

State Law Regarding Research Involving Humans

Background

This document presents information from Iowa state law on the legal age to consent to treatments or procedures and mandatory reporting requirements.

Definitions

Child: A child by Department of Health and Human Services (DHHS) definition is a person who has 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. By Food and Drug Administration (FDA) definition, a child is a person who has not attained the legal age for consent to treatments or procedures involved in clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted. For purposes of research conducted in the state of Iowa, the term “child” as used in both the DHHS and FDA definitions is analogous to “minor” under Iowa Code and is viewed as “an unmarried person under the age of eighteen years.” (Iowa Code 600A.2(12))

Guardian: A legal guardian in the state of Iowa is defined as a person who is not the parent of a child, but who has been appointed by a court or juvenile court having jurisdiction over the child, to have a permanent self-sustaining relationship with the child and to make important decisions which have a permanent effect on the life and development of that child and to promote the general welfare of that child. A guardian may be a court or a juvenile court.

Iowa State Law Provisions on Mandatory Reporting

Current abuse of a dependent adult

NOTE: See Iowa Code Chapter 235B; see Iowa Code 235E for similar requirements for dependent adults in certain facilities and programs.

Dependent adult is defined in §235B.2(4) as follows:

“Dependent adult” means a person eighteen years of age or older who is unable to protect the person’s own interests or unable to adequately perform or obtain services necessary to meet essential human needs, as a result of a physical or mental condition which requires assistance from another, or as defined by departmental rule.

Dependent adult abuse is defined in §235B.2(5) and includes willful or negligent acts or omissions of a caretaker toward a dependent adult that involve certain physical injuries, sexual offenses, exploitation (physical and financial), or deprivation of minimum necessary care. §235B.2(5) should be consulted to understand the full scope of conduct constituting dependent adult abuse.

Mandatory reporter – Iowa Code §235B.3(2) identifies certain persons who must report suspected dependent adult abuse if that person in the course of employment examines, attends, counsels, or treats a dependent adult who is reasonably believed to have suffered such abuse. Those persons include, but are not limited to, health practitioners, social workers, certified psychologists, outreach persons, and employees of community mental health centers,

supported community living service organizations, sheltered workshops or work activity centers. §235B.3(2) should be consulted for a full list of persons required to report dependent adult abuse.

Permissive reporter – Iowa Code §235B.3(5) states that “any other person who believes a dependent adult has suffered abuse may report the suspected abuse to the department of human services.”

Current child abuse

NOTE: see §232.69

Child is defined in §232.68(1) as “any person under the age of eighteen years.”

Child abuse is defined in §232.68(2) and includes the acts or omissions of a person toward a child that involve certain physical and mental injuries, sexual offenses, failure to provide necessary care, permitting a child to engage in certain illegal activities, the presence of illegal drugs in the child’s body, manufacturing dangerous substances or engaging in bestiality in the child’s presence of the child or cohabiting with a person on the sex offender registry. §232.68(2) should be consulted to understand the full scope of conduct constituting child abuse.

Mandatory reporter is defined in Iowa Code §232.69(1) and includes certain persons who must report suspected child abuse if that person in the course of their professional practice or employment examines, attends, counsels, or treats a child who is reasonably believed to have suffered such abuse. Those persons include, but are not limited to, health practitioners, social workers, certified psychologists, licensed school employees, community college instructors, mental health professionals, and employees and operators of child care centers, head start programs, family development and self-sufficiency grant programs and healthy opportunities for parents to experience success – healthy families Iowa programs. §232.69(1) should be consulted for a full list of persons required to report child abuse. It should also be noted that whether a report must be made depends on whether the person who allegedly engaged in the abuse is responsible for the care of the child and the age of the child. Iowa Code §232.69(1).

Permissive reporter is defined in Iowa Code §232.69(2), which states that “any other person who believes that a child has been abused may make a report” as set forth in the Iowa Code.

Other reporting

The general licensing provisions for a number of health care professions (see Iowa Code chapter 147) require reporting a gunshot, stab wound, certain burns, or “other serious bodily injury” that is being treated by the person licensed under that chapter and that appears to have been received in connection with the commission of a criminal offense.

Reportable Conditions

NOTE: see §641—1.1-1.3 (139A)

Additional state laws provide for the notification and surveillance of reportable communicable and infectious diseases, poisoning and conditions. Of note, in Iowa these include cancer and birth defects with reporting to the State Health Registry located at the University of Iowa. When it is possible that identification of a reportable condition may occur in the research setting, investigators must include this information and the reporting requirements in the informed consent document.

Intent to Hurt Self or Others

Common law (not statute) generally requires that one report a demonstration of a current intent to hurt oneself or others.

Human Stem Cell Research and Cloning

NOTE: see Iowa Code 707C

A person shall not intentionally or knowingly do any of the following:

- Perform or attempt to perform reproductive cloning
- Participate in performing, or in an attempt to perform, human reproductive cloning
- Transfer or receive, in whole or in part, for the purpose of shipping, receiving, or importing, the product of human reproductive cloning

Applicability of the Laws of Other States

In cases of human subjects research under the authority of the ISU IRB(s) but conducted outside of the state of Iowa, the ISU IRB confers with the ISU Office of University Counsel regarding the applicability of other state, national, or international laws to the particular project. These cases are identified in the pre-review process of an application to the IRB and the advice of counsel is sought prior to the approval of the study. In general, the ISU IRB will apply the law of the state in which the research is being conducted. For example, if a project involves children and one of the recruitment sites is in a bordering state, the laws of the bordering state will be evaluated as to which individuals meet the DHHS and FDA definition of “children” at that site.

Document History

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