

RHODE ISLAND DEPARTMENT OF HEALTH ALL-PAYER CLAIMS DATABASE DATA USE AGREEMENT FOR RHODE ISLAND STATE REQUESTERS

This Data Use Agreement ("Agreement") is effective beg	inning on the date that the last party
signs this Agreement ("Effective Date"), ends upon proje	ct completion, anticipated to be
("End Date"), and is between the parties,	("Receiving Organization") and
the Rhode Island Department of Health ("RIDOH").	

- 1) Purpose. This Agreement specifies the terms and conditions under which RIDOH may release and the Receiving Organization may obtain, use, and disclose Rhode Island All-Payer Claims Database data files or reports specified in Section 5 of this Agreement, and/or any derivative files ("APCD Data").
- 2) Applicable Law. This Agreement is subject to the *Rules and Regulations Pertaining to the Rhode Island All-Payer Claims Database* (216-RICR-10-10-05), pursuant to the Administrative Procedures Act (R. I. Gen. Laws Chapter 42-35), the Confidentiality of Health Care Communications Information Act (R. I. Gen. Laws Chapter 5-37.3), the Health Information Portability and Accountability Act, and all other applicable laws including, but not limited to, R23-17.17 RI-APCD.

3) Terms.

- (1) The terms and conditions of this Agreement can only be changed by a written modification by the parties to this Agreement or by the parties adopting a new agreement.
- (2) If an Applicable Law requires a change in this Agreement, the parties will consider that change to be made automatically, but only to the minimum extent required by that Applicable Law. Following amendment of the Agreement in this manner, the parties shall, as necessary, work together to clarify their respective obligations with respect to any new requirements under the modified Applicable Law.
- (3) If there is a conflict between the terms or conditions of this Agreement, on the one hand, and any other agreement between the parties, on the other hand, the terms and conditions of this Agreement shall prevail.
- (4) If an extension to this Agreement is necessary, the duration may be extended in writing only and fully executed by the parties specified in this Agreement.
- 4) Project and Application. This Agreement pertains to the project entitled _____ as described in the project's contract and incorporated into this Agreement as Exhibit A. This Agreement shall apply to any duly approved amendment to, or restatement of, the contract referred to in the immediately preceding sentence. Any other projects, users, and users require separate approvals.



5) Covered Data. This Agreement pertains to the following files, in accordance with the specifications, as requested and approved in Exhibit A:

Type of File	Years

6) Attachments. The parties mutually agree that the following specified Exhibits are part of this Agreement:

Exhibit A: Project Contract (Application or Data Request Form)

Exhibit B: Certificate of Data Destruction

Exhibit C: Attestation for a Requested Use or Disclosure of Protected

Health Information Potentially Related to Reproductive Health Care

7) Ownership of Information. The Receiving Organization agrees that RIDOH owns and retains ownership of all APCD Data released to the Receiving Organization under this Agreement. The Receiving Organization will not disclose, release, reveal, show, sell, rent, lease, loan, submit, present or otherwise grant access to the APCD Data unless specifically approved.

8) APCD Data Use.

- (1) The Receiving Organization will use APCD Data only for the purposes identified in Exhibit A.
- (2) The Receiving Organization will ensure that access to APCD Data is provided only to the authorized individuals, including employees, agents, and/or approved subcontractors.
- (3) The Receiving Organization and its authorized individuals will not attempt to identify individuals in the APCD data in any way.
- (4) The Receiving Organization will not link APCD Data to any other data sources other than those purposes approved in Exhibit A.
- 9) APCD Data Disclosure. The Receiving Organization will strictly adhere to the following provisions in all reports, analyses, displays, products, and other data uses ("Outputs") to prevent identification of individuals.
 - 1) All Outputs must adhere to the CMS cell size suppression policy, as stated in the *CMS Identifiable Data Use Agreement, Section 9*, available at https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS-R-



<u>0235.pdf</u>. This policy stipulates: "that no cell (*e.g.*, admittances, discharges, patients, services) 10 or less may be displayed. Also, no use of percentages or other mathematical formulas may be used if they result in the display of a cell 10 or less."

- 2) Outputs must use complementary cell suppression techniques to ensure that cells with 10 or fewer observations cannot be identified by manipulating data in the Output.
- 3) Member-level records may not be disseminated or published in any form.
- 4) Further description of the CMS cell size suppression policy and examples of common scenarios and possible options is available here: https://resdac.org/articles/cms-cell-size-suppression-policy

10) Pre-Dissemination Review of all Outputs.

- (1) The Receiving Organization shall submit all Outputs to RIDOH at least 30 days prior to any information being disseminated by the Receiving Organization beyond itself and its authorized users. Dissemination includes but is not limited to submitting such Outputs to journals, publications, peer review processes, federal or state agencies, presentations, or other public forums.
- (2) RIDOH will make every reasonable effort to review the Outputs within the expiration of the 30-day period referred to above, to confirm that the Receiving Organization has met all terms and conditions of this Agreement. RIDOH and the Receiving Organization agree that the Receiving Organization will not disseminate any Output unless it has been reviewed by RIDOH. If RIDOH cannot reasonably review the Outputs before the expiration of the 30-day period, RIDOH will (a) alert the Receiving Organization of this fact, by e-mail, no fewer than five days prior to the expiration of the 30-day period and (b) make a good faith effort to review such Outputs as soon as is practicable.
- (3) RIDOH will not review Outputs for the purposes of validating study results or for data quality/integrity purposes.
- (4) Every Output shall contain the following disclaimer: "Data for this [report][analysis][product] was obtained through an approved request to the Rhode Island All-Payer Claims Database as administered by the Rhode Island



Department of Health (RIDOH). Data was obtained for [year(s)]. RIDOH is not responsible for the author's analysis, opinions and conclusions contained in this document."

- (5) RIDOH reserves the right to disseminate Outputs for its own purposes and in its discretion.
- 11) Safeguards. The Receiving Organization will implement and maintain the data security guidelines specified in the project's contract as outlined in sections of Exhibit A. The Receiving Organization will not undertake any unsecured telecommunication or transfer of APCD Data. The Receiving Organization agrees that APCD Data may not be physically moved, transmitted, or disclosed in any way without written approval from RIDOH, unless such movement, transmission or disclosure is required by law.
- **12)** Co-Investigators: List all co-investigators, including those from other agencies and/or institutions. Co-investigators include any individuals with access to the data or who meaningfully contribute to the project.

Name	Degree(s)/Qualifications	Project Role	Agency/Dept.	Email:

- 13) Subcontractors. If subcontractors are utilized, the Receiving Organization agrees to enter into a written contract with each agent and subcontractor receiving or accessing RI APCD Data, binding the subcontractor to the terms and conditions of this Agreement.
- 14) Reporting and Mitigating Unauthorized Uses or Disclosures of Data.
 - (1) The Receiving Organization agrees to report any unauthorized use, reuse, or disclosure of APCD Data to RIDOH within 48 hours of becoming aware of the incident. The report will include the date of the incident; any harmful effects that may or have been caused by the unauthorized use or disclosure; details about the most likely causes of the incident and how it occurred; and a description of the APCD Data accessed, used, or disclosed.
 - (2) If RIDOH has reasonable belief that the Receiving Organization has made use, reuse, or disclosure of the APCD Data, RIDOH may, at its sole discretion, require the Receiving Organization to:



- (a) Investigate and report to RIDOH the Receiving Organization's determinations regarding any alleged or actual unauthorized use or disclosure.
- (b) Promptly resolve any issues or problems identified by the investigation.
- (c) Submit a corrective action plan outlining the steps that the Receiving Organization will take to prevent future unauthorized use or disclosure.
- (d) Return or destroy the APCD Data received from RIDOH under this Agreement.
- (3) The Receiving Organization will preserve evidence relating to each incident, including log report data to be shared with RIDOH within fourteen (14) calendar days of request. The Receiving Organization agrees to cooperate with RIDOH, and other related State and Federal agencies in any investigation into unauthorized use, reuse or disclosure.
- (4) RIDOH will send written notification to the Receiving Organization about the start and end dates of the cure period and documentation to prove the remedy has been implemented. Thereafter, RIDOH may accept this proof or terminate the agreement.
- (5) The Receiving Organization will disclose each incident in future applications for APCD Data. RIDOH will consider past incidents involving unauthorized use, reuse or disclosure of APCD Data in its review of future requests from the Receiving Organization. Prior incidents may impact the Receiving Organization's ability to access APCD Data in the future.

15) Termination.

- (1) If RIDOH determines that the Receiving Organization has violated a material term of this Agreement, RIDOH may terminate this Agreement immediately via written notification. Upon request, RIDOH may grant the Receiving Organization a period of up to thirty (30) calendar days to cure the violation.
- (2) Upon termination, the Receiving Organization will return or destroy all APCD Data and will not retain, nor allow any of its agents or subcontractors to retain, any APCD Data received under this Agreement. The Receiving Organization's duty to destroy APCD Data includes, but is not limited to, the obligations to destroy all copies of APCD Data including electronic backup medium, and to destroy all APCD Data in accordance with the methods established by the U.S. Department of Health and Human Services (HHS) *Guidance to Render Unsecured Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals.* The Receiving Organization will confirm destruction in writing to RIDOH within 30 calendar days via Exhibit B: Certificate of Data Destruction or Retention.
- (3) The following Sections survive expiration or termination of this Agreement: 2, 3, 7, 8, 9, 11, 12, 13, 14, and 16.



- **16) Government Access.** The Receiving Organization will provide requested records to the Director of RIDOH. Neither the Receiving Organization nor RIDOH waives any attorney-client, accountant-client, or other legal privilege or confidentiality because of this Agreement.
- 17) Indemnification. The Receiving Organization agrees to indemnify, hold harmless and defend RIDOH, Rhode Island and its affiliates, from and against any and every claim, cause of action, obligation, liability, judgment, damage, loss, cost, expense, and fee (including without limitation reasonable attorneys' and court fees) arising out of or relating to the Receiving Organization's breach of this Agreement, willful negligence, or failure to perform its obligations under this Agreement. If RIDOH, in its sole discretion, determines that the risk of harm created by such a breach or alleged breach of APCD Data requires notification of affected individuals and/or other remedies, the Receiving Organization agrees to carry out such remedies under the direction of and without cost to RIDOH. No other agreement between the parties alters a party's liability under this Agreement, but this Agreement does not limit a party's liability under any other agreement.
- **18)** Correspondence. Each party will send any reports or notices required under this Agreement to the other party via email or first-class mail according to the contact information listed below.

Receiving Organization Contact	RIDOH Contact
Name:	Jerome Larkin
Title:	Director of RIDOH
Address:	3 Capitol Hill Providence, RI 02908
Phone:	Phone: 401-222-5960
Email:	Email:

19) Authority. Each signatory agrees by signing below that it has authority to sign this Agreement on behalf of the party the signatory represents. Each entity agrees to be bound by the terms and conditions of this Agreement.

Receiving Organization:	RIDOH
Authorized Signatory	Authorized Signatory
Name:	Name: Sam Viner-Brown
Title:	Title: Chief, Center of Health Data and
	Analysis
Signature:	Signature:
Date:	Date:
Phone:	Phone: 401-222-5122
Email:	Email: samara.vinerbrown@health.ri.gov



Exhibit A Project Contract



Exhibit B Certificate of Data Destruction

Receiving Organization Name:	
Date:	
DUA Number:	

INSTRUCTIONS:

This Certificate must be completed and returned to RIDOH within 30 days of the End Date (project completion date) specified in the DUA number listed above.

Section 1: Completed by Receiving Organization
Please check the appropriate box below:
☐ I certify that the Receiving Organization has destroyed all APCD Data received from RIDOH under the DUA number listed above, including copies, subsets, and manipulated files, held by all individuals who had access to, and from all electronic media, in accordance with the terms and conditions of the DUA.
☐ I certify that the Receiving Organization has been approved by RIDOH to retain all APCD Data received from RIDOH under the DUA number listed above until [date]. Attach documentation of the approval.
Section 2: Completed by Receiving Organization
Media Types, and Methods of Destruction (include any specific tools used):
Destroyed by (print name and title): Date Destroyed:
Section 3: Receiving Organization Certification (Initials required)
I hereby certify that all ePHI data and backups have been destroyed, including all copies of the data on any portable media. Furthermore, no ePHI data has been retained by the Receiving Organization or any subcontracted entities.
Section 4: Receiving Organization's Authorized Signature
Authorized person's signature: Date:
Authorized person (print name and title)
Section 5: RIDOH Authorized Signature
Authorized person's signature: Date: Date:
Authorized person (print name and title)



Exhibit C

Attestation for a Requested Use or Disclosure of Protected Health Information Potentially Related to Reproductive Health Care

Pursuant to the Final Rule at 89 F. R. 32976 (effective July 2024) when a HIPAA covered entity¹ or business associate² receives a request for protected health information (PHI)³ potentially related to reproductive health care,⁴ it must obtain a signed attestation that clearly states the requested use or disclosure is not for the prohibited purposes described below, where the request is for PHI for any of the following purposes:

- Health oversight activities⁵
- Judicial or administrative⁶ proceedings

- Law enforcement⁷
- Regarding decedents, disclosures to coroners and medical examiners⁸

Prohibited Purposes. Covered entities and their business associates may not use or disclose PHI for the following purposes:

- (1) To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care.
- (2) To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care.
- (3) To identify any person for any purpose described in (1) or (2).

The prohibition applies when the reproductive health care at issue (1) is lawful under the law of the state in which such health care is provided under the circumstances in which it is provided, (2) is protected, required, or authorized by Federal law, including the United States Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided, or (3) is provided by another person and presumed lawful.¹⁰

Instructions

Information for the Person Requesting the PHI

- > By signing this attestation, you are verifying that you are not requesting PHI for a prohibited purpose and acknowledging that criminal penalties may apply if untrue. 11
- You may not add content that is not required or combine this form with another document except where another document is needed to support your statement that the requested disclosure is not for a prohibited purpose. For example, if the requested PHI is potentially related to reproductive health care that was provided by someone other than the covered entity or business associate from whom you are requesting the PHI, you may submit a document that supplies information that demonstrates a

¹ See 45 CFR 160.103 (definition of "Covered entity").

² See 45 CFR 160.103 (definition of "Business associate").

³ See 45 CFR 160.103 (definition of "Protected health information").

⁴ See 45 CFR 160.103 (definition of "Reproductive health care").

⁵ See 45 CFR 164.512(d).

⁶ See 45 CFR 164.512(e).

⁷ See 45 CFR 164.512(f).

⁸ See 45 CFR 164.512(g)(1).

⁹ See 45 CFR 164.502(a)(5)(iii)(A).

¹⁰ See 45 CFR 164.502(a)(5)(iii)(B), (C). For more information on the presumption and when it applies, see 45 CFR 164.502(a)(5)(iii)(C).

¹¹ See 42 U.S.C. 1320d-6.

¹² See 45 CFR 164.509(b)(3) and (c)(iv).

substantial factual basis that the reproductive health care in question was not lawful under the specific circumstances in which it was provided.¹³

Information for the Covered Entity or Business Associate

- You may not rely on the attestation to disclose the requested PHI if any of the following is true:
 - It is missing any required element or statement or contains other content that is not required. 14
 - It is combined with other documents, except for documents provided to support the attestation.¹⁵
 - You know that material information in the attestation is false.¹⁶
 - A reasonable covered entity or business associate in the same position would not believe the requestor's statement that the use or disclosure is not for a prohibited purpose as described above.¹⁷
- If you later discover information that reasonably shows that any representation made in the attestation is materially false, leading to a use or disclosure for a prohibited purpose as described above, you must stop making the requested use or disclosure. 18
- You may not make a disclosure if the reproductive health care was provided by a person other than yourself and the requestor indicates that the PHI requested is for a prohibited purpose as described above, unless the requestor supplies information that demonstrates a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided.¹⁹
- You must obtain a new attestation for each specific use or disclosure request.²⁰
- You must maintain a written copy of the completed attestation and any relevant supporting documents.²¹

¹³ See 45 CFR 164.502(a)(5)(iii)(B)(3), (C)(2).

¹⁴ See 45 CFR 164.509(b)(2)(ii).

¹⁵ See 45 CFR 164.509(b)(3).

¹⁶ See 45 CFR 164.509(b)(2)(iv).

¹⁷ See 45 CFR 164.509(b)(2)(v).

¹⁸ See 45 CFR 164.509(d).

¹⁹ See 45 CFR 164.502(a)(5)(iii)(B)(3), (C)(2).

²⁰ See 89 FR 32976, 33031.

²¹ See 45 CFR 164.530(i).

Attestation Regarding a Requested Use or Disclosure of Protected Health Information Potentially Related to Reproductive Health Care

The entire form must be completed for the attestation to be valid.

Name of person(s) or specific identification of the class of persons to receive the requested PHI.
e.g., name of investigator and/or agency making the request
Name or other specific identification of the person or class of persons from whom you are requesting the use or disclosure.
e.g., name of covered entity or business associate that maintains the PHI and/or name of their workforce member who handles requests for PHI
Description of specific PHI requested, including name(s) of individual(s), if practicable, or a description of the class of individuals, whose protected health information you are requesting.
e.g., visit summary for [name of individual] on [date]; list of individuals who obtained [name of prescription medication] between [date range]
I attest that the use or disclosure of PHI that I am requesting is not for a purpose prohibited by the HIPAA Privacy Rule at 45 CFR 164.502(a)(5)(iii) because of one of the following (check one box): The purpose of the use or disclosure of protected health information is not to investigate or impose liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care or to identify any person for such purposes. The purpose of the use or disclosure of protected health information is to investigate or impose liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care, or to identify any person for such purposes, but the reproductive health care at issue was not lawful under the circumstances in which it was provided. I understand that I may be subject to criminal penalties pursuant to 42 U.S.C. 1320d-6 if I knowingly and in violation of HIPAA obtain individually identifiable health information relating to an individual or disclose individually identifiable
health information to another person.
Signature of the person requesting the PHI
Date
If you have signed as a representative of the person requesting PHI, provide a description of your authority to act for that person.

This attestation document may be provided in electronic format, and electronically signed by the person requesting protected health information when the electronic signature is valid under applicable Federal and state law.