/*Here is the Federal Register notice waiving local institutional review board requirements for d4T testing.*/

National institutes of Health

Waiver of Local Institutional Review Board Requirement; d4T (Trade name Stavudine)

AGENCY: National institutes of Health, HHS.
ACTION: Notice.
SUMMARY: The National Institutes of Health is announcing the waiver of the applicability of the title 45 CFR part 46 (protection of human subjects) requirement of local Institutional Review Board (IRB) review for the protocol AI455-900 under the "Expanded Availability of Investigational New Drugs Through a Parallel Track Mechanism for People with AIDS and other HIV-Related Disease," known as "Parallel Track" (57 FR 13250).

FOR FURTHER INFORMATION CONTACT:

Diane Aiken, Building 31. room 513-59, Office for Protection from Research Risks, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892 ((301) 496-7005).

SUPPLEMENTARY INFORMATION: Pursuant to 46.101(i) of title 45 of the Code of Federal Regulations, the Secretary of Health and Human Services (HHS) waived, on December 8, 1992, the HHS regulations requiring local IRB review for the investigational new drug d4T (trade name Stavudine) under the Bristol Meyers-Squibb Company's protocol AI455-900. Protocol AI455-900 makes the investigational drug d4T available through parallel track, that is, d4T will be available in one of two comparison doses to patients who have not responded to or who are intolerant to AZT or ddI and who are ineligible for the controlled clinical trial of d4T. This parallel track protocol was reviewed nationally by the AIDS Program Advisory Committee (APAC) and, following consideration of the human subject protections, was recommended for approval. Because of the APAC's careful review and recommendation for approval, the Food and Drug Administration also waived its requirement for local IRB review and approval of this protocol.

The HHS regulations requiring local IRB review and approval apply to any institutions, conducting this research, which have Multiple Project Assurances on file with HHS/Office for

Protection from Research Risks, in the absence of this waiver. Although with this waiver, local IRB review is not mandatory. Each local IRB retains the option of reviewing the protocol.

Dated: February 2, 1993.

Bernadine Healy,

Director, NIH

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