INDIANA DEPARTMENT OF CHILD SERVICES	**INDIANA DEPARTMENT OF CHILD SERVICES** **CHILD WELFARE POLICY**	
	Chapter 8: Out-of-Home Services	**Effective Date:** September 1, 2018
	Section 34: Participation in Medical Studies and Drug Trials	**Version:** 2

STATEMENTS OF PURPOSE *This policy applies to youth under the age of 18 and those over the age of 18 who are not able to consent to their own care.*

The Indiana Department of Child Services (DCS) will request authorization from the Court prior to the participation of a child in out-of-home care in a medical study or drug trial. DCS will file a motion with the Court regarding the child's participation after **all** of the following criteria have been met:

1. The child's parent, guardian, or custodian consents in writing to the child's participation;

   Exception: A court order regarding the child's participation should be requested when the parent, guardian, or custodian refuses to sign consent, cannot be located, or Termination of Parental Rights (TPR) has been finalized.

2. The Child and Family Team (CFT) recommends the child's participation;

   Exception: A court order regarding the child's participation should be requested when the parent and the CFT disagree regarding the child's participation.

3. DCS receives written approval for the child's participation from:
   a. The child's physician or therapist, and
   b. The Court Appointed Special Advocate (CASA) or Guardian ad Litem (GAL) appointed to the child, if applicable; and

4. The study includes participants outside of the child welfare system.

   Note: Numbers 1, 3(b), and 4 above are required by federal law.

DCS must receive the authorization of the court prior to a child's participation in a 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:

1. Notify the FCM Supervisor and Local Office Director (LOD)/Division Manager (DM) immediately when a request for a child's participation in a medical study or drug trial is received;
2. Review the request and gather additional information if the request is not complete;

The request must contain the following information; inclusion of additional information is optional:

a. The child's name, date of birth, and the case management system's case 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 administered,
d. Potential side effects and/or adverse reactions that may occur,
e. The benefits of participation 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 the child's participation, and
h. A signed statement from the child's parent, guardian, or custodian giving his or her written consent or written refusal to consent for the child to participate or documentation of efforts to locate the parent, guardian, or custodian (unless TPR has been finalized);

3. Schedule and facilitate a CFT Meeting to discuss the child's participation;

   Note: The request may be considered complete even if the parent, guardian, or custodian and the CFT disagree regarding the child's participation; the parent, guardian, or custodian cannot be located; or TPR has been finalized.

4. Discuss the medical study or drug trial with the child, if age and developmentally appropriate, and assist the child with preparing a written statement regarding his or her wishes;
5. Verify the Institutional Review Board (IRB) working with the researchers appoints an advocate to the child involved in the research (see Related Information);
6. Provide the complete request (including all information listed above), the CFT recommendation, the child's written statement (if age and developmentally appropriate), and any additional relevant information to the DCS Staff Attorney for review and filing of a motion with the Court;
7. Ensure the following are notified of the court's decision:
   a. The FCM Supervisor, LOD/DM
   b. The child's parent, guardian, or custodian, unless TPR has occurred,
   c. The child, if age and developmentally appropriate;
   d. The CFT;
   e. The child's physician or therapist who recommends participation,
   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; and

8. Upload the court order, the original request, and documentation of all notifications to the case management system case file within five (5) business days following the receipt of the court order.

The DCS Staff Attorney will:

1. Review the request for the child's participation in a medical study or drug trial, including the CFT recommendation, the child's statement, and any additional information provided; and
2. File a motion with the court regarding the child's participation.

PRACTICE GUIDANCE

N/A

FORMS AND TOOLS

N/A

RELATED INFORMATION

Drug Trial or Medical Study Advocate for the Child

The person appointed by the IRB as the drug trial or medical study advocate for the child 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 his or her participation in the research. The U.S. Department of Health and Human Services (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.