CARILION CLINIC INSTITUTIONAL REVIEW BOARD
Standard Operating Guidelines

Title: 3 8: Reviews Requiring Special Consideration: WARDS OF STATE AND EMANCIPATED MINORS	
Original Date: May 2011	**Revision Date:** 8-23, 2-26
Primary Sponsor: Human Research Protections Office	**Approved By:** Director of the Human Research Protections Office

Objective:

To describe the requirements for assent/consent for wards and emancipated minors.

General Description:

Children in court-appointed and state custody are excluded from Carilion Clinic IRB review and approval, unless a specific request has been made (and supported) to include them. If inclusion of children in court-appointed and state custody has been requested in the review process, the approval letter from the Carilion Clinic IRB will note if the approval is extended to this protected group. Unlike Virginia Code, which does not refer to "wards of the state," federal regulations at 45 CFR 46.409 specifically use such language. For research to be conducted in Virginia, this policy will broadly interpret "wards of the state'" to mean children, below the age of 18 years and not emancipated, who have been assigned a "person or judicial or other body authorized by law or regulation" to consent on their behalf to participation in human subjects research."

For research that will be conducted outside of Virginia, relevant law for the jurisdiction in which the research is being conducted will determine the definition of "child" as well as applicable definitions for children who are considered "wards of the state." Note that different states may have varying definitions for who may serve as an LAR on behalf of a prospective child participant, especially for one in court-appointed or state custody. The criteria for emancipated minor and legal authorization may also differ between states.

Procedure:

In Virginia, an individual below the age of 18 years of age who is legally emancipated (with legal documentation to verify such status) is permitted to make all decisions concerning research participation as would someone 18 and older who also has capacity to make decisions. See on Emancipated Minors below for more information.

In Virginia, children who are less than 18 years of age, are not emancipated minors, and are in the custody of the state or any other agency, institution, or entity can be included in research only with the signature of an individual named as the Legally Authorized Representative (LAR). The Commonwealth of Virginia (§ 32.1-162.16) lists those who can serve as an LAR in the following order of priority (with item 8 referring to children in court-appointed custody):

1. The parent or parents having custody of a prospective subject who is a minor

2. The agent appointed under an advance directive, as defined in § 54.1-2982, executed by the prospective subject, provided the advance directive authorizes the agent to make decisions regarding the prospective subject's participation in human research,

3. The legal guardian of a prospective subject,

4. The spouse of the prospective subject, except where a suit for divorce has been filed and the divorce decree is not yet final,

5. An adult child of the prospective subject

6. A parent of the prospective subject when the subject is an adult,

7. An adult brother or sister of the prospective subject or

8. Any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective subject to such subject's participation in the particular human research.

State Limitations When Consent Given By Legally Authorized Representative:

The state of Virginia (§ 32.1-162.18) makes the following limitations upon research when the consent of a legally authorized representative (such as in the case of a child who is in state custody) is required:

1. A legally authorized representative may not consent to non-therapeutic research unless it is determined by the human research committee that such non-therapeutic research will present no more than a minor increase over minimal risk to the human subject.

2. A legally authorized representative may not consent to participation in human research on behalf of a prospective subject if the legally authorized representative knows, or upon reasonable inquiry ought to know, that any aspect of the human research protocol is contrary to the religious beliefs or basic values of the prospective subject, whether expressed orally or in writing.

3. A legally authorized representative may not consent to participation in human research involving non-therapeutic sterilization, abortion, or psychosurgery. Neither may a legally authorized representative consent to admission of a child for research purposes to a facility operated by the State Department of Mental Health, Mental Retardation or Substance Abuse Services or to a state or licensed hospital that provides care and treatment for persons with mental illness.

Specific Federal Regulatory Limitations for Research Involving Children who are in court-appointed or state custody:

In addition to the requirements of the Virginia, the DHHS regulation at 45 CFR46.409 [Wards] applies to children who are wards of the state AND involved in research under Children's Categories 45 CFR 46.406 { Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition} and 45 CRF 46.407 { Research not otherwise approvable which

presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children}:

(1) 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: (a) related to their status as wards; or (b) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(2) If the research is approved under condition (1) above, 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

IRB Special Requirements for Children in Court-appointed or State Custody:

Given the regulations stated above and the special conditions noted below, which are unique to children in court-appointed or state custody, it is the policy of the Carilion Clinic IRB to require that a specific request be made to the IRB prior to involving such children in human subjects research, not previously approved to include children in state custody.

Additional IRB review criteria for research involving children in state custody:

Category §46.404{ Research not involving greater than minimal risk} or §46.405 { Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects}: For all research determined by the IRB to involve children under categories 404 or 405, all 5 of the following conditions must be met:

1. The research was approved by the IRB under children's category §46.404 or §46.405.
2. The IRB has determined that the research is therapeutic or if non-therapeutic, represents no more than minimal risk to the subject.
3. The IRB has determined that the research does not pose additional risks to children in court-appointed or state custody (as vulnerable research subjects) and/or could not reasonably be accomplished without their inclusion.
4. The LAR does not override known or reasonably known religious or value restrictions of the child in court-appointed or state custody (or parents or guardians) and otherwise acts in accordance with the laws of the Commonwealth (noted above).
5. Assent is requested of the child, as appropriate given the age and maturity of the child.

Category §46.406 or §46.407 : For all research determined by the IRB to involve children under categories 406 or 407, all 9 of the following conditions must be met:

1. The research was approved by the IRB under children's category §46.406 or §46.407.

2. The research was approved by the IRB as a study focused on evaluating the status of wards OR conducted in a setting where the majority of children involved as subjects are NOT in court-appointed or state custody.

3. The IRB has determined that the research is therapeutic or if non-therapeutic, represents no more than minor increase over minimal risk to the subject.

4. The IRB has determined that the research does not pose additional risks to children in court-appointed custody (as vulnerable research subjects) and/or could not reasonably be accomplished without their inclusion.

5. The LAR does not over-ride known or reasonably know religious or value restrictions of the child in state custody and otherwise acts in accordance with the laws of Virginia.

6. An advocate is appointed for each child who is in court-appointed or state custody. The advocate may serve on behalf of more than one child at a time and must be prepared to document appropriate background and experience to act in the best interests of the child for the duration of the research, document their willingness accept the role of advocate for the child, document that they have no other association with the research/investigator(s)/guardian organization, except as the role of advocate or member of the IRB.

7. The IRB will be involved in determining whether the parents of a child in court-appointed custody are to be informed of the child's possible involvement in research and whether parental refusal may be considered.

8. Assent is requested of the child, as appropriate, given the age and maturity of the child.

9. If the research is under way, yet was not approved by the IRB to involve children in court-appointed or state custody, and the investigator learns that a subject is eligible for enrollment and is in the custody of the state, the investigator should communicate with the IRB regarding how to proceed BEFORE the child is enrolled in the study. Further direction may include submission of written request, rationale, and process to allow such children as participants in the research (using the IRB change form).

Emancipated Minors:

According to the Code of Virginia, an "emancipated minor" is a person below the age of 18 years who has obtained a court order declaring him or her to be such based upon one or more of the following factors:

1. Legitimately married or divorced; and/or

2. On active duty in a branch of the U.S. Armed Forces; and/or

3. Willingly living separate and apart from a parent or guardian with consent and acquiescence of parents or guardian and supporting him or herself and competently managing his or her own financial affairs.

The Department of Motor Vehicles indicates legally emancipated status on a driver's license if the court order for emancipation was provided to the DMV by the individual.

NOTES:

- Emancipation is not "self-declared." Principal Investigator and IRB consideration of emancipation requires the presence of a court order or specific documentation on a driver's license or state issued identification card.
- Emancipated minors are subject to the similar consent process as adults.
- Emancipated minors do not meet the federal or state definition of "children" in Virginia. Hence, neither DHHS nor FDA Subpart D apply to research involving emancipated minors.
- In Virginia, an individual below the age of 18 years of age who is legally emancipated (with legal documentation to verify such status) is permitted to make all decisions concerning research participation as would someone 18 and older who is also capable of making informed decisions. In such cases, the "legal age for consent," as described in both HHS and FDA definitions, has been attained. The individual is no longer considered a "child'" under Virginia law or federal definitions. Consequently, the individual's consent, not assent, is obtained, and parental/guardian permission is not required.
- For research that will be conducted outside of Virginia, relevant law for the jurisdiction in which the research is being conducted will determine the definition of an emancipated minor. PIs should provide relevant information concerning the legal recognition of emancipated minor in other states, especially if such individuals are targeted in the research.

Responsibility:

It is the responsibility of the principal investigator to determine if research will include a child in the custody of the state or an emancipated minor. For research to be conducted outside of Virginia, the PI is to consider the legal status of children who are 'wards of the state' or individuals who are 'emancipated minors' according to the jurisdiction in which the research is being conducted. Such consideration is to be reported in the IRB submission.