

Age of Consent for Clinical Research

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U.S. federal regulations require adults (or their legally authorized representative) to give informed consent before participating in a clinical trial (21 CFR §50.20). For children, parental permission is required, with assent by the child if the child is capable of giving assent. The National Commission for Protection of Human Subjects of Biomedical and Behavioral Research concluded that children age seven or older can assent to participation in a clinical trial. The institutional review board (IRB) for each study determines whether all children or individual children in the study are capable of assenting (21 CFR §50.55).

U.S. federal law does not define who is a child, or "minor" in legal terms. In the United States, this question is governed by the laws of each state. As children become adults, they gain different rights at different ages, for example:

- Age 14-18: Drive automobile
- Age 15-19: Marry without parental consent (age 15-18 with parental consent)
- Age 18: Enlist in armed forces (age 17 with parental consent)
- Age 18: Vote in government elections
- Age 18-21: Sign legal contracts
- Age 21: Purchase alcoholic beverages

The "age of majority" is the age at which people automatically obtain freedom from parental control and responsibility, i.e., become "legally emancipated." At that time, they gain the legal rights and obligations of an adult, especially the right to sign contracts and the obligation to be bound by those contracts. In a few states, the age of majority may occur at different ages for different rights and obligations. Unless otherwise specified by state law, a person becomes an adult and is able to give informed consent at the age of majority.

In some states, a minor may become legally emancipated before the age of majority. In general, emancipation is complete, but in some cases, early emancipation may be limited to certain purposes, e.g., the right to own property or make decisions about a pregnancy. In some states, for some or all purposes, early emancipation may occur automatically upon marriage or entry into military service. A court may also emancipate a minor upon agreement between the minor and the parents, if the minor is living independently apart from his/her parents, or in cases of parental misconduct. Typically, unless otherwise specified by state law, emancipated minors can give informed consent for clinical trials. However, prior to obtaining informed consent from an emancipated minor, make sure that early emancipation applies to the specific person and circumstances. In some states, case law may provide guidance.

Table 1 sets forth applicable laws for the 50 states and the District of Columbia. The summaries have been interpreted from data on the Internet, which may itself be interpreted. If more than one age of consent applies, the older age governs. Some of the laws are ambiguous or very narrowly defined. For example, some states differentiate between people who have borne a child (Minnesota) and people who are parents (e.g., Kentucky, Maine and Pennsylvania). The legal definition of "parent" may vary by state, e.g., biological or legal parent, or with or without custody. Some states allow minors in military service to give informed consent; others require active military service. Foreign military service may or may not qualify. A close reading of the statutes and a review of the pertinent case law are the only way to be sure of exact legal requirements. Fortunately, most of the

sources provide legal citations. Clinlaw provides extensive statutory text; USLegal and Juvenile Law Center provide citations.

Table 1. Age of Consent by State^{1,2}

Alabama	Age of majority: 19 years. For healthcare: 14 years, graduated from high school, married or pregnant.
Alaska	Age of majority: 18 years. For healthcare: 18 years, married, living apart from parents with financial independence, or if parent cannot be contacted.
Arizona	Age of majority: 18 years. For healthcare: emancipated, married or homeless living apart from parent.
Arkansas	Age of majority: 18 years. For healthcare: 18 years, emancipated, married, or of sufficient intelligence to appreciate the consequences of medical treatment.
California	Age of majority: 18 years. For medical care: 15 years or living apart from parents. For mental healthcare: 12 years.
Colorado	Age of majority: 18 years. For medical treatment: 18 years with decisional capacity, 15 years if living apart from parents, or married.
Connecticut	Age of majority: 18 years. For healthcare: 18 years. For mental healthcare: 14 years (with notice to parents within five days).
Delaware	Age of majority: 18 years. For healthcare: 18 years or married.
District of Columbia	Age of majority: 18 years. For healthcare: 18 years.
Florida	Age of majority: 18 years. For healthcare: 18 years, married, or 16 years with court order.
Georgia	Age of majority: 18 years. For healthcare: 18 years or married. "Mature minor" exception not recognized.
Hawaii	Age of majority: 18 years.
Idaho	Age of majority: 18 years or married. Medical care: any person of ordinary intelligence and awareness to comprehend the need for, nature of, and significant risks contemplated. For release of medical records: 14 years.
Illinois	Age of majority: 18 years. For medical procedure: 18 years, married, parent, pregnant or, if emancipated, 16 years and mature, with demonstrated capacity to manage affairs without parents.
Indiana	Age of majority: 21 years. For healthcare: 18 years, emancipated, married, 14 years and independent from parents, or in military.
Iowa	Age of majority: 18 years or married.
Kansas	Age of majority: 18 years or married and 16 years. For healthcare: 18 years, emancipated through court action, 16 years and married, or 16 years and parent or guardian is not immediately available.
Kentucky	Age of majority: 18 years. For healthcare: married, emancipated or parent. For mental health treatment: 16 years. For minors with disabilities: 21 years.
Louisiana	Age of majority: 18 years. For medical or surgical care or services by a hospital, public clinic or state-licensed physician: a minor who is or believes himself to be afflicted with an illness or disease may execute own consent; the consent of a spouse, parent, guardian or other fiduciary is not necessary.

Maine	Age of Majority: 18 years. For medical care: 18 years, emancipated, living apart from parents or legal guardian for at least 60 days and independent of parental support, is or was legally married, is or was in the U.S. military. For treatment of abuse for drugs/alcohol, emotional/psychological problems, certain hospital care that does not exceed 16 hours, family planning services (if a parent, married or physician's judgment of harm without services), venereal diseases, collection of sexual assault evidence, and social work services: minor can give consent. To give blood: 17 years.
Maryland	Age of majority: 18 years. For medical treatment: married or parent. For mental health treatment: 16 years.
Massachusetts	Age of majority: 18 years. For healthcare: currently or previously married, parent, pregnant, living apart from parents, or in military.
Michigan	Age of majority: 18 years. For mental healthcare: 14 years, excluding use of psychotropic drugs.
Minnesota	Age of majority: 18 years. For healthcare: 18 years, married, has borne a child, or living apart from parents.
Mississippi	Age of majority: 21 years. For healthcare: 18 years, married, emancipated, with sufficient intelligence, or female in connection with pregnancy.
Missouri	Age of majority: 18 years. For healthcare: 18 years, or married or parent.
Montana	Age of majority: 18 years. For healthcare: emancipated, currently or previously married, parent, pregnant, high school graduate, is or living apart from parents and self-supporting.
Nebraska	Age of majority: 19 years or married.
Nevada	Age of majority: 18 years. For medical care: 18 years, emancipated, married, has borne a child, living apart from parents for at least four months, or is in danger of suffering a serious health hazard.
New Hampshire	Age of majority: 18 years. For medical care: 18 years.
New Jersey	Age of majority: 18 years or upon marriage.
New Mexico	Age of majority: 18 years. Medical, dental or psychiatric care: 18 years, married or emancipated; (16 years if married, court-ordered or in the military).
New York	Age of majority: 21 years. For mental healthcare: 18 years or married, parent, emancipated or, if parents are unavailable, 16 years.
North Carolina	Age of majority: 18 years. For healthcare: 18 years or emancipated.
North Dakota	Age of majority: 18 years. Emergency care in a life-threatening situation: minor may consent.
Ohio	Age of majority: 18 years. For healthcare/research subject to regulation by Department of Mental Health: 18 years. Mental health services: 14 years (treatment may be provided without consent of parent or guardian for a limited time, except for use of medication).
Oklahoma	Age of majority: 18 years or married. For healthcare: 18 years, married, has dependent child, emancipated or living apart from and not supported by parent or guardian.
Oregon	Age of majority: 18 years. For healthcare: 15 years. For mental healthcare: 14 years.
Pennsylvania	Age of majority: 18 years (statutory) 21 years (contracts). For healthcare: 18 years, married or parent.
Rhode Island	Age of majority: 18 years. For healthcare: 16 years or married.

South Carolina	Age of majority: 18 years. For health services other than operations (unless operation is deemed essential to the health and life of the child): 16 years. Any married minor or spouse of the married minor can consent to diagnostic, therapeutic and postmortem procedures.
South Dakota	Age of majority: 18 years. For medical care: 18 years or emancipated (16 years). Treatment for mental illness: 18 years, married or emancipated.
Tennessee	Age of majority: 18 years. A minor parent may consent to the medical care of such minor's child.
Texas	Age of majority: 18 years. For medical treatment: 18 years. For mental healthcare research: Minor's assent is required.
Utah	Age of majority: 18 years or married. For healthcare: 18 years.
Vermont	Age of majority: 18.
Virginia	Age of majority: 18 years. For healthcare: Emancipated, married, with a child, active military service, or living apart from parents with their acquiescence. For emergency care where parent is unavailable: 14 years (under age 14, consent not required).
Washington	Age of majority: 18 years. For mental health treatment: 13 years for inpatient or outpatient, and 12 years for treatment by Dept. of Social Services.
West Virginia	Age of majority: 18 years. "Mature minor" and "emancipated minor" are considered to be adults for purpose of healthcare consent.
Wisconsin	Age of majority: 18 years. For mental healthcare: 14 years or older.
Wyoming	Age of majority: 18 years. For healthcare: 18 years, emancipated, married, in active military service, or living apart from parent or guardian and managing own affairs.

References

1. Most data obtained from Clinlaw, Thompson Publishing Group, last accessed 3/26/08 at www.thompson.com/public
2. Age of majority data also obtained from USLegal, Inc. (lawdigest.uslegal.com/minors/age-of-majority), Juvenile Law Center (www.jlc.org/index.php/agerequirements/majority), and FinAid Page, LLC (www.finaid.org/savings/ugma.phtml), all last accessed 3/26/08.

Disclaimers

Information on the Internet may be ambiguous or contradictory, especially with respect to early emancipation of minors. This article is not legal or regulatory advice. Consult your legal or regulatory advisor for legal or regulatory advice.

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