Position Statement on the Confidentiality of Medical Research Records

The investigator should explain to the patient or subject the extent of the confidentiality of the information furnished. If identifying data may be of potential interest to civil, criminal, or administrative authorities, the investigator should, wherever possible, obtain a written waiver in advance from the officials concerned. If there is a court order to divulge such information, it should be released only after a thorough and proper judicial review of the facts.

Before authorizing transfer of any data to other research personnel the investigator must receive assurance in writing that the aforementioned principles will be followed.

Modern data processing systems create problems in the application of these principles. The primary responsibility for ensuring the confidentiality of records rests with the investigator regardless of the method by which such records are stored.

Federal and state legislation should be enacted that implements these stated principles. The task force felt that the statutes enacted by various states offered many good suggestions, particularly the Maryland Annotated Code, Article 43 Section 149-C (1957-Repl. Vol. 1969); Article 35 Section 102, and Article 75-C Section 11; and the Connecticut Public Acts (1969), Public Act Number 819 Sections 5 and 6. These represent good examples of sound, useful, and workable legislation that may serve as general models. The task force suggests, however, stronger sanctions for instances when these laws are abused.