3. THE AIDS CLINICAL TRIALS GROUP; AND

4. THE COMMUNITY PROGRAMS FOR CLINICAL RESEARCH IN AIDS.

(3) "FDA" MEANS THE FEDERAL FOOD AND DRUG ADMINISTRATION.

(4) "MEMBER" MEANS A POLICYHOLDER, SUBSCRIBER, INSURED, OR CERTIFICATE HOLDER OR A COVERED DEPENDENT OF A POLICYHOLDER, SUBSCRIBER, INSURED, OR CERTIFICATE HOLDER.

(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