



Wards of the State

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Approved By: Michele Kennett, JD, MSN, LLM
Associate Vice Chancellor for Research

Michele Kennett

Table of Contents

- Purpose
- Scope
- Policy/Procedure

1.0 Purpose

This guideline provides an overview of IRB policy for children who are “Wards of the State” and are being enrolled in human subject’s research as research participants. This guideline applies Federal regulations and Missouri State laws.

2.0 Scope

The SOP applies to both bio-medical and social-behavioral-educational research involving wards of the state in research falling under the purview of the University of Missouri Institutional Review Board.

3.0 Policy/Procedure

Foster parents **can** consent for ordinary, necessary medical treatment and medical treatment which may be reasonably necessary in a medical emergency when consultation with the Children's Division is not medically feasible under the circumstances for foster

Wards of the State

Page 2 of 6

children (Wards of the State) in their care. Foster parents **cannot** consent for foster children (Wards of the State) in their care to undergo non-emergency, extraordinary medical treatments and procedures, be the subject of experimental treatments and procedures or participate in research. The guidelines below describe the proper steps required to enroll a foster child (ward of the state) in a research study.

GUIDELINE:

I. Participation of Minor Wards of the State in Behavioral Research.

A. Study is classified as one of the two risk categories below as listed in the IRB approval letter:

- Research not involving greater than minimal risk (45 CFR 46.404)
- Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects (45 CFR 46.405)

Before Enrolling Wards of the State, **approval** is needed from:

- University of Missouri IRB
- Missouri Department of Social Services, Children's Division.
 - An application (<http://dss.mo.gov/cd/info/forms/pdf/886-4454s.pdf>) must be submitted to the Department of Social Services, Children's Division to conduct research using Wards of the State. Include in the application:
 - University of Missouri IRB approval
 - Copies of Informed Consent

II. High probability that participants may become Wards of the State.

A. Study is classified as one of the two risk categories below as listed in the IRB approval letter:

- Research not involving greater than Minimal Risk (45 CFR 46.404)
- Research involving Greater than Minimal Risk but presenting the prospect of direct Benefit to the individual subjects (45 CFR 46.405)

Before Enrolling Wards of the State, **approval** is needed from:

- University of Missouri IRB
- Missouri Department of Social Services, Children's Division

Wards of the State

Page 3 of 6

- An application (<http://dss.mo.gov/cd/info/forms/pdf/886-4454s.pdf>) must be submitted to the Department of Social Services, Children's Division to conduct research using Wards of the State. Include in the application:
 - University of Missouri IRB approval
 - Copies of Informed Consent

B. Study is classified as one of the two risk categories below as listed in the IRB approval letter:

- Greater than Minimal Risk Research and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition (45 CFR 46.406)
- Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (45 CFR 46.407)

Approval is needed from:

- University of Missouri IRB
- Missouri Department of Social Services, Children's Division
 - An application (<http://dss.mo.gov/cd/info/forms/pdf/886-4454s.pdf>) must be submitted to the Department of Social Services, Children's Division to conduct research using Wards of the State. Include in the application:
 - University of Missouri IRB approval
 - Copies of Informed Consent
 - Missouri Children's Division Regional Director of the child's legal jurisdiction. (This may need to be done on a child by child basis.)



CD Mailing List
(04-09-08).doc

III. Potential for a Ward of the State to be asked to participate in research:

Research protocol **does not** anticipate enrolling Wards of the State, but a Ward of the State is eligible for the research study.

A. Study is classified in one of the risk categories defined below under 45 CFR 46.404; .405; .406; .407:

- Research not involving greater than Minimal Risk (45 CFR 46.404)
- Research involving research Greater than Minimal Risk but presenting the prospect of Direct Benefit to the individual subjects (45 CFR 46.405)

Wards of the State

Page 4 of 6

- Greater than Minimal Risk Research and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition (45 CFR 46.406)
- Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (45 CFR 46.407)

Procedure(s) and Approval:

1. When the Ward of the State presents, determine the relationship of the adult to the child and if the child is a Ward of the State by asking the adult. Document response.
2. If the adult is the foster parent and the child is a Ward of the State (foster child) the following steps will need to be followed:
 - a. Consent must be obtained from the Case Manager of the Missouri Children's Division
 - A fax signature from the Case Manager of the Missouri Children's Division is acceptable
 - Email signature is **not** currently acceptable, as not all MU systems comply with FDA Part 11 regulations regarding electronic signatures
 - b. To demonstrate that the study complies with 21 CFR 50.56 and 45 CFR 46.410 at the time of IRB renewal the PI must state how many Wards of the State have been enrolled to date.
3. Child becomes a Ward of the State after consent and assent has been appropriately obtained. At the time that it is known that the child has become a Ward of the State:
 - a. Consent must be obtained from the Case Manager of the Missouri Children's Division.
 - A fax signature from the Case Manager is acceptable
 - Email signature is **not** currently acceptable, as not all MU systems comply with FDA Part 11 regulations regarding electronic signatures
 - b. To demonstrate that the study complies with 21 CFR 50.56 and 45 CFR 46.410 at the time of IRB renewal the PI must state how many Wards of the State have been enrolled to date.

IV. Federal Requirements for use of Wards in research

Wards of the State: A child, who, as determined by the State where the child resides, is a foster child, is a Ward of the State or is the custody of a public child welfare agency.

Wards of the State

Page 5 of 6

45 CFR 46.410 Wards:

(a)

Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is:

- (1) Related to their status as wards; or
- (2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall 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 and who is not 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.

21 CFR 50.56 Wards: (a) Children who are wards of the State or any other agency, institution or entity can be included in clinical investigations approved under Sec. 50.53 or Sec. 50.54 only if such clinical investigations are:

- (1) Related to their status as wards; or
- (2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the clinical investigation is approved under paragraph (a) of this section, the IRB must require appointment of an advocate for each child who is a ward.

- (1) The advocate will serve in addition to any other individual acting on behalf of the child as guardian or in loco parentis.
- (2) One individual may serve as advocate for more than one child.
- (3) The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interest of the child for the duration of the child's participation in the clinical investigation.
- (4) The advocate must not be associated in any way (except in the role as advocate or member of the IRB) with the clinical investigation the investigator(s), or the guardian organization.

V. Emergent situations:

1. There is a life-threatening emergency
2. The IRB must approve the research and waiver of consent in accordance with 45 CFR Part 46 and 21 CFR Part 50 (if applicable).

[Return to Table of Contents](#)

4.0 Related SOP

Informed Consent – Types and Elements