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**SUBJECT:** Informed Consent/ Parental Permission  
and Assent Process

**POLICY:** RA:HRPP:07.02

**DATE EFFECTIVE:**

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## **I. POLICY**

It is the policy of Children's National Medical Center (CNMC) to comply with all federal (45 CFR 46.116, 46.408; 21 CFR 50 Subpart B, 21 CFR 50.55), state, and local regulations that pertain to informed consent, parental permission, and assent to participate in research.

An investigator may not involve a human being as a subject in research unless s/he has obtained the legally effective consent of the subject or the subject's legally authorized representative.

In the District of Columbia, Maryland, and Virginia, the general age of consent is 18 years old. CNMC requires that investigators obtain assent from children and adolescents 7 through 17 years of age unless the Institutional Review Board (IRB) determines that a waiver is justified (45 CFR 46.116).

### **Definitions:**

**Informed Consent** is not merely a signature on a form, but a process of mutual communication. The process starts before any form is signed and continues throughout the entire study. The written consent form is a formalization of the agreement to participate, and it is used to document an interactive process.

Within pediatrics, the concept of informed consent shifts from that of a competent adult who grants informed consent to participate in research, to that of parents who grant permission to involve their children in research. IRB policies and procedures use the term informed consent for simplicity; however, it should be recognized, in the case of children, that it is actually parental permission that is being documented and granted.

**Assent** is defined as a child's "affirmative agreement" to participate in research. Federal regulations require that assent be obtained directly from the child or adolescent, in addition to obtaining written parental/guardian permission. Assent is required unless:

- The subject is incapable of providing it because of immaturity or cognitive abilities; or
- The research holds out the prospect of a direct benefit that is only available through participation in the research. This most frequently occurs in research that offers a therapeutic benefit; or/and
- The CNMC Institutional Review Board has granted a waiver of assent (45 CFR 46.116).

In these situations, a parent's decision may override a child's refusal to assent.

**II. ACCOUNTABLE EXECUTIVE AND REVIEWER(S)**

- A. Accountable Executive: Chief Academic Officer/ Institutional Official for the Federalwide Assurance
- B. Department Responsible for Review: Office for the Protection of Human Subjects
- C. Committee Responsible for Review: Institutional Review Board Executive Committee  
Research Policy/Procedure Working Group

**III. APPROVAL**

Approved by:

IRB Executive Committee	11/12/2009
	Date
Research Policy/Procedure Working Group	
	Date
Mark L. Batshaw, M.D., Chief Academic Officer	
	Date

**IV. APPLICABILITY**

Areas where the policy and procedure applies: Children’s Research Institute, Children’s National Medical Center

Persons to whom the policy and procedure applies: Investigators, study staff, Institutional Review Board, Office for the Protection of Human Subjects

**V. REVIEW OR REVISION DATE**

Original:

**VI. REFERENCES**

AAHRPP Elements:

Federal Regulations: U.S. Department of Health and Human Services (DHHS) 45 CFR 46.116, 46.408

**Food and Drug Administration (FDA) 21 CFR 50, Subpart B,  
Informed Consent of Human Subjects; 21 CFR 50.55**



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**SUBJECT:** Informed Consent/ Parental Permission  
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**I. PROCEDURE**

- A. Informed consent must be obtained from a prospective research participant prior to initiating research activities, including recruitment and screening procedures.
- B. The Children's National Medical Center (CNMC) Institutional Review Board (IRB) must approve the informed consent process and method of documentation prior to study implementation, indicating whether the proposed consent process is appropriate for the proposed research activities and the target population as a part of the overall IRB approval of the study.
- C. A key requirement of human subject protection is voluntary participation. The process of obtaining informed consent/ parental permission and assent must assure that both the child/adolescent and the parents/guardians fully understand the research, understand what they are being asked to do, and understand the associated risks and benefits of the research for which they are providing consent/permission/assent.
- D. Principles of Informed Consent/ Parental Permission and Assent
  - 1. The Belmont Report informs us that respect for persons requires that subjects "to the degree they are capable, be given the opportunity to choose what shall or shall not happen to them." A subject's choice incorporates three elements: information, comprehension, and voluntariness.
    - a) **Information** is critical for a person to make an informed choice as to whether he or she, or his or her child, should participate in research. The Belmont Report suggests providing information that the "reasonable volunteer" will want to know. It is important that families understand the difference between what is necessary for their care and what is being proposed specifically for research. It is also important to recognize that some families will want more information than others, and investigators must be prepared to provide what a reasonable person would want to know, and more information, if requested.
    - b) **Comprehension** will vary subject to subject and family to family. The manner in which information is provided may impact comprehension. It must be recognized that individuals may need to be presented information in a variety of ways in order to comprehend the

information. In particular, information must be presented in language understandable to the subject and his/her family. Comprehension may require that time be provided to allow subjects to think about participation and to ask questions.

- c) **Voluntariness** requires conditions free of coercion and/or undue influence, including conditions under which an individual or family may agree or disagree without any fear of repercussions.
2. The process of informed consent begins by meeting with patients and their families and discussing the research. In pediatrics, this must be a family centered activity that involves the child or adolescent, the parent/guardian, and, sometimes, other caregivers. In some situations it may be appropriate to spend time with the child or adolescent alone, without the parent/guardian present. This may make it easier for the child to ask questions and not feel coerced by a parent/guardian. Consideration is to be given to the best method for obtaining consent and assent, and is to include issues such as the nature, location, and urgency of the research and family dynamics.
  3. Investigators are to consider innovative and creative ways to provide children and families with information about the study during the informed consent process. Examples include:
    - a) Videotapes/photographs of research procedures;
    - b) Pre-visits to the site of the research to see equipment (e.g., MRIs);
    - c) Comics that explain the nature of the research;
    - d) Encouraging and arranging for potential families to speak with families/patients who have participated in research;
    - e) Distributing educational material about clinical research or specific types of research procedures (e.g., gene therapy, cancer trial pamphlets).
  4. Investigators must explain the research in terms that both the children and the parents/guardians can understand. The burden of ensuring that a parent, guardian, child, or adolescent who might participate in research genuinely understands the research falls on the researcher. Subjects and families must be able to describe what they are consenting to do. It is recommended that the researcher not only answer questions, but also ask questions to be certain that family members understand the research before a subject enrolls in a study. Asking questions can further discussion, prompt the subject and parents to think more carefully about their involvement, and help the researcher decide whether the subject and parent/guardian adequately understand the project.
  5. The questions that an investigator may consider asking are to be open-ended and nondirective. Some examples of such questions include:
    - a) **"Could you explain to me what we are going to ask you to do in this study? This will help me be to be sure that you understand**

**the research."**

*Instead of:* "Do you understand the research and what will happen?"

b) **"What more would you like to know about this study?"**

*Instead of:* "Do you have any questions?"

c) **"Can you tell me the possible good and bad things that may happen if you take the experimental drug?"**

*Instead of:* "Do you understand there are some good and bad things that could happen if you take this drug?"

6. Because informed consent continues throughout the entire research activity, subjects and their families must be kept apprised of new information regarding the study. They must have the opportunity to ask, and be encouraged to ask, ongoing questions. Subjects and families are kept up-to-date through verbal discussions, written materials and, when necessary, by having a subject re-sign a written informed consent document that contains additional information. It is important to keep in mind that subjects/families retain the right to withdraw at anytime, and to remind them of that fact.
7. It is important that no exculpatory language, through which the subject or family are made to waive or appear to waive any of the subject's legal rights, may be communicated. Nor will exculpatory language be used through which the subject or family releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

E. Appropriate Timing for Informed Consent

1. Special consideration is to be given to the timing and location of all communications concerning informed consent, including when and where informed consent is obtained. When possible, potential subjects/parents are not to be presented with all of the information at once or at the last minute. The amount of time required will vary with protocols and individuals. Busy and hectic environments may also distract a child's, adolescent's, or parent's attention.
2. When possible, all family members are to be given time to think about whether they want to participate, and are to have the opportunity to speak with others before proceeding. The consent process may be segmented; conversations, further questions, and the signing of the informed consent form may take place over several visits, and the time between discussion of the protocol and the signing of the consent may vary.

F. Who Should Obtain Consent/Assent

1. Investigators are responsible, on a per protocol basis, for designating appropriate individuals to obtain consent/assent for a protocol. Only members of the research team who have experience in all elements of the study may

provide a complete and accurate description of the research, and answer questions and concerns. Some considerations include:

- a) The technicality of the details of the protocol, and who can best explain them.
  - b) Who is best able to answer the questions that may come up?
  - c) It may be possible to have two individuals involved in the consent process. Often the investigator provides information, and a research nurse is made available to follow up and provide additional information.
  - d) Who is able to spend as much time with the families as they require?
  - e) If an investigator is also the family's physician, can the family distinguish the different roles?
2. Although other study staff may participate in the process, only a licensed physician investigator listed on the protocol is permitted to obtain informed consent for any research study that:
    - a) Is determined by the IRB to involve either greater than minimal risk with the prospect of direct benefit to individual subjects, or a minor increase over minimal risk with no direct benefit; and
    - b) Involves a medical procedure (e.g., surgery, infusion), the use of an investigational drug/biologic or device, the "off-label" use of an FDA-regulated drug or device, or utilizes any other research procedure that would require medical expertise in order to fully explain the study rationale, procedures, or expected side effects.
  3. The IRB will allow other medically-trained individuals, such as a licensed nurse or non-licensed physician investigator, to obtain informed consent if those individuals would be permitted, in a clinical setting, to perform the procedures for which consent is required. In all such cases, the rationale and justification for this approach and the qualifications and training of the relevant study staff must be submitted to the IRB for review and approval.
  4. For all other research studies, the IRB will determine on a case-by-case basis at initial and continuing review whether the PI has adequately described in the protocol who will be conducting the consent process and whether that person is actually qualified and trained to engage the participant in the informed consent process.

#### G. Who Should Provide Consent/Permission and Assent

1. General Requirements for Consent
  - a) Both Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations require that informed consent be obtained from the subject or legally authorized representative. For subjects who are minors, parents and guardians are asked to document their permission to allow their children to

participate in research by signing an Informed Consent/Parental Permission Form prior to enrollment. The consent of both parents is required unless the determination has been made that the consent of one parent is sufficient. The IRB will advise investigators as to whether one or both parental signatures are required.

- b) Informed consent must be documented on a written consent form currently approved by the IRB and signed by the subject or the subject's legally authorized representative. (See RA:HRPP:07.03 and 07.03P, *Documentation of Informed Consent/Parental Permission and Assent*). Valid forms display the IRB approval stamp, indicating the study's expiration date. A signed copy is to be given to the person signing the form. Unless otherwise approved by the IRB, a copy of the signed consent form is to be placed in the medical record if the study involves medical interventions, to ensure the safety of the patients who participate in research. **Informed consent must be obtained before the initiation of any screening procedures performed solely for the purpose of research.**
- c) The study investigator or designee is also required to sign the consent document to attest to the fact that all the elements of informed consent have been explained to the subject/legally authorized representative (parent/guardian) and all questions have been answered to the best of the investigator's ability (RA:HRPP:07.03, 07.03P).

## 2. Parents' Right to Consent to Participation of Their Children in Research

- a) Parents may generally approve their child's participation in research, assuming that regulatory and other ethical requirements for the research are met, including the child's assent where indicated (see section G.9 below). For this purpose, "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)).
- b) In the District of Columbia, Maryland, and Virginia, the general age of consent is 18 years old and, for the vast amount of research, persons under 18 will therefore be "children" for whom a parent's consent will be valid. Parental consent does not negate the need for adequate provisions for soliciting a child's assent.

## 3. Determining Whether Permission Should Be Obtained from One or Both Parents/Guardians

- a) The IRB shall determine, in accordance with and to the extent that consent is required by 45 CFR 46.116 of the Common Rule, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404 (not greater than minimal risk) or 45 CFR 46.405 (greater than minimal risk, potential for direct benefit).



the other (this happens rarely, and primarily in cases of abuse); or if only one parent is alive or competent; or if some person or agency other than the parent has been assigned legal custody of the child by law or court order. In cases where a child has been removed from parental custody, and legal custody in some form has been granted to the Department of Social Services, an agency, or foster parents, it is advisable to discuss the case with the CNMC Legal Department.

7. If the IRB finds that permission from one parent is sufficient for the research when the research is minimal risk or greater than minimal risk with the potential for direct benefit, investigators are to consider the family's circumstances to determine whether it is prudent or in the child's best interests to seek the permission of both parents or guardians. Investigators may encounter individual family situations in which additional steps must be taken. Investigators must be sensitive to each subject's family dynamics, and the implications of such dynamics on decisions regarding whether or not permission from both parents is reasonable in order to proceed with the research.
8. When a subject (child or adolescent) has been temporarily removed from parental custody and some form of legal custody has been granted to the Department of Social Services or similar government agency, then generally the department of Social Services or related government agency may consent for the research and the biological parents may consent for research as long as parental rights have not been permanently removed. The Department of Social Services or similar government agency or foster parent(s) should present written documentation from a court or government agency indicating who may consent for medical/clinical care and research for the child. Consult with the CNMC Legal Department regarding such cases.
9. Age of Assent from Minor Subjects
  - a) In addition to obtaining parental/guardian permission, federal regulations require that assent be obtained directly from the child or adolescent when, in the judgment of the Institutional Review Board, the child or adolescent is capable of providing assent.
  - b) It is CNMC policy to require assent from children and adolescents 7 through 17 years of age. To obtain assent, the research procedure and its risks and benefits must be explained to the child/adolescent in language, and at a level, that they can understand. This will vary greatly depending on the age and cognitive ability of the child. Even when assent is not required, the child is to be provided with information regarding the research.
  - c) Individual subjects or populations of subjects may not have the cognitive and emotional maturity to understand the research project and decide whether or not to participate. Although the Institutional Review Board (IRB) may require that assent be obtained, investigators must use their discretion to determine whether a subject is capable of

providing assent. Investigators are to document the rationale when assent is not obtained.

- d) If the investigator anticipates that all or some of the children/ adolescents who participate in a particular protocol will not be capable of providing assent, the investigator may submit to the IRB a request for a waiver of assent. (The “Request for Waiver of Assent to Participate in a Clinical Research Project” form is available on the IRB and Office for the Protection of Human Subjects intranet site.) The justification for a waiver of assent should detail the reasons that the child(ren) will be unable to assent, taking into account the ages, maturity and psychological state of the children involved.
- e) The IRB determines, on a protocol-by-protocol basis, whether assent may be waived for all or some of the subjects. This decision is based on the determination by the IRB that the capability of some or all of the children is so limited that they cannot be reasonably consulted, or the procedure or intervention involved holds out the prospect of direct benefit that and is only available in the context of the research.
- f) If the IRB approves a waiver of assent for some of the subjects (i.e., some of the children are cognitively and psychologically capable of giving assent), the investigator must document the subjects for whom assent is waived using an “Acknowledgement of Waiver of Assent to Participate in a Clinical Research Project” form (available on the IRB/OPHS internet site). One acknowledgement form is to be completed for each subject who is not assented, and a copy of the form is to be placed in the child’s research record if the study involves medical interventions.

#### 10. Minors’ Refusal to Assent

- a) In general, a minor’s decision not to participate in research should be respected.
- b) There are two situations in which a parent’s decision may override a child’s refusal to assent:
  - i. The subject is incapable of providing assent because of immaturity or cognitive abilities; or
  - ii. The research holds out the prospect of a direct benefit that is only available through participation in the research. This most frequently occurs in research that offers a therapeutic benefit.

#### 11. Minors’ Right to Consent in Certain Circumstances

- a) There are certain exceptions to the requirement of parental permission that flow from special provisions allowing consent for individuals less than 18 years of age (see Appendix A, Emancipation Provisions for the District of Columbia, Maryland, and Virginia). For example, in rare circumstances, such as in some public health studies involving blood draws, consent by a 17-year old or younger may be specifically allowed or required. More commonly, researchers have to consider

the applicability of D.C., Maryland, and Virginia law authorizing a minor to consent to his or her own medical care if the minor is, for example:

- i. married;
  - ii. pregnant; or
  - iii. seeking care for substance abuse, a mental or emotional condition, or a sexually transmitted disease.
- b) Despite the apparent objectivity of this definition, there are two key complexities in applying it to research:
- i. First, even in a non-research, purely clinical context, the law does not compel clinicians to treat minors in the above categories as able to consent despite a sound clinical judgment that, in fact, the person is not able to understand the nature and consequences of what they are offered. In addition, although the law is not clear on this point, many attorneys would read the provisions focused on certain conditions (e.g., substance abuse treatment, or pregnancy) as implicitly limited to care directly related to those conditions, rather than authorizing consent to any health care whatsoever. It is therefore the policy of CNMC to recognize that minors within some of these categories may not only need or benefit from family or other adult assistance, advice, and support but that, for example, the fact of parenthood may not equate with a fully adult ability to appreciate the risks, benefits, and alternatives for indicated care. For that reason, sound and sensitive clinical judgment that is attentive to both a minor's rights *and* the minor's actual competence and needs is to be brought to bear, and is to include a determination as to whether involvement of family or other adults familiar to the minor is necessary and appropriate. In addition, special care is to be taken where the decision is of extraordinary impact, or when the physician or members of another care team have concerns about the wisdom, appropriateness, or depth of the minor's expressed preference or decision. Assuming that the care team agrees with the minor on designated care, the investigator should always consult the CNMC Legal Department concerning the application of these statutes in such situations to determine whether some sort of judicial ratification is to be sought. (Use the 24/7 attorney-on-call pager if necessary: 202-259-0699).
  - ii. Second, by their terms, these DC, Maryland, and Virginia statutes apply to clinical care, and are of unsettled application to research. Where research is "therapeutic," where it offers care not available outside of the research, or where it presents care alternatives for which there is genuine equipoise concerning which treatment is preferred, and the greater part of the research consists in this otherwise-clinical core and related

measurements to assess it, it is safe to rely on the statutes as authorizing a minor to consent on his or her own behalf, assuming the IRB finds an ethically appropriate balance of risks and benefits, and the clinical team believes that the minor understands the decision and its ramifications in accordance with the standards described above and is truly capable of engaging in adult like consent. Similarly, if the research is minimal risk with some prospect of direct benefit of a clinical nature, and the greatest part of the research consists in this otherwise clinical core and related measurements to assess it, it is generally safe to rely on these statutes as authorizing not just non-research care, but care in a research context. However, in any circumstance in which there is doubt, including any circumstances other than those described above, the Office for the Protection of Human Subjects (OPHS) and the Legal Department are to be consulted. These offices will assess whether the statutory categories are apt, will relate them to sound application of the Belmont principles, and will also identify any conflicts between the clinical best interests of the minor and the minor's participation in the research.

- c) Investigators are also to be aware that a parent's right to consent for a minor is open to question when research presents greater than minimal risk with no prospect of direct benefit to the individual subjects. Unlike the first exception above, in which minors may consent for themselves because of categorical capacity related to their personal circumstances, this exception tends to arise on a protocol-wide basis as a result of the study design. Recent judicial decisions in Maryland, if applied here, would suggest that parents have no right to consent to expose their children to substantial risks without direct therapeutic benefit in a research context without judicial approval. This category of research, if federally funded, is subject to a so-called "407 panel review" (45 CFR 46.407). Although federal regulations require the consent of both parents if reasonably available, the IRB, with guidance from the Legal Department, may in some circumstances recommend additional judicial approval beyond the requirements of the "407" regulation. (It is not expected that this type of situation will arise for all research that falls within the 46.407 category.) Researchers should note that this area of law is evolving rapidly, and that CNMC will take the steps necessary to comply with the law.

## 12. Consent by Judicially Approved Guardians and other Surrogates

- a) Under federal regulations, consent to participate in research may be obtained from the subject's "legally authorized representative." For a child subject whose parents are deceased, not competent, or judicially deprived of the right to consent (as in certain abuse and neglect cases), a "legally authorized representative" is a guardian appointed by a court.

- b) Investigators are not to assume that a guardian is authorized to consent to a child's participation in all research. Guardian powers, including those of government agencies such as the Department of Social Services, may be limited by the terms of a court order to certain forms of care decision, and it is not uncommon for a guardian to be required to return to court for decisions not specifically countenanced by the court order. In addition, **the authority to make health care decisions is not the same as the authority to consent to research participation.**
  - c) Investigators are to be clear on the terms of the guardian's authority (a guardian should be able to readily produce a copy of the pertinent court order); are to consult with the CNMC Legal Department; and are to recognize that a court is most likely to approve such authority in situations where the research is "therapeutic," where it offers care not available outside of the research, or where it presents care alternatives for which there is genuine equipoise concerning which treatment is preferred.
  - d) Generally, non-parent family members who are not court-appointed guardians are not authorized to consent to participation in research unless their role can be justified on other grounds, such as the emergency nature of the minor's condition. Nonetheless, such family members can play an important supportive role for a minor who is technically able to consent as described above.
  - e) Investigators are responsible for determining changes in guardianship. An addendum to the consent form may be used to request that a child's legally authorized representative inform the PI of any change. A template is available on the IRB/OPHS website.
13. Surrogate Consent for Adults without Sufficient Decision-Making Capacity to Effectively Exercise Their Right to Informed Consent
- a) In limited instances, Children's National Medical Center provides care and offers research participation to adults whose unusual condition, or history of continuous treatment or relationship with a specific hospital program, provides a compelling reason to agree to their requests to continue to be treated at CNMC. From time to time, such individuals present with questionable decision-making capacity, but are otherwise ethically appropriate, potential subjects for a research study.
  - b) The IRB applies 45 CFR 46, Subpart D (Additional Protections for Children Involved as Subjects in Research) to provide additional protections for adults with diminished decision making capacity, with the exception that surrogate consent must be obtained from a legally authorized representative (LAR), rather than parental permission.
    - i. Individuals with impaired decision making capacity are to be included in the process of consent to the extent possible and consistent with their desires and abilities. Investigators must make adequate provisions to determine a cognitively impaired

adult's ability to comprehend all the elements of effective informed consent.

- ii. When it is determined that a subject lacks decision-making capacity, investigators are to identify the adult individual's LAR or surrogate decision-maker and solicit the surrogate's informed consent (permission) to enroll the individual in the research. The authority of such surrogates often applies to clinical care, and may be of unclear application to research. Investigators are advised to consult with the CNMC Legal Department regarding identification of a surrogate decision-maker who is legally authorized to make research-related decisions for a cognitively impaired adult.
- c) When consent will be provided by a LAR, the assent of the research subject should be sought at the outset and, as appropriate, throughout the course of research involvement, unless the subject is incapable of providing assent.
- d) See RA:HRPP:08.13 and 08.13P, *Additional Protections for Adults with Questionable Decision Making Capacity*, for further information.

#### 14. Obtaining Consent when Minor Subjects Become Adults or Otherwise Acquire Capacity to Consent during the Course of Research

- a) Any research study that involves continuing diagnostic or therapeutic procedures or any form of research intervention (e.g., surveys) is not to proceed with a minor subject after that subject becomes an adult until the subject provides informed consent as described in this policy. This is to occur regardless of the sophistication of the minor subject when assent was provided, or the level of detail provided in the assent document. Consent should be obtained at the time of next contact with the now-adult subject for research activities.
- b) The conduct of all forms of research in which there are continuing interactions with the subject (e.g., result reporting, informational follow-up) requires that such subjects be reminded of their right to withdraw from the study, including:
  - i. Their right to revoke HIPAA authorization, to the extent that such authorization is revocable under the terms of the informed consent and the authorization signed by their parents or guardian; and
  - ii. Their right to revoke any other right granted in the study, (e.g., rights with respect to use of tissue samples) to the extent it would be revocable by their parents or guardians were they still minors.

#### H. Submissions to the Institutional Review Board

1. The investigator must provide a detailed description of the intended method for obtaining informed consent and submit all informed consent documents

(full written informed consent/parental permission documents, oral scripts, short forms and the written summary, and assents) to the IRB for review and approval prior to use.

2. The investigator is responsible for providing the IRB with the information required to complete a thorough review of the content of the informed consent process. The following information regarding the nature and circumstances of the consent must be provided in the application (initial, continuing, modification) for IRB review and approval:
  - a) The name of the person who will conduct the consent process;
  - b) The information to be communicated to the prospective subject or parent(s)/Legally Authorized Representative (LAR);
  - c) The person(s) who will provide consent/permission and assent;
  - d) The timing of the process for obtaining consent, any waiting period between informing the subject or parent(s)/LAR and obtaining consent/assent, and whether the proposed consent process provides a subject or parent(s)/LAR sufficient opportunity to consider whether or not to participate in the research;
  - e) Circumstances of the consent process include steps taken to minimize the possibility of undue influence or coercion;
  - f) No exculpatory language through which a subject or parent(s)/LAR would waive or appear to waive any of his/her legal rights to withdraw from the research, or language that would release or appear to release the investigator, the sponsor, CNMC, or its agents from liability for negligence;
  - g) Language understandable by the prospective subject population, and, if necessary, be translated into a language the subject or parent(s)/LAR understands.
    - i. The IRB prohibits the exclusion of non-English speaking individuals from research protocols unless there is a sufficient justification for the exclusion. In particular, if a research protocol offers a potential for direct benefit that may only be available within the context of the research, the exclusion of non-English speaking individuals becomes ethically problematic. Investigators are obliged to consider the potential that study populations may include non-English speaking individuals and to plan for this while developing the protocol.
    - ii. The protocol must reflect the methods for assuring full understanding, possibly with the assistance of an interpreter or by using translated informed consent documents. The application must include details regarding who will conduct the consent procedures/discussion, communicate other information, and be available to answer questions in a language understandable to the participants.
3. When the investigator submits an application to the IRB, the IRB Regulatory Analyst assigned to the study will conduct a pre-review of the entire

application and make an initial determination whether the consent/assent process is described adequately. If the Analyst determines that the application is incomplete or that additional information is required, he/she will send administrative modifications to the investigator for clarification. Once the administrative modification revisions are received from the investigator, the IRB Analyst will forward the transaction for review by the appropriate process (expedited or full board review).

4. The assigned reviewer is responsible for conducting a complete review of the application and for confirming the appropriateness of the process for obtaining consent/parental permission and assent. The reviewer is required to use the Reviewer Feedback Form to document his or her conclusions. For studies requiring review at a convened meeting of the IRB, the committee is to consider the consent/assent process when it makes its approval determination.

## **II. REVIEW OR REVISION DATE**

Original:

## **III. REFERENCES**

AAHRPP Element(s):

Federal Regulations: U.S. Department of Health and Human Services (DHHS) 45 CFR 46.111(a)(4), 46.116, 46.407, 46.408  
Food and Drug Administration (FDA) 21 CFR 50.20, 56.111(a)(4)

Policies and Procedures: RA:HRPP:07.03 and 07.03P, *Documentation of Informed Consent/Parental Permission and Assent*  
RA:HRPP:08.13 and 08.13P, *Additional Protections for Adults with Questionable Decision Making Capacity*

Forms: Request for Waiver of Assent to Participate in a Clinical Research Project,  
Acknowledgement of Waiver of Assent to Participate in a Clinical Research Project,  
LAR Consent Addendum

**Appendix A. Emancipation Provisions for the District of Columbia, Maryland, and Virginia**

Jurisdiction	Emancipation Definition	Termination of Parental Rights	Age of Majority
<p>District of Columbia</p>	<p><b>D.C. Code § 7-1231.02</b>            (10) "Emancipated minor" means any minor who is living separate and apart from his or her parent(s) or legal guardian, with or without the consent of the parent(s) or legal guardian and regardless of the duration of such separate residence, and who is managing his or her own personal and financial affairs, regardless of the source or extent of the minor's income.</p> <p>(18) "Minor" means a person under 18 years of age, but shall not include a person who is an emancipated minor or who is married.</p> <p><b>22 DC ADC § 699</b>            Minor who is or has been married; or who is serving or has served in the armed forces; or who is employed and contributing more than half of his or her own support if residing with his or her parents; or who is residing apart from his or her parents and managing his or her own affairs; or who is making the major decisions affecting his or her own life.</p>	<p><b>§§4-1301.09a(d); 16-2353; 16-2354(b)</b>            Abandonment or extreme parental disinterest, abuse/neglect, mental illness or deficiency, alcohol or drug induced incapacity, sexual abuse, abuse/neglect or loss of rights of another child, child judged in need of services/dependent, child's best interest, child in care 15 of 22 months (or less), felony assault of child or sibling, murder/manslaughter of sibling child, need for continuity and care, quality of relationship, location of parent(s) unknown</p>	<p><b>D.C. Code §46-101 (2001)</b>             18</p>

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Maryland	<p><b>MD Hum. Res. 7.02.04.02</b>  F. "Emancipated Minor" means a child who is freed from the custody of the parent and from the obligation to render services to the parent.</p> <p><b>MD Rules, Rule 10-209</b>  (c)(1) Petition required for emancipation.</p> <p>(c)(5)(B) Marriage of minor is cause for emancipation.</p> <p><b>Md. Health-Gen Code § 20-102</b>  (a)(1) Minor has same capacity to consent as an adult if minor is married.</p>	<p><b>§§5-313; 5-525.1(b)(1)</b>  Abandonment or extreme parental disinterest, abuse/neglect, mental illness or deficiency, alcohol or drug induced incapacity, felony conviction/incarceration, failure of reasonable efforts, sexual abuse, abuse/neglect or loss of rights of another child, failure to maintain contact, failure to provide support, child judged in need of services/dependent, child's best interest, child in care 15 of 22 months (or less), felony assault of child or sibling, murder/manslaughter of sibling child, child continuously out of parental custody, identity of parent(s) unknown, convicted of crime of violence against other parent</p>	<p><b>Article – Rules of Interpretation, § 24</b></p> <p>18</p>

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<p>Virginia</p>	<p><b>§16.1-331, 333 and 334</b></p> <p>Minor must be at least 16 years old.</p> <p>The court may enter an order declaring the minor emancipated if, after a hearing, it is found that:</p> <p>(i) <i>the minor has entered into a valid marriage</i>, whether or not that marriage has been terminated by dissolution; or</p> <p>(ii) <i>the minor is on active duty with any of the armed forces of the United States of America</i>; or</p> <p>(iii) <i>the minor willingly lives separate and apart from his parents or guardian, with the consent or acquiescence of the parents or guardian, and that the minor is or is capable of supporting himself and competently managing his own financial affairs.</i></p> <p>An order that a minor is emancipated shall have the following effects:</p> <p>1. The minor may consent to medical, dental, or psychiatric care, without parental consent, knowledge, or liability</p>	<p><b>§§13.34.180; 13.34.190; 13.34.132</b></p> <p>Abandonment or extreme parental disinterest, abuse/neglect, mental illness or deficiency, alcohol or drug induced incapacity, felony conviction/incarceration, failure of reasonable efforts, sexual abuse, abuse/neglect or loss of rights of another child, failure to maintain contact, failure to provide support, child judged in need of services/dependent, child's best interest, child in care 15 of 22 months (or less), felony assault of child or sibling, murder/manslaughter of sibling child, voluntary relinquishment, identity or location of parent unknown, aggravated circumstances.</p>	<p><b>Title 14, Chapter 1-101</b></p> <p>18</p>