

42 C.F.R. § 2a.5

Contents of application; research projects in which drugs will be administered.

(a) In addition to the information required by § 2a.4 and any other pertinent information which the Secretary may require, each application for an authorization of confidentiality for a research project which involves the administering of a drug shall contain:

(1) Identification of the drugs to be administered in the research project and a description of the methods for such administration, which shall include a statement of the dosages to be administered to the research subjects;

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