Breast Cancer Surveillance Consortium (BCSC)
Documents external researchers need to sign in order to use BCSC Data

Five of the seven Breast Cancer Surveillance Consortium (BCSC) data collection sites are defined as covered entities by the Health Insurance Portability and Accountability Act (HIPAA). The other two sites are either not a covered entity or they obtain data only from subjects who consent for the release of data to BCSC. To meet HIPAA requirements, data released to Group Health by the five covered entities is governed by a data use agreement between each covered entity and Group Health.

Since BCSC data from all seven sites resides at Group Health and may be released by Group Health (which is also a covered entity), BCSC releases data to other entities only through the use of a business associate agreement, data use agreement, and/or an IRB waiver of consent plus accounting of disclosures, as appropriate. As of this writing, only data use agreements have been needed or issued.

The BCSC shares data with non-BCSC investigators for collaborative research purposes. The BCSC collaborative research agreement[1] outlines the responsibilities of the BCSC, the SCC, and the non-BCSC investigator who is the project leader. **Prior** to conducting any research using BCSC data, the project leader must sign the collaborative agreement. If any data is released to the project leader, the custodian of the data (generally the project leader or the statistician) must also sign the agreement. The signed document must be then sent to the Statistical Coordinating Center (SCC).

The BCSC provides data in aggregate form whenever possible, including the fewest variables necessary to answer the scientific question of interest. When the BCSC sends **aggregated de-identified data** *(e.g.*, does not include any site, facility, radiologist or patient identifiers including study ID numbers) to non-BCSC investigators, no additional documents need to be signed.

If a **non-aggregated de-identified dataset** is sent to a non-BCSC investigator(s), the investigator(s) must send the following documents to the SCC before the dataset is released:
1. An AHRQ-NCI Memorandum of Understanding (MOU) [2] signed by anyone with access to the data.
2. A copy of the data recipient's IRB approval or the institution's/IRB's determination of exemption

When the SCC sends a **limited dataset** to non-BCSC investigators (e.g., a dataset containing identifiers such as zip codes and/or dates) the investigators must send the following documents to the SCC before the dataset is released:
1. A HIPAA data use agreement[3] signed by the Principal Investigator
2. An AHRQ-NCI MOU[2] signed by anyone with access to the data.
3. A copy of the data recipient's IRB approval or the institution's/IRB's determination of exemption

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[1] A BCSC collaborative research agreement – This agreement was developed by the BCSC co-chairs with the oversight of the Steering Committee and specifies that the data and tables will only be used for approved scientific projects. The agreement also describes guidelines of use such as the publication guidelines.

[2] An AHRQ-NCI Memorandum of Understanding (MOU) - a MOU between AHRQ and NCI to provide further protections of the BCSC, specifically for facilities and BCSC sites. The MOU provides assurances to the BCSC participating sites that the confidential facility and organizational level data collected for BCSC research will have AHRQ's protection from disclosure in any reports, analyses, or any research data that are generated for publication or release by BCSC-related projects. The MOU also provides confidentiality protections of research subject data. Data collected for AHRQ's collaborative research projects are subject to the confidentiality provisions of 42 U.S.C. 299c-3(c) (also cited as 924(c) of the US Public Health Service (PHS) Act). This statute requires, in effect, that no identifying information obtained in the course of the AHRQ-supported BCSC projects may be used for any purpose other than that for which it is provided to the BCSC, and that such information may not be published or released unless the individual data subject(s) or person(s) or organization(s) providing the information has or have consented to such uses or disclosures

[3] HIPAA data use agreement - The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal statute designed to improve health-care data usage by setting the first comprehensive national standards for protecting patient privacy, communicating data electronically, and assuring the security of electronic patient information. Under HIPAA, a covered entity may use or disclose protected health information but must take additional steps to guard the privacy of this information. Because Group Health is a covered entity, if the SCC releases limited datasets to outside investigators that includes protected health information, a data use agreement must be created with those investigators.