Washington University in St. Louis

3/17/14
Human Research Protection Office
Box 8089
(314) 633-7400
Fax (314) 367-3041

WARDS OF THE STATE
(Foster Children)

Purpose: This guideline provides an overview of HRPO's procedures for enrolling children who are "Wards of the State" in human subjects research as research participants. This guideline applies Federal regulations and Missouri State laws.

Role of Foster Parents in Research: Foster parents **cannot** consent for foster children (Wards of the State) in their care to participation in experimental treatments and procedures or to participate in research. The guidelines below describe the proper steps required to enroll a foster child (ward of the state) in a research study.

Type of Study	**WU IRB Requirements**	**MO Children's Division (CD) Research Committee Requirements**
I. Research targets or there is a high probability Wards of State included.	Submit to WU IRB indicating in Section VI of the myIRB application that Wards of State will be enrolled.	Submit to CD Research Committee with WU IRB Approval and Written consent document.
II. A. Research does not target or anticipate enrolling Wards of State, but a Ward is identified during the course of the study that would be eligible to participate. B. A child already enrolled becomes a Ward during the course of the study	Submit a modification to the appropriate myIRB study and revise Section VI to indicate Wards of State will be enrolled.	Submit to CD Research Committee with WU IRB Approval and Written consent document.
III. Medical Chart Reviews with high likelihood minors may be Wards of State	Submit to WU IRB stating Wards are one population	Submit to CD Research Committee with WU IRB Approval (consent may be waived by IRB)
IV. Emergent or Life-threatening situation that involves a Ward and the Ward will ***be treated with an investigational drug or device***	Follow procedures on HRPO website: http://hrpohome.wustl.edu/emergency_pt_treatment.aspx	CD local office approval is necessary. Contacts for the local office can be found at: http://dss.mo.gov/cd/office/. See below for the CD letter explaining the CD procedure. For after hours and weekends, call the hotline at 573-751-3448.

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Additional Information for Review of Categories I-III:

For research that falls into Categories I-III in the table above, the following steps need to occur prior to inviting a Ward of State to consider enrolling in research study:

1. Submit a New or Modification application via the myIRB system for the study in which the Ward(s) will be enrolled.

2. Obtain IRB approval for the project/modification.
   a. *Carefully* review the IRB meeting minutes available in the myIRB system which may contain conditions of approval or additional procedures required related to enrollment of wards of the state. For example, if the IRB determines that the study falls into particular risk classifications under the federal regulations, the approval may require that an advocate be appointed for each Ward of State to be enrolled in the study. This individual would need to be someone independent of the research team and independent of the person(s) determined by the Missouri Department of Social Services to be the person(s) providing consent for enrollment. (Further information about risk classification of studies involving children is provided in the Regulations section of this document below.)
   b. The IRB approval letter and approved consent document (if applicable) will be available via the myIRB system once the study is approved by the IRB.

3. After IRB approval, submit an application to the Missouri Department of Social Services, Children's Division.
   a. Complete the application available at: http://dss.mo.gov/cd/info/forms/pdf/886-4454s.pdf)
   b. Include with your application to the Children's Division:
      i. WU IRB approval letter (available in the myIRB system)
      ii. A copy of your WU IRB approved and stamped Informed Consent Document (available in the myIRB system)
      iii. Children's Division cover letter.
   c. Send the application via e-mail to CD.ResearchCommittee@dss.mo.gov or send via postal mail to:
      Children's Division Research Committee
      PO Box 88
      Jefferson City, MO 65103

4. Obtain concept approval to enroll Wards of State from the Missouri Children's Division Research Committee.

5. Obtain CD local office approval for each individual Ward of the State you wish to enroll in the research study.
   a. *Carefully* review any conditions of approval provided in the approval documents from the Children's Division. Depending on the specific circumstances of the study, the Children's Division may require, for example, that other members of the Family Support Team be consulted and/or required to give consent for enrollment of a Ward. (This will need to be done on a child by child basis.)
   b. *If* there are any conditions of approval from the Children's Division, submit a Modification via the myIRB system to update your approved protocol to reflect these additional requirements.
   c. A listing of the Authorized Representatives of the Missouri Children's Division is available at: http://dss.mo.gov/cd/office/

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REGULATIONS:

Food and Drug Administration (FDA) Regulations:

21 CFR 50.24: Exception from Informed Consent Requirements for Emergency Research
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.24

21CFR 50.55: Wards
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.55

21CFR 50.56: Additional Safeguards for Children in Clinical Investigations
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.56

Health and Human Services (HHS) Regulations:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd

DEFINITIONS:

"Authorized Representatives" of the Missouri Children's Division: are those individuals designated by the Children's Division from time to time authorized to sign a research consent form to enroll a Ward of State in a human subjects research study. The ward's case manager is considered an Authorized Representative.

"Advocate" defined in 45 CFR 46.409 is interpreted to mean an individual who works for the welfare of the child such as a Guardian ad litem.

"Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. (45 CFR 46.402 and 21 CFR 50.3 (n))

"Child" under Missouri State law: for purposes of the foster care system is defined as any person under the age of 17 years of age and any person over seventeen but not yet 18 alleged to have committed a status offense (RSMo 211.021(2) and RSMo 211.031.1(2)) or any person under the retained jurisdiction of the juvenile courts until age of 24 years of age (RSMo 211.041)

"Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. (45 CFR 46.402(a)); 21 CFR50.3 (o))

"Family Support Team (FST):" includes those caring for or involved in the care and welfare of the child such as the Biological Parents, Adoptive Family, Case Manager, Case Worker, Foster Parents, Guardian ad Litem, Guardian, Juvenile Office/Officer, Judge and representatives from the Missouri Children's Division.

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"Guardian" is defined as an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care (45 CFR 46.402). 21 CFR 50.3 (s) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care when general medical care includes participation in research. For purposes of these guidelines, a guardian also means an individual who is authorized to consent on behalf of a child to participate in research. Under Missouri State law, "Guardian" is defined as one appointed by the court to have the care and custody of the person of a minor (RSMo 475.010(6)).

Informed Consent: The informed consent process involves three key features: (1) disclosing to potential research subjects information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate in the research. Informed consent must be legally effective and prospectively obtained. HHS regulations at 45 CFR 46.116 and 45 CFR 46.117 describe the informed consent requirements. (OHRP website, 2012)

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. (21 CFR 50.3 (l) and 45 CFR 46.102)

"Parent" is defined as a child's biological or adoptive parent. (45 CFR 46.402(d); 21 CFR 50.3 (p) and RSMo 211.021 (5))

"Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research. (45 CFR 46.402; 21 CFR 50.3 (r))

Research Application submitted to the Missouri Division of Family Services should consist of a completed Missouri Department of Social Services Application to Conduct Research/Study, a copy of the WU IRB approval letter, and a copy of the WU IRB approved consent form.

Task Force:

Sarah Fowler-Dixon PhD, WU Human Research Protection Office
James Harrison, Acting Director Missouri Children's Division
Debra Hendricks, Missouri Children's Division HIPAA Privacy Office
Michelle Jenkerson RN, WU Research Participant Advocate
Linda K. Miller, Missouri Children's Division Accreditation & Quality Improvement Unit Manager
Meliny Staysa MSW, Missouri Children's Division Quality Assurance Unit Manager

Updates done in conjunction with: Mark Gutchen, Missouri Children's Division General Council; Patricia Hart, JD, Washington University Office of General Council; Debra Hendricks, Missouri Children's Division; Alicia Jenkins, Missouri Children's Division; Martha Jones, MA, WU Human Research Protection Office; Nancy Pliske, JD Washington University Office of General Council; Susan Savage, Missouri Children's Division and Jeanne Velders, JD WU Human Research Protection Office

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Emergent or Life-threatening Situation: CD Procedure

You have received this letter because Washington University is requesting to treat a child or youth on your caseload (or from your circuit, if you are the on-call worker) with an investigational drug or device. Please note the professionals treating this child consider this to be an emergent or life-threatening situation and believe there are benefits to use this investigational technique.

Such treatment may be allowed under Children's Division policy (see Section 8.3 of the Child Welfare Manual) but will require you to take the following steps:

1. Make an immediate referral of this matter to your supervisor, who should then take it up the chain of command to the level of field support manager or regional director.
2. Share with your supervisors any pertinent information you might have regarding the child's medical history or treatment history that might help them make an informed decision regarding the use of the investigational treatment.
3. The field support manager or regional director will then evaluate the situation and make a determination, based on policy and existing protocols regarding medical treatment of children in the custody of the state. (Note that you may be asked to convene emergency family support team meetings or work with your local court to expedite decisions that might impact the child's safety and well-being. Please follow the directives of your supervisors in regard to this matter.)

The Children's Division and Washington University strive to make the best possible medical and treatment choices to support the welfare of all children, and especially those for whom the state has care and custody. We appreciate your assistance in assuring this matter is handled as expediently as possible.