INDIANA DEPARTMENT OF CHILD SERVICES	**INDIANA DEPARTMENT OF CHILD SERVICES** **CHILD WELFARE POLICY**	
	Chapter 8: Out-of-Home Services	**Effective Date:** June 1, 2008
	Section 34: Participation in Medical Studies and Drug Trials	**Version:** 1

STATEMENTS OF PURPOSE **OLD POLICY: N/A**

The Indiana Department of Child Services (DCS) will approve participation by a child in out-of-home care in a medical study or drug trial, if **all** of the following criteria have been met:

1. The child's parent, guardian, or custodian consents in writing to the child participating in the medical study or drug trial;
2. The Child and Family Team (CFT) recommends participation;

   Exception: Parental consent is not required, if parental rights have been terminated or the parent, guardian, or custodian cannot be located. This exception applies to both numbers 1 and 2 above.

3. The child's physician or therapist recommends participation in the medical study or drug trial;
4. The study includes participants outside of the child welfare system; and
5. The Court Appointed Special Advocate (CASA) or Guardian ad Litem (GAL) appointed to the child approves participation.

   Note: 1, 4, and 5 are required by federal law.

DCS has the right to deny a request for participation in a medical study or drug trial for any reason, even if all of the criteria listed above have been met.

DCS has the right to request a court order authorizing participation in a medical study or drug trial, if the CFT believes that participation is in the best interest of the child, but the parent, guardian, or custodian does not consent.

DCS must receive a formal request for participation from one (1) of the following persons:

1. The child's parent, guardian, or custodian;
2. The CFT;
3. An attorney representing the child or the child's parent, guardian, or custodian;
4. The child's CASA or GAL; or
5. The child's physician or therapist.

The DCS Local Office Director or a designee must approve all requests for participation in writing prior to the child being enrolled in the medical study or drug trial.

Code References

1. 21 CFR 50.56: Protection of Human Subjects, Wards
2. 45 CFR 46.409: Additional Protections for Children Involved as Subjects in Research

PROCEDURE

The Family Case Manager (FCM) will ensure that the requestor of the particular drug trial or medical study:

1. Ensures that the Institutional Review Board (IRB) working with the researchers appoints an advocate (see Related Information); and
2. Submit a written request for participation to the DCS Director. The request must contain the following information; inclusion of additional information is optional:
   a. The child's name, date of birth, and case ID number,
   b. Information about the medical study or drug trial including, but not limited to: the name, host, start date, duration, any compensation the child will receive, and number of participants,
   c. The specific treatments and/or drugs that will be used,
   d. Potential side effects and/or adverse reactions that may occur,
   e. The benefits participation will have for the child,
   f. A signed statement from the medical study or drug trial director stating that the group of children participating in the research includes children outside of the child welfare system,
   g. A signed statement from the child's physician or therapist recommending that the child participate,
   h. A signed statement from the advocate appointed to the child stating that participation is in the best interest of the child,
   i. A signed statement from the child's parent, guardian, or custodian giving his or her written consent for the child to participate, and
   j. Submit the request via mail (fax and email **are not** acceptable) to:
      Director
      Indiana Department of Child Services
      402 W Washington St
      Indianapolis, IN 46204

The DCS Local Office Director or a designee will:

1. Review all requests and make a formal decision as to whether DCS will allow the child to participate in the requested medical study or drug trial;
2. Assure that written notification of the decision is sent to the following persons:
   a. The child's parent, guardian, or custodian,
   b. The attorney representing the child or the child's parent, guardian, or custodian, if applicable,
   c. The child's CASA or GAL , if applicable,
   d. The child's physician or therapist who recommends participation,
   e. The appropriate DCS Regional Manager, DCS Local Office Director, and FCM,
   f. The child's resource parent(s),
   g. The requestor,
   h. The drug trial or medical study advocate appointed to the child, and
   i. Any person not listed above who received a copy of the request.

3. Assure that the original request and a copy of the written decision are included in the child's case file.

PRACTICE GUIDANCE

N/A

FORMS AND TOOLS

N/A

RELATED INFORMATION

Advocates for the Child

The person appointed as the advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research. The advocate should represent the individual child subject's interests throughout the child's participation in the research. The Health and Human Services Administration (HHS) and the Food and Drug Administration (FDA) regulations further require that the advocate not be associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization. One (1) individual may serve as advocate for more than one (1) child.

Participation and Termination of Parental Rights (TPR)

In the event that parental rights have been terminated, a court order should be obtained allowing the child to participate in the drug trial or medical study.