UNIVERSITY OF CALIFORNIA
SANTA CRUZ
Institutional Review Board

# Policy on State and Local Laws

Effective date: 9/20/2019

## I. Background

UC Santa Cruz must follow any state and local laws pertaining to human subjects research in addition to federal regulations and UC and UCSC policies and procedures. This policy outlines the pertinent additional laws that affect human subjects research.

IRB members are to be aware of the state law that may be relevant to the conduct of human subject research and to apply to the consideration of whether research meets the criteria for approval. They must also consider whether disclosure of the implications of the law is required for legally effective informed consent.

The IRB will apply the most stringent law when federal law and other applicable laws apply. However, UC legal counsel may provide assistance when applying state and local laws that govern research involving human subjects, including when the research is conducted outside State of California in conjunction with federal regulations.

## II. Definitions

a. *Clone:* the practice of creating or attempting to create a human being by transferring the nucleus from a human cell from whatever source into a human or nonhuman egg cell from which the nucleus has been removed for the purpose of, or to implant, the resulting product to initiate a pregnancy that could result in the birth of a human being.
b. *Human reproductive cloning*: the creation of a human fetus that is substantially genetically identical to a previously born human being.
c. *Medical experiment:* (a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, as defined in California Health and Safety Code (Section 24170-24179.5) Section 109920 or 109925, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject; (b) The investigational use of a drug or device as provided in Sections 111590 and 111595; and (c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.

## III. Illegal Drug/Controlled Substance Research

a. California requires proposed research projects involving certain opioid, stimulant, and hallucinogenic drugs classified as Schedule I and Schedule II controlled substances to be pre-reviewed and authorized by the Research Advisory Panel of California in the Attorney General's Office.
    i. Investigators must submit applications to the panel for research projects involving: any Schedule I controlled substance; human research using any Schedule I or Schedule II controlled substance; or research for the treatment of drug abuse using any drug, scheduled or not.

## IV. Medical Experimentation

a. The Medical Experimentation Act requires that individuals be provided the Subject's Bill of Rights prior to participation in a medical experiment. See above definition of a medical experiment.
b. The California Experimental Subject's Bill of Rights is a stand-alone document and must be provided in addition to the IRB approved Informed Consent document.

## V. Surrogate Decision Maker

a. For medical experiments that relate to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of research participants, investigator may obtain surrogate informed consent if the following requirements apply:
    i. For purposes of obtaining informed consent required for medical experiments in a nonemergency room environment, if a person is unable to consent and does not express dissent or resistance to participation, surrogate informed consent may be obtained from a surrogate decision maker with reasonable knowledge of the subject, who shall include any of the following persons, in the following descending order of priority:
        1. The person's agent pursuant to an advance health care directive;
        2. The conservator or guardian of the person having the authority to make health care decisions for the person;
        3. The spouse of the person;
        4. An individual as defined in Section 297 of the California Family Code;
        5. An adult son or daughter of the person;
        6. A custodial parent of the person;
        7. Any adult brother or sister of the person;
        8. Any adult grandchild of the person;

9. An available adult relative with the closest degree of kinship to the person.

b. When there are two or more available persons who may give surrogate informed consent and who are in the same order of priority, if any of those persons expresses dissent as to the participation of the person in the medical experiment, consent shall not be considered as having been given. When there are two or more available persons who are in different orders of priority, refusal to consent by a person who is a higher priority surrogate shall not be superseded by the consent of a person who is a lower priority surrogate.
c. For purposes of obtaining informed consent required for medical experiments in an emergency room environment, if a person is unable to consent and does not express dissent or resistance to participation, surrogate informed consent may be obtained from a surrogate decision maker who is any of the following persons:
    1. The person's agent pursuant to an advance health care directive;
    2. The conservator or guardian of the person having the authority to make healthcare decisions for the person;
    3. The spouse of the person;
    4. An individual defined in Section 297 of the California Family Code;
    5. An adult son or daughter of the person;
    6. A custodial parent of the person;
    7. Any adult brother or sister of the person.
d. When there are two or more available persons described above, refusal to consent by one person shall not be superseded by any other of those persons. Surrogate decision makers shall exercise substituted judgment, and base decisions about participation in accordance with the person's individual health care instructions, if any, and other wishes to the extent known to the surrogate decision maker. Otherwise, the surrogate decision maker shall make the decision in accordance with the person's best interests. In determining the person's best interests, the decision maker shall consider the person's personal values and their best estimation of what the person would have chosen if they were capable of making the decision.
e. The IRB must approve the involvement of a surrogate decision maker in research involving the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of research participants.

## VI. Human Cloning

No person shall clone a human being or engage in human reproductive cloning; no person shall purchase or sell an ovum, zygote, embryo, or fetus for the purpose of cloning a human being. The department may adopt, interpret, and

update regulations, as necessary, for purposes of more precisely defining the procedures that constitute human reproductive cloning. See cloning definitions above.

**VII. Mandatory Reporting**

Per UC Office of the President, a mandated reporter is a University Employee, Official, or Volunteer who is required under the Child Abuse and Neglect Reporting Act due to their licensure or profession, or otherwise by virtue of their University position or activities (e.g., an employee or administrator whose duties bring the administrator or employee into contact with children on a regular basis, or who supervises those whose duties bring the administrator or employee into contact with children on a regular basis, as to child abuse or neglect occurring on that institution's premises or at an official activity of, or program conducted by, the institution, or an athletic coach, including, but not limited to, an assistant coach or a graduate assistant involved in coaching, at public or private postsecondary institutions, to report child abuse and neglect to specified authorities). An “Employee” is any individual who has a relationship with the University for which compensation is paid through the University’s payroll system. An “Official” (referred to as an “administrator” in CANRA) is any individual who, other than as an Employee (for example, as an independent contractor or a volunteer) supervises Employees performing official University business or directs or manages official University programs. A “Volunteer” is an individual providing a service to the University under the supervision of the University (other than as an Employee, Official, or Student), without receipt of monetary compensation. “Without-compensation” academic personnel are “volunteers”.

**VIII. Sexually Transmitted Diseases**

a. Every physician or other person who makes a diagnosis of, treats or prescribes for a case of sexually transmitted disease designated as reportable is required to report the case immediately to the Department of Health. Reports include the name, address, age, sex, race, stage of disease, treatment, and control of the disease.
b. Children 13 years of age or younger must be reported to the Department of Health.
c. Reporting is required for children where sexual abuse is suspected regardless of injury to the Department of Health. The Department of Health will notify the Department of Children’s Services.

**IX. Confidentiality of Research Records involving Acquired Immune Deficiency Syndrome (AIDS) Patients**

a. The informed consent of each research subject with Acquired Immune Deficiency Syndrome (AIDS) must be obtained in accordance with UCSC IRB policies and procedures prior to their participation per state law, separate from federal regulations.
b. Each research subject shall be provided with a written explanation, in language understandable to the research subject, of the rights and responsibilities of investigators and research subjects set forth in this policy.
c. As used in this policy, “confidential research records” shall include any data in a personally identifying form, including name, social security number, address, employer, or other information that could, directly or indirectly, in part or in sum, lead to the identification of the individual research subject, developed or acquired by any person in the course of conducting research or a research study relating to AIDS.
d. As used in this policy, “disclosed” means to disclose, release, transfer, disseminate, or otherwise communicate all or any part of any confidential research record orally, in writing, or by electronic means to any person or entity, or to provide the means for obtaining the records.
e. Confidential research records developed or acquired by any person in the course of conducting research, or a research study relating to AIDS, shall be confidential and shall not be disclosed by any person in possession of the research record, nor shall these records be discoverable, nor shall any person produce any confidential research record except in the following situations:
    i. Confidential research records may be disclosed in accordance with the prior written consent of the research subject to whom the confidential research records relate, but only to the extent, under the circumstances, to the persons and for the purposes the written consent authorizes. Any disclosure made pursuant to such prior written consent shall contain the following statement:
    ii. This information has been disclosed to you from a confidential research record the confidentiality of which is protected by state law and any further disclosure of it without specific prior written consent of the person to whom it pertains is prohibited. Violation of these confidentiality guarantees may subject you to civil or criminal liabilities
f. Confidential research records may be disclosed without prior written consent of the research subject to whom the confidential research records relate in the following circumstances:
    i. To medical personnel to the extent it is necessary to meet a bona fide medical emergency of a research subject; and
    ii. To the California Department of Health Services for the conduct of a special investigation of the sources of morbidity and mortality and the effects of localities, employments, conditions and circumstances on the

public health and for other duties as may be required in procuring information for state and federal agencies regarding the effects of those conditions on the public health.

g. The content of any confidential research record shall be disclosed to the research subject, the legal representative of the research subject if the research subject is a child, or the personal representative of a deceased research subject to whom the record pertains within 30 days after a written request is made for such records by the research subject, the legal representative.
h. Nothing in this policy shall preclude the disclosure of information in order to further research efforts, including, but not limited to, the publication, dissemination, or sharing of raw data, statistics, or case studies, so long as no confidential research records concerning any research subject are disclosed.

## X. Use of State Death Data Records

State of California death data files containing personal identifying information may be released to persons expressing a valid scientific interest, as determined by the appropriate committee constituted for the protection of human subjects that is approved by the DHHS and has a general assurance pursuant to 45 CFR Part 46.

## XI. Confidentiality of Records involving Hereditary Disorders

a. All testing results and personal information from hereditary disorders programs obtained from any individual, or from specimens from any individual, shall be held confidential and be considered a confidential medical record except for information that the individual, parent, or guardian consents to be released, provided that the individual is first fully informed of the scope of the information requested to be released, of all of the risks, benefits, and purposes for the release, and of the identity of those to whom the information will be released or made available.
b. Except for data compiled without reference to the identity of any individual, and except for research purposes, provided that pursuant to 45 CFR Part 46 the research has first been reviewed and approved by an institutional review board that certifies the approval to the custodian of the information and further certifies that in its judgment the information is of such potentially substantial public health value that modification of the requirement for legally effective prior informed consent of the individual is ethically justifiable.

## XII. Assisted Oocyte Production

Prior to obtaining informed consent from a subject for assisted oocyte production or any alternative method of ovarian retrieval on a subject for the purpose of procuring oocytes for research or the development of medical therapies, a physician and surgeon shall provide to the subject a standardized medically accurate written summary of health and consumer issues associated with AOP and any alternative methods of oocyte retrieval.

## XIII. Prisoners in Biomedical and Behavioral Research

a. No biomedical research shall be conducted on any prisoner in California. A physician who provides medical care to prisoners may provide a patient who is a prisoner with a drug or treatment available only through a treatment protocol or treatment IND if the physician determines that access to that drug is in the best medical interest of the patient, and the patient has given informed consent in accordance with Penal Code (Section 3500 – 3523) Section 3521.
b. Behavioral research shall be limited to studies of the possible causes, effects and processes of incarceration and studies of prisons as institutional structures, or of prisoners as incarcerated persons, which present minimal or no risk and no more than mere inconvenience to the subjects of the research. Any physical or mental injury of a prisoner resulting from the participation in behavioral research, regardless of how the injury occurred, shall be treated promptly and on a continuing basis until the injury is cured. Informed consent shall not be required for participation in behavioral research when the California Department of Corrections determines that it would be unnecessary or significantly inhibit the conduct of such research. In the absence of such determination, informed consent shall be required for participation in behavioral research.
c. In any behavioral research, the California Department of Corrections must determine the following:
    i. That the risks to the prisoners consenting to research are outweighed by the sum of benefits to the prisoners and the importance of the knowledge to be gained;
    ii. That the rights and welfare of the prisoners are adequately protected, including the security of any confidential personal information;
    iii. That the procedures for selection of prisoners are equitable and that subjects are not unjustly deprived of the opportunity to participate;
    iv. That adequate provisions have been made for compensating research related injury;

v. That the rate of remuneration is comparable to that received by non-prisoner volunteers in similar research;
vi. That the conduct of the activity will be reviewed at timely intervals; and
vii. That legally effective informed consent will be obtained by adequate and appropriate methods.

d. A prisoner shall be deemed to have given their informed consent only if each of the following conditions has been satisfied:
    i. Consent is given without duress, coercion, fraud, or undue influence;
    ii. The prisoner is informed in writing of the potential risks or benefits, or both, of the proposed research;
    iii. The prisoner is informed orally and in writing in the language in which the subject is fluent of each of the following:
        1. An explanation of the biomedical or behavioral research procedures to be followed and their purposes, including identification of any procedures which are experimental;
        2. A description of all known attendant discomfort and risks reasonably to be expected;
        3. A disclosure of any appropriate alternative biomedical or behavioral research procedures that might be advantageous for the subject;
        4. The nature of the information sought to be gained by the experiment;
        5. The expected recovery time of the subject after completion of the experiment;
        6. An offer to answer any inquiries concerning the applicable biomedical or behavioral research procedures; and
        7. An instruction that the person is free to withdraw their consent and to discontinue participation in the research at any time without prejudice to the subject.

e. At the time the prisoner is informed in writing of the potential risks or benefits, or both, of the proposed research, they must also be given information as to the amount of remuneration they will receive for the research, and the manner in which the prisoner may obtain prompt treatment for any research-related injuries. The amount of remuneration must be comparable to that which is paid to non-prisoner volunteers in similar research.

## XIV. Elder Abuse and Dependent Adult Civil Protection Act

a. A physician investigator, while conducting human subjects research, who discovers or reasonably suspects that a study subject: (1) Has been the

victim of a wound or other physical injury caused by a firearm (either self-inflicted or inflicted by another); or (2) Is suffering from any wound or other physical injury inflicted upon the study subject where the injury is the result of assaultive or abusive conduct, has a legal obligation to make two reports to the local law enforcement agency.

b. The first report must be made immediately by telephone or as soon as practically possible. The second report must be made in writing within two working days on a "Suspicious Injury Report" Form published by California's Office of Emergency Services (Form OES-920). Both the oral and written report must include the name of the injured person, if known; the injured person's whereabouts; the character and extent of the person's injuries; and the identity of any person the injured person alleges inflicted the assault or abusive conduct.
c. In the event a physician investigator becomes aware of or reasonably suspects that a study subject has been the victim of any of the injuries set forth in this policy, the physician investigator should immediately notify the IRB to ensure that the proper reports are made.
d. When the investigator is not a physician or “mandated reporter,” the investigator can make a voluntary report to the appropriate agency. If such information is discovered unexpectedly (i.e., not anticipated given the study design or subject population), the Investigator should seek advice from his/her department chair or dean or from the Office of Research Compliance Administration or designee, who may refer the question to UC Legal Counsel.
e. If an Investigator is planning a study that is designed or likely to elicit information about sexual or physical abuse, or neglect of an elder or dependent adult, the IRB application and consent/assent forms must indicate how discovery of such information will be managed.

**XV.** **Committee for the Protection of Human Subjects** of the California Health and Human Services Agency (CHHSA) and California Information Practices Act, Civil Code, Section 1798.24 (SB 13)

a. For identifiable UC data sent to Data Repositories under California Civil Code 1798.24, the Principal Investigator is responsible for complying with all applicable federal and state laws regarding the confidentiality of information (such as the California Information Practices Act).
b. Research funded by CHHSA or any of its departments must be sent to the CHHSA Committee for the Protection of Human Subjects for review. The CPHS serves as the institutional review board (IRB) for the California Health and Human Services Agency.

c. The CHHSA CPHS must also review when identifiable data held by the University of California (UC) will be released or when identifiable data will be received from another state agency, as these situations both fall under the terms of the California Civil Code 1798.24, as amended in 2005. Unless subjects have provided informed consent no more than 30 days before the disclosure, or in the time limit specified in the informed consent document, or another exception exists as outlined in the law, the release of identifiable information to or by UC requires review by the Committee for the Protection of Human Subjects of the California Health and Human Services Agency.

## XVI. Mandatory Reporting of Child Abuse or Neglect

a. The intent and purpose of the Child Abuse and Neglect Reporting Act is to protect children from abuse and neglect. A “Mandated reporter" (as defined in California Penal Code Section 11165.7) is required to report known or reasonably suspected child abuse or neglect immediately. The report should include (to the extent known) the name, address, and age of the child, the name address of the person responsible for the care of the child, and the facts requiring the report to: any Police Department; any Sheriff Department; county Welfare Department; or county Probation Department, if designated by county to receive mandated reports.
b. Ethical and legal obligations apply whenever child abuse or neglect is suspected. Investigators should be aware that, in most instances, the same reporting expectations pertain in research settings as in clinical settings. UCSC investigators may fall into categories that constitute mandated reporters.
c. When the mandated reporter status is not clear, the investigator can make a voluntary report to the appropriate agency.
d. If an Investigator is planning a study that is designed or likely to elicit information about sexual or physical abuse of a child, the IRB application and consent/assent forms must indicate how discovery of such information will be managed.
e. If such information is discovered unexpectedly (i.e., not anticipated given the study design or subject population), the Investigator should seek advice from his/her department chair or dean or from the Director of ORCA or their designee, who may refer the question to UC Legal Counsel.

## XVII. Parental Consent for Children to Participate in Research

For K-12 students - tests, questionnaires, surveys, or examinations containing any questions about the pupil's or the pupil’s family’s personal beliefs or practices

in sex, family life, morality, and religion require written parental consent (permission).

## XVIII. When Minors May Consent as Adults, Including Emancipated Minors, under California Law

a. In accordance with California law, there are certain situations in which the IRB permits minors to consent to participation in research as adults without parental permission. If the Investigator and/or the IRB is not familiar with such laws, they may need to consult with the UCOP Legal Counsel Compliance about enrolling a minor in a research study without parental permission to ensure that the applicable legal requirements are met.
b. The IRB interprets California law relating to emancipated minors as authorizing an emancipated minor to give consent to participation in any type of research, even if the research does not involve treatment. To be emancipated, the minor must meet one of the following requirements set out in California Family Code § 7002: (1) Have entered into a valid marriage, whether or not it has been dissolved; (2) Be on active duty with the armed forces; or (3) Have received a court declaration of emancipation.
c. Research That Does Involve Treatment -All minors who are “emancipated” under California Family Code § 7002 may consent to participation in a research study that involves medical treatment. In addition, the IRB interprets a variety of other California statutes as authorizing certain non-emancipated minors to consent to research involving specific types of medical treatment, including: outpatient mental health treatment; prevention/treatment of pregnancy; medical care related to diagnosis/treatment of a communicable reportable disease or condition; care for rape; care for sexual assault; care for alcohol or drug abuse.
d. California Family Code Section 6922 Chapter 12 (20 of 23) the IRB regards minors “living separate and apart” within the meaning to consent to research involving medical or dental care if: (1) The minor is age 15 or older; (2) The minor is living separately and apart from their parents or guardian with or without the consent of a parent or guardian and regardless of the duration of the separate residence; and (3) The minor is managing their own financial affairs, regardless of the source of the minor's income. The IRB requires that any investigator that is not familiar with these laws and proposes to enroll a minor without parental permission to contact the IRB staff for further guidance.

## XIX. References

a. UC Irvine Policy Applicable State Laws and Regulations

b. University of California Policy Reporting Child Abuse and Neglect
c. California Health and Safety Code - Section 11480-11481
d. California Health and Safety Code - Section 24170-24179.5
e. California Health and Safety Code - Sections 24185-24187
f. California Health and Safety Code - Section 102231 – 102232
g. California Health and Safety Code - Section 111515-111545
h. California Health and Safety Code - Section 120500-120605
i. California Health and Safety Code - Section 121075-121125
j. California Health and Safety Code - Sections 123420-123450
k. California Health and Safety Code - Sections 124320-125300
l. California Health and Safety Code - Section 124980
m. California Health and Safety Code - Sections 125330-125355
n. California Penal Code - Section 3500 – 3520
o. California Penal Code - Section 11164-11174.3
p. California Education Code - Section 51513
q. California Welfare and Institutions Code - Section 15601
r. Committee for the Protection of Human Subjects of the California Health and Human Services Agency (CHHSA) and California Information Practices Act, Civil Code, Section 1798.24 (SB 13)