

October 1, 2009

## RELEASE OF VA DATA TO STATE CANCER REGISTRIES

**1. PURPOSE:** This Veterans Health Administration (VHA) Directive provides policy on releasing Department of Veterans Affairs (VA) Central Cancer Registry data to the State Cancer Registries.

### 2. BACKGROUND

a. Reporting of the cancer data from VA medical centers to the State Cancer Registries is at present neither uniform nor always congruent with VA existing guidelines. The rationale for reporting VA Central Cancer Registry data to the State Cancer Registries is to ensure a complete understanding of the national cancer burden and mortality.

b. Title 38 United States Code (U.S.C.) § 5701(f) allows for the disclosure of VA patient names and addresses to a civil government agency or criminal law enforcement organization instrumentality charged with the protection of public health or safety pursuant to a written request from the agency that indicates the information is provided for a purpose authorized by law.

c. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule allows for the disclosure of health information to a public health authority for the purpose of preventing or controlling disease including the conduct of public health surveillance under Title 45 Code of Federal Regulations (CFR) 164.512(b).

d. The Privacy Act of 1974 provides authority for VHA to disclose Protected Health Information (PHI), excluding 38 U.S.C. § 7332 protected information, to a State Cancer Registry upon written request pursuant to Routine Use 10 under 24VA19, "Patient Medical Records-VA" Privacy Act System of Records.

e. Some States have released data obtained from VA to researchers or to other State Cancer Registries with patient identifiers (such as name, social security number, date of birth, address, zip code, etc.). VA has determined that VHA health care facilities may report VA cancer data to the States, but re-disclosure of VA data with patient identifiers by the State is not permitted.

**3. POLICY:** It is VHA policy that every VHA health care facility and the VA Central Cancer Registry must obtain a Data Use Agreement (DUA) (see Attachments A&B), in addition to a signed, written request letter from the State in order for VA to release or disclose data to a State Cancer Registry. *NOTE: The written request may be considered a standing written request for ongoing reporting to the State Cancer Registry if continuous reporting is required. A standing request is valid for 3 years, at which time it must be reissued.*

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**4. ACTION:** The facility Director (in the case of release from a VHA health care facility) or the VA Central Cancer Registry National Coordinator (in the case of release from the VA Central Cancer Registry) is responsible for ensuring:

a. Names, addresses, and medical information about patients with cancer are not disclosed to a State Public Health Authority, such as a State Cancer Registry, unless an appropriate written request letter is received and a DUA is executed.

b. The written request letter from the state is on the state agency's letterhead stationery, and that it includes:

(1) A citation of the State law that requires health care providers to report names, addresses, and medical record data to the State Cancer Registry and the State law that authorizes the State to enforce or compel compliance with the cancer reporting requirement, e.g., power to sanction or issue cease and desist orders;

(2) The purpose of the request and agreement that the State will not allow the information to be used for any purpose other than that which is stated in the request;

(3) A statement that the organization, agency, or instrumentality is aware of the penalty provision of 38 U.S.C. § 5701(f); and

(4) The signature of the head of the agency, or the official designee.

c. Electronic transfer of data is accomplished in a secure manner.

d. An Information Security Officer (ISO) reviews all DUAs before they are signed to make sure they meet VA Handbook 6500 guidelines.

***NOTE:** Facility staff may seek the assistance of the Regional Counsel, when appropriate, in evaluating the applicable law relative to the statutory authority of the State Cancer Registry to require cancer reporting and to enforce compliance with the reporting requirement.*

e. That a DUA is completed and signed using the DUA Template in Attachment A (for release of data from VHA facilities) or Attachment B (for release of data from the VA Central Cancer Registry). The DUA must address the:

(1) Use or purpose of the requested VA data.

(2) Safeguards the State intends to employ to protect the VA data in their possession. These safeguards must address HIPAA security rule compliant controls that are implemented to protect the information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction.

(3) State's authorized use and disclosure of the VA data.

(4) Security requirements necessary for transporting or transmitting the VA data to the State in accordance with VA Handbook 6500, Information Security Program.

(5) Procedures for reporting any data breaches to VA.

(6) State point(s)-of-contact for all data exchange issues.

f. That a copy of the completed DUA is provided to the VA Central Cancer Registry Director.

## **5. REFERENCES**

a. VHA Handbook 1605.1, Privacy and Release of Information

b. VA Directive and Handbook 6500, Information Security Program

**6. FOLLOW-UP RESPONSIBILITY:** The VHA Office of Patient Care Services (11), Medical Surgical Services (111), is responsible for the contents of this Directive. Questions may be referred to the National Program Director of Oncology at (202) 461-7120.

**7. RESCISSIONS:** VHA Directive 2007-023 is rescinded. This VHA Directive expires October 31, 2014(date).

Gerald M. Cross, MD, FAAFP  
Acting Under Secretary for Health

**DISTRIBUTION:** E-mailed to the VHA Publication Distribution List 10/5/09

Attachment

**ATTACHMENT A**

**DATA USE AGREEMENT**

**AGREEMENT FOR EXCHANGE BETWEEN VETERANS HEALTH  
ADMINISTRATION (VHA), \_\_\_(INSERT DEPARTMENT OF VETERANS AFFAIRS  
(VA) FACILITY OR PROGRAM OFFICE NAME)\_\_\_ AND \_\_\_(INSERT OUTSIDE  
STATE AGENCY NAME)\_\_\_**

This Agreement establishes the terms and conditions under which the \_\_\_(Insert VA Facility Name)\_\_\_ will provide, and \_\_\_(Insert Name of Outside Agency)\_\_\_, its contractors and agents, will use the data to be very specific in why data is being shared including the purpose, authorized use and disclosure of the VA data, and state the method of transfer and how that will be accomplished in accordance with VA Handbook 6500, including security requirements)\_\_\_ . Any other uses will be subject to prior approval by the \_\_\_(Insert Name of the VA Facility Director)\_\_\_.

**TERMS OF THE AGREEMENT**

1. This Agreement is by and between the \_\_\_(Insert STATE Agency Name)\_\_\_, its contractors and agents, and \_\_\_(Insert VA Facility Name)\_\_\_, a component of the United States Department of Veterans Affairs (VA).
2. This data use agreement (DUA) covers the transfer and use of data by the \_\_\_(Insert STATE Agency Name)\_\_\_ and \_\_\_(Insert VA Facility Name)\_\_\_, for the project specified in this agreement. This Agreement supersedes any and all previous data use agreements regarding data specified in this DUA.
3. The terms of this Agreement can be changed only by a written modification of the agreement by the agency signatories (or their designated representatives) to this Agreement or by the parties adopting a new agreement in place of this Agreement.
4. The \_\_\_(Insert VA Facility Name)\_\_\_ retains all ownership rights to the data file(s) provided to the \_\_\_(Insert STATE Agency Name)\_\_\_ under this Agreement.
5. The \_\_\_(Insert Title of person responsible STATE Agency Name)\_\_\_ will be designated as custodian of the VA data for the \_\_\_(Insert STATE Agency Name)\_\_\_ and will be responsible for complying with all conditions of use and for establishment and maintenance of appropriate administrative, technical, and physical security safeguards as specified in this Agreement to prevent unauthorized use and disclosure of the \_\_\_(Insert VA Facility Name)\_\_\_'s data provided under this agreement. The \_\_\_(Insert STATE Agency Name)\_\_\_ agrees to notify the \_\_\_(Insert VA Facility Name)\_\_\_ within 15 days of any change of custodianship.

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a. **Technical Representative for** \_\_\_(Insert VA Facility Name)\_\_\_

Insert Name and Phone Number  
Address

b. **Custodian for** \_\_\_(Insert STATE Agency Name)\_\_\_

Insert Name and Phone Number  
Address

6. The following named individuals are designated as their agencies' Points of Contact for performance of the terms of the Agreement.

a. **Point-of-contact on behalf of** \_\_\_(Insert VA Facility Name)\_\_\_

Insert Name and Phone Number  
Address

b. **Point-of-contact on behalf of** \_\_\_(Insert STATE Agency Name)\_\_\_

Insert Name and Phone Number  
Address

7. Except as VHA shall authorize in writing, the \_\_\_(Insert STATE Agency Name)\_\_\_, its contractors and agents, shall not disclose, release, reveal, show, sell, rent, lease, loan, or otherwise grant access to the VHA data covered by this Agreement to any person or entity outside the \_\_\_(Insert STATE Agency Name)\_\_\_ and its team of subcontractors to the project. The \_\_\_(Insert STATE Agency Name)\_\_\_ agrees that access to the data covered by this Agreement shall be limited to the minimum number of individuals who need the access to VA data to perform this Agreement.

8. The parties mutually agree that any derivative data or file(s) that is created from the original data may be retained by the \_\_\_(Insert STATE Agency Name)\_\_\_ until the project specified in this DUA has been completed. The use of the data will be for the time period covered by the written request (Insert Time Frame).

9. The Agreement may be terminated by either party at any time for any reason upon 30 days written notice. Upon such notice, the VA facility will notify the \_\_\_(Insert STATE Agency Name)\_\_\_ to destroy or return such data at \_\_\_(Insert STATE Agency Name)\_\_\_ expense using the same procedures stated in the above paragraph of this section.

10. Access to the VA data shall be restricted to authorized \_\_\_(Insert STATE Agency Name)\_\_\_ employees, contractors, agents and officials who require access to perform their official duties in accordance with the uses of the information as authorized in this Agreement. Such personnel shall be advised of: (1) the confidential nature of the information; (2) safeguards required to protect the information; and (3) the administrative, civil and criminal penalties for noncompliance contained in applicable Federal laws. The \_\_\_(Insert STATE Agency Name)\_\_\_ agrees to limit access to, disclosure of and use of all data provided under this Agreement. The Requestor \_\_\_(Insert STATE Agency Name)\_\_\_ agrees that access to the data covered by this Agreement shall be limited to the minimum number of individuals who need the access to the VA Central Cancer Registry's data to perform this Agreement.

11. The information provided may not be disclosed or used for any purpose other than as outlined in this Agreement. If the \_\_\_(Insert STATE Agency Name)\_\_\_ wishes to use the data and information provided by the \_\_\_(Insert VA Facility Name)\_\_\_ Information Owner under this Agreement for any purpose other than those outlined in this Agreement, the \_\_\_(Insert STATE Agency Name)\_\_\_ shall make a written request to the \_\_\_(Insert VA Facility Name)\_\_\_ Information Owner describing the additional purposes for which it seeks to use the data. If the \_\_\_(Insert VA Facility Name)\_\_\_ Information Owner determines that the \_\_\_(Insert STATE Agency Name)'s\_\_\_ request to use the data and information provided hereunder is acceptable, the \_\_\_(Insert VA Facility Name)\_\_\_ Information Owner shall provide the \_\_\_(Insert STATE Agency Name)\_\_\_ with written approval of the additional use of the data.

12. The \_\_\_(Insert STATE Agency Name)\_\_\_ may not reuse the \_\_\_(Insert VA Facility Name)\_\_\_ original or work file(s) for any other purpose.

13. The \_\_\_(Insert STATE Agency Name)\_\_\_ will provide appropriate administrative, technical, and physical safeguards to ensure the confidentiality and security of the VA data and to prevent unauthorized use or access to it. \_\_\_(Specify safeguards to be utilized)\_\_\_.

14. In the event that the \_\_\_(Insert VA Facility Name)\_\_\_ determines or has a reasonable cause to believe that the \_\_\_(Insert STATE Agency Name)\_\_\_ disclosed or may have used or disclosed any part of the data other than as authorized by this Agreement or other written authorization from the appropriate System Manager or the person designated as VA's Responsible Official in this Agreement, the \_\_\_(Insert VA Facility Name)\_\_\_ in its sole discretion may require the \_\_\_(Insert STATE Agency Name)\_\_\_ to:

a. Promptly investigate and report to the \_\_\_(Insert VA Facility Name)\_\_\_ the \_\_\_(Insert the (STATE Agency Name)'s determinations regarding any alleged or actual unauthorized use or disclosure)\_\_\_;

b. Promptly resolve any problems identified by the investigation;

c. If requested by the \_\_\_(Insert Name of the VA Facility)\_\_\_, submit a formal response to an allegation of unauthorized disclosure; and

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d. If requested, return the \_\_\_(Insert VA Facility Name)\_\_\_'s data files to the \_\_\_(Insert VA Facility Name)\_\_\_. If the \_\_\_(Insert VA Facility Name)\_\_\_ reasonably determines or believes that unauthorized disclosures of VA's data in the possession of \_\_\_(Insert STATE Agency Name)\_\_\_ have taken place, the \_\_\_(Insert VA Facility Name)\_\_\_ may refuse to release further data to the \_\_\_(Insert STATE Agency Name)\_\_\_ for a period of time to be determined by the \_\_\_(Insert VA Facility Name)\_\_\_, or may terminate this Agreement.

15. All questions of interpretation or compliance with the terms of this Agreement should be referred to the \_\_\_(Insert Name of VHA's Responsible Official)\_\_\_, or successor.

16. Authority for VHA to share this data for the purpose indicated is under the HIPAA Privacy Rule is 45 CFR 164.512(b), under the Privacy Act is Routine Use #10 under the "Patient Medical Records - VA" (24VA19) Privacy Act system of records notice and under 38 U.S.C. 5701(f), which allows for the disclosure of VA patient names and addresses to a civil or criminal law enforcement government agency or instrumentality charged with the protection of public health or safety pursuant to a written request from the agency that indicates the information is provided for a purpose authorized by law.

17. On behalf of both parties the undersigned individuals hereby attest that \_\_\_(Insert Name of One Party)\_\_\_ and \_\_\_(Insert Name of Second Party)\_\_\_ are authorized to enter into this Agreement and agrees to all the terms specified herein.

\_\_\_\_\_  
(VA's Responsible Official  
Organization Transferring  
Data)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(STATE's Responsible  
Official Organization  
Receiving Data)

\_\_\_\_\_  
(Date)

Concur/Non-Concur:

\_\_\_\_\_  
(VA Facility's Information Security Officer Name  
and Organization)

\_\_\_\_\_  
(Date)

**ATTACHMENT B**

**DATA USE AGREEMENT**

**AGREEMENT FOR EXCHANGE BETWEEN VETERANS AFFAIRS (VA) CENTRAL  
CANCER REGISTRY AND \_\_\_(INSERT OUTSIDE STATE AGENCY NAME)\_\_\_**

This Agreement establishes the terms and conditions under which the VA Central Cancer Registry will provide, and (Insert Name of Outside Agency), its contractors and agents, will use the data to (Be very specific in why data is being shared including the purpose, authorized use and disclosure of the VA data, and state the method of transfer and how that will be accomplished in accordance with VA Handbook 6500, including security requirements).

**TERMS OF THE AGREEMENT**

1. This Agreement is by and between the (Insert STATE Agency Name), its contractors and agents and the VA Central Cancer Registry, a component of the United States Department of Veterans Affairs (VA).
2. This data use agreement covers the transfer and use of data by the (Insert STATE Agency Name) and the VA Central Cancer Registry, for the project specified in this agreement. This Agreement supersedes any and all previous data use agreements.
3. The terms of this Agreement can be changed only by a written modification of the agreement by the agency signatories (or their designated representatives) to this Agreement or by the parties adopting a new agreement in place of this Agreement regarding data specified in this DUA.
4. The VA Central Cancer Registry retains all ownership rights to the data file(s) provided to the (Insert STATE Agency Name) under this Agreement.
5. The (Insert Title of person responsible STATE Agency Name) will be designated as custodian of the VA data for the (Insert STATE Agency Name) and will be responsible for complying with all conditions of use and for establishment and maintenance of appropriate administrative, technical, and physical security safeguards as specified in this Agreement to prevent unauthorized use and disclosure of (Insert VA Facility Name)'s data provided under this agreement. The (Insert STATE Agency Name) agrees to notify the (Insert VA Facility Name) within 15 days of any change of custodianship.

a. **Technical Representative for the VA Central Cancer Registry**

Insert Name and Phone Number  
Address

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b. **Custodian for** \_\_\_(Insert STATE Agency Name)\_\_\_

Insert Name and Phone Number  
Address

6. The following named individuals are designated as their agencies' Points of Contact for performance of the terms of the Agreement.

a. **Point-of-contact on behalf of the VA Central Cancer Registry**

Insert Name and Phone Number  
Address

b. **Point-of-contact on behalf of** \_\_\_(Insert STATE Agency Name)\_\_\_

Insert Name and Phone Number  
Address

7. Except as VHA shall authorize in writing, the (Insert STATE Agency Name)\_\_\_, its contractors and agents, shall not disclose, release, reveal, show, sell, rent, lease, loan, or otherwise grant access to the VHA data covered by this Agreement to any person or entity outside the \_\_\_(Insert STATE Agency Name)\_\_\_ and its team of subcontractors to the project. The \_\_\_(Insert STATE Agency Name)\_\_\_ agrees that access to the data covered by this Agreement shall be limited to the minimum number of individuals who need the access to VA data to perform this Agreement.

8. The parties mutually agree that any derivative data or file(s) that is created from the original data may be retained by the \_\_\_(Insert STATE Agency Name)\_\_\_ until the project specified in this DUA has been completed. The use of the data will be for the time period covered by the written request (Insert Time Frame).

9. The Agreement may be terminated by either party at any time for any reason upon 30 days written notice. Upon such notice, the VA Central Cancer Registry will notify the \_\_\_(Insert STATE Agency Name)\_\_\_ to destroy or return such data at \_\_\_(Insert STATE Agency Name)\_\_\_ expense using the same procedures stated in the above paragraph of this section.

10. Access to the VA data shall be restricted to authorized \_\_\_(Insert STATE Agency Name)\_\_\_ employees, contractors, agents and officials who require access to perform their official duties in accordance with the uses of the information as authorized in this Agreement. Such personnel shall be advised of: (1) the confidential nature of the information; (2) safeguards required to protect the information; and (3) the administrative, civil and criminal penalties for noncompliance contained in applicable Federal laws. The \_\_\_(Insert STATE Agency Name)\_\_\_ agrees to limit access to, disclosure of and use of all data provided under this Agreement. The Requestor \_\_\_(Insert STATE Agency Name)\_\_\_ agrees that access to the data covered by this Agreement shall be limited to the minimum number of individuals who need the access to the VA Central Cancer Registry's data to perform this Agreement.

11. The information provided may not be disclosed or used for any purpose other than as outlined in this Agreement. If the \_\_\_(Insert STATE Agency Name)\_\_\_ wishes to use the data and information provided by the VA Central Cancer Registry under this Agreement for any purpose other than those outlined in this Agreement, the \_\_\_(Insert STATE Agency Name)\_\_\_ shall make a written request to the VA Central Cancer Registry describing the additional purposes for which it seeks to use the data. If the VA Central Cancer Registry determines that the \_\_\_(Insert STATE Agency Name)'s\_\_\_ request to use the data and information provided hereunder is acceptable, the VA Central Cancer Registry shall provide the \_\_\_(Insert STATE Agency Name)\_\_\_ with written approval of the additional use of the data.
12. The \_\_\_(Insert STATE Agency Name)\_\_\_ may not reuse VA Central Cancer Registry's original or work file(s) for any other purpose.
13. The \_\_\_(Insert STATE Agency Name)\_\_\_ will provide appropriate administrative, technical, and physical safeguards to ensure the confidentiality and security of the VA data and to prevent unauthorized use or access to it. \_\_\_(Specify safeguards to be utilized)\_\_\_.
14. In the event that the VA Central Cancer Registry determines or has a reasonable cause to believe that the \_\_\_(Insert STATE Agency Name)\_\_\_ disclosed or may have used or disclosed any part of the data other than as authorized by this Agreement or other written authorization from the appropriate System Manager or the person designated as VA's Responsible Official in this Agreement, the VA Central Cancer Registry in its sole discretion may require the \_\_\_(Insert STATE Agency Name)\_\_\_ to:
  - a. Promptly investigate and report to the VA Central Cancer Registry the \_\_\_(Insert the STATE Agency's determinations regarding any alleged or actual unauthorized use or disclosure)\_\_\_;
  - b. Promptly resolve any problems identified by the investigation;
  - c. If requested by the VA Central Cancer Registry, submit a formal response to an allegation of unauthorized disclosure; and
  - d. If requested, return the VA Central Cancer Registry's data files to the VA Central Cancer Registry. If the VA Central Cancer Registry reasonably determines or believes that unauthorized disclosures of VA's data in the possession of \_\_\_(Insert STATE Agency Name)\_\_\_ have taken place, the VA Central Cancer Registry may refuse to release further data to the \_\_\_(Insert STATE Agency Name)\_\_\_ for a period of time to be determined by the VA Central Cancer Registry, or may terminate this Agreement.
15. All questions of interpretation or compliance with the terms of this Agreement should be referred to the \_\_\_(Insert Name of VA's Responsible Official)\_\_\_ , or successor.
16. Authority for VHA to share this data for the purpose indicated is under the HIPAA Privacy Rule is 45 CFR 164.512(b), under the Privacy Act is Routine Use #10 under the "Patient Medical Records-VA" (24VA19) Privacy Act system of records notice and under 38 U.S.C. 5701(f),

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which allows for the disclosure of VA patient names and addresses to a civil or criminal law enforcement government agency or instrumentality charged with the protection of public health or safety pursuant to a written request from the agency that indicates the information is provided for a purpose authorized by law.

17. On behalf of both parties the undersigned individuals hereby attest that \_\_\_(Insert Name of One Party)\_\_\_ and \_\_\_(Insert Name of Second Party)\_\_\_ are authorized to enter into this Agreement and agrees to all the terms specified herein.

\_\_\_\_\_  
(VA's Responsible Official  
Organization Transferring  
Data)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(STATE's Responsible  
Official Organization  
Receiving Data)

\_\_\_\_\_  
(Date)

Concur/Non-Concur:

\_\_\_\_\_  
(VA Central Cancer Registry's Information  
Security Officer Name and Organization)

\_\_\_\_\_  
(Date)