



Data Confidentiality and the Annual Call for Data



Annually, the Commission on Cancer (CoC) of the American College of Surgeons (ACoS), in a joint effort with the American Cancer Society (ACS), collects data from the CoC-Approved Cancer Programs. These data are sent to a secure web site server, dedicated entirely to the National Cancer Data Base (NCDB). The data items submitted meet the definition of a limited data set as defined within the Health Insurance Portability and Accountability Act (HIPAA) (45 C.F.R. § 164.514(e)(2)). Case identification information is limited to the CoC Facility ID Number (FIN) and the registry case accession number. These items are collected merely for administrative purposes. Only the reporting registry can link the accession number to a specific patient.

A data use agreement is in place between American College of Surgeons and each participating program in order for the CoC to meet the business associate obligations rendered to participating programs (45 C.F.R. § 164.514(e)(4)). The evaluations and analyses of the data become the foundation of the quality improvement process of the local cancer program, a requisite for remaining a CoC-Approved program. Both of these functions fall under the rubric of health care operations as defined by the HIPAA regulations (CFR §164.501). Any generalizable knowledge that may be gleaned from the analyses is secondary to the health care operation functions. Dissemination of analyses through publications and presentations is for the purpose of the mission of the Commission – to improve cancer care outcomes at the national and local level.

Data Confidentiality and Special Studies

These CoC Special Studies are part of a continuing effort to evaluate the ongoing quality of care provided for selected cancers and, as noted above, fall within the permitted activities of the HIPAA. The intent of these studies is to evaluate and promote the quality of care at the local level. This activity falls within the scope of the ACoS Business Associate Agreement and the HIPAA, Administrative Simplification Act (CFR §164.501).

An IRB review is not needed, unless it is a particular hospital's policy to conduct an IRB for any study. The secondary data is retrospective and the analyses provided are for the purpose of assisting CoC-approved cancer programs with the evaluation of treatment that has already occurred and how this relates to aggregated information from other similar hospitals.

These studies do not *directly* impact treatment of individual patients. No patient identifiers (e.g. name, social security number, address) are collected as part of the study. Case identification information is limited to the CoC Facility ID Number (FIN) and the registry case accession number. These items are collected merely for administrative purposes. Only the reporting registry can link the accession number to a specific patient.