

The purpose of this document is to provide VDSS IRB guidance (issued 3/27/2023) to researchers on frequently asked questions related to parent, guardian, and Legally Authorized Representatives (LARs) consent when conducting research with children in Virginia’s foster care system.

Q1. Who is authorized to give consent for a child to participate in a research study?

A1. Generally, one or both parents or legal guardians must be provided with the information ordinarily required for informed consent, so that they may decide whether to allow the child to participate. Children capable of assent must also express their willingness to participate.

If there are two parents available to give permission, but they disagree about allowing their child to participate in the study, the child should not be enrolled unless that disagreement can be resolved. This policy applies to all permissible categories of research involving children.

Q2. In which types of research is parental informed consent required for a child to participate in a research study?

A2. According to federal regulations ([§46.404 -46.408](#)), because children cannot legally provide consent for research on their own behalf, permission by at least one parent or legal guardian is required prior to enrollment of a minor in a research study unless a *Request for Waiver of Informed Consent* (available on the IRB [Forms web page](#)) is approved by the VDSS IRB (see **Q13 below**). Additionally, the following also applies:

- Research involving no more than minimal risk requires permission from at least one parent (or guardian). (*federal regulation §46.404*)
- Research involving more than minimal risk but that presents the prospect of direct benefit to individual subjects requires permission from at least one parent (or guardian). (*federal regulation §46.405*)
- Research involving more than minimal risk and that presents the prospect of no direct benefit to individual subjects, besides generalizable knowledge about the subject’s disorder or condition (i.e., societal benefit) requires permission from both parents.* (*federal regulation §46.406*)
- Research that presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children, but does NOT provide direct benefit to the subject or societal (indirect) benefit, requires permission from both parents.* (*federal regulation §46.407*)

*Unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. If these circumstances are present, the researcher should document this in the subject's research record.

Q3. If the child is in foster care (“a ward of the state”), who is authorized to provide consent?

A3. Researchers planning a study that includes minor children in foster care (“a ward of the state”) should have a protocol in place to obtain consent from the child’s parent(s) or legal guardian (also known as a “legally authorized representative”) to participate in research. This includes all minor children, even children whose families’ parental rights have been terminated.

If the parent/guardian is unavailable or unable to provide consent, [guidance](#) from the federal Office for Human Research Protections ([OHRP](#)) requires an appointed advocate not affiliated with the researcher or institution conducting the research to provide consent. If no advocate is available, then the child is not allowed to participate.

Currently, Virginia's social services system (state and local departments of social services) and the IRB do NOT have a mechanism in place for appointing a special advocate for foster children for their participation in research.

Q4. In which types of research is parent (or guardian) informed consent required for a foster child (“a ward of the state”) to participate in a research study?

A4. The same regulations for parent (or guardian) consent, child assent, and study participation apply for foster children (“wards of the state”) as with other children (**see Q3 above**), with the exception of two categories of research which have additional approval considerations and study participant safeguards: (*federal regulation [§46.409](#)*)

- Research that involves more than minimal risk and presents the prospect of no direct benefit to individual subjects, besides generalizable knowledge (i.e., societal benefit). (*federal regulation [§46.406](#)*)
- Research not otherwise approvable that presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children, but does NOT provide direct benefit to the subject or societal (indirect) benefit. (*federal regulation [§46.407](#)*)

For these two research categories, wards of the state can be included ONLY if the research is:

- Related to their status as wards, or
- Conducted in schools, camps, hospitals, institutions, or similar settings where the majority of children involved are not wards.

Additionally, the IRB must require the 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. *Currently, Virginia's social services system (state and local departments of social services) and the IRB do NOT have a mechanism in place for appointing a special advocate for foster children for their participation in research.*

Q5. What is a “legally authorized representative”?

A5. “Legally authorized representative,” or LAR, 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. Typically, the LAR refers to the parent(s) or legal guardian. However, there are other categories of adults who may have the authority to consent for a minor asked to participate in research. Refer to the Code of Virginia [§32.1-162.16](#).

An attorney may be appointed to make such a decision. Nonetheless, the attorney shall not be employed by the person, institution, or agency conducting the human research. Moreover, no official or employee of the institution or agency conducting or authorizing the research shall be qualified to act as a legally authorized representative.

Q6. Is the foster parent recognized as a legal guardian?

A6. No. The foster parent is not recognized as the legal guardian of a child in foster care. There is one circumstance under which a foster parent may provide consent: If the foster parent has signed an adoption agreement to adopt the child in question. (see Q8 below).

Q7. Can a foster parent provide consent for the foster child in their care?

A7. No, the foster parent is not legally recognized as a guardian and cannot provide consent for the foster child in their care.

Q8. Can the adoptive parent provide consent for the foster child to participate in research?

A8. Yes. Once an adoption agreement is in place, even before the courts finalize an adoption, the adoptive parents can generally make these decisions for foster children in their care. This circumstance is very time limited and not applicable for most children in foster care.

Q9. Is the local department of social services recognized as the legal guardian for the foster child?

A9. No. Although the local social services department (and local board) usually has legal authority over the child, they are not considered the legal guardian. In Virginia, the child's case manager cannot serve as the legally authorized representative, per [22 VAC 40-890-10](#).

Q10. Does the state agency (Virginia Department of Social Services) have a designated LAR for the foster child? Do the local departments of social services have a LAR on staff?

A10. No. Neither VDSS nor the local departments of social services have a process for establishing a LAR to represent the interests of youth in foster care regarding foster children participating in research.

Q11. Can the foster child's DSS case manager potentially serve as the LAR?

A11. No. By law, the case manager cannot make decisions or take actions that a parent or legal guardian would, such as signing an Individualized Education Plan (IEP), consenting to emergency or non-emergency medical care or treatment, etc. The right of the parents to be decision-makers for children in foster care is expressly preserved in these circumstances.

The VDSS Division of Family Services does not allow the child's case manager in the local department of social services to represent the child's interests and make decisions about their participation in research studies. This is for two reasons: 1) There could potentially be a conflict of interest, or the appearance of such, if the local agency or case manager allows or doesn't allow the child to participate in research, especially if the state or local agency sponsors or supports the research study; 2) the conflict could have a negative impact on the case manager's ability to work with the child's family.

Q12. Are emancipated minors exempt from the rule to have a parent or guardian consent on behalf of the foster child?

A12. Yes. If the minor child is legally emancipated (the order of emancipation is granted by a court), the subject can directly consent to participate in research.

Q13. Can the requirement for obtaining parental informed consent be waived?

A13. Yes, in certain situations. The IRB may waive the requirement for parental consent if it determines that the research study is designated for conditions or for a specific population (e.g., neglected or abused children) for which parental or guardian permission is not a reasonable requirement to protect the subjects (see [45 CFR 46.408](#)). Examples: if subjects are involved in a study that asks about their history of victimization, in which the parent may have been a perpetrator; or if it's personally embarrassing or discomfoting to subjects if the parents are aware of their participation in a study that deals with a sensitive subject area (e.g., the child's engaging in sexual or drug activity).

If the IRB grants this type of waiver based on this criterion, it must substitute an appropriate mechanism for protecting the children-subjects. The choice of such mechanism will depend on the nature and purposes of the proposed research activities; the risk and anticipated benefit to the children-subjects; and the age, maturity, status, and condition of the proposed subject population.

Q14. What happens when a foster child's parent or legal guardian is unwilling or unable to make decisions on behalf of the foster child?

A14. It depends on the situation or type of decision. For example, if a parent is unavailable or refuses medical treatment for their child, the local department of social services that oversees the child's case has the option to petition the courts for permission to authorize medical treatment. Normally, the child is assigned a Guardian ad Litem to represent their interests in court proceedings.

The public school divisions in Virginia also have a lengthy process by which they can establish a LAR to represent the child in cases of IEPs (Individualized Education Plans). Generally, the school requires three attempts to contact the parent, and then they can establish a legally authorized representative (LAR) from a pool of approved people. According to the Division of Family Services' Assistant Director, it rarely reaches this point.

The child's participation in research is not one of the matters taken up by the courts. The view of the VDSS Division of Family Services is that it would be more appropriate to consider establishing a neutral, third party (external to VDSS and the LDSS) to serve as a LAR when the child's parent(s) are not available to provide consent. At this time, VDSS and the IRB do not have a system in place for appointing legal advocates regarding allowing children to participate in research.

Q15. If a foster child turns 18, can they consent for themselves?

A15. Yes, once the child turns 18, unless there are extenuating circumstances (e.g., the youth is cognitively impaired and unable to understand consent), they are allowed to provide consent for themselves. This is also true for youth who are 18 to 21 years old and remain in extended foster care.

Resources:

U.S. Office for Human Research Protections, DHHS - <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html>

University of Pittsburgh Human Research Protection Office - <https://www.hrpo.pitt.edu/policies-and-procedures/research-involving-children>



VIRGINIA DEPARTMENT OF
SOCIAL SERVICES

**Guidance on Informed Consent for Children in Foster Care
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University of Virginia Human Research Protection Program - <https://research.virginia.edu/irb-hsr/vulnerable-subjects-children-minors>