

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 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, 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

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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](#)).

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.

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 Flexible Policy may be eligible for increased research categories with children than defined in the federal regulations.

- a) Requirements for assent and parental permission may be altered or waived for reasons other than those outlined in 45 CFR 46.408.
- b) Research that would otherwise be subject to the requirements at 45 CFR 46.407 may be handled locally, not through the Secretary of HHS.
- c) Online surveys, in-person focus groups, and/or interviews involving minors as long as the information collected does not place the individual at greater than minimal risk (exempt category 8)

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.

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 7 years - Formal assent of the child is not a necessary condition for participating in a research protocol.
- For children 14 years or older - Formal assent is required for participating in a research protocol.
- For children 7 - 13 years - Many of 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.

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.

- 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.

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 discuss how consent of that now adult subject will be obtained.

Newborn blood spots

Research involving newborn blood spots requires the written permission of the parent, whether the specimen is identifiable or not. The *Newborn screening saves lives Reauthorization act of 2014 (Public Law no: 113-240)*, includes the requirement for parental permission and specifically identifies that all newborn dried spots be considered human research regardless of whether the specimens are identifiable.

Inclusion of Wards in research (45 CFR §46.409)

Wards 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](#)) only if such research is:

- (1) Related to their status as wards; or
- (2) 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](#)).

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The IRB shall require 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), or the guardian organization.

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* 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:

- A. 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;
- B. Any peace officer, member of the clergy, priest or Christian Science practitioner;
- C. The parent, stepparent or guardian of the minor;

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- D. School personnel or domestic violence victim advocate who develop the reasonable belief in the course of their employment; or
- E. 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* (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. See [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. §36-3620.

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. §36-3620.

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.