§ 1.468 Relationship to Federal statutes protecting research subjects against compulsory disclosure of their identity.

(a) Research privilege description. There may be concurrent coverage of patient identifying information by the provisions of §§1.460 through 1.499 of this part and by administrative action taken under Sec. 303(a) of the Public Health Service Act (42 U.S.C. 241(d) and the implementing regulations at 42 CFR Part 2a); or Sec. 502(c) of the Controlled Substances Act (21 U.S.C. 872(c) and the implementing regulations at 21 CFR 1316.21). These ‘‘research privilege’’ statutes confer on the Secretary of Health and Human Services and on the Attorney General, respectively, the power to authorize researchers conducting certain types of research to withhold from all persons not connected with the research the names and other identifying information concerning individuals who are the subjects of the research.

(b) Effect of concurrent coverage. Sections 1.460 through 1.499 of this part restrict the disclosure and use of information about patients, while administrative action taken under the research privilege statutes and implementing regulations protects a person engaged in applicable research from being compelled to disclose any identifying characteristics of the individuals who are the subjects of that research. The issuance under §§1.490 through 1.499 of this part of a court order authorizing a disclosure of information about a patient does not affect an exercise of authority under these research privilege statutes. However, the research privilege granted under 21 CFR 291.505(g) to treatment programs using methadone for maintenance treatment does not protect from compulsory disclosure any information which is permitted to be disclosed under those regulations. Thus, if a court order entered in accordance with §§1.490 through 1.499 of this part authorizes a VA facility to disclose certain information about its patients, the facility may not invoke the research privilege under 21 CFR 291.505(g) as a defense to a subpoena for that information.

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