

**DATA USE AGREEMENT
BETWEEN THE
[REQUESTOR]
AND THE
VERMONT DEPARTMENT OF HEALTH
FOR
“[STUDY NAME]”**

I. Parties and Purpose

A. Parties

This data use agreement is entered into by and between [REQUESTOR] and the Vermont Department of Health (VDH), through the Vermont Commissioner of Health.

B. Purpose

Under this Agreement, the VDH will furnish certain confidential information to [REQUESTOR] in order to continue to collaborate on the project entitled “[STUDY NAME]” (together hereinafter the “Project”). This Project is more fully described in Attachment A, which is hereby incorporated by reference into this Agreement.

II. Authority

[STATUTE] authorizes the Commissioner of Health to provide confidential information to health researchers for [REFERENCE TO TYPE OF AUTHORIZED RESEARCH]. Before releasing confidential information, the Commissioner must first obtain from such researchers evidence of the approval of their academic committee for the protection of human subjects established in accordance with 45 CFR Part 46.

III. Evidence of Approval

A. [REQUESTOR] IRB Approval

In accordance with 45 CFR Part 46, [REQUESTOR] has obtained approval of the [ORGANIZATION or AHS] Institutional Review Board (IRB) for the Project, which is the basis of this Agreement. Evidence of this approval is provided as Attachment B, which is hereby incorporated by reference into this Agreement.

B. Subsequent Research Project Approvals

If a researcher not employed by or affiliated with [REQUESTOR] requests Project data pursuant to Section IV.B.1.a. of this agreement, [REQUESTOR] will provide VDH with the approval of the [REQUESTOR or AHS] Institutional Review Board (IRB) for the subsequent research project. VDH will have the opportunity to administratively review and approve the data request prior to [REQUESTOR]'s release of the data to the researcher, but VDH will not duplicate any IRB approval already granted. If VDH has not responded at the end of seven days after VDH receives notice of the data request and the [REQUESTOR or AHS] IRB approval, then [REQUESTOR] shall be free to release data to the researcher.

IV. Agreement

A. VDH

1. VDH will provide [DESCRIPTION OF DATA] to [REQUESTOR].
2. VDH will provide the data in an agreed upon format. The password protected data file will be sent [DESCRIBE SECURE TRANSFER METHOD AND NOTIFICATION OF ACCEPTANCE].

B. [REQUESTOR]

1. [REQUESTOR] will keep confidential and privileged all identifying information associated with the Project data provided by VDH to [REQUESTOR] under this Agreement. [REQUESTOR] will not share any identifying information provided by VDH with any other party, except:
 - a. with third parties, solely for research use only, under the protections and processes provided in Attachment C.
 - b. that which must be disclosed by [REQUESTOR] to comply with laws or regulations of the State of Vermont or the United States relating to health or safety or other governmental purpose, provided that [REQUESTOR] obtains VDH approval prior to disclosure.
2. [REQUESTOR] may otherwise release VDH data in aggregate form that does not provide any identifying information or could be used in combination with other data sources to identify individuals.
3. [REQUESTOR] will not use nor release the data for any purpose other than those contemplated by or permitted under this Agreement.

4. [REQUESTOR] will adhere to all applicable professional standards to ensure that no data that are presented, published, or released, in any format or medium, allow any individual to be identified.
5. [REQUESTOR] will make any publications or other public disclosures utilizing the data available to VDH for review prior to release to ensure that such public disclosure of the data is consistent with the terms of this Agreement. This review is intended only to verify compliance with the terms of this Agreement and will not examine content, conclusions, or grammar. The preview and response will take up to three business days from the time of receipt. Responses will be by email.
6. [REQUESTOR] will provide VDH with a copy of third party researchers' publications immediately upon publication.
7. [REQUESTOR] may be monitored during the course of its stewardship of the data through VDH site visits.
8. Except as provided in Section IV.B.1, [REQUESTOR] will not release nor permit others to release identifying information in full or in part to any person except with the written approval of VDH.
9. [REQUESTOR] will not contact any individual whose data is solely provided by the VDH to [REQUESTOR], unless authorized by VDH, specified in Attachment A, and allowed under this Agreement.
10. [REQUESTOR] will provide VDH with a list of all individuals who have authorized access to the Project data. These individuals will be required to sign a VDH confidentiality assurance statement, provided as Attachment D, which includes penalty for non-compliance and breaches of confidentiality. Copies of all signed assurances will be given to VDH within fifteen business days of signing this Agreement and prior to VDH delivering data to [REQUESTOR].
11. [REQUESTOR] shall abide by the appropriate administrative, technical, procedural, and physical safeguards established to protect the confidentiality of the data and to prevent unauthorized access to the data and as described in the [REQUESTOR] Confidentiality and Security Procedures (Attachment E). Security procedures should include, but not be limited to, locking access to all electronic and print files. VDH must be immediately notified if [REQUESTOR]'s identified contact person, [CONTACT PERSON], or overall responsible party changes due to personnel turnover, or for any other reason.

12. Within two business days, [REQUESTOR] shall report to VDH any information of which it becomes aware concerning any use or disclosure of PHI or Limited Data Set information that is not permitted by this Agreement or under HIPAA. This report shall identify the nature of the violating use or disclosure, the PHI or Limited Data Set information used or disclosed, what corrective action the [REQUESTOR] has or will take to prevent further violations, including any mitigation, and provide any other information as VDH may request.
13. Both parties assume the risks of their own actions and inactions under this contract, with each reserving its right to seek compensation for the negligent or wrongful acts or omissions of the other.

V. Term and Reach

This Agreement shall remain in effect until such time as it is terminated or modified by the Parties. This Agreement may be amended and/or modified by mutual written consent, and it may be terminated upon thirty (30) days written notice by either party. In the event this Agreement is terminated or modified by either party, the confidential and privileged nature of all cancer case information provided pursuant to this Agreement before such termination or modification shall be maintained in accordance with the terms of this Agreement, unless otherwise agreed upon by the parties, or unless altered by operation of applicable law, and [REQUESTOR]'s responsibility for any breach of confidentiality will survive such termination or modification. Data provided by the VDH to [REQUESTOR] will be encrypted and stored per the terms of Section IV.B.11 for [DURATION]. Data provided to [REQUESTOR] under this Agreement will be destroyed by [REQUESTOR] or returned to VDH within 12 months after funding of the Project ceases.

Signed:

[REQUESTOR]

By: _____

[NAME OF OVERALL RESPONSIBLE PARTY]

[TITLE]

Date: _____

Vermont Department of Health

By: _____

Wendy Davis, MD

Commissioner

Date: _____

Attachments

- A. Project Description
- B. Project IRB Approval
- C. [REQUESTOR] Data Release Procedures
- D. VDH Confidentiality Statement
- E. [REQUESTOR] Confidentiality and Security Procedures