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INFORMATION MEMORANDUM

To: State Child Welfare Agencies

Subject: Foster Children as Human Subjects in Drug Trials

Legal and Related References: 45 CFR 46.101; 45 CFR 46.409; 21 CFR 50.56

Purpose: This Information Memorandum provides guidance to State agencies regarding the use of children in foster care as subjects in clinical trials of new drugs.

Information: During the 1980's and 1990's, researchers conducted clinical trials of AIDS drugs on hundreds of HIV - infected children in foster care in at least seven States (Illinois, Louisiana, Maryland, New York, North Carolina, Colorado and Texas.) Through these trials, infected children had access to treatment that would not have been available otherwise and much useful scientific data were gained as well. However, it is not clear whether all of these children had independent advocates assigned to them by the health institution conducting the research, as required by law. It is also appears that some States may have failed to obtain proper consent from parents or guardians in a number of cases.

The purpose of this Information Memorandum is to remind State agencies that any time children in foster care are used as subjects of clinical research, it is imperative that the rights of these children be protect through the appointment of an independent advocate and by gaining consent from a guardian. As always, the health and well-being of children who cannot speak for themselves must be the State's highest concern. Further, the requirements for independent advocates and proper consent apply not only to clinical trials involving new drugs, but also to any research setting in which children in foster care are the subjects.

Allowing children in the foster care system to take part in clinical trials or other research is not prohibited, and States may continue to do so if they believe that children will ultimately benefit. However, it is important that States that currently allow children in foster care to participate in clinical trials exercise extreme diligence, in view of the fact that these children, having been removed from their families, are by definition more vulnerable and in need of even more protection than children in the general population.

Inquires: HHS - Associate Commissioner, ACF/ACYF/CB

/s/

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