

Annotated Code of Maryland
(2000 Replacement Volume and 2001 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article - Health - General

SUBTITLE 16. HUMAN SUBJECT RESEARCH.

13-1601.

(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(B) "FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS" MEANS:

(1) TITLE 45, PART 46 OF THE CODE OF FEDERAL REGULATIONS, AND ANY SUBSEQUENT REVISION OF THOSE REGULATIONS; AND

(2) WITH RESPECT TO RESEARCH THAT IS SUBJECT TO THE JURISDICTION OF THE FEDERAL FOOD AND DRUG ADMINISTRATION, TITLE 21, PARTS 50 AND 56 OF THE CODE OF FEDERAL REGULATIONS, AND ANY SUBSEQUENT REVISION OF THOSE REGULATIONS.

(C) "HUMAN SUBJECT" ~~MEANS A LIVING INDIVIDUAL ABOUT WHOM AN INVESTIGATOR CONDUCTING RESEARCH OBTAINS:~~

~~(1) DATA THROUGH INTERVENTION OR INTERACTION WITH THE INDIVIDUAL, OR~~

~~(2) IDENTIFIABLE PRIVATE INFORMATION HAS THE MEANING STATED IN THE FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS.~~

(D) "INSTITUTIONAL REVIEW BOARD" ~~MEANS ANY BOARD, COMMITTEE, OR OTHER GROUP FORMALLY DESIGNATED BY AN INSTITUTION TO APPROVE THE INITIATION OF, AND TO CONDUCT PERIODIC REVIEW OF, RESEARCH INVOLVING A HUMAN SUBJECT HAS THE MEANING STATED IN THE FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS.~~

(E) "RESEARCH" ~~MEANS A SYSTEMATIC INVESTIGATION, INCLUDING RESEARCH DEVELOPMENT, TESTING, AND EVALUATION, DESIGNED TO DEVELOP OR CONTRIBUTE TO GENERAL KNOWLEDGE HAS THE MEANING STATED IN THE FEDERAL REGULATIONS ON THE PROTECTION OF HUMAN SUBJECTS.~~

(F) "RESEARCH PROTOCOL" ~~MEANS A WRITTEN EXPLANATION OF THE OBJECTIVES AND METHODS OF PROPOSED RESEARCH.~~