THE UNIVERSITY OF ARIZONA
Research
Innovation & Impact

Research Involving Children

When does Human Research involve Children?

A study is considered to include children when a person who is under the age of 18 (in the state of Arizona) participates in a Human Research study through interaction or intervention with the research team, or collection of a child's identifiable data.

Requirements for Inclusion of Children in Human Research

Investigators must provide protocol specific justification to the IRB upon a request to include children, so that the IRB may make a determination that the enrollment of children in the research is justified.

Definitions (45 CFR §46.402)

- *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.
- *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.
- *Parent* means a child's biological or adoptive parent.
- *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.
- *Homeless minor* is defined as "an individual under the age of eighteen years living apart from his parents and who lacks a fixed and regular nighttime residence or whose primary residence is either a supervised shelter designed to provide temporary accommodations, a halfway house or a place not designed for or ordinarily used for sleeping by humans" (A.R.S. §44-132(C)).

Categories of Research Involving Children

There are four (4) categories of research with children permissible under both the Office for Human Research (OHRP) and the Food and Drug Administration (FDA).

1. No greater than minimal risk to children is presented (45 CFR §46.404/21 CFR §50.51).
2. The research involves greater than minimal risk to subjects with prospect of direct benefit to the individual subjects (45 CFR §46.405/21 CFR §50.52).
3. The research involves greater than minimal risk to children presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject (45 CFR §46.406/21 CFR §50.53).
4. The research does not meet the requirements of any of the above categories, and the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children (45 CFR §46.407/21 CFR §50.54). Projects that fall into this category require review by the federal agency, after consultation with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following opportunity for public review and comment.

The IRB will decide whether the proposed Human Research activities fit within the regulatory categories when the project is reviewed using the justification provided by the investigator.

Research Involving Children

Requirements for Obtaining Minor Assent and Parental Permission (45 CFR §46.408)
Minors are not able to consent to research activities for themselves. Therefore, the parent/legal guardian must give permission to participate in the research and the minor may give assent to participate. The investigator must provide an explanation of how parental permission and minor assent will be obtained. A statement of the proposed method of obtaining parental permission and minor assent along with protocol-specific discussions of the justification of the process must be included for complete IRB review.

Minor Assent
Assent of a minor participating in research is required, however depending on the age, level of maturity, etc. of each child participating in the study different consent/assent permissions may be approved by the IRB. ***The IRB does not require the signature of the minor be obtained.*** In general, the IRB follows these standards:

For children under 8 years of age (0-7 years): Formal assent of the child is not a necessary condition for participating in a research protocol.

- For children 8 - 13 years of age: Many children have limited capacity to understand what participation in a research protocol means. Nonetheless, the IRB expects that investigators provide to children in this age range developmentally appropriate information about the study.
- For children 14 years of age or older: Formal assent is required for participating in a research study.

Parental Permission
Parental permission can be obtained through various mechanisms. Ideally, written parental permission is obtained; however, the IRB may waive the signature requirement or waive parental permission entirely. The investigator is responsible for providing the IRB with appropriate protocol specific justification for the proposed method. If consent for a child to participate in research is obtained from an individual other than biological or adoptive parents, the individual providing such permission must provide written documentation of the legal ability to consent to the child's medical care. A copy of this documentation is to be kept with the consent document in the research records.

Additional information can be found here:

- Adequate provisions are made for soliciting the permission of parents or guardians: see 45 CFR §46.408, 45 CFR §46.116(c), or 45 CFR §46.116(d).
- Adequate provisions are made for soliciting the assent of the children: see 45 CFR §46.408(a), 45 CFR §46.116(c), or 45 CFR §46.116(d).
- If assent will be obtained from at least some of the children, a discussion of how assent will be documented.

What if One Parent is Not Available?
When a study involves children and the research poses greater than minimal risk with no potential for direct benefit (45 CFR §46.406/21 CFR §50.53 or 45 CFR §46.407/21 CFR §50.54), "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". The federal regulations do not provide specific guidance about what constitutes "not reasonably available".

Meeting These Requirements

If the parent who is present can provide documented proof that s/he has sole legal responsibility for the child, permission from that parent is sufficient. Such proof would include a copy of the court order granting sole custody and legal decision-making authority to the parent who is present, including sole legal authority to make medical decisions for the child or a copy of the birth certificate listing "unknown" for the other parent.

"Not reasonably available" does not refer to a situation in which one parent is simply not present during the consenting process. A parent who is "not reasonably available" is one who cannot be contacted by phone, email, mail or fax. Some examples of not reasonably available include:

- The other parent is on active military duty
- The other parent is incarcerated
- The whereabouts of the other parent are unknown

If the other parent is "not available" simply because s/he is at work, traveling, or caring for other children, or even if s/he lives in another city or state, it is the investigators' responsibility to attempt to obtain that parent's permission before enrolling the child in the research.

If the signature of both parents is required, the parent who is present should be asked to provide the other parent's contact information, including address, home and work phone and fax numbers, email address, etc., and a concerted effort should be made to contact the absent parent by phone. Once contacted, a research investigator or other research staff who is eligible to obtain parental permission based on the eIRB *Local Study Team Members* Smartform must be available to provide him or her with all the information required to make a fully informed decision about whether to permit the child's participation. Since written informed consent is required, the approved consent document should be mailed and/or faxed, along with a cover letter or note from the investigator explaining the circumstances. The executed consent can be returned via mail, email, or fax. In the event of a time sensitive consent, the IRB will also permit the parent to take a picture of the signature page with a smart phone and send it via text messaging.

If the absent parent cannot be reached by telephone, email or fax after repeated attempts and no other contact information is available, the investigator may determine that the parent is "not reasonably available." Note that it is very important to retain dated copies of any letters, faxes or emails sent to the absent parent, and a log of all phone calls –attempted and answered – should be kept and documentation entered into the research record. **IMPORTANT NOTE**: If the second parent subsequently responds and refuses to provide permission, the child's participation must end.

The amount of time and effort that investigators should devote to contacting an absent parent will vary depending on the individual circumstances and the constraints posed by the research protocol. However, investigators must have standard operating procedures in place for contacting the absent parent, and all such efforts must be documented in the research record.

Re-consent of Children When they Become Adults

If study procedures (including identifiable data analysis) are ongoing when a child turns the age of majority (18 in Arizona), then the child must be re-consented to continue participation in the study as an

adult; including continued collection of information from their medical record and future use of specimens. The investigator must explain how consent of that now adult participant will be obtained.

Expansion of Categories Involving Children

The University of Arizona has adopted flexible procedures for projects that are not federally funded, supported, or otherwise subject to the federal rules. Projects that meet the requirements of the UA HSPP Guidance, *Flexible Review* may be eligible for increased research categories with children than defined in the federal regulations.

- Requirements for assent and parental permission may be altered or waived for reasons other than those outlined in 45 CFR 46.408. For example, passive parental permission may be appropriate if the school district generally uses this process for normal school activities.
- Research that would otherwise be subject to the requirements at 45 CFR 46.407 may be handled locally, not through the Secretary of HHS.
- Online surveys, in-person focus groups, and/or interviews involving minors, as long as the information is minimal risk may be considered exempt.

Inclusion of Wards in Research (45 CFR §46.409)

Wards are minors who are in the custody of the State. They can be included in minimal risk research (45 CFR §46.404) and research with direct benefit (45 CFR §46.405) with no special requirements.

If wards will be included in research that is greater than minimal risk with no direct benefit (45 CFR §46.406) or research not otherwise approvable (45 CFR §46.407) then the research must be:

- Related to their status as wards; or
- Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards (45 CFR §46.409).

The IRB requires appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s).

Pregnancy Test Results

Researchers are not required to inform the parents of the results of a minor's pregnancy test conducted in the context of research **unless**:

- The research consent form signed by the parents includes an expectation on the part of the researcher to do so, OR
- The researcher is also the minor's medical provider
  - The researcher will need the parent's consent for further medical care provided to the minor.

In all cases, the consent form should include whether, to what extent, and when the research record will be available to the parent/minor.

Mandatory Reporters

Minors (under the age of 18 years who are not married, judicially emancipated or homeless) do not have the capacity to consent to sexual activity, whether with each other or with adults. Researchers who are mandatory reporters (per A.R.S. §13-3620) and who discover that a minor has been engaged in sexual activity or is pregnant has an obligation to report that finding to *Arizona's Division of Child Support Services* if the minor is under the age of 14, or if the minor, of whatever age, has had sexual contact with an adult.

Researchers who are mandatory reporters have no duty to report situations in which minors, who are between the ages of 14-17, engage in sexual activity with each other, unless there is another basis upon which to report suspected abuse.

Under A.R.S. §13-3620, the following persons are required to report alleged child abuse/neglect:

- Any physician, physician's assistant, optometrist, dentist, osteopath, chiropractor, podiatrist, behavioral health professional, nurse, psychologist, counselor or social worker who develops the reasonable belief in the course of treating a patient;
- Any peace officer, member of the clergy, priest or Christian Science practitioner;
- The parent, stepparent or guardian of the minor;
- School personnel or domestic violence victim advocate who develop the reasonable belief in the course of their employment; or
- Any other person who has responsibility for the care or treatment of the minor.

If the researcher falls into one of the above categories, s/he is a mandatory reporter under this statute. If you ever have any questions regarding your obligation to report to *Arizona Division of Child Support Services* (or *Arizona Adult Protective Services*), contact the UA Office of the General Counsel.

Abortion

Absent a judicial order, under Arizona law all un-emancipated minors are required to obtain parental consent before obtaining an abortion (A.R.S. §36-2152). However, that statute contains no requirement that a researcher who is aware of a minor's desire to obtain an abortion inform the parent of that information. Note, however, that mandatory reporters as described above may have a duty to report under A.R.S. §13-3620.

Contraception

At present, Arizona law does not require a researcher to disclose information regarding a minor's decision to use contraceptives, although a UA researcher could not prescribe them to the minor him or herself, even if he or she were the minor's treating physician, without the parent's consent. Note, however, that mandatory reporters as described above may have a duty to report under A.R.S. §13-3620.

Providing Information about Free Reproductive and Sexual Health Services

A UA researcher may be able to provide this information depending upon the scope of the research project and the extent to which the parent consented to the child's participation. If the parents did not consent to the researcher providing that information to the minor (i.e., it is not part of the research project), doing so falls outside of the scope of acceptable communication with the minor. The researchers could provide that information to the parents, or to the minor IF the consent form signed by the parent includes the parent's agreement for such information to be disseminated.