ATTACHMENT 6

Data Sharing Agreement Form

National Breast and Cervical Cancer Early Detection Program (NBCCEDP)
Minimum Data Elements (MDEs)
Data Sharing for Special Use Agreement

Background

The National Breast and Cervical Cancer Early Detection Program (NBCCEDP) is a program of the Division of Cancer Prevention and Control (DCPC), NCCDPHP established by the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354). The purpose of the NBCCEDP is to reduce breast and cervical cancer morbidity and mortality among low income, medically under-served women by providing community based screening and diagnostic services. For women diagnosed with cancer or pre-cancer, the NBCCEDP assures access to treatment services. The NBCCEDP currently funds 68 cooperative agreement grantees in all 50 states, the District of Columbia, 12 tribal organizations and 5 U.S. territories.

The NBCCEDP grantees collect surveillance data on women served through the program. These data are submitted twice a year by all NBCCEDP grantees to CDC and represent a minimum set of data collected by grantees on all women served through the NBCCEDP. Called the Minimum Data Elements (MDEs), these are surveillance data primarily used for program monitoring, quality assurance, and evaluation. Secondary research analysis of data is conducted by scientists in DCPC and sometimes scientists outside of CDC.

Policy Statement

This agreement is authorized through CDC IRB Protocol 1976, Collection and Analysis of Minimum Data Elements Data Set from the National Breast and Cervical Cancer Early Detection Program.

Results from the program are shared with the public through reports available on the CDC website. The National Report is a comprehensive report on the first 12 years of the program and reports incremental screening results and outcomes by age and race at the national aggregate level. Also available through the public website is a limited set of grantee-specific data, reported as a five-year aggregate, and includes volume and demographic profiles of women screened through the program, screening results and diagnostic outcomes.

Proposed research activities involving the use of MDE data through a ***Data Sharing for Special Use Agreement*** are reviewed and approved through a DCPC interdisciplinary team called the MDE Committee.

CDC does not release grantee-specific data to other grantees or in response to external inquiries without the grantee's permission, through either communication with NBCCEDP Program Directors or through their Council.

The special use dataset will be generated from a subset of the NBCCEDP analysis dataset used at CDC and will be provided in a format determined for each request. Data may be restricted based on completeness, quality and applicability to requested use, reasons of invading the privacy of the subject, or sensitivity of release. Data will be stripped of all program, provider, patient and geographic indicators and may be provided in aggregate form rather than service-level records.

Data Sharing for Special Use Agreement

There are specific laws that insure the confidentiality of individuals diagnosed with cancer when information about their cancer is entered into a database for the purpose of establishing a research resource. 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 disclosure, will be prosecuted to the full extent of the law.

In order for the Division of Cancer Prevention and Control to provide a dataset to you for secondary analysis, it is necessary that you agree to the following provisions.

I, _____, as principal investigator on this proposed analysis of the NBCCEDP MDEs, agree to the following requirements for the use of the data and assure compliance with the requirements.

1. I will not use nor permit others to use the data in any way other than for statistical reporting and analysis. I will not use nor permit others to use these data to conduct analyses other than those described in the proposal which accompanies this statement. I will not conduct analyses other than those specifically approved by CDC.

2. I will not present nor publish analyses that include any restricted uses of the data, without written approval of CDC, including the following:
   - Cell of less than five individuals/records
   - Identification of a specific grantee or provider
   - Aggregation of data at the grantee or provider level, or <u>any</u> geographic unit of data.

3. I will not release nor permit others to release the data in full or in part to any person other than those listed as collaborators in the attached proposal, except within the written approval of CDC.

4. I will provide information on how the data will be stored and safeguarded from unauthorized access.

5. I will involve a DCPC collaborator in the project. If a DCPC collaborator is a co-author on a publication, CDC publication clearance is required.

6. I will not attempt nor permit others with access to the data to attempt to learn the identity of any person or provider whose data are contained in the supplied file(s). If the identity of a subject should be discovered inadvertently, then I will make no use of this knowledge. I will inform the Division of Cancer Prevention and Control of discovery so they can prevent future discoveries. I pledge that neither I nor other members of my team will inform anyone else of the discovered identity.

7. When the proposed analyses are completed, I will assure that all copies of these data are destroyed or returned to CDC and provide written confirmation that this was completed.

8. All written or oral presentations of the results of the analyses will include an acknowledgement of the CDC as the original source of the data.

9. As a courtesy, I agree to submit an abstract, expected date of publication, and journal name for articles resulting from analysis of the data at least four weeks prior to publication, and a copy of the article after publication.

10. Other conditions or special circumstances, as specified:

Signed:_____ Date:_____

My signature indicates my agreement to comply with these requirements and above stated provisions. Deliberately making a false statement regarding any matter within the jurisdiction of any department or agency of the Federal Government violates 18 USC 1001 and is punishable by fine or prison.

Please return **this signed** form, **list of investigators** and **project summary** to:

Janet Royalty, MS
Division of Cancer Prevention and Control
NCCDPHP, Centers for Disease Control and Prevention
4770 Buford Hwy, N.E., Mailstop K-57
Atlanta, GA 30341-3724
Phone: (770) 488-3085 Fax: (770) 488-3230

Project Investigators

*** Investigators outside of CDC's Division of Cancer Prevention and Control (DCPC) are required to include a DCPC collaborator.**

	Primary Investigator	**DCPC Collaborator***
Name		
Email		
Phone		
Institution		
Address		
	Co-Investigator	**Co-Investigator**
Name		
Email		
Phone		
Institution		
Address		
	Co-Investigator	**Co-Investigator**
Name		
Email		
Phone		
Institution		
Address		
	Co-Investigator	**Co-Investigator**
Name		
Email		
Phone		
Institution		
Address		

Project Summary

1. **Project Title:**

2. **Abstract:**

3. **Brief description of the project (Background, Study Questions, Methods):**

4. **Data Requested** (Specify data elements and years of data. A listing of MDE data elements available upon request). **Years of data requested:** _____

Data Element Name	Proposed Use

5. **Proposed Draft Table Shells (a generic example is provided)**

Year of Pap

Age Group	2000	2003	2005	2008
18-44				
45-64				
65 and older				

6. **Intended/Potential Use of Study Findings:**

7. **Procedures/Methods for Dissemination, Notification and Reporting of Results**

8. **Procedures/Methods to Safeguard Data and Assure Confidentiality:**

9. **Procedures/Methods for Handling of Unexpected or Adverse Events:**

10. **Procedures for Destruction of Dataset at Study Completion:**

11. **Project start and end dates: Start _____ End _____**

INVESTIGATORS SHOULD CONSULT WITH THEIR INSTITUTION ABOUT LOCAL HUMAN SUBJECTS/IRB REQUIREMENTS. CDC RECOMMENDS THAT YOU SUBMIT YOUR STUDY PROTOCOL FOR LOCAL IRB REVIEW.