



PARENTAL PERMISSION

Definitions

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

Parent: A child's biological or adoptive parent. Utah state law specifies that any parent, whether an adult or a minor, may provide consent to health care for his/her child.

Guardian: The DHHS and FDA definition of a guardian is an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

In Utah, a guardian is a person who has qualified as a guardian pursuant to testamentary or court appointment, or by written instrument. Utah state law allows for a guardian to "consent to any health care not prohibited by law" for the guardian's ward and therefore meets the DHHS and FDA definition of guardian. The University of Utah IRB will accept permission from a guardian for a child to participate in research provided that the researcher has established that the guardian has legal authority to do so. The researcher should retain a copy of the documentation that validates an individual's status as a guardian.

Federal Research Regulations

Parental permission is required for children involved in research as outlined in Subpart D (Additional Safeguards for Children Involved in Research). In order for the IRB to determine whether one or both parents must provide permission, the IRB must first determine which approvable category the children's research falls under. The categories are as follows:

- (1) Research involving no greater than minimal risk. ^[45 CFR 46.404; 21 CFR 50.51]
- (2) Research involving interventions or procedures that present greater than minimal risk but offers the prospect of direct benefit or may contribute to the well-being of the individual child. ^[45 CFR 46.405; 21 CFR 50.52]
- (3) Research involving interventions or procedures that present a minor increase over minimal risk and no prospect of direct benefit to individual children, but likely to yield generalizable knowledge about the child's disorder or condition. ^[45 CFR 46.406; 21 CFR 50.53]
- (4) Research not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Research in this category must be reviewed and approved by the Secretary of DHHS or the Commissioner of the FDA. ^[45 CFR 46.407; 21 CFR 50.54]

For more information, please refer to the Investigator Guidance Series: Research Involving Children.

Description

Children may be included in research only if parental permission is obtained in writing from the parents or legal guardian as described in this guidance, except where the IRB has explicitly waived such permission or in cases where the person is no longer considered to be a child (refer to the Investigator Guidance Series: Research Involving Children for the definition of "child").

When permission is to be obtained:

The IRB may find that the permission of one parent is sufficient for research to be conducted in accordance with categories (1) or (2) above.

If research is to be conducted under categories (3) or (4) above, both parents must give their permission unless 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.

When permission is to be waived:

The required elements of informed consent also apply to parental permission. The elements of parental permission may be altered or waived entirely consistent with the provisions for waiver contained in 45 CFR 46.116. Parental permission may not be

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altered or waived for FDA regulated research.

In addition to the provisions for waiver contained in 45 CFR 46.116, a waiver may be granted if the IRB determines that a non-FDA regulated research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the children (e.g. neglected or abused children). This waiver may be granted only when an appropriate mechanism for protecting the children who will participate is substituted and provided the waiver is not inconsistent with federal, state, or local law.

Documentation of Parental Permission:

The requirements for documentation of parental permission are the same as for documentation of informed consent. A waiver of documentation may be granted according to the same conditions as with documentation of informed consent (waivers may not be granted for FDA regulated research).

References & Links

*Additional Protections for the
Inclusion of Children in
Research (OHRP): 45 CFR 46,
Subpart D*

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd>

*Additional Protections for the
Inclusion of Children in
Research (FDA): 21 CFR 50
Parental Permission
Templates*

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50&showFR=1&subpartNode=21:1.0.1.1.19.4>

<http://irb.utah.edu/forms/>