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**Boston
Children's
Hospital**

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Department Research
Applicability Boston Children's
Hospital- Policies
& Procedures

Assent and Parental Permission Policy/Procedure

Internal Approval

SVP, Research Administration

EVP, Chief Scientific Officer

Scope

This policy applies to the Boston Children's Hospital (BCH) Research department and the respective staff.

Definitions

Assent: A child's "affirmative agreement" to participate in research.

Children: For this purpose of this policy, "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". In Massachusetts, 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.

Guardian: An individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

Parent: A child's biological or adoptive parent.

Parental Permission: The agreement of parent(s) or guardian(s) to the participation of their child or ward in research.

Policy Statements

This policy provides information and guidance concerning consenting families: parental/guardian permission and child assent.

It is the policy to comply with all federal and state regulations that pertain to informed consent, parental permission, and assent. Assent and parental/guardian permission must be obtained in accordance with IRB determinations for research involving children.

Procedures

Parental/Guardian Permission

1. The IRB determines that unless parental permission can be waived, adequate provisions are to be made for soliciting the permission of the parent(s) or legal guardian(s).
2. Special regulations governing research involving children allow that competent parents may generally approve a minor's participation in research, assuming that regulatory and other ethical requirements for the research are met, including the minor's assent where indicated.
3. The Institutional Review Board shall determine, in accordance with and to the extent that consent is required by Department of Health & Human Services (HHS) §46.116 of Subpart A and U.S. Food & Drug Administration (FDA) 21CFR50.20, that adequate provisions are made for soliciting the permission of each child's parent/guardian.
4. In accordance with the regulations the IRB will determine whether one or both parents/guardians are required to provide permission.
 - a. The IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404, 50.51 (minimal risk) or §46.405, 21CFR50.52 (greater than minimal risk, potential for direct benefit).
 - b. Where research is covered by §46.406, 21CFR50.53 and §46.407, CFR50.54 (greater than minimal risk, no prospect of direct benefit) and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal custody of the child.
5. Generally, the IRB will require that permission be obtained from both parents or the legal guardians, if reasonably available and competent to consent, even when the research potentially offers direct benefit, when the research presents:
 - a. Significant increases in magnitude or probability of risk, above the alternative approaches; or
 - b. The research procedure is so novel that the risks are unknown; or
 - c. Potential risks that could be life threatening or severely debilitating, or that have the potential to cause major irreversible morbidity (e.g. blindness, hearing loss, paralysis, stroke).
6. The IRB will advise investigators as to whether the signature of one or both parents is required

on the approval letter.

Guidance if the IRB Finds that Permission from One Parent/Guardian is Sufficient

1. 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 determine whether it is prudent or in the child's best interests to seek the permission of both parents or guardians.
2. Investigators may encounter individual family situations in which additional steps must be taken.
3. 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/guardians is reasonable in order to proceed with the research.
4. When children are under the shared legally custody of two parents/guardians, each parent/guardian's rights of decision-making are to be respected to the greatest extent possible.
5. Researchers should be guided by sound clinical and ethical judgment and are to be alert to the need for family consensus, just as they are with clinical interventions.
6. Those situations in which it is reasonable to believe that it is in the best interests of the family and child to obtain permission from both parents/guardians include the following:
 - a. When both parents/guardians are known to be involved in the child's care, and the investigator has reason to believe that there may not be family consensus on participation in research.
 - b. When a non-custodial parent/guardian consents to research that will affect the child's care by a custodial parent/guardian or impose obligations on the custodial parent/guardian.
 - c. When the family has shown signs of mutual antagonism or stress related to reaching consensus on clinical decisions.
 - d. When consent by one parent/guardian might reasonably or predictably affect the potential subject's relationship with the other parent/guardian.
 - e. When one parent/guardian is known to disregard the wishes of the other parent.
 - f. When one parent/guardian is known to object to the research for reasons that, accordingly, would caution against proceeding with a clinical intervention in similar circumstances.
7. The Office of General Counsel should be consulted when the subject has been removed from parental/guardian custody, and legal custody in some form has been granted to the Department of Children and Families, an agency, or foster parents. Moreover, all questions are to be directed to the Office of General Counsel.

Determining if a Parent/Guardian is "Reasonably Available"

1. The parent/guardian's role in the care and/or decision making of the child, even on a limited basis, is such that his or her involvement and availability may be ascertained from the Boston Children's Hospital record.

2. The parent/guardian's whereabouts are known at the time the child is approached for research purposes.
3. If in situations in which the above referenced criteria are met, the investigator is unable to contact the parent/guardian, then the investigator is to document the attempts made, including the date of the attempt and the method of attempted contact (e.g. phone, fax, email). After multiple attempts at contact are made (usually three at a minimum), it may be reasonable to conclude that the parent/guardian is not reasonably available.
4. Although the IRB generally requires both parents/guardians' signatures, situations may exist in which one parent accompanies a child to an acute care visitor emergency, and to require the signature of both parents/guardians would represent a significant impediment to the initiation of an investigational procedure that carries a potential for direct benefit.
5. In situations where the provision of immediate and emergent care would be thwarted by the process of seeking both parents' consent in advance, and only one parent is reasonably available, one parent's consent may be relied upon.
6. However, the rationale for proceeding in this situation is to be well documented in the research and medical records, and appropriate and reasonable attempts are to be made to notify the other parent/guardian as soon as possible.
7. Even where a protocol generally requires both parents/guardians' permission, the permission of both parents is **NOT** required if a court grants decision-making authority solely to one parent, excluding any court-ordered consent role for the other, 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.
8. In cases where a child has been removed from parental custody, and legal custody in some form has been granted to the Department of Children and Families, an agency, or foster parents, it is advisable to discuss the case with the Office of General Counsel.

Legally Authorized Representative, Judicially Approved Guardians, or other Surrogates

1. Under the federal regulations, consent to participate in research may be obtained from the subject's "legally authorized representative."
2. For a child 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.
3. Investigators are not to assume that a guardian is authorized to consent to a child's participation in all research.
4. Within the state of Massachusetts, guardian powers, including those of government agencies such as the Department of Children and Families, 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.
5. In addition, the authority to make health care decisions is not the same as the authority to consent to research participation.
6. For these reasons, investigators are to:
 - a. 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);
 - b. Consult with the Office of General Counsel; and
 - c. 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.
7. In the state of Massachusetts, non-parent family members who are not court-appointed guardians are not authorized to consent to participation in research. Nonetheless, such family members can play an important supportive role for a minor who is technically able to consent as described above.

Documentation of Parent/Guardian Permission

1. The IRB requires the signature of the subject or legally authorized representatives (parent/guardian) on informed consent documents unless a waiver or alteration of consent is approved.
2. During the review process, the IRB determines the signatures required and incorporates these requirements in the final approved consent/assent forms.
3. All consent documents must contain the date that the participant and (if the participant is a minor, under the age of 18) the participant's parents or the participant's legally authorized representative (guardian).
4. A variety of legally recognized arrangements exist, including those that involve custody of children, guardians for children, wards, and children in foster home situations. However, not all guardians have the legal right to consent to research for a child. In many instances, biological parents maintain this right. Moreover, differences exist in consent procedures related to clinical care versus research. For these reasons it is important that investigators contact the IRB Office or the Office of General Counsel if questions arise as to who has authority to consent for a child under the age of 18.
5. If the IRB reviews research that is conducted in another state or country, the determination as to who may sign the consent and who is a legally authorized representative must be determined by the locality where the research takes place.

Assent

1. In addition to obtaining written parental/guardian permission, federal regulations require that assent be obtained directly from the child/adolescent. Assent is required unless:
 - a. The subject is incapable of providing it because of immaturity or cognitive abilities;
 - or**
 - b. 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.
2. In these situations, a parent's decision may override a child's refusal to assent. Even when assent is not required, the child is to be provided with information regarding the research.

3. To obtain assent, the research procedure and its potential 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.

IRB Determination of Assent

1. The IRB will determine, on a protocol by protocol basis, whether assent is required. This decision is based on the population being studied and the potential for direct benefit. The final letter of protocol approval sent to an investigator indicates whether assent is required.
2. If the IRB determines that the capability child/adolescent in the specific study population is so limited that they cannot reasonably be consulted, or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child/adolescent and is available only in the context of the research, the assent of the child/adolescent is not a necessary condition for proceeding with the research.
3. Additional steps in the child/adolescent assent documentation process include:
 - a. The investigator is to indicate on the protocol application their initial determination as to whether assent may be obtained from the subject population.
 - b. During the review process the IRB is to review the investigator's justification and determine whether assent is required.
 - c. The investigator is to be advised in the approval notification whether assent is required.
 - d. The IRB minutes are to document the IRB's determination.

Capability of Assent

1. It is generally believed that children 7 to 18 years of age may be capable of providing assent. However, the content of the assent process will vary by age group.
2. For ages 7-14 the assent would likely include a more practical discussion based on a description of the procedures involved and the duration of the research.
3. For subjects 14 -18, in addition to a discussion about procedures and duration, more abstract concepts that include potential future consequences of the research, risks such as loss of confidentiality, or the consideration of alternatives and the "rights of subjects" should be included.
4. Although the IRB may require that assent be obtained, investigators must use their discretion to determine whether the subject is capable of providing assent.
5. Regardless of age there should be consideration of emotional state.
6. In addition, individual subjects or populations of subjects may not have the cognitive and emotional maturity to understand the research project and decide whether to participate or not.
7. If the IRB asks that assent be obtained, investigators are to document the rationale when assent is not obtained as a specific justified situation

A Minor's Right to Consent in Certain Circumstances

There are certain exceptions to this generalization, that flow from special provisions allowing consent for

individuals under 18 years of age. For example, in rare circumstances, such as in some public health studies involving blood draws, consent by a minor under the age of 18 may be specifically allowed or required. More commonly, researchers have to consider the applicability of Massachusetts law authorizing a minor to consent to his or her own "medical or dental care" if:

1. Married, widowed, or divorced
2. Is the father or mother of a child
3. Is enlisted in the military
4. Is pregnant or believes herself to be pregnant
5. Is seeking care for a drug addiction, family planning or treatment of a sexually transmitted disease,
6. For those between 16 to 18 years of age, seeking to voluntarily commit themselves for mental health treatment

Despite the apparent objectivity of this definition, there are two key complexities in applying it to research:

1. First, even in a non-research, purely clinical context, this law does not compel clinicians to treat minors in those categories as able to consent when there is 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 use disorder 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 Boston Children's Hospital 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 should 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. The Office of General Counsel should be consulted concerning the application of this statute in such situations, (use the 24/7 attorney-on-call pager if necessary) and such consultation is to address, assuming the care team agrees with the minor on designated care, whether some sort of judicial ratification can be sought.
2. Second, by its terms, the statute applies to clinical care, and is 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 care and related measurements to assess it, it is safe to rely on the statute 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 care and related measurements to assess it, it is generally safe to rely on this statute as authorizing not just non-research care, but care in a research context. However, in any circumstance in which there is doubt including any other circumstances than those described above, the Office of Clinical Research Compliance and the Office of General Counsel 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.

- a. Investigators are also to be aware that a parent's right to consent for a minor is open to question when research presents more than a minor increase over minimal risk, with no prospect for direct benefit. 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 outside of Massachusetts, 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." Although federal regulations require the consent of both parents if reasonably available, the IRB, with guidance from General Counsel, 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 407 category.) Researchers should note that this area of law is evolving rapidly, and that Boston Children's Hospital will take the steps necessary to comply with the law.

Documentation of Assent

1. Obtaining assent consists of a discussion with the child/adolescent combined with the need for signing actual documents. In considering assent, the emphasis should always be on the detailed discussion/interaction. Written materials may be helpful for reference but should not be used as the only means of communication with the child/adolescent research subject.
2. The regulations do not specify how one needs to document assent and therefore, there are several methods.
3. Since there is regulatory flexibility on how to document assent the IRB has developed some overarching categories to be consistent in guiding the research community as to when a separate form is required. It is also acknowledged that other institutions and sponsors may have their own requirements for assent that may need to be considered.
4. In some situations, the IRB will ask that the child/adolescent sign the parental permission form, to indicate their willingness to participate.
 - a. The approved consent form will include a space for the child/adolescent to sign.
 - b. These consents will also contain a section where investigators are required to document the reason(s) why it is not feasible or appropriate to obtain assent from a particular child/adolescent.

- In other situations, determined by the IRB, the committee may require a separate assent form. These assent forms must be simple and easy to understand.

Parental/Guardian Permission and Assent Process

- The decision to participate in research should be a family-centered decision with special consideration and attention given to each parent and the pertinent child or adolescent. In some situations, it may be appropriate to spend time with the child/adolescent alone, without the parent/guardian present. This may make it easier for the child to ask questions and not feel coerced or unduly influenced by a parent/guardian.
- Consideration should be given to the best method for obtaining consent: **parental permission** and **assent**, and should include attention to such factors as the nature, location, and urgency of the research, and family dynamics.
- Consideration should be given to the timing and location of all communications concerning informed consent (assent/parental permission), including when and where it is given. Potential subjects/parents should not be presented with all 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/adolescent/parent's attention. When possible, all family members should be given time to think about whether they want to participate and should 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.
- Investigators should consider innovative and creative ways to provide children and families with information about the study during the informed consent process. Examples include:
 - Videotapes/photographs of research procedures,
 - Pre-visits to the site of the research to see equipment (e.g., MRIs),
 - Encouraging and arranging for potential families to speak with families/patients who have participated in research,
 - Distributing educational material about clinical research or specific types of research procedures (e.g., gene therapy, cancer trial pamphlets).
- The burden of ensuring that a parent/guardian, child/adolescent who might participate in research genuinely understands the research falls on the researcher.
- 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 lead to further discussion, prompt the subject and parents to think more carefully about their involvement, and help the researcher decide whether the parent/guardian and child/adolescent adequately understand the research. The questions that an investigator may consider asking should be open-ended and nondirective. Examples include the following:

Instead of saying this:	Ask this:
Do you understand the research and	Could you explain to me what we are going to

Instead of saying this:	Ask this:
what will happen?	ask you to do in this study? This will help me be sure that you understand the research.
Do you have questions?	What more would you like to know about this study?
Do you understand there are some good and bad things that could happen if you take this drug?	Can you tell me the possible good and bad things that may happen if you take this experimental drug?

Parents/Guardians as Research Subjects

1. At times, research that primarily targets children may also include adults. For example, a parent/guardian of the minor may be approached with research study survey questions.
2. Consent should be obtained and documented adequately from any individual who is the focus of the research activities.
3. A parental permission signature for their child is not adequate to demonstrate consent by a parent for their own participation in a research study.
4. IRB approved consent form signature sections should be adequately formatted to demonstrate the parent/guardian's consent as a research subject, in addition to their permission as legal guardian for a minor subject.

Related Content

- Department of Health and Human Services Regulations (HHS 45 CFR 46)
 - §46.116: Adequate provisions of Subpart A
 - §46.404: Minimal risk
 - §46.405: Greater than minimal risk, direct benefit
 - §46.406: Greater than minimal risk, no direct benefit
- U.S. Food & Drug Administration CFR – Code of Federal Regulations Title 21
 - 21CFR50.51: Minimal risk
 - 21CFR50.52: Greater than minimal risk, direct benefit
 - 21CFR50.53: Greater than minimal risk, no direct benefit
- IRB Policies
 - General Information: Informed Consent and Parental Permission
 - Consent Guidance When Turning the Age of Majority
 - Informed Consent with Non-English Speakers

Approval Signatures

Step Description	Approver	Date
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Applicability

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