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Consent Guidance When Turning the Age of Majority

Background

To continue to participate in human subject research, individuals enrolled as children with parental or guardian consent must be re-consented when they become adults unless a waiver of consent is granted. In most states in the US a minor turning 18 years of age acquires the legal right to direct their own health care and participation in research activities and previous parental permissions lose their validity. It is therefore necessary to re-consent participants who were enrolled in a study as a minor and continue to remain active in human subject research activities after reaching the age of 18 years.

Scope

This guideline applies to all Boston Children's Hospital (BCH) licensed locations, BCH operational and clinical departments, and staff (inclusive of W-2 employees, contracted staff, and members of the medical staff irrespective of their appointment category or employer). As applicable, the guideline also applies to foundation practices leasing space at hospital-licensed locations.

Definitions

Age of Majority is the legally defined age at which a person is considered an adult, with the attendant rights and responsibilities of adulthood. The age of majority is defined by state laws and is usually between 18 and 21 years of age. The age of majority also differs country to country.

Guideline Statements

This guidance is intended to provide information on acceptable methods to comply with the regulatory requirements. The guidance addresses research when the research participant reaches the age of majority and:

A. continues to participate in research activities that involve assessments, interventions, or the continued acquisition of identifiable private data or specimens, and/or

B. continues in activities that are limited to the continued use of identifiable data/specimens collected prior to the 18th birthday (for example repository collections).

Process Steps

Research Activities that include assessments, interventions, interactions, or collection of private identifiable data/specimens

Any participant that reaches the age of majority and continues to participate in research activities, including the collection of identifiable data/specimens, must provide consent unless a waiver of consent is granted for the research. Investigators are responsible for tracking when a participant turns the age of majority and acquiring consent as close to that birthday as feasible. Research activities and collection of specimens and data should not occur after the participant reaches the age of majority until consent from the participant is obtained.

If a participant reaches the age of majority and does not have the capacity to consent, new consent must be obtained from the legally appointed guardian as the original parental/guardian permission does not remain valid.

Investigators are asked to consider the possibility of a participant reaching the age of majority during their research. Factors to consider include age eligibility and the length of the study. Investigators should ideally include this information in the initial protocol application, but an amendment may also be submitted to include or revise the plan. The CHeRP application includes specific questions which will prompt the investigator to identify whether participants will reach the age of majority and address the plan for seeking consent. Investigators should consider the following guidance when developing their plan for participants who reach the age of majority during the study:

A. If the participant remains a patient or research participant at Boston Children's Hospital and is actively being followed, there is an opportunity to obtain **written consent**. Participants may:
    1. sign a new consent document at the next scheduled visit.
    2. be sent the consent document by mail or email and asked to sign and return it.
    3. electronically sign the consent form consistent with the approved protocol and Research Computing requirements.

B. It is acknowledged that participants turning the age of majority may not be accessible. For example, they may be at college, seen infrequently, or have transitioned their care to other providers. In a situation when the research protocol only requires data collection from the medical record, or the interaction is limited (e.g., only involving the completion of questionnaires), the investigator may choose to apply to the IRB for a waiver of informed consent documentation and obtain consent by another method (i.e., **verbal consent**). This situation is limited to research activities that present no more than minimal risk of harm to participants and do not involve procedures for which written consent is normally required outside of the research context. In these situations, the IRB may approve a verbal consent process and documentation of the consent discussion.

C. In some situations, the IRB may grant a complete **waiver of consent** in accordance with federal regulatory requirements. A waiver may be appropriate in research where the participant is not actively engaged and research is limited to the continued collection of existing secondary data (e.g., medical record data). In some situations a waiver of consent may be permitted after a number of attempts have been made to contact the participant.

D. Investigators seeking a waiver of informed consent documentation from the IRB to allow for a method other than written consent (e.g. verbal consent) or complete waiver of informed consent are responsible for detailing how the research meets criteria for waiver of consent documentation or complete waiver of informed consent in the CHeRP application. The IRB will review the application and determine if all regulatory requirements are met to grant waiver.

Protocols that collect specimens/data while the participant is a minor that will continue to use the collected specimens/data for research after the participant turns the age of majority.

The IRB recognizes the collection of samples/data from a pediatric cohort remain a valuable resource for ongoing and future research. In many situations sample are collected and stored for indefinite periods of time, although the participant is no longer followed by the researcher or clinically at the hospital. If the samples are anonymous and there is no way to ascertain the identity of the participant the continued use of the samples is not considered human subject research, and no further action is required.

However, if an investigator wishes to maintain the identity of the participant, or a link to the participant, the investigator should request a complete waiver of informed consent for the continued use of the existing samples and data. A waiver of consent will be considered in those cases in which 1) the participant's continuing participation (use of their samples and data) constitutes no more than minimal risk, and 2) the study meets the other requirements for waiver under 45 CFR 46.116(d), including the requirement that the "research could not practicably be carried out without the waiver." Generally, the IRB will deem it impracticable to re-consent an adult who was enrolled as a child if there are no additional research interventions or interactions. Examples include:

- Participants whose parents gave parental permission for their samples to be entered into a biorepository.
- Participants whose parents gave parental permission for their data to be entered into a database.
- Participants enrolled in an interventional trial with parental permission in which all intervention or interaction prescribed by the protocol, including follow-up visits, has concluded prior to participant reaching adulthood.

For repository or registry research, investigators should consider the possible future use of identifiable samples and acknowledge this possibility in the initial protocol application by fully documenting in the appropriate smartform how the research meets all conditions for waiver of consent.

Related Content

- Department of Health and Human Services Regulations
    - 45 CFR 46.117c: Documentation of informed consent

- 45CFR 46.116f: General waiver or alteration of consent

- U.S. Food & Drug Administration CFR – Code of Federal Regulations
  - ◦ 22 CFR56.109c1: Waiver of documentation of informed consent 21
  - ◦ 21 CFR50.25: Elements of informed consent
  - 21CFR50.3: Definition of minimal risk
  - 21CFR56.102i: Definition of minimal risk

- IRB Policies:
  - 6.1 General Information - Informed Consent and Parental Permission
  - 6.2 Special Considerations - Assent and Parental Permission
  - 6.3 Waivers and Alterations of Informed Consent/Parental Permission/Assent Children
  - 6.6 Remote Consent: Process and Documentation

Approval Signatures

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Applicability

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