

~~(3) THE PROPOSED TREATMENT HAS BEEN REVIEWED AND APPROVED BY TWO QUALIFIED INSTITUTIONAL REVIEW BOARDS; OR~~

(V) AN INSTITUTIONAL REVIEW BOARD OF AN INSTITUTION IN THE STATE THAT HAS A MULTIPLE PROJECT ASSURANCE CONTRACT APPROVED BY THE OFFICE OF PROTECTION FROM RESEARCH RISKS OF THE NIH;

~~(4) (3) THE FACILITY AND PERSONNEL PROVIDING THE TREATMENT ARE PROVIDING THE TREATMENT WITHIN THEIR SCOPE OF PRACTICE, EXPERIENCE, AND TRAINING CAPABLE OF DOING SO BY VIRTUE OF THEIR EXPERIENCE, TRAINING, AND VOLUME OF PATIENTS TREATED TO MAINTAIN EXPERTISE;~~

~~(6) (4) THERE IS NO CLEARLY SUPERIOR, NONINVESTIGATIONAL TREATMENT ALTERNATIVE; AND~~

~~(6) (5) THE AVAILABLE CLINICAL OR PRECLINICAL DATA PROVIDE A REASONABLE EXPECTATION THAT THE TREATMENT WILL BE AT LEAST AS EFFICACIOUS EFFECTIVE AS THE NONINVESTIGATIONAL ALTERNATIVE.~~

(F) THE COVERAGE UNDER SUBSECTION (D) OF THIS SECTION MAY BE PROVIDED ON A CASE BY CASE BASIS IF THE TREATMENT IS BEING PROVIDED IN A PHASE I CLINICAL TRIAL FOR ANY LIFE-THREATENING CONDITION OTHER THAN CANCER.

~~(D) (G) IN ADDITION TO CONJUNCTION WITH THE PROVISIONS OF SUBSECTION (C) (D) OF THIS SECTION, A POLICY OR PLAN POLICY, PLAN, OR CONTRACT SHALL PROVIDE COVERAGE FOR PATIENT COSTS COST INCURRED FOR DRUGS AND DEVICES THAT HAVE BEEN APPROVED FOR SALE BY THE FDA WHETHER OR NOT THE FDA HAS APPROVED THE DRUG OR DEVICE FOR USE IN TREATING THE PATIENT'S PARTICULAR CONDITION, TO THE EXTENT THAT THE DRUGS OR DEVICES ARE NOT PAID FOR BY THE MANUFACTURER, DISTRIBUTOR, OR PROVIDER OF THAT DRUG OR DEVICE.~~

(H) (1) AN ENTITY SEEKING COVERAGE FOR TREATMENT IN A CLINICAL TRIAL APPROVED BY AN INSTITUTIONAL REVIEW BOARD UNDER SUBSECTION (E)(2)(V) OF THIS SECTION SHALL POST ELECTRONICALLY AND KEEP UP-TO-DATE A LIST OF THE CLINICAL TRIALS MEETING THE REQUIREMENTS OF SUBSECTIONS (D) AND (E) OF THIS SECTION.

(2) THE LIST SHALL INCLUDE, FOR EACH CLINICAL TRIAL:

(I) THE PHASE FOR WHICH THE TRIAL IS APPROVED;

(II) THE ENTITY APPROVING THE TRIAL;

(III) WHETHER THE TRIAL IS FOR TREATMENT OF CANCER OR ANOTHER LIFE-THREATENING DISEASE AND, IF NOT CANCER, THE PARTICULAR DISEASE; AND

(IV) THE ESTIMATED NUMBER OF PARTICIPANTS IN THE TRIAL.