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42 C.F.R. § 2.52

Scientific research.

(a) *Use and disclosure of patient identifying information.* Notwithstanding other provisions of this part, including paragraph (b)(2) of this section, patient identifying information may be used or disclosed for the purposes of the recipient conducting scientific research if:

(1) The person designated as director or managing director, or person otherwise vested with authority to act as chief executive officer or their designee, of a part 2 program or other lawful holder of data under this part, makes a determination that the recipient of the patient identifying information is:

(i) A HIPAA covered entity or business associate that has obtained and documented authorization from the patient, or a waiver or alteration of authorization, consistent with 45 CFR 164.508 or 164.512(i), as applicable;

(ii) Subject to the HHS regulations regarding the protection of human subjects (45 CFR part 46), and provides documentation either that the researcher is in compliance with the requirements of 45 CFR part 46, including the requirements related to informed consent or a waiver of consent (45 CFR 46.111 and 46.116) or that the research qualifies for exemption under the HHS regulations (45 CFR 46.104) or any successor regulations;