.1b-c?			X	
If requesting a custom data set, is it clear what elements are being requested?	X			PI is requesting de-identified provider names, which are not available. PI may de-identify the provider data if desired.
Is the Payers tab completed in the Data Element Workbook?	X			
If requesting Medicare FFS data, is the project at least partially funded and directed by OHA? (Per our DUA			X	Research is not partially funded by OHA, so is not eligible to receive Medicare FFS data.

Task	Yes	No	N/A	Notes
with CMS, Medicare FFS data may be shared outside of OHA for research **if** OHA is partially funding and directing the project.)				
If requesting a limited data set, does Payers tab align with response in 4.1b?			X	
If requesting a custom data set, is it clear what payers are being requested?	X			
Passes Minimum Necessary Review?	X			
Adequately justified each data element requested (provide rationale and list any data elements not adequately justified in notes)?	X			
Adequately described filters and algorithms for including and excluding claim lines (provide rationale and list strengths and weaknesses of algorithms in notes)?	X			Filtering based on relevant diagnosis codes and Oregon residence. Denied claims, PEBB, OEBB, self-insured, and orphan claims will be excluded.
Consider the elements requested and whether additional elements can be excluded, redacted, or additionally filtered without unreasonably impairing the ability to accomplish the project purposes. Is data requested the minimum necessary? (If no, identify data elements that may be excluded, redacted, or additionally filtered in notes.)	X			
Section 5 complete?		X		
Techniques described are adequate to prevent re-identification in 5.1?	X			
If project requires linkage to another data source, does PI adequately justify necessary linkages in 5.2c?			X	
If project requires linkage to another data source, does PI propose adequate steps to prevent re-identification in 5.2d?			X	
Organization's data privacy and security policies attached?	X			
If any third parties are identified in Section 2, are third party data privacy and security policies attached?			X	

Task	Yes	No	N/A	Notes
Adequately described data management plans in 5.3b?	X			
Adequately described personnel, technical, physical and administrative safeguards in 5.3c-e?	X			PI will be data custodian.
Adequately described plans for destruction of data in 5.3g?	X			
Adequately described procedures implemented to prevent future breach if staff working on the project have a history of security breach in 5.3h?			X	
Section 6 complete?			X	Custom data request.
If limited data is being requested, is payment included?			X	
Does question 4.1 correspond with files selected and number of years input in row c of payment table?			X	
Is cost calculated correctly?			X	
If payment is not included, are one of the boxes (found below the cost chart in 6.1) checked?			X	
If payment is not included for "another reason", is there an explanation?			X	
Does explanation make sense and, if needed, have you discussed explanation with APAC Program Manager?			X	
Section 7 complete?	X			
All checklist boxes checked?	X			
Application signed?	X			
Using your professional opinion, does this application fall into one of the categories below. If yes, please write the category in the "notes". If no, please explain in the "notes" section if the applicant did not adequately explain their application and any follow-up questions you may have OR if the purpose described in the application simply does not fall into one of the categories below.	X			1. Limited data set for research.

Allowed Purposes for Sharing APAC Data

Limited Data Sets

1. Limited data sets may ONLY be shared for research, public health activities or health care operations. 45 CFR 164.514(e)
    - *Per DOJ: We CAN share limited data sets for health care operations of requesting entity.*
2. We may share a limited data set with a Business Associate if a limited data set will meet the Business Associate's needs.
    - *Per DOJ: Execute a modified BAA and DOJ's preference is that the BAA is attached to the contract*

Notes

- Limited data sets may be shared with covered and non-covered entities if a DUA is executed.
- Research requests for limited data sets must have IRB approval.
    - Per Stacy on 11/23/15

Data with Direct Identifiers

1. Direct Identifiers may be shared with Business Associates for work done on OHA's behalf. 45 CFR 164.502(e)
    - *Per DOJ: Execute a modified BAA and DOJ's preference is that the BAA is attached to the contract*
2. Direct Identifiers may be shared with another covered entity for the purposes of OHA's own treatment, payment or health care operations. 45 CFR 164.506(c)(1)
    - *Per DOJ: Execute a modified BAA, instead of DUA, with non-covered entity component of OHA*
3. Direct Identifiers may be shared with a health care provider for treatment. 45 CFR 164.506(c)(2)
4. Direct Identifiers may be shared with another covered entity or health care provider for payment activities of the entity that receives the information. 45 CFR 164.506(c)(3)
5. Direct Identifiers may be shared with another covered entity for health care operation activities of the entity receiving the data IF both entities have had a relationship with the individual who is subject to the PHI being requested and the PHI pertains to such relationship and the disclosure is for quality assurance and similar activities or for the purpose of health care fraud and abuse detection or compliance. 45 CFR 164.506(c)(4)
6. Direct Identifies may be shared with a public health authority for the purposes of preventing or controlling disease, injury, disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority. 45 CFR 164.512(b)
7. Direct Identifiers may be shared with researchers that have an IRB approval. 45 CFR 164.512(i)(1)(i)
8. Direct Identifiers may be shared with researchers if research participant authorizes the use or disclosure of information about him or herself. 45 CFR 164.508. Authorization must include elements in 45 CFR 164.508(c)(1)-(2).

Notes:

- Direct Identifiers can be shared with covered entities for TPO as described above.

- Direct Identifiers can be shared with Business Associates, Public Health and researchers, if guidelines above are met. In these instances, the requesting organization does not necessarily have to be a covered entity

Medicare FFS Data

1. Per our DUA with CMS, Medicare FFS data may be used for Oregon's Health System Transformation efforts as described in our DUA with CMS.
2. Furthermore, Medicare FFS data may be shared outside of OHA for research **if** OHA is partially funding and directing the project and a privacy board or IRB have given approval.
3. Any document creation from this data must adhere to CMS cell suppression policy: No cell 10 or less may be displayed.

Appendix D—Staff review for DRC (standardized for all Health Analytics' data requests)

Office of Health Analytics Application Number: 5031

Staff Review Checklist

Staff Name: Oliver

1. Data Source(s) Requested:

MMIS	**APAC**	CPMS/MOTS
Hospital Discharge Data	OPRCS	
Student Wellness Survey	CAHPS	Physician Workforce Survey
BRFSS	MHSIP	YSS-F
OHIS	Workforce Licensing Data	ASC
Other		

2. Application materials included:

Application **Y** N N/A

Payment Y N **N/A**

Data Elements Worksheet **Y** N N/A

IRB Approval **Y** N N/A

DUA Y N **N/A**

3. Has the requestor provided an overview of the project and adequately explained the need for the data? **Y** N

   Notes: research on the value of cardiovascular care.

4. Has the requestor adequately justified the need for the specific data files and elements requested? **Y** N

   Notes:

5. Has the requestor asked for the minimum necessary data to accomplish the stated purpose? **Y** N

   Notes: filtered by diagnoses.

6. Has the requestor adequately described safeguards in place to protect the data and comply with privacy and security requirements? **Y** N

   Notes:

7. Recommendation for request: **Approve** Deny Request more info

Notes: