

Investigator: _____ Date: _____
Last name, first

Project title: _____

**Prostate Disease Oriented Team DATA USE AGREEMENT (DUA)
PRINCIPAL INVESTIGATOR**

Information regarding persons with cancer is sensitive. Therefore, specific laws have been enacted to insure the confidentiality of individuals included in cancer registry data. In utilizing data on such individuals for research purposes, it is absolutely necessary to insure, to the extent possible, that uses of such data will be limited to research. Uses for any other reason, particularly those resulting in personal disclosures, will be prosecuted to the full extent of the law. In addition, release of information about the providers, i.e. the physicians and hospitals that provide care for cancer patients, may compromise the willingness of these providers to cooperate with the activities of the cancer registries. Therefore, considerations regarding the privacy of providers are also of great importance.

In order for the HCI Prostate Disease Oriented Team (PDOT) to provide the CCR data to you, it is necessary that you agree to the following provisions:

1. You agree that the statements and methods made in your attached research proposal are complete and accurate.
2. You will not use the data for purposes other than described in your research proposal.
3. You will not permit others to use the data except for collaborators within your institution involved with the research as described in your proposal. Within your institution or organization, access to the PDOT data shall be limited to the minimum number of individuals necessary to achieve the purpose stated in your proposal.
4. You will establish and maintain the appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it, as described in your proposal. You agree to allow PDOT personnel to conduct on-site inspections to ensure compliance with the data storage / confidentiality /security policies.
5. You agree not to place the PDOT data on personal computers, portable devices and removable media unless they data is encrypted in accordance with Health and Human Services HIPAA, HCI and University of Utah policies. Portable devices include any non-fixed equipment that contains an operating system which may be used to create, access or store PDOT data. This includes but is not limited to laptops, personal digital assistants (PDAs), and smart phones. Removable media include, but are not limited to: CDs, DVDs, MP3 players, removable memory, and USB drives (thumb drives). If approved, all data stored on any of these devices must be password protected AND encrypted. Approved encryption standards must be FIPS-140 compliant and include Advanced Encryption Algorithm (AES) that uses a 128, 192, or 256-bit key size. In the event that the data are lost or stolen, you agree to report the loss to the PDOT contact within 24-hours/first business day of discovering the loss.
6. You may use an institutionally provided VPN to link to a time sharing system for data access. In this case, the home based PC may support the VPN but the PDOT data must remain on the institution's server.
7. You will store all media on which the PDOT data are delivered in a secure location, such as a locked file cabinet in a locked office, only accessible by you or appropriate designated staff.

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8. All PDOT data must reside at your institution under your purview. If you plan to move to a different institution, you must contact the PDOT in writing prior to moving for instructions on how to handle the PDOT data. You may not duplicate any PDOT files prior to moving nor can you take PDOT data with you without written permission from the PDOT. If you chose not to take the data with you, you must destroy the files or designate a new PI prior to moving.
9. You will not attempt to link nor permit others to link the PDOT data with individually identified records in another database without the written consent from the applicable registries and the PDOT .
10. You agree that you will not attempt to contact the individuals that are identifiable within the PDOT data.
11. No findings or information derived from the PDOT data may be released if such findings contain any combination of data elements that might allow the deduction of a patient's or providers' identity. You agree that PDOT leadership shall be the sole judge as to whether the anonymization sufficiently precludes one from identifying or deducing the identity of a specific patient, provider or registry with a reasonable degree of certainty.
12. You agree to provide the PDOT contact with a copy of all manuscripts to be submitted for publication prior to submission. You further agree not to submit such findings to any third party until receiving PDOT's approval from the PDOT contact to do so. PDOT agrees to make a determination about approval and to notify the user within 4 weeks after receipt of any findings. PDOT's review of the findings is for the purpose of assuring that data confidentiality is maintained and that individual patients and/or providers cannot be identified. PDOT may withhold approval for publication if PDOT reviewers determine that the format in which data are presented may result in identification of individual patients and/or providers. PDOT may also review that the focus of the paper is consistent with research questions that were described in the request for PDOT data. The PDOT may decline to approve manuscripts that are beyond the scope of what is in the data request.
13. You agree that in the event the PDOT determines or has a reasonable belief that you have violated any terms of this agreement, PDOT may request that you return the data and all derivative files to the PDOT. You understand that as a result of PDOT's determination or reasonable belief that a violation of this agreement has taken place, the PDOT may refuse to release further PDOT registry data to you for a period of time to be determined by the PDOT.
14. All files received may be retained for a maximum of five years. At the completion of the project or five years from receipt all files including all back-up files and original media must be destroyed and notification of destruction must be sent to PDOT. Investigators who need to retain files beyond that period must contact PDOT.
15. You agree to provide the PDOT with a written progress report of your work each 6 months until the project has been terminated.

Signature of Principal Investigator (In the case of students and fellows, the department chair or advisor from the student's academic institution must sign the data request)

Your signature indicates that you agree to comply with the above stated provisions and all University of Utah policies.

Name – (printed or typed)

Institution/Organization

Street Address

City/State/ZIP code

Phone number – including Area Code

Fax number

Email address

Signature

Date

Dear Investigator

Thank you for your interest in the Prostate Disease Oriented Team CCR data. Please use this application form to request data files. In order to facilitate the review process, you must complete and provide all items *on this form*. Do not say “see attached”. Be sure to review and include all required elements as listed in the application checklist. Incomplete applications will be delayed. You must submit this completed form *electronically* to the pDOT contact (Carlee Jenkins) along a completed and signed Data Use Agreement (DUA). The original signed DUA must also be mailed or hand-delivered to the pDOT contact.

Thank you

Jonathan Tward and William Lowrance
Co-Leaders, pDOT

Questions should be sent to the pDOT contact:

Carlee Jenkins
Carlee.Jenkins@hci.utah.edu

Application Checklist

To be sent by email attachment to the pDOT contact:

- Application:
 - Your description of the project **must** include:
 - statement of main hypothesis / specific research question
 - description of study subjects to be included in the analysis
 - brief explanation of how key components of the study will be obtained/identified within the PDOT CCR Database– specifically:
 - cohort selection criteria
 - covariates
 - outcomes
 - description of the personnel involved
 - timeline for completion
 - references can be included, if relevant.
 - You **must** include an explanation of data storage and protection. Please be specific as to the location of all files and media and all protections that will be in place.
- Completed and signed Data Use Agreement (DUA)
- Letter from funder (if applicable)

To be sent by campus or regular mail to the pDOT contact:

- Completed and signed DUA

MAILING ADDRESS:

Please send any questions to the SEER-Medicare contact at Carlee.jenkins@hci.utah.edu

APPLICATION FOR pDOT CCR DATA
 (Please complete all information in this form)

I. Contact information

Project Title: < enter project title >

Principal Investigator: *(students or fellows may NOT be listed as the PI)*

Name:					
Institution:					
Address:					
		City		State	
Email:			Phone:		Fax:

Student /fellow contact:

Name:					
Institution:					
Address:					
		City		State	
Email:			Phone:		Fax:

II. Project Description:

- A. Title
- B. Brief overview of your project (one or two sentences)
- C. Description of the Project (between 1-5 pages). This description **must** include:
- statement of main hypothesis/research question
 - description of study subjects and cancer sites/phases to be included in the analysis
 - brief explanation of how key components of the study will be obtained/identified within the data– specifically:
 - cohort selection criteria
 - covariates
 - outcomes
 - description of the personnel involved
 - timeline for completion
 - references can be included, if relevant.
- D. Data Storage and Protection: Please provide the following:
- the specific location of the data and where/how the data will be stored
 - how the data will be protected from unauthorized access.
 - information on the storage/protection of the media you receive containing the original files.
 - assurances that no attempt will be made to identify individual patients, hospitals or physicians
 - assurances that publications and presentations of the data will not allow identification of patients, hospitals or physicians.

Example of the minimum detail you need to provide:

“All data will be maintained on the HCI servers located in the Huntsman Cancer Institute Bldg at the University of Utah.. Access to the server is protected by [firewalls, encryption, etc] and all accounts will be password protected. Access to the data on the server is limited to researchers involved in the project. All media files (thumb drives, cd’s DVD’s,etc.) with the original data will be stored in a locked file cabinet in my office, Room 624 of the School of Public Health. All computers used in the storage of the patient data will be compliant with University of Utah policies and regulations and be compliant with HIPAA regulations”

- E. Funding Source: If your organization is a consulting firm, contractor, or pharmaceutical company, then your application must include a letter from the funder indicating that you are free to work and publish your findings without limitations by the funder. This letter must come from a person in authority on company letterhead.