Cancer Registry Data Access for Research
Data Request Process

State	Vermont
IRB of Record	Vermont Agency of Human Services (AHS) IRB
Initial Cancer Registry Contact Required Prior to Submitting Application	Yes
Type of Contact	Phone or email
Initial Required Documentation	The researcher must first submit to the Vermont Cancer Registry (VCR): 1. Research request information including: requester name and contact information; purpose of data request; years of data requested; case selection criteria; list of variables requested; names and titles of individuals who will access the data; security procedures used to protect data; planned date for receiving data; and time period of the study (through data destruction phase). 2. IRB application, approval and either (1) HIPAA authorization or (2) waiver of HIPAA authorization for recruitment purposes. If AHS IRB approval is required, the researcher must submit: 1. AHS IRB application 2. HIPAA Authorization or Waiver of HIPAA Authorization 3. Protocol Summary 4. Informed Consent Form and, if applicable, assent forms 5. Study materials including survey instrument, interview or focus group protocol 6. Resume of researcher and other key project staff 7. Certificate of Completion of online tutorial for IRB Researchers 8. Assurance statement that IRB commitments will be followed
How to Submit	The researcher must submit package to: Alison Johnson, Chief Vermont Cancer Registry Vermont Department of Health 108 Cherry Street Burlington, VT 05401 VCR Chief Phone: 802-863-7644 Email: alison.johnson@vermont.gov
Process	1. The researcher must first contact Alison Johnson, the VCR Chief, at 802-863-7644 to discuss the research proposal. 2. The VCR Chief will send the researcher an email documenting the required information that will need to be submitted. 3. The VCR Chief will review the package with the Vermont Department of Health Legal Department and will determine if IRB review is required. The Vermont

	Agency of Human Services (AHS) IRB is the preferred IRB. If a researcher has already obtained approval from either the UVM or Dartmouth IRB to conduct the study, the AHS IRB has the option of accepting their determination. 4. The VCR Chief will inform the researcher of the next step in the approval process. 5. If AHS IRB approval is required, the researcher will need to submit the IRB Application, along with the HIPAA Authorization or Waiver of HIPAA Authorization. 6. The researcher will send the submission package to the VCR Chief, who will forward the package to the AHS IRB. The AHS IRB may ask the researcher to attend the IRB meeting at which the proposal is reviewed. 7. Once IRB approval is received, the VCR Chief will notify the researcher. 8. The Vermont Department of Health (VDH) will draft a Data Use Agreement (DUA) for the researcher to review. Any issues with the terms of the agreement will be negotiated between the researcher and the VDH. 9. Once the DUA is agreed upon by all parties, the DUA is forwarded to the Commissioner of the Department of Health for signature. 10. Signatures for the DUA will then be obtained from the researchers. 11. The VCR will send the data to the researcher via secure transfer per DUA attachment. 12. The researcher will send a confirmation of receipt to the VCR Chief. 13. The researcher must notify the AHS IRB in writing of the completion of the research project within twenty working days of the completion date.
Pediatric Research Considerations	Applications for approval of access to pediatric cancer data are the same.
Patient Contact and Consent Procedures	For all research involving patient contact, the VCR will contact the patient's physician to obtain non-objection to contact the patient. • Once the physician does not object, the VCR will send the patient an introductory letter introducing the study and notifying the patient that the researcher will contact them regarding participation in the study. • Unless the patient declines by notifying the VCR, the VCR will provide the researcher with the patient contact information. The researcher can then contact the patient.
Sponsorship from Local Researcher Required	No
Fees	The Cancer Registry fee is $34.20/hour for creating the data set. If the request involves a data linkage, there is an hourly analyst fee.
Timeframe	The approval process usually takes 2-4 months.
Special Notes	AHS IRB approval is required. If a researcher has already obtained approval from either the University of Vermont or Dartmouth IRB to conduct the study, the AHS IRB has the option of accepting their determination. • When protocols need review, the AHS IRB will meet the first Tuesday of each month.