

I. PURPOSE

This standard operating procedure is intended to define which minors do not meet the definition of children for the purposes of adhering to applicable Federal regulations and State law.

The Office of Human Research Protections OHRP has clarified on its website when minors may provide their own informed consent.

“HHS regulations at 45 CFR 46.402(a) define “children” as “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.” If research on a specific treatment involves solely treatments or procedures for which minors can give consent outside the research context (under applicable state and local laws, for example, research on sexually transmitted diseases or pregnancy), such individuals would not meet the definition of children as defined at 45 CFR 46.402(a). Thus, subpart D would not apply to the research and parental permission (or waiver thereof) is not a consideration for these minors. Under these circumstances, minors may provide their own informed consent.”

The law of Pennsylvania does, under certain circumstances, allow a minor (an individual under age eighteen) to consent to treatments or procedures (see Appendix 1). These minors are therefore not “children” under the Federal Regulations. When research is conducted outside of Pennsylvania, the applicable state laws are followed.

In determining who is a “child” or “guardian” when conducting research outside Pennsylvania, applicable state laws will be applied. When the research is conducted at sites outside Pennsylvania where CHOP operates (e.g. in New Jersey), CHOP policies and applicable state law will be followed. When necessary, CHOP Legal Counsel will be consulted.

II. POLICY STATEMENT

Minors who are permitted under state law and hospital policy (**CHOP Policy RI-5-01**) to consent to treatment will be permitted to provide their own consent for research. To participate in the research, the minor must be (1) competent to understand the research, including, but not limited to, the purpose of the research, the nature of the procedures and the risks and benefits and (2) the research procedures must be limited in scope to treatments or procedures for which the minor can consent outside the research context.

III. SCOPE

This policy applies to all research involving treatments or procedures to which minors may consent under state law.

IV. DEFINITIONS

Children: 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 Pennsylvania, persons aged 18 years or older can consent to their own medical, dental and health care. Pennsylvania law also allows persons under the age of 18 years to consent to a wide variety of medical testing and treatment and health care services. [See, CHOP Policy: Consent for Care in Pennsylvania (RI-5-01)].

Minor: A person who has not yet reached the age of majority in the state where the research is conducted.

V. PROCEDURES

A. Determining When a Minor May Consent

The Investigator submits to the IRB the protocol and supplementary material with an explanation of the following:

1. The criteria that will be used to determine whether or not the minor has the legal right to consent (e.g., they are seeking diagnosis, counseling or treatment for a sexually transmitted disease);
2. The procedures to be employed to assure the minor possesses the ability to comprehend all of the elements of informed consent as delineated in **IRB SOP 701** (Sections V.B. and V.C.);

B. Consent for Participation in Research When a Minor Consents for Treatment

The IRB determines the consent requirements when the consent of the minor is considered valid for diagnosis, treatment or counseling.

C. Protections for Minors who are Not Children

1. The IRB does not consider subpart D protections when reviewing research involving minors who are not children. When a determination has been made that a minor is not a “child”, the following are not considered applicable:

- (a) **IRB SOPs 501 and IRB 504**

(b) 45 CFR 46, Subpart D and 21 CFR 50, Subpart D

2. The IRB may apply additional protections for minors who can consent for themselves. The IRB considers the ability of minors to understand the nature of the research, likelihood of direct benefit, the availability of alternatives outside of the research context, the risks and benefits, and other factors that might be of importance prior to approval of the research.

VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.401 - 409

21 CFR 50.50 – 54

OHRP FAQs: Research with Children FAQs - accessed 11/29/2022 at:
<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html>

VII. REFERENCES TO OTHER APPLICABLE SOPS

IRB SOP 501: Vulnerable Subjects

IRB SOP 504: Research Involving Children

CHOP Policy: Consent for Care in Pennsylvania (RI-5-01)

VIII. RESPONSIBILITIES

Title	Responsibility
Chair, CPHS	The Chair or designee is responsible for assuring that research that involves minors who are not children is limited to the condition(s) for which they are receiving treatment.
Investigator	The investigator is responsible for protecting the rights and welfare for minors who are not children. They must ensure that the minor has both the right to consent and the capacity to consent.

IX. ATTACHMENTS

OHRP Research with Children FAQs (<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html>) : If by law a child is able to consent to treatment without parental permission, can they also consent to participate in research related to that treatment?

CHOP Policy: Consent for Care in Pennsylvania (RI-5-01)

Rosado LM: Consent to Treatment and Confidentiality Provisions Affecting Minors in Pennsylvania. 2nd Edition, 2006. Juvenile Law Center, Philadelphia, PA.

Accessed at <https://www.yumpu.com/en/document/read/34217132/consent-to-treatment-and-confidentiality-provisions-affecting-minors>

X. REVISIONS:

- 06-10-2010 Revised for to update formatting to match other SOPs and to correct minor formatting issues. It is also noted that the CHOP Healthcare Network no longer has operations in the State of Delaware.
- 07-08-2010 Revised to reflect AAHRPP's recommendations to include processes when conducting research outside Pennsylvania
- 09-25-2018 Revised to update links and definitions.
- 12-13-2022 Revised to make administrative edits.

XI. APPROVAL

Approval Indicator: Approved by Amy Schwarzhoff and Barbara Engel on 12/13/22
Amy Schwarzhoff, Director, Human Subjects Research and Barbara Engel, Chair, CPHS

XII. APPENDIX

A: Age of Majority and Consent to Medical Treatment*

State	Age/Situation	Statute
Pennsylvania	18	35 PA Stat. §10101
New Jersey	18	NJ Stat. §9:17B-4
Delaware¶	18	1 Del. Code §701

* The only states where the age of majority is greater than 18 are Alabama (19) and Nebraska (19).

B: Emancipation

State	Age/Situation	Statute
Pennsylvania	Married 16+, living independently 16+, orphan Court order	55 Pa. Code 145.62
New Jersey	Married Military service Has child or is pregnant Court order	NJ Stat. §2C:25-19
Delaware	Court order*	No state statute*

* Requires court order

C: Mature Minor Provisions

State	Age/Situation	Statute
Pennsylvania	Married	35 PA Stat. §10101
	Pregnant (or has been pregnant)	35 PA Stat. §10103
	Minor parent (may consent to child's medical treatment)	35 PA Stat. §10102
	High school graduate	35 PA Stat. §10101
New Jersey	Married	NJ Stat. § 9:17A-1
	Pregnant (on own behalf or for child)	NJ Stat. § 9:17A-1
	Minor parent (may consent to child's medical treatment)	NJ Stat. § 9:17A-1
	Military service	NJ Stat. § 55:14L-2
Delaware	Married	13 Del. Code §707
	Pregnant (related to pregnancy)	13 Del. Code §710
	Minor parent (may consent to child's medical treatment)	13 Del. Code §707

D: Minor Consent for Certain Conditions or Disorders

State	Condition	Age	Statute
Pennsylvania	STD testing/treatment	Any minor	35 Pa Stat. Ann. §10103:
	HIV testing/treatment	Any minor	35 Pa Stat. Ann. §521.14a
	Reportable disease	Any minor	35 Pa Stat. Ann. §10103
	Alcohol or drug abuse treatment	Any minor	35 Pa Stat. Ann. §10103
	Blood donation	Any minor	71 Pa Stat. Ann. §1690.112
	Mental health	14+	35 Pa Stat. Ann. §10103 35 Pa Stat. §10101; 55 Pa. Code 5100
New Jersey	STD testing/treatment (parents may be informed without minor consent)	Any minor	NJ Stat. §9:17A-4
	Alcohol or drug abuse treatment	Any minor	NJ Stat. §9:17A-4
	Emergency care when minor has been sexually assaulted	Any minor	NJ Stat. §9:17A-4
	Blood donation	18+	NJ Stat. §9:17A-6
Delaware	STD testing/treatment	12+	13 Del. Code §710
	HIV testing	12+	13 Del. Code §710
	Family planning	12+	13 Del. Code §710
	Alcohol or drug abuse treatment	14+	16 Del. Code §2210
	Blood donation	17+	13 Del. Code §709

Appendix 2: Consent for Treatment in Pennsylvania

In general, in Pennsylvania the age of consent for medical treatment is 18 years. Minors who are independent and living on their own may be declared emancipated minors by the court and may consent for themselves. Minors less than 18 years of age may consent if they have graduated from high school, if they are or have been pregnant, if they are or have been married and competent minors also may consent to treatment for themselves under any of the following circumstances:

- Medical or health services to test for or treat sexually transmitted disease or any other reportable disease (Pa. State Health Regulations Chapter 27, including Subchapter B (Reporting of infections, disease and conditions) and §27.96 (minors));
- Medical or health services to test for HIV;
- Medical or health services to test for reportable diseases to the State including, including measles, mumps, chickenpox, Lyme disease, influenza, pertussis and meningococcal infections. (A long list of diseases and conditions is reportable, 28 Pa. Code 27.21a; see Appendix 2). With respect to whether a minor has the right to consent with respect to a particular disease appearing on this list, the IRB reserves the right to make that determination on an individualized case-by-case basis.);
- Conditions related to drug or alcohol use;
- Confidential testing for pregnancy as well as all medical and health services to treat pregnancy, except for abortion;
- Seeking diagnosis, treatment (including inpatient care) or counseling for mental health issues, provided that the minor is at least 14 years of age; (the parent or legal guardian of a minor may also consent independently to diagnosis, treatment or counseling for mental health issues (including inpatient treatment)).

A minor who has been married or who has borne a child may consent to medical, dental and healthcare services for his or her child.