



OFFICE OF HEALTH ANALYTICS  
All Payer All Claims Data Reporting Program  
Kate Brown, Governor

Oregon  
**Health**  
Authority

421 SW Oak Street, Suite 850  
Portland, OR 97204  
[oregon.gov/oha/HPA/ANALYTICS](http://oregon.gov/oha/HPA/ANALYTICS)

### **APAC Data Use Agreement Amendment – Limited of Custom Data Sets**

#### **Instructions**

Use this form for amendments or renewals of Limited or Custom All Payer All Claims (APAC) data request applications that have been submitted, approved, and have an executed Data Use Agreement. If you have not received an Application Number and wish to make changes to your submitted application, please contact [Apac.Admin@dhsoha.state.or.us](mailto:Apac.Admin@dhsoha.state.or.us).

The Application Number and Applicant Name must match the information from the original application and Data Use Agreement. Please list changes in the appropriate section and provide sufficient details to allow staff to evaluate the request. All changes supersede the original application and Data Use Agreement.

Send this completed form to:

[APAC.Admin@dhsoha.state.or.us](mailto:APAC.Admin@dhsoha.state.or.us)

Or

Office of Health Analytics - APAC  
421 SW Oak Street, Suite 850  
Portland, OR 97204

If you have questions while completing this application, please follow these steps:

1. Visit the APAC website for more information about the APAC Reporting Program at <http://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx>.
2. Visit the APAC Data Request page for more information about the data request process at <http://www.oregon.gov/oha/HPA/ANALYTICS/Pages/APAC-Data-Requests.aspx>.
3. Review the [APAC Frequently Asked Questions](#) to determine if your question has been answered there.
4. If you still have questions,
  - a. Direct questions about APAC or this application to: [APAC.Admin@dhsoha.state.or.us](mailto:APAC.Admin@dhsoha.state.or.us)
  - b. Direct data privacy questions to: [dhsprivacy.help@state.or.us](mailto:dhsprivacy.help@state.or.us)
  - c. Direct data security questions to: [dhsinfo.security@state.or.us](mailto:dhsinfo.security@state.or.us)

**SECTION 1: PROJECT INFORMATION**

**1.1 Contact Information:** Please provide the project contact information below.

Applicant name: Craig Broberg, MD MCR  
(must be the same applicant of original project)

Application Number 3630 Review ICD9&10 codes CHD from Tertiary Care Institutions  
(example: APACYYYYXXXX or XXXX\_description\_of\_project):

Organization: Oregon Health and Science University

Address: UHN 62, 3181 SW Sam Jackson Pk Rd

City: Portland State: OR Zip: 97221

Phone: 503-494-7400

Email: brobergc@ohsu.edu

Original Application Date: November 2014

**Is this an *amendment* (changes to the application—including revising project staff, request of additional data not specified in original application, etc.) or a *renewal* of an expiring Data Use Agreement or Institutional Review Board approval without any changes to the original application? Please choose only one. An amendment will also renew the Data Use Agreement.**

Amendment  Please continue to Section 2

Renewal  Please continue to Section 3

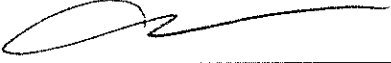
**SECTION 2: AMENDMENT**

(Skip this section and proceed to Section 3 if you are renewing an executed Data Use Agreement that is about to expire and not requesting further changes to the content of the original application. This amendment form may only be used to add or remove staff members working on the project or to request additional data.)

**2.1 List any additional staff that will be working on the project.**

Name: Abigail Khan Role: Coinvestigator Email: khaab@ohsu.edu

The undersigned individual has read and is hereby bound by all terms and conditions of the original Data Use Agreement referenced in Section 1 of this amendment.

 4.3.18  
Signature Date

Name: Katrina Ramsey Role: Data Analyst Email: ramseyk@ohsu.edu

The undersigned individual has read and is hereby bound by all terms and conditions of the original Data Use Agreement referenced in Section 1 of this amendment.

\_\_\_\_\_  
Signature Date

Name: \_\_\_\_\_ Role: \_\_\_\_\_ Email: \_\_\_\_\_

The undersigned individual has read and is hereby bound by all terms and conditions of the original Data Use Agreement referenced in Section 1 of this amendment.

\_\_\_\_\_  
Signature Date

Name: \_\_\_\_\_ Role: \_\_\_\_\_ Email: \_\_\_\_\_

The undersigned individual has read and is hereby bound by all terms and conditions of the original Data Use Agreement referenced in Section 1 of this amendment.

\_\_\_\_\_  
Signature Date

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**2.2 List any staff that will no longer be working on the project:**

Name: Luke Burchill	Role: Coinvestigator
Name: Joel McLary	Role: Coinvestigator
Name:	Role:
Name:	Role:
Name:	Role:

**2.3 What is the reason for the amendment?**

Staff changes, and request for additional data from 2015 and 2016.

No other changes.

**2.4 Did the original application include an Institutional Review Board review and approval?**

Yes  No

(If no, proceed to question 2.7)

**2.5 Is the amendment within the scope of the original IRB approval?**

Yes  No

If yes, please explain:

We have not made any alterations to the query or data analysis plan.

If no, requestor must submit new application, not an amendment.

**2.6 Is an amended IRB approval attached?** (An amended IRB approval is *required* for any amendments to the scope of the project.)

Yes  No

Date amended IRB approval expires: 1/31/2019

**2.7 Are you requesting additional data files, data elements, or years of data?**

Yes  No

(If yes, proceed to questions 2.8-11. If no, skip questions 2.8-11.)

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**2.8 Limited Data Sets:** In the table below, indicate which additional data file(s) you are requesting. Refer to the Data Element Workbook for more information about the data elements included in each Limited data set. *Please note:* OHA will only provide the minimum necessary required data for the project at hand. In other words, you will only receive those data elements that you request and adequately justify.

a. Are you requesting a Limited data set?

Yes       No

*If yes, please complete parts b and c below.*

b. In the table below, indicate which Limited data file(s) you are requesting (refer to Question 2.11 for the cost of each file).

		Payer					
		All Payers <sup>1</sup>	Medicaid	Medicare Advantage	Commercial Insurance	OEBB/PEBB	Medicare FFS <sup>2</sup>
Claims Data File	Episodes of Care <sup>3</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	All Medical Claims <sup>4</sup>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Hospital Inpatient Claims	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Emergency Department Claims	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Ambulatory Surgery Claims	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Ambulatory Outpatient Claims	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	All Pharmacy Claims <sup>5</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

c. Please indicate the year(s) requested for the data files selected above.

2011     2012     2013     2014     2015     2016

<sup>1</sup> All Payers includes Medicaid, Medicare Advantage, and Commercial Insurance (including OEBB/PEBB).

<sup>2</sup> Medicare FFS data will only be given to projects in which OHA is funding and directing. Projects requesting Medicare FFS data will also need to be approved by requester's Institutional Review Board.

<sup>3</sup> Episodes of Care file contains all medical claims, all pharmacy claims, and fields from the Medical Episode Grouper (MEG). MEG is a proprietary grouping algorithm that creates episodes that describe a patient's complete course of care for a single illness or condition. If requesting Episodes of Care file, no other data file is needed.

<sup>4</sup> All Medical Claims file includes hospital inpatient, emergency department, ambulatory surgery and ambulatory outpatient claims, and other hospital treatment settings. If requesting all medical claims, you do not need to request these other data sets.

<sup>5</sup> All Pharmacy Claims file contains only pharmacy claims.

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**2.9 Custom Data Sets:** Refer to the *Data Elements Collected by APAC* section of the Data User Guide for a list of data elements available. Please note: OHA will only provide the minimum necessary data for the project. In other words, you will only receive those data elements that you request and adequately justify.

a. Are you requesting a Custom data set?

Yes       No

**2.10 Data Element Workbook:** For both Limited and Custom data set amendment requests, please complete the Data Element Workbook according to the instructions on the “Instructions” tab and attach it to this amendment.

Data Element Workbook completed and attached, including justifications for each element requested and payers tab completed.

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**2.11 Cost of Data:** If requesting additional data from the Limited data set, please calculate the cost below. (This table should match the files/years selected in Questions 2.8b and 2.8c.) **Please include payment with the application.** Checks should be made to Oregon Health Authority and will not be cashed until application is approved. If requesting a Custom data set, an invoice will be sent if/when OHA approves request.

		Payers					
		All Payers	Medicaid	Medicare Advantage	Commercial Insurance	OEBB/PEBB	Medicare FFS
Claims Data File	Episodes of Care	<input type="checkbox"/> \$3,000	<input type="checkbox"/> \$1,000	<input type="checkbox"/> \$1,000	<input type="checkbox"/> \$1,000	<input type="checkbox"/> \$1,000	<input type="checkbox"/> \$1,000
	All Medical Claims	<input checked="" type="checkbox"/> \$1,500	<input type="checkbox"/> \$500	<input type="checkbox"/> \$500	<input type="checkbox"/> \$500	<input type="checkbox"/> \$500	<input type="checkbox"/> \$500
	Hospital Inpatient Claims	<input type="checkbox"/> \$375	<input type="checkbox"/> \$125	<input type="checkbox"/> \$125	<input type="checkbox"/> \$125	<input type="checkbox"/> \$125	<input type="checkbox"/> \$125
	Emergency Department Claims	<input type="checkbox"/> \$375	<input type="checkbox"/> \$125	<input type="checkbox"/> \$125	<input type="checkbox"/> \$125	<input type="checkbox"/> \$125	<input type="checkbox"/> \$125
	Ambulatory Surgery Claims	<input type="checkbox"/> \$375	<input type="checkbox"/> \$125	<input type="checkbox"/> \$125	<input type="checkbox"/> \$125	<input type="checkbox"/> \$125	<input type="checkbox"/> \$125
	Ambulatory Outpatient Claims	<input type="checkbox"/> \$375	<input type="checkbox"/> \$125	<input type="checkbox"/> \$125	<input type="checkbox"/> \$125	<input type="checkbox"/> \$125	<input type="checkbox"/> \$125
	All Pharmacy Claims	<input type="checkbox"/> \$1,500	<input type="checkbox"/> \$500	<input type="checkbox"/> \$500	<input type="checkbox"/> \$500	<input type="checkbox"/> \$500	<input type="checkbox"/> \$500
	a. Total each column	\$1,500					
	b. Add column totals	\$1,500					
	c. Enter number of years of data requested (Q2.8.c)	2					
	d. Multiply rows b and c	\$3,000					
	e. OHA Production Cost	\$560					
f. Add rows d and e for Total Payment	\$3,560						

Check box if payment is not included because Custom data set is requested.

Check box if payment is not included for another reason. Please explain.

**SECTION 3: RENEWAL**

Please check the appropriate boxes. This section is for those renewing an existing Data Use Agreement or Institutional Review Board approval that is about to expire without requesting further changes to the content of the original application.

- OHA Data Use Agreement Renewal (for applicants in which the OHA Data Use Agreement is about to expire)

By checking the above box, applicant hereby attests that the project shall continue to be conducted as specified in the Data Use Agreement referenced in Section 1 and the project has been renewed by Principal Investigator's Institutional Review Board, if applicable. (If original application required Institutional Review Board approval, an amended Institutional Review Board approval is **required** for renewal outside the original Institutional Review Board approval timeframe.)

Amended Institutional Review Board approval documentation is attached.   
Original Institutional Review Board approval is still valid for more than 3 months.   
Original application did not include Institutional Review Board approval.

- Institutional Review Board Approval Renewal (for applicants in which the OHA Data Use Agreement is still valid, but the original Institutional Review Board approval is about to expire)

By checking the above box, applicant hereby attests that the project shall continue to be conducted as specified in the Data Use Agreement referenced in Section 1 and the project has been renewed by applicant's Institutional Review Board. (Amended Institutional Review Board approval is **required** for renewal outside the original Institutional Review Board approval timeframe.)

Amended Institutional Review Board documentation is attached.




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**Section 4: Signatures**

Except as expressly amended above, all other terms and conditions of the Data Use Agreement and any previous amendments are still in full force and effect. Data Recipient certifies that any representations, warranties and certifications contained in the Data Use Agreement are true and correct as of the effective date of this amendment and with the same effect as though made at the time of this amendment. This amendment shall be effective as of the date signed by OHA. The ability of Data Recipient to use the Data under this amendment is valid for two years from the effective date.

SIGNATURES:

  
\_\_\_\_\_  
*Data Recipient authorized signature*  
**Craig Broberg, MD**  
\_\_\_\_\_  
*Printed name*

2/15/18  
\_\_\_\_\_  
*Date*  
**Assoc. Professor**  
\_\_\_\_\_  
*Title*

\_\_\_\_\_  
*OHA authorized signature*  
  
\_\_\_\_\_  
*Printed name*

\_\_\_\_\_  
*Date*  
  
\_\_\_\_\_  
*Title*

Return completed form to [APAC.Admin@dhsaha.state.or.us](mailto:APAC.Admin@dhsaha.state.or.us).

Completed form may also be printed and mailed to:  
APAC Program Manager  
Office of Health Analytics  
421 SW Oak St., Suite 850 - APAC  
Portland, OR 97204

APPROVAL OF SUBMISSION

February 1, 2018

Dear Investigator:

On February 1, 2018, the IRB reviewed the following submission:

IRB ID:	IRB00010517	MOD or CR ID:	MODCR00004954
Type of Review:	Modification and Continuing Review		
Title of Study:	Congenital heart databases and the accuracy of coded data		
Title of modification	CR for 2017		
Principal Investigator:	Craig Broberg		
Funding:	None		
IND, IDE, or HDE:	None		
Documents Reviewed:	<ul style="list-style-type: none"> <li>• APAC Request Form.pdf</li> <li>• Brief Project Description.doc</li> <li>• Cover Memo CH Database.docx</li> <li>• Detailed Answers to APAC Questions.docx</li> <li>• PPQ.pdf</li> <li>• Protocol Amd. - 6-27-2014.doc</li> <li>• WoA.doc</li> </ul>		

The IRB granted final approval on 2/1/2018. The study is approved until 1/31/2019.

Review Category: Expedited Category #5

Copies of all approved documents are available in the study's **Final** Documents (far right column under the documents tab) list in the eIRB.

**Ongoing IRB submission requirements:**

- Six to ten weeks before the expiration date, you are to submit a continuing review to request continuing approval.
- Any changes to the project must be submitted for IRB approval prior to implementation.
- Reportable New Information must be submitted per OHSU policy.

- You must submit a continuing review to close the study when your research is completed.

### **Guidelines for Study Conduct**

In conducting this study, you are required to follow the guidelines in the document entitled, "[Roles and Responsibilities in the Conduct of Research and Administration of Sponsored Projects](#)," as well as all other applicable OHSU [IRB Policies and Procedures](#).

### **Requirements under HIPAA**

If your study involves the collection, use, or disclosure of Protected Health Information (PHI), you must comply with all applicable requirements under HIPAA. See the [HIPAA and Research](#) website and the [Information Privacy and Security](#) website for more information.

### **IRB Compliance**

The OHSU IRB (FWA00000161; IRB00000471) complies with 45 CFR Part 46, 21 CFR Parts 50 and 56, and other federal and Oregon laws and regulations, as applicable, as well as ICH-GCP codes 3.1-3.4, which outline Responsibilities, Composition, Functions, and Operations, Procedures, and Records of the IRB.

Sincerely,

The OHSU IRB Office

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

Office of Health Analytics

Application Number: **3630**

## 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/APayment  Y  N  N/AData Elements Worksheet  Y  N  N/AIRB Approval  Y  N  N/ADUA  Y  N  N/A (pending additional signatures)3. Has the requestor provided an overview of the project and adequately explained the need for the data?  Y  N

Notes: This is a continuation of PI’s existing research. The amendment simply adds two new staff and requests two additional years of data. Data elements and analyses have not changed.

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

Notes: DRC may rely on the justification from the original request.

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

Notes: DRC may rely on the MNR from the original request.

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: This is a very routine and non-controversial amendment.

**Appendix G – Staff checklist and Minimum Necessary Review (MNR) for amendments or renewals**

Staff Reviewer: James Oliver

Agreement Number:

3630\_Review\_ICD9&amp;10\_codes\_CHD\_from\_Tertiary\_Care\_Institutions\Amendment 5

**Purpose**

The purpose of the staff checklist for amendment or renewals is to assess whether applicant completely and adequately filled out the amendment form.

**Instructions**

Complete all sections. If you check “no” on any question, please detail in the “notes” section of the same row why you checked “no” and what applicant must do in order to receive a “yes”.

1.

Task	Yes	No	N/A	Notes
Agreement number entered?	<b>X</b>			
Does agreement number and applicant listed in amendment/renewal match the agreement number and applicant in original application?	<b>X</b>			
Did applicant choose either “Amendment” or “Renewal”?	<b>X</b>			
<b>Section 2 – Amendment (Must go to DRC for review)</b>	<b>X</b>			
Have all additional staff signed stating they have read and are bound to the terms of the original DUA?	<b>X</b>			
If original application included IRB approval, does the amendment fall inside the scope of the original IRB approval?	<b>X</b>			
Does IRB approval have more than 3 months left? (Can be either the original IRB sent with original application is valid for more than 3 months or an amended IRB is attached and is valid for more than 3 months)	<b>X</b>			Expires 1/31/2019.
If amended IRB approval is attached, does IRB application number on amendment match IRB application number on original IRB approval?	<b>X</b>			

If requesting new/more data, is Data Element Workbook attached?		X		Data elements have not changed from the original request.
Do all requested elements have a year requested, filters applied and justification response in Data Element Workbook?	X			2015 and 2016.
If requesting a limited data set, does Data Element Workbook align with response in 2.8b-c?			X	
If requesting a custom data set, is it clear what elements are being requested?	X			Same data elements as prior request.
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 with CMS, Medicare FFS data may be shared outside of OHA for research <b>only if</b> OHA is partially funding and directing the project.)			X	Not eligible to receive Medicare FFS.
If requesting a limited data set, does Payers tab align with response in 2.8b?			X	
If requesting a custom data set, is it clear what payers are being requested?			X	
If Limited data is being requested, is payment included	X			
Do 2.8b and 2.8c correspond with the files selected and the number of year input in row c of the payment table?	X			
Is cost calculated correctly?	X			
Passes Minimum Necessary Review?	X			
Adequately justified each data element requested (provide rationale and list any data			X	DRC may rely on justification from original data request as data elements and analyses have not changed.

elements not adequately justified in notes)?				
Adequately described filters and algorithms for including and excluding claim lines (provide rationale and list strengths and weaknesses of algorithms in notes)?			X	
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	DRC may rely on MNR from original data request as data elements and analyses have not changed.
<b>Section 3 – Renewal (DUAs can be renewed without DRC approval)</b>		X		
If applicant is renewing OHA agreement, does applicant include proper IRB documentation if necessary? (In notes, please state whether an amended IRB approval is attached, the original IRB is still valid, or original application did not include an IRB approval.)			X	
If applicant is renewing IRB approval, did applicant include renewed IRB approval?			X	
Does IRB application number on renewal memo match IRB application number on original IRB approval?			X	
<b>Signatures</b>	X			
Is amendment signed?	X			