Legislation Details (With Text)

File #:	Res 2192-2009	**Version:**	*	**Name:**	Administration for Children's Services to access medical and clinical trial records of children enrolled in clinical trials while in foster care between 1985 and 2005 for research purposes.
Type:	Resolution			**Status:**	Filed
				In control:	Committee on General Welfare
On agenda:	9/30/2009				
Enactment date:				**Enactment #:**	
Title:	Resolution calling on the New York State Department of Health to allow the New York City Administration for Children's Services to access medical and clinical trial records of children enrolled in clinical trials while in foster care between 1985 and 2005 for research purposes.				
Sponsors:					
Indexes:					
Attachments:					

Date	Ver.	Action By	Action	Result
9/30/2009	*	City Council	Introduced by Council	
9/30/2009	*	City Council	Referred to Comm by Council	
12/31/2009	*	City Council	Filed (End of Session)	

Res. No. 2192

Resolution calling on the New York State Department of Health to allow the New York City Administration for Children's Services to access medical and clinical trial records of children enrolled in clinical trials while in foster care between 1985 and 2005 for research purposes.

By Council Members de Blasio, Brewer, Jackson, James, Liu, Mark-Viverito, Mendez, Sanders Jr., Seabrook and Mealy

Whereas, In 2004, serious allegations surfaced regarding New York City's enrollment of foster children in clinical trials for HIV/AIDS drugs; and

Whereas, Claims were made that minority children were disproportionately selected to participate, in some cases against their parents' wishes, and were physically abused and neglected as they were experimented on and exposed to toxic medications; and

Whereas, While some members of the medical community praised the trials as allowing children access to potentially life-saving medication, many advocates believe that the clinical program

needed more safeguards to protect vulnerable children; and

Whereas, In March 2004, the federal Office of Human Research Protections swiftly investigated the allegations, and found that one hospital which administered several clinical trials granted premature approval in some studies without gathering enough information about the foster children selected as subjects and maintained inadequate records; and

Whereas, In addition to the federal investigation, ACS commissioned a study with the Vera Institute of Justice (Vera) and a panel of medical experts to review the child welfare records of the children enrolled in the clinical trials and the City's policies regarding foster children enrolled in clinical testing; and

Whereas, Vera agreed to conduct the assessment on the grounds that ACS search its files for children who might have participated in the trials and that ACS provide Vera's staff with complete access to its files, records and relevant staff that were involved; and

Whereas, Vera was also to have full editorial control over the final report and that the project was to be overseen by Vera's own advisory board, to increase the integrity of the research findings; and

Whereas, Vera's report titled "The Experiences of New York City Foster Children in HIV/AIDS Clinical Trials" identified 532 New York City foster children who participated in 88 clinical trials and observational studies between 1985 and 2005; and

Whereas, After more than four years, Vera's investigation revealed that there was no evidence that any children died as a direct result of the trials, children were not removed from their homes to participate, and foster children were not selected based on their race; and

Whereas, The study indicated that city officials acted in the best interest of the children, however, proper protocol and documentation of consent were not consistent at ACS; and

Whereas, Some of the deficiencies uncovered included the participation of children in medication trials that were phase I trials, which involved the testing of safety of doses and pose the

greatest risk to subjects; and

Whereas, The children's cases were not reviewed by the necessary special medical advisory panel as required, and in some instances children participated in trials that were reviewed by this panel yet had not been recommended for participation in such trials; and

Whereas, The study shows that inadequate records of parental consent were maintained and that consent forms from parents and guardians were missing in approximately one-fifth of cases; and

Whereas, Vera believes that some of the missing documentation can be found in the children's medical records, yet the state Department of Health (DOH) will not allow ACS, nor Vera's staff, to review the complete records and clinical trial documents; and

Whereas, While it is encouraging that the independent review commissioned by Vera dispelled many of the scathing allegations, without unfettered access to medical records, there remains concern that some children participated in clinical trials without the proper consent and safeguards; and

Whereas, Only when DOH allows their records to be open and accessible to the ACS, can it be verified that the remaining, unaccounted for children were not illegally and unwillingly forced to be a part of clinical trials or whether the children were harmed or even worse, given their involvement in the trials; now, therefore, be it

Resolved, That the Council of the City of New York calls on the New York State Department of Health to allow the New York City Administration for Children's Services to access medical and clinical trial records of children enrolled in clinical trials while in foster care between 1985 and 2005 for research purposes.

JM/mbt
LS# 7070
April 20, 2009