



## **RHODE ISLAND DEPARTMENT OF HEALTH DATA USE AGREEMENT**

This Data Use Agreement (“Agreement”) is effective beginning on the date that the last party signs this Agreement (“Effective Date”), ends upon project completion, anticipated to be (“End Date”), and is between the parties, (the “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 RIDOH data files or reports specified in Section 4 of this Agreement, and/or any derivative files (“RIDOH Data”).

### **2) APPLICABLE LAW**

This Agreement is subject to the Confidentiality of Health Care Communications Information Act (R. I. Gen. Laws Chapter 5-37.3), the Health Information Portability and Accountability Act (Pub. L. 104–191, 110 Stat. 1936, 21 August 1996) (as amended and including all regulations promulgated thereunder, “HIPAA”), the Rhode Island Identity Theft Protection Act of 2015 (R. I. Gen. Laws Chapter 11-49.3), and all other applicable laws (“Applicable Law”).

### **3) TERMS**

- A. 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.
- B. 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.
- C. 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.
- D. If an extension to this Agreement is necessary, the duration may be extended in writing only by the parties specified in this Agreement.

### **4) COVERED DATA**

This Agreement pertains to the following files, in accordance with the specifications and as requested and approved in Exhibit A:



Type of File	Time Period

**5) ATTACHMENTS**

The parties mutually agree that the following specified Exhibits are part of this Agreement:

- A. Exhibit A: RIDOH Data
- B. Exhibit B: RIDOH Data Display and Reporting Policy
- C. Exhibit C: Certificate of Data Destruction or Retention

**6) OWNERSHIP OF INFORMATION**

The Receiving Organization agrees that RIDOH owns and retains ownership of all RIDOH 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 RIDOH Data unless specifically approved in Exhibit A.

**7) RIDOH DATA USE**

- A. The Receiving Organization will use RIDOH Data only for the purposes identified in Exhibit A.
- B. The Receiving Organization will ensure that access to RIDOH Data is provided only to the authorized individuals listed in Exhibit A, including employees, agents, and/or approved subcontractors.
- C. The Receiving Organization and its authorized individuals will not attempt to identify individuals in the RIDOH Data in any way.
- D. The Receiving Organization will not link RIDOH Data to any other data sources other than those approved in Exhibit A and for the purposes approved in Exhibit A.
- E. The Receiving Organization will cite any and all applicable exceptions or designations that support disclosure of RIDOH Data to it, if necessary, including but not limited to permitted disclosures under HIPAA, in Exhibit A.

**8) RIDOH DATA DISCLOSURE**

The Receiving Organization will strictly adhere to the provisions of Exhibit B: RIDOH Data Display and Reporting Policy in all reports, analyses, displays, products and other data uses (“Outputs”) to prevent identification of individuals.



## 9) PRE-DISSEMINATION REVIEW OF ALL OUTPUTS

- A. 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.
- B. RIDOH will make every reasonable effort to review the Outputs before 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.
- C. RIDOH will not review Outputs for the purposes of validating study results or for data quality/integrity purposes.
- D. Every Output shall contain the following disclaimer:
- E. “Data for this [report][analysis][product] was obtained through a request to the Center for Vital Records, Rhode Island Department of Health (RIDOH). RIDOH is not responsible for the author’s analysis, opinions and conclusions contained in this document.”
- F. RIDOH reserves the right to disseminate Outputs for its own purposes and in its own discretion.

## 10) SAFEGUARDS

The Receiving Organization will not undertake any unsecured telecommunication or transfer of RIDOH Data. The Receiving Organization agrees that RIDOH Data may not be physically moved, transmitted or disclosed in any way other than the way(s) indicated in Exhibit A, without written approval from RIDOH unless such movement, transmission or disclosure is required by law.

## 11) SUBCONTRACTORS

If subcontractors are utilized, the Receiving Organization agrees to enter into a written contract with each agent and subcontractor receiving or accessing RIDOH Data, binding the subcontractor to the terms and conditions of this Agreement.



## **12) REPORTING/MITIGATING UNAUTHORIZED USES OR DISCLOSURES OF DATA**

- A. The Receiving Organization agrees to report any unauthorized use, reuse or disclosure of RIDOH 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 RIDOH Data accessed, used, or disclosed.
- B. If RIDOH has reasonable belief that the Receiving Organization has made use, reuse or disclosure of the RIDOH Data, RIDOH may, at its sole discretion, require the Receiving Organization to:
  - i. Investigate and report to RIDOH the Receiving Organization's determinations regarding any alleged or actual unauthorized use or disclosure;
  - ii. Promptly resolve any issues or problems identified by the investigation;
  - iii. Submit a corrective action plan outlining the steps that the Receiving Organization will take to prevent future unauthorized use or disclosure;
  - iv. Return or destroy the RIDOH Data received from RIDOH under this Agreement.
- C. 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 an unauthorized use, reuse or disclosure.
- D. 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.
- E. The Receiving Organization will disclose each incident in future applications for RIDOH Data. RIDOH will consider past incidents involving unauthorized use, reuse or disclosure of RIDOH Data in its review of future requests from the Receiving Organization. Prior incidents may impact the Receiving Organization's ability to access RIDOH Data in the future.

## **13) TERMINATION**

- A. 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.
- B. Upon termination, the Receiving Organization will return or destroy all RIDOH Data and will not retain, nor allow any of its agents or subcontractors to retain, any RIDOH Data received under this Agreement. The Receiving Organization's duty to destroy RIDOH Data includes, but is not limited to, the obligations to destroy all copies of RIDOH Data including electronic backup medium, and to destroy all RIDOH 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 via Exhibit C: Certificate of Data Destruction or Retention.

- C. The following Sections survive expiration or termination of this Agreement: 2, 3, 6, 7, 8, 10, 11, 12, 13, and 15.

**14) 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.

**15) 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 RIDOH 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.

**16) 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
<b>Name:</b>	
<b>Title:</b>	
<b>Address:</b>	3 Capitol Hill Providence, RI 02908
<b>Phone:</b>	Phone:
<b>Email:</b>	Email:



## 17) 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.

### Authorized Signatory

**Name:**

**Title:**

**Signature:**

**Phone:**

**Email:**

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**Rhode Island Department of Health**

### Authorized Signatory

**Name:**

**Title:**

**Signature:**

**Phone:**

**Email:**



## **EXHIBIT A – RIDOH Data**

Clearly state the general purpose of your study. (What will the study accomplish?)

Provide a broad overview of how the data you are requesting will be used to achieve the purpose of this study. Please include a description of both the study population and any control groups that are utilized.

Will the requested data be linked with individual-level records in other database/datasets?

If yes, please describe how to linkage will be accomplished, including who will be performing the linkage and what data fields will be used to link to other databases.



Will the data be used to contact subjects? If yes, please explain.

Who will have access to the data? (Name and Title)





***For Vital Records Requests:***

<b>REQUESTED DATA ELEMENTS</b>			
<b>Vital Record Type:</b>	<b>Marriages</b> <input type="checkbox"/>	<b>Deaths</b> <input type="checkbox"/>	<b>Births</b> <input type="checkbox"/>
<ul style="list-style-type: none"> <li>• <i>Social Security Numbers are fully restricted by Rhode Island State Statute and are not available for any request.</i></li> <li>• <i>Any request for confidential data will be directed to the Institutional Review Board (IRB).</i></li> </ul>			
<b>Year(s):</b>			
<b>Requested data fields/variables:</b>  <i>e.g., decedent's name, town of residence, low birthweight, race, etc. Data dictionaries are available upon request.</i>			
<b>Requested Data Format:</b>	<b>Excel</b> <input type="checkbox"/>	<b>CSV</b> <input type="checkbox"/>	<b>Other:</b> <input type="checkbox"/>
<b>Requested Delivery Method:</b>	<b>Large Files:</b> FileZilla <input type="checkbox"/> Globalscape <input type="checkbox"/> SFTP <input type="checkbox"/> _____ Networked Secure Folder (RIDOH Only) <input type="checkbox"/> Other: <input type="checkbox"/> _____		
<b>Other information necessary to complete this request:</b>			
<b>Requested deadline for receipt of data: Please give date and reason.</b>			
<b><i>Please allow 4 weeks turnaround time.</i></b>			



## **EXHIBIT B – RIDOH Data Display and Reporting Policy**

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-0235.pdf>. 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.”

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.

Member-level records may not be disseminated or published in any form.



## EXHIBIT C – Certificate of Data Destruction or Retention

Receiving Organization Name:

Date:

Instructions: This Certificate must be completed and returned to RIDOH within 30 days of the End Date specified in the Agreement.

### Section 1: Completed by Receiving Organization

Please check the appropriate box below:

- I certify that the Receiving Organization has destroyed all RIDOH Data received from RIDOH under the DUA 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 RIDOH Data received from RIDOH under the DUA listed above until \_\_\_\_\_ [date]. Attach documentation of the approval.

Media Types, and Methods of Destruction (include any specific tools used): \_\_\_\_\_

Destroyed by (print name and title):

Date:

### 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 (Exceptions \_\_\_\_\_)



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: \_\_\_\_\_

Authorized person (print name and title) \_\_\_\_\_