100 GD.7 Select State and Federal Laws and Regulations Applicable to Human Research

Overview

The Common Rule and FDA regulations do not pre-empt other state and federal laws relating to the conduct of human research or to other aspects of the research itself. This guidance document describes related federal and state laws which may have bearing on the conduct of human research at Yale. The descriptions provided below are intended to assist investigators and the IRB in determining when such laws and regulations may apply and are not intended to provide the detailed information required to ensure compliance with these laws/regulations. Investigators and IRB staff should consult the applicable regulation for additional information and/or counsel. Investigators are advised also to seek additional information when conducting research outside Connecticut as there are likely to be state or international laws which would apply.

45 CFR §46 Common Rule

45 CFR 46 describes the requirements for IRB review and approval of research involving human subjects. Subpart A of 45 CFR 46 is known as the Common Rule as it has been adopted by the following federal agencies:

Department of Health and Human Services (45 CFR §46)

Department of Agriculture (7 CFR §1C)
Department of Energy (10 CFR §745)

National Aeronautics and Space Administration (14 CFR §1230)
Department of Commerce (15 CFR §27)

Consumer Product Safety Commission (16 §CFR 1028)

International Development Cooperation Agency & Agency for International Development (22 CFR §225)

Department of Housing and Urban Development (24 CFR §60)

Department of Justice (28 CFR §46)

Department of Defense (32 CFR §219)

Department of Education (34 CFR §97)

Department of Veterans Affairs (38 CFR §16)

Environmental Protection Agency (40 CFR §26)

National Science Foundation (45 CFR §690)

Department of Transportation (49 CFR §11)

Subparts B (pregnant women), C (prisoners) and D (children) have been adopted only by DHHS.

21 CFR §50 FDA Regulations on Informed Consent

Informed consent requirements for FDA regulated research are described in 21 CFR §50 and differ slightly from the requirements of the Common Rule. Most notably, FDA does not have provisions for waiver of consent or waiver of consent documentation, except in emergency research (21 CFR §50.24).

21 CFR §56 FDA Regulations on IRB Review

21CFR56 describes the FDA requirements related to IRB review and approval of research involving human subjects.

21 CFR §312 FDA Regulations on New Drug Applications

This part contains procedures and requirements governing the use of investigational new drugs, including procedures and requirements for the submission to, and review by, the Food and Drug Administration of investigational new drug applications (IND's).

21 CFR §600 FDA Regulations on Biological Products

Requirements related to the handling of and research involving biological products.

21 CFR §812 FDA Regulations on Investigational Devices

This part provides procedures for the conduct of clinical investigations of devices.

45 CFR §164 HIPAA Privacy and Security Rules

HIPAA applies to research involving protected health information (PHI). PHI includes identifiable information related to current or future health, healthcare or payment for health care. Research creating or accessing PHI is required to conform to HIPAA's requirements related to privacy and security of this information. Additional information on research use of PHI is available at www.hipaa.yale.edu .

34 CFR §98 Protection of Pupil Rights Amendment (PPRA)

PPRA applies to educational institutions receiving funds from the US Department of Education and requires parental consent for administration of any surveys or questionnaires involving 1) political affiliations; 2) mental and psychological problems; 3) sex behavior and attitudes; 4) illegal, anti-social self-incriminating and demeaning behavior; 5) critical appraisals of other individuals with whom the student has close family relationships; 6) legally recognized privileged and analogous relationships; or 7) income, other than that required to determine eligibility for participation in a program or for receiving financial assistance.

34 CFR §99 Family Educational Rights and Privacy Act (FERPA)

FERPA provides protection of academic records and is applicable to educational institutions receiving funding from the US Department of Education. Generally speaking, FERPA requires student or legally authorized representative written authorization for any disclosure of identified student records. Researchers may have access only to de-identified records, with or without a code applied by the educational institution without such written authorization.

CGSA § 1-56r Decision Making Designations

This section allows an individual to designate another person to act on their behalf in certain contexts. In particular, this section allows health care decisions to be made by a personal representative as described in 19a-576.

CGSA § 17a-101 et seq. Child Abuse Reporting

Connecticut General Statutes describe who is mandated to report child abuse as well as the content of such reports. Additional information is available for the Department of Children and Families at http://www.ct.gov/dcf/cwp/view.asp?a=2556&q=314388

CGSA § 17b-450 et seq. Elder Abuse Reporting

Connecticut mandates that certain individuals report suspected elder abuse as described in this section. Additional information is available at http://www.ct.gov/dss/cwp/view.asp?a=2353&q=305232

CGSA § 19a-583 et seq. Confidentiality of AIDS-Related Information

AIDS-related information is subject to mandated reporting requirements and its disclosure is protected such that patient authorization is required in cases other than those mandated under state law.

CGSA § 52-146 et seq. Confidential Communications

Connecticut limits disclosure of certain communications including doctor-patient, psychiatrist-patient, etc. as described in Chapter 899.

CGSA § -42-297 Sweepstakes Requirements

Connecticut state law regarding gaming allows “sweepstakes” to be conducted without a license or permit but requires certain information to be disclosed in any advertising, including word of mouth advertising. In particular, such advertisements must include 1) the value of the prize, 2) odds of winning, 3) any restrictions on winning, and 4) name of sweepstakes sponsor. Note that “raffles” and “lotteries” require a permit under state law.

CGSA §46b-150b et seq, Emancipation Statutes

Any minor who has reached his/her sixteenth birthday and is residing in this state, or any parent or guardian of such minor, may petition the superior court for juvenile matters or the probate court for the district in which either the minor or the parents or guardian of such minor resides for a determination that the minor named in the petition be emancipated. These statutes set forth the requirements for a minor to be granted an order of emancipation, describe the effect of emancipation, and allow for emancipation under common law.

CGSA §17a-238 Rights of persons under supervision of Commissioner of Mental Retardation

Connecticut state law requires that each person placed or treated under the direction of the Commissioner of Mental Retardation in any public or private facility be protected from harm and receive humane and dignified treatment which is adequate for such person's needs and for the development of such person's full potential at all times, with full respect for such person's personal dignity and right to privacy consistent with such person's treatment plan as determined by the commissioner. The involvement of state-protected individuals in human subjects research requires the Commissioner’s oversight and monitoring prior to its being undertaken.

CGSA §19a-36-A1 et seq. Reportable disease and laboratory findings

Diseases and results of laboratory tests that are mandated to be reported under state law are described herein.

DoDI 3216.02 Department of Defense Instruction and its references

Regulations that govern human subjects protections for research conducted by or supported by the Department of Defense. Yale maintains an executed DoD Addendum with the Department of Defense, assuring compliance with these regulations.