

(5) "MULTIPLE PROJECT ASSURANCE CONTRACT" MEANS A CONTRACT BETWEEN AN INSTITUTION AND THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES THAT DEFINES THE RELATIONSHIP OF THE INSTITUTION TO THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES AND SETS OUT THE RESPONSIBILITIES OF THE INSTITUTION AND THE PROCEDURES THAT WILL BE USED BY THE INSTITUTION TO PROTECT HUMAN SUBJECTS.

~~(4)~~ (6) "NIH" MEANS THE NATIONAL INSTITUTES OF HEALTH.

~~(5) "PATIENT" MEANS A POLICYHOLDER, SUBSCRIBER, OR CERTIFICATE HOLDER OR A COVERED DEPENDENT OF A POLICYHOLDER, SUBSCRIBER, OR CERTIFICATE HOLDER.~~

~~(6)~~ (7) (I) "PATIENT COST" MEANS ~~ANY THE~~ COST OF A MEDICALLY NECESSARY HEALTH CARE SERVICE THAT IS INCURRED AS A RESULT OF THE TREATMENT BEING PROVIDED TO THE PATIENT MEMBER FOR PURPOSES OF THE CLINICAL TRIAL.

(II) "PATIENT COST" DOES NOT INCLUDE:

1. THE COST OF AN INVESTIGATIONAL DRUG OR DEVICE;
2. THE COST OF NONHEALTH CARE SERVICES THAT A PATIENT MAY BE REQUIRED TO RECEIVE AS A RESULT OF THE TREATMENT BEING PROVIDED FOR PURPOSES OF THE CLINICAL TRIAL;
3. COSTS ASSOCIATED WITH MANAGING THE RESEARCH ASSOCIATED WITH THE CLINICAL TRIAL; OR
4. COSTS THAT WOULD NOT BE COVERED UNDER THE PATIENT'S POLICY ~~OR PLAN~~, PLAN, OR CONTRACT FOR NONINVESTIGATIONAL TREATMENTS.

(B) THIS SECTION APPLIES TO:

(1) INSURERS AND NONPROFIT HEALTH SERVICE PLANS THAT PROVIDE HOSPITAL, MEDICAL, SURGICAL, OR PHARMACEUTICAL BENEFITS TO INDIVIDUALS OR GROUPS ON AN EXPENSE-INCURRED BASIS UNDER A HEALTH INSURANCE POLICY OR CONTRACT ISSUED OR DELIVERED IN THE STATE--AND

(2) HEALTH MAINTENANCE ORGANIZATIONS THAT PROVIDE HOSPITAL, MEDICAL, SURGICAL, OR PHARMACEUTICAL BENEFITS TO INDIVIDUALS OR GROUPS UNDER CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE.

(C) THIS SECTION DOES NOT APPLY TO A POLICY ~~OR PLAN~~, PLAN OR CONTRACT PAID FOR UNDER TITLE XVIII OR TITLE XIX OF THE SOCIAL SECURITY ACT.

~~(C) A POLICY OR PLAN SUBJECT TO THIS SECTION SHALL PROVIDE COVERAGE FOR ALL PATIENT COSTS INCURRED AS A RESULT OF A TREATMENT BEING PROVIDED IN ACCORDANCE WITH A CLINICAL TRIAL FOR A LIFE THREATENING, DEGENERATIVE, OR PERMANENTLY DISABLING CONDITION OR A CONDITION ASSOCIATED WITH OR A COMPLICATION OF A LIFE THREATENING, DEGENERATIVE,~~