Q1: Whose permission is needed before a child can participate in research?

A: Children are regarded as a vulnerable population, incapable of providing meaningful informed consent because of their cognitive and emotional immaturity. Parental permission is required as an additional protection for participants who have not reached adulthood which, in the District of Columbia, Maryland, and Virginia, is 18 years of age.

As shown in the table below, the level of risk presented by the research determines whether one or both parents/guardians must provide written permission for their child’s participation.

<table>
<thead>
<tr>
<th>Required Signatures</th>
<th>Research Risk Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>One parent/guardian</td>
<td>• Minimal risk</td>
</tr>
<tr>
<td></td>
<td>• Greater than minimal risk with the prospect of direct benefit to individual subjects</td>
</tr>
<tr>
<td>Both parents/guardians¹</td>
<td>• Greater than minimal risk with no prospect of direct benefit to individual subjects</td>
</tr>
</tbody>
</table>

¹ Exceptions apply if 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.

Q2: At what age is assent required from children participating in research, and how should it be documented?

A: Children’s National policy requires that assent be obtained from children ages 7 through 17 years. Assent by children ages 7 through 11 must be documented using an Affidavit of Person Obtaining Assent added to the parental permission form. For subjects 12 through 17 years of age, assent must be documented by obtaining their signature on a separate form. This form must be consistent with the Children’s National Assent Form template.

Q3: Does consent/parental permission have to be obtained if the research involves only a retrospective review of medical records?

A: It depends. The IRB may waive the requirement for an investigator to obtain informed consent/parental permission if all of the following are true:

- The research involves no more than minimal risk to subjects;
- The waiver will not adversely affect subjects’ rights and welfare;
- The research could not practicably be carried out without the waiver; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation

The HIPAA Privacy Rule may also apply. See Q4.
Q4: Does HIPAA Authorization have to be obtained if the research involves only a retrospective review of medical records?

A: If individually identifiable protected health information (PHI) is to be used or disclosed as part of the retrospective record review, valid HIPAA Authorization must first be obtained from each subject (or parent/guardian) unless the IRB or Privacy Board grants a waiver of authorization. To grant a waiver of HIPAA Authorization, the IRB must determine:

- The use or disclosure of PHI involves no more than a minimal risk to the privacy of subjects;
- The research could not practicably be conducted without the waiver; and
- The research could not practicably be conducted without access to and use of the PHI.

Q5: A child meets eligibility criteria for a research study but her parents are not available in person to sign the informed consent/parental permission form. Can parents give valid permission over the telephone for their child to participate in research?

A: No. Although parental consent/permission obtained over the phone is acceptable for clinical treatment, it is not legally effective for research unless the IRB has granted a waiver of documentation of informed consent/parental permission. If no waiver of documentation has been granted, the investigator should deliver, fax, or email the consent form to the parents and review it with them over the phone. The consent/permission form signed by the parents must be received by the investigator before the child can be enrolled in the research.

Federal regulations do not permit the IRB to grant a waiver of documentation for research regulated by the Food and Drug Administration (FDA).

Q6: What makes a study eligible for a waiver of documentation of informed consent/parental permission?

A: The IRB may waive the requirement for an investigator to obtain a signed consent/parental permission form if the research is not regulated by the Food and Drug Administration (FDA) and:

- The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality, or
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Q7: What process should be used to obtain informed consent/parental permission when the subject or parent/guardian does not speak English?

A: A complete written translation of the English version of the consent form must be used when the investigator expects that more than an incidental number of non-English speaking subjects will be approached for enrollment. A translated version of the “short form” consent document should be used when a non-English speaking subject (or
parent) is unexpectedly encountered and a written translation of the entire IRB-approved consent form is not available.

Whether using a complete written translation of the consent document or the short form, a qualified interpreter must be used for the oral presentation of the full consent and assist with answering subjects’ questions.

Q8: What is a “short form” consent document?
A: The “short form” is a generic document that states that the elements of informed consent required by the regulations have been presented orally to the subject (or parent/guardian). For non-English speaking subjects (or parents/guardians), the short form must be written in a language they understand. The short form must be signed and dated by the subject (or parent/guardian) and a witness to the oral presentation (frequently the interpreter) who is fluent in both English and the translated language.

Q9: When a “short form” consent document is used, should the non-English speaking subject or parent/guardian sign the full English version of the IRB-approved consent form?
A: No. As shown in the table below, the subject or parent/guardian must sign and date only the short form that has been translated into his or her language. The person obtaining consent/parental permission must sign and date the full English version of the IRB-approved consent form. A bilingual witness to the oral presentation of the full consent (frequently the interpreter) must sign both forms.

Under no circumstances should a person who does not read and comprehend English sign a consent form that is written in English.

<table>
<thead>
<tr>
<th>Signatory</th>
<th>Full Consent Form (English)</th>
<th>Short Form Consent (Translated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject/Parent</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Person obtaining consent</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Witness</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Q10: When is a witness required for informed consent?
A: A witness to the process of informed consent is required in the following circumstances:
• A “short form” is used to document informed consent (see Q8);
• A subject (or parent/guardian) is illiterate and the consent document must to read to him/her;
• Communication impairments limit the ability of the subject (or parent/guardian) to unambiguously register consent;
• The IRB expressly requires a witness due to the nature of the research and anticipated condition of the subjects (or parents/guardians)

Q11: What must happen when a child participating in a study becomes an adult?

A: If a subject is enrolled in a study as a child and turns 18 years old while still a participant, he or she must give informed consent as an adult to continue in the study. The Investigator must give the subject the option of signing a consent document or discontinuing participation at the earliest opportunity once the subject turns 18. This includes individuals whose specimens and information have been collected for inclusion in a biorepository or data registry.

Q12: Are there any special requirements for enrolling adult subjects with impaired decision-making capacity in research?

A: Special protections must be provided for adults with impaired decision-making capacity. Prior to enrolling such an adult into a research study, the investigator must submit to the IRB a plan for assessing the adult’s capacity to provide meaningful informed consent. If the adult lacks the capacity to give consent, the investigator must also submit to the IRB:

• A plan for identifying the person’s legally authorized representative (LAR) and obtaining the LAR’s informed consent/permission;
• A plan for obtaining the assent of the impaired adult

Consult with the Children’s National OPHS and Legal Department for additional information.