1. PURPOSE
	1. This policy establishes how to determine which individuals meet the following DHHS and FDA definitions:
		1. Legally Authorized Representative
		2. Children
		3. Guardian
2. REVISIONS FROM PREVIOUS VERSION

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| **Version** | **Date** | **Revisions** |
| R00 | 3/25/14 | Original issue |
| R01 | 12/01/18 | Update to Toolkit 4.0 and 4.1; includes minor administrative changes |
| R01 | 11/25/19 | Annual review, updated logo no changes |
| R01 | 12/16/2020 | Annual review, no changes |
| R01 | 10/19/2021 | Annual review, no changes |
| R01 | 11/15/22 | Annual review, no changes |
| R01 | 11/13/23 | Annual review, no changes |

1. POLICY
	1. Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a legally authorized representative.
		1. In New York, the Family Health Care Decisions Act (FHCDA) establishes a hierarchy of surrogate decision-makers for health care decisions:
			1. § 2994-d. Health care decisions for adult patients by surrogates. 1. Identifying the surrogate. One person from the following list from the class highest in priority when persons in prior classes are not reasonably available, willing, and competent to act, shall be the surrogate for an adult patient who lacks decision-making capacity. However, such person may designate any other person on the list to be surrogate, provided no one in a class higher in priority than the person designated objects:
				1. (a) A guardian authorized to decide about health care pursuant to article eighty-one of the mental hygiene law;
				2. (b) The spouse, if not legally separated from the patient, or the domestic partner;
				3. (c) A son or daughter eighteen years of age or older;
				4. (d) A parent;
				5. (e) A brother or sister eighteen years of age or older;
				6. (f) A close friend.
		2. For research outside New York State, a determination of who is a legally authorized representative is to be made with consultation from legal counsel.
	2. DHHS and FDA’s Subpart D applies to all research involving children.
		1. When research is conducted in New York State, all individuals under the age of 18 are considered children, unless a court grants application for early emancipation (see below for additional info).
			1. Emancipation is when a parent gives up control over their minor child. In New York, a parent must support his or her child until age 21, or until the child becomes ‘emancipated.’ So, the age of emancipation is 21 unless other factors exist that may trigger an early emancipation only upon application to a Court. Under NY law, a grant of public assistance or care may be made to an emancipated minor in his own right if he is otherwise eligible. For this purpose, emancipated minor means a person over 16 years of age who has completed his compulsory education, who is living separate and apart from his family and is not in receipt of or in need of foster care (N.Y. Comp. Codes R. & Regs. tit. 18, § 349.5). Additionally, children who become economically independent of their parents through employment, entry into the military service, or marriage are emancipated, and, if the children withdraw from parental control and supervision, they are considered to be constructively emancipated. For an emancipated child under the age of 18, parental consent is still required to receive routine health care; however, parental consent is not required for services by a physician in an emergency, because of a sexually transmitted disease (STD), for family planning services, for alcohol or mental health treatment, or if the child is pregnant, a parent, or married.
				1. New York Public Health Law section § 2504 gives minors who are married or who have a child the statutory authority to consent to their own health care; however, several NY courts have demonstrated support for the proposition that all emancipated minors may consent to their own health care.
		2. For research outside New York State, a determination of who is a child is to be made with consultation from legal counsel.
	3. Unless the IRB has waived the requirement to obtain consent, when research involves children consent may only be obtained from biologic or adoptive parents or an individual legally authorized to consent on behalf of the child to general medical care[[1]](#footnote-2). Before obtaining permission from an individual who is not a parent, contact legal counsel.
2. RESPONSIBILITIES
	1. Investigators are to follow this policy when obtaining permission for adults unable to consent or children to take part in research.
3. PROCEDURE
	1. None
4. MATERIALS
	1. None
5. REFERENCES
	1. 45 CFR §46.102, 45 CFR §46.402
	2. 21 CFR §50.3
1. This is the DHHS and FDA definition of “guardian” [↑](#footnote-ref-2)