	INDIANA DEPARTMENT OF CHILD SERVICES **CHILD WELFARE POLICY**
	Chapter 8: Out-of-Home Services **Section 34:** Participation in Medical Studies and Drug Trials
	Effective Date: November 1, 2023 — **Version:** 3

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POLICY OVERVIEW

This policy applies to youth under 18 years of age and those over 18 years of age who are not able to consent to their own care.

It may be beneficial for some children to participate in medical studies or drug trials, as they will be able to access new medications or treatments that are not otherwise available.

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PROCEDURE

The Indiana Department of Child Services (DCS) must receive 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, if age and developmentally appropriate, agrees to participate;
2. The child's parent, guardian, or custodian consents in writing to the child's participation unless their consent is not required by state or federal law;

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

3. 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, guardian, or custodian objects regarding the child's participation.

4. 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.

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

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; and

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 number in the case management system,
    b. Information about the medical study or drug trial including, but not limited to:
        i. The name of the medical study or drug trial;
        ii. Host;
        iii. Start date;
        iv. Duration;
        v. Number of participants;
        vi. The specific treatments and/or drugs that will be administered;
        vii. Potential side effects and/or adverse reactions that may occur; and
        viii. The benefits of participation for the child, including but not limited to any compensation the child will receive.

    c. A signed statement from the medical study or drug trial director stating that the group of children participating in the research study includes children outside of the child welfare system,
    d. A signed statement from the child's physician or therapist recommending the child's participation in the study, and
    e. A signed statement from the child's parent, guardian, or custodian giving written consent or written refusal to consent for the child to participate in the study, unless TPR has been finalized.

    Note: Documentation of efforts to locate the parent, guardian, or custodian must be included with the request and entered in the case management when a parent, guardian, or custodian is unable to be located.

3. Schedule and facilitate a CFT Meeting to discuss the study and obtain the CFT's recommendation regarding whether the child should participate. See policy 5.07 Child and Family Team Meetings for additional guidance;
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 the child's wishes;
5. Verify the Institutional Review Board (IRB) working with the researchers appoints an advocate to the child who will participate in the research. See Practice Guidance for additional 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 and 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,
    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.

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

The DCS Staff Attorney will:

1. Review the:
   a. Request for the child's participation in a medical study or drug trial,
   b. CFT recommendation,
   c. Child's statement, and
   d. Any additional information provided.

2. File a motion with the court regarding the child's participation.

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RELEVANT INFORMATION

Definitions

N/A

Forms and Tools

N/A

Related Policies

- 5.07 Child and Family Team Meetings

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LEGAL REFERENCES

- IC 16-36-1-3: Consent for own healthcare; minor's blood donation
- 21 CFR 50.56: Protection of Human Subjects, Wards
- 45 CFR 46.409: Additional Protections for Children Involved as Subjects in Research

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PRACTICE GUIDANCE – DCS POLICY 8.34

Practice Guidance is designed to assist DCS staff with thoughtful and practical direction on how to effectively integrate tools and social work practice into daily case management in an effort to achieve positive family and child outcomes. Practice Guidance is separate from Policy.

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's interests throughout the child's 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, or the guardian organization. One (1) individual may serve as advocate for more than one (1) child.

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