



### **APAC: Data Request Application Amendment**

Use this form for amendments or renewals of All Payer All Claims data applications that have been submitted, approved and have received an Application Number. If you have not received an Application Number and wish to make changes to your submitted application, please contact [apac.admin@state.or.us](mailto:apac.admin@state.or.us).

The Data Use Agreement Number and Principal Investigator must match the information contained within the original application. Please list changes in the appropriate section and provide sufficient details to allow staff to evaluate the request. All changes supersede the original application.

Completed form should be sent to:

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

Or

Office of Health Analytics - APAC

421 SW Oak Street, Suite 850

Portland, OR 97204

Direct any questions about APAC or this application to: [APAC.Admin@dhsaha.state.or.us](mailto:APAC.Admin@dhsaha.state.or.us)

Direct data privacy questions to: [dhsprivacy.help@state.or.us](mailto:dhsprivacy.help@state.or.us)

Direct data security questions to: [dhsinfo.security@state.or.us](mailto:dhsinfo.security@state.or.us)

More information about the APAC Reporting Program is posted on our website at <http://www.oregon.gov/oha/OHPR/RSCH/Pages/apac.aspx>.

The Oregon Health Authority

#### *Vision*

A healthy Oregon

#### *Mission*

Helping people and communities achieve optimum physical, mental and social well-being through partnerships, prevention, and access to quality, affordable health care.

#### *Aims*

The Health Authority will transform the health care system in Oregon by:

- Improving the lifelong health of Oregonians
- Increasing the quality, reliability, and availability of care for all Oregonians
- Lowering or containing the cost of care so it's affordable to everyone

**Section 1: Contact information**

Applicant name (must be Principal Investigator of original project):

Aaron Caughey

Application Number (example: APACYYYYXXXX or XXXX\_description\_of\_project): APAC20140002.

Organization: Oregon Health & Science University (OHSU)

Address: 3181 S.W. Sam Jackson Park Rd

City: Portland State: OR Zip: 97239-3098

Phone: 503-494-2391

Email: caughey@ohsu.edu

Original Application Date: August 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

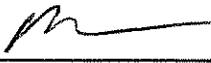
**Section 2: Amendment**

(Skip this section and proceed to Section 3 if you are renewing an approved application 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.)

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

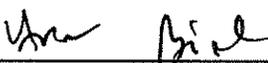
Name: Bernie Lau Role: Research Staff Email: laub@ohsu.edu

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.

 5/31/2016  
Signature Date

Name: Fran Biel Role: Research Staff Email: biel@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.

 5/31/2016  
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

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

2. List any staff that will no longer be working on the project:

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

3. What is the reason for the amendment?

Bernie Lau and Fran Biel are members of our research team who joined the group after we started working with APAC data. They will be working on several APAC- related projects and so we would like for them to be approved as users of the data set.

4. Did the original application include an Institutional Review Board review and approval?

Yes  No

(If no, proceed to question 7)

5. Is the amendment within the scope of the original IRB approval?

Yes  No

If yes, please explain:

We are only requesting for new members of our team to be approved as users of our APAC data. The aims of our research and methodology remain the same.

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

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: \_\_\_\_\_

7. Are you requesting additional data files or data elements?

Yes  No

(If yes, proceed to question 8-9. If no, skip question 8-9.)

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8. In the table below, indicate which additional data file(s) you are requesting. Refer to the limited data set workbook on the website (<http://www.oregon.gov/oha/OHPR/RSCH/pages/apac.aspx>) for more information about the data elements included in each file. Please note OHA will only provide the minimum necessary required data for the project at hand. Use the limited data set workbook to justify why each data element requested is the minimum necessary required. Attach limited data set workbook to this amendment.

		Payers					
		All Payers <sup>1</sup>	Medicaid	Medicare Advantage	OEBB/PEBB	Private Commercial Insurance	Medicare FFS <sup>2</sup>
Data File	Hospital inpatient claims						
	Emergency room claims						
	Ambulatory surgery claims						
	Ambulatory outpatient claims						
	All Medical Claims <sup>3</sup>						
	All Pharmacy Claims <sup>4</sup>						
	Episodes of care <sup>5</sup>	✓					

9. Please indicate the year(s) requested for the data files selected above.\*

2011            2012            2013            ✓ 2014

\*2010 data is available, but incomplete. If you would like 2010 data, please request a "custom data set" below.

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

<sup>2</sup> Medicare FFS data will only be given to projects in which OHA is funding and directing.

<sup>3</sup> All Medical Claims file includes hospital inpatient, ambulatory surgery and ambulatory outpatient claims and other hospital treatment settings.

<sup>4</sup> All Pharmacy Claims file contains only pharmacy claims.

<sup>5</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.

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10. Do you want a custom data set?

Yes                      No

If yes, please describe the data elements requested and a justification for each in the "Custom" tab of the limited data set workbook. Attach limited data set workbook to this amendment.

11. If requesting additional data from the standard limited data set files, please calculate the cost below. (This table should match the files/years selected in Question 8 and 9.) 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	OEBB/PEBB	Private Commercial Insurance	Medicare FFS
Data File	Hospital inpatient claims	\$500	\$100	\$100	\$100	\$100	\$100
	Emergency room claims	\$500	\$100	\$100	\$100	\$100	\$100
	Ambulatory surgery claims	\$500	\$100	\$100	\$100	\$100	\$100
	Ambulatory outpatient claims	\$500	\$100	\$100	\$100	\$100	\$100
	All Medical Claims	\$1,000	\$200	\$200	\$200	\$200	\$200
	All Pharmacy Claims	\$1,000	\$200	\$200	\$200	\$200	\$200
	Episodes of care	\$2,000	\$400	\$400	\$400	\$400	\$400
	a                      Total each column	\$ 2,000	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0
	b                      Add column totals	\$ 2,000					
	c    Enter number of years of data requested	1					
	d                      Multiply row b and c	\$ 2,000					
	e                      OHA Production Fee	\$ 560					
f                      Add row d and e for Total Payment	\$ 2,560						

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

### Section 3: Data Use Agreement Renewal

Please check the appropriate boxes. This section is for those renewing an approved application or IRB approval that is about to expire without requesting further changes to the content of the original application.

- ✓ OHA Agreement renewal (for Investigators in which the OHA Data Use Agreement is about to expire)

By checking the above box, Investigator 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 IRB approval, an amended IRB approval is **required** for renewal outside the original IRB approval timeframe.)

Amended IRB approval documentation is attached.

Original IRB approval is still valid for more than 3 months. ✓

Original application did not include IRB approval.

IRB Approval renewal (for Investigators in which the OHA Data Use Agreement is still valid, but the original IRB approval is about to expire)

By checking the above box, Investigator 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. (Amended IRB approval is **required** for renewal outside the original IRB approval timeframe.)

Amended IRB documentation is attached.

### 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

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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*

5/31/16  
\_\_\_\_\_  
*Date*

\_\_\_\_\_  
*OHA authorized signature*

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

Return completed form to [apac.admin@state.or.us](mailto:apac.admin@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

**Research Integrity Office, L106-RI**

3181 SW Sam Jackson Park Road

Portland, OR 97239-3098

(503) 494-7887

*Memo*

**Date:** September 24, 2015

**To:** Jonathan Snowden, PhD

**From:** Kathryn Schuff, MD, MCR, Chair, Institutional Review Board  
Elizabeth Haney, MD, Vice-Chair, Institutional Review Board  
Lynn Marshall, ScD, Vice-Chair, Institutional Review Board  
Penny Hogarth, MD, Vice-Chair, Institutional Review Board  
Kara Manning Drolet, PhD, Associate Director, OHSU Research Integrity Office  
Andrea Johnson, JD, CIP, Assistant Research Integrity Officer, Institutional Review Board  
David Holmgren, MS, IRB Manager, Institutional Review Board  
William Hoffman, PhD, MD, VA IRB Co-Chair

**IRB #:** IRB00008649

**Study Title:** Trends and current practice in obstetrics and perinatal outcomes in Oregon, 1990 - 2011

**CR ID:** CR00024766

**CR Name:** CRQ 2015

## Continuing Approval

The above submission was reviewed and approved for one year effective 9/24/2015.

Review category: Expedited Category #5

Copies of all approved documents are available in the study's Official Documents list in the eIRB. Any additional documents that require an IRB signature (e.g. IIAs, IAAs, DUAs) will be posted when signed. If this applies to your study, you will receive a notification when these additional signed documents are available.

### 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.
- Unanticipated problems and protocol deviations must be submitted per OHSU policy.
- You are required to submit a termination request when your research is completed.

### Guidelines for Study Conduct

In conducting this study, you are required to follow the guidelines in the document "[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.