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Policy:
In addition to federal regulations 45 CFR 46 and Food and Drug Administration (FDA) regulations 21 CFR 50 and 21 CFR 56 and other applicable DHHS regulations, it is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) that Investigators follow state and local laws. The following California state laws are relevant to human subjects research.

CALIFORNIA HEALTH AND SAFETY CODE

I. Illegal Drug/Controlled Substance Research - Research Advisory Panel of California, CA Health and Safety Code (Section 11480-11481)
   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.
   B. Investigators must submit applications to the panel for research projects involving:
      1. Any Schedule I controlled substance;
      2. Human research using any Schedule I or Schedule II controlled substance; or
      3. Research for the treatment of drug abuse using any drug, scheduled or not.

II. Human Experimentation - California Health and Safety Code (Section 24170-24179.5)
The California Protection of Human Subjects in Medical Experimentation Act
   A. The Medical Experimentation Act requires that individuals be provided the Subject's Bill of Rights as part of the informed consent process prior to participation in a medical experiment.
   B. A "medical experiment" is defined as: (a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, as defined in 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.
   C. The Subject's Bill of Rights is a separate document and must be provided in addition to the Informed Consent document approved by the IRB.
   D. To view the UCI Experimental Subjects Bill of Rights go to: http://www.research.uci.edu/forms/docs/irb-consent-forms/3_experimental-subjects-b-o-r.doc

III. Surrogate Decision Maker – California Health and Safety Code (Section 24178) (See Procedure 30C and Policy 39 for more information)
   A. With respect to 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:
   B. 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.

C. 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.

D. 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.

E. 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.

F. 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.

IV. Human Cloning – California Health and Safety Code (Sections 24185-24187)

A. 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.

1. "Clone" means 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.

2. "Human reproductive cloning" means the creation of a human fetus that is substantially genetically identical to a previously born 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.

V. Experimental Use of Drugs and Consent for Minors Provision - California Health and Safety Code (Section 111515-111545)

A. Under the California Health and Safety Code, an "experimental drug" means any drug or device intended solely for investigational use by investigators qualified by scientific training and experience to investigate the safety and effectiveness of drugs or devices. A drug or device is an "experimental drug" only if the drug or device complies with all of the provisions in federal law relating to exemption from investigational new drug requirements for drugs 21 U.S.C. Section 355(i), and all of the following additional requirements are met:

1. The investigator must submit to the California Department of Health Services (hereinafter "the Department"), before any clinical testing of a drug or device, reports by the manufacturer or sponsor of the investigation of the drug or device of preclinical tests, including tests on animals, of the drug or device adequate to justify the proposed clinical testing.
2. The manufacturer or the sponsor of the investigation of a drug or device proposed to be distributed to investigators for clinical testing must obtain a signed, notarized agreement from each of the investigators involved that patients to whom the drug or device is administered will be under the investigator's personal supervision, or under the supervision of investigators responsible to them, and that they will not supply the drug or device to any other investigator, or to clinics, for administration to human beings.
3. The manufacturer or the sponsor of the investigation of a drug or device must establish and maintain records and make reports to the Department of data, including, but not limited to, analytical reports by investigators obtained as a result of the investigational use of the drug or device as the Department finds will enable it to evaluate the safety and effectiveness of the drug or device in the event of the filing of an investigational new drug (IND) or device application to the Department.
4. The manufacturer or sponsor of the investigation must require investigators using the drugs or devices for investigational purposes to certify to the manufacturer that they will comply with the requirements of California Health and Safety Code Sections 111515-111545.
5. The investigator(s), manufacturer(s), or sponsor(s) shall additionally comply with any other conditions the Department may adopt as regulations necessary for the protection of the public health, even if these additional regulations provide protections beyond those required under federal law.

B. An "experimental drug" *does not* include any investigational new drug for which a investigator has submitted an IND application and received approval of that application from either the FDA (if the investigational new drug application was submitted to the FDA) or the Department (if the investigational new drug application was submitted to the Department).

C. Prior to prescribing or administering an experimental drug, the investigator must obtain the informed consent of all subjects to whom they intend to administer the experimental drug.

D. If the study subject is a child, the investigator must obtain informed consent from the parent or guardian of the subject as well as the subject, so long as the subject is seven years of age or older. Informed consent by, and on behalf of, a child shall only be for the prescribing or administering of an experimental drug that is related to maintaining or improving the health of the subject or related to obtaining information about a pathological condition of the subject.

E. Informed consent given by a study subject to the prescribing or administering of experimental drugs may be revoked *at any time* by either verbal or written communication to the investigator or to anyone supervising the administration of the experimental drug.

F. The experimental activity as a whole, including the informed consent process, shall be reviewed and approved by the IRB prior to administering an experimental drug. A copy of any informed consent procedures approved by the IRB shall be filed with the Department prior to the commencement of the experiment.

VI. Mandatory Reporting of Sexually Transmitted Disease - California Health and Safety Code (Section 120500-120605)

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.

VII. Confidentiality of Research Records involving Acquired Immune Deficiency Syndrome (AIDS) Patients - California Health and Safety Code (Section 121075-121125)

A. Prior to the participation of an individual in a research study relating to Acquired Immune Deficiency Syndrome (AIDS), the informed consent of each research subject must be obtained in accordance with UCI IRB policies and procedures governing informed consent.

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:

1. 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:

   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:
   1. To medical personnel to the extent it is necessary to meet a bona fide medical emergency of a research subject; and
   2. 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.

VIII. Use of State Death Data Records - California Health and Safety Code (Section 102231 – 102232)

A. 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.

IX. Abortions and Use of Fetal Material – California Health and Safety Code (Sections 123420-123450)

A. Except in a medical emergency requiring immediate medical action, no abortion shall be performed upon a minor unless she first has given her written consent (assent) to the abortion and also has obtained the written consent (permission) of one of her parents or legal guardian.

X. Embryos for Research – California Health and Safety Code (Sections 124320-125300)

A. A physician and surgeon or other health care provider delivering fertility treatment shall provide his or her patient with timely, relevant, and appropriate information to allow the individual to make an informed and voluntary choice regarding the disposition of any human embryos remaining following the fertility treatment; covers consent requirements for donation of embryos for research.

XI. Confidentiality of Records involving Hereditary Disorders - California Health and Safety Code (Section 124980)

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 – California Health and Safety Code (Sections 125330-125355)

A. 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.

ADDITIONAL CALIFORNIA LAWS:

XIII. Prisoners in Biomedical and Behavioral Research - Penal Code (Section 3500 – 3523)

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 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:

1. 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;
2. That the rights and welfare of the prisoners are adequately protected, including the security of any confidential personal information;
3. That the procedures for selection of prisoners are equitable and that subjects are not unjustly deprived of the opportunity to participate;
4. That adequate provisions have been made for compensating research related injury;
5. That the rate of remuneration is comparable to that received by non-prisoner volunteers in similar research;

6. That the conduct of the activity will be reviewed at timely intervals; and
7. 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:
   1. Consent is given without duress, coercion, fraud, or undue influence;
   2. The prisoner is informed in writing of the potential risks or benefits, or both, of the proposed research;
   3. The prisoner is informed orally and in writing in the language in which the subject is fluent of each of the following:
      a. An explanation of the biomedical or behavioral research procedures to be followed and their purposes, including identification of any procedures which are experimental;
      b. A description of all known attendant discomfort and risks reasonably to be expected;
      c. A disclosure of any appropriate alternative biomedical or behavioral research procedures that might be advantageous for the subject;
      d. The nature of the information sought to be gained by the experiment;
      e. The expected recovery time of the subject after completion of the experiment;
      f. An offer to answer any inquiries concerning the applicable biomedical or behavioral research procedures; and
      g. 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.
   4. 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 - California Welfare and Institutions Code (Section 15600 - 15637)

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 Executive Director of Research Protections 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 Lead Investigator is responsible for complying with all applicable federal and state laws regarding the confidentiality of information (such as the California Information Practices Act).

- 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.
- 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.

ADDITIONAL CALIFORNIA LAWS APPLICABLE TO CHILDREN

XVI. Mandatory Reporting of Child Abuse or Neglect - Child Abuse and Neglect Reporting Act - California Penal Code (Section 11164-11174.3)

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:

1. Any Police Department;
2. Any Sheriff Department;
3. County Welfare Department; or
4. 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. UCI 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 Executive Director of Research Protections or designee, who may refer the question to UC Legal Counsel.

XVII. Parental Consent for Children to Participate in Research – California Education Code (Section 51513)

A. 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 (California Family Code 7022)

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. Any Type of Research - 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:

A. Outpatient mental health treatment;
B. Prevention/treatment of pregnancy;
C. Medical care related to diagnosis/treatment of a communicable reportable disease or condition;
D. Care for rape;
E. Care for sexual assault;
F. Care for alcohol or drug abuse.

XIX. 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.

XX. Responsibilities of IRB Members

A. 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.

B. IRB members are to be aware of the state law that may be relevant to the conduct of human subject research and to consider whether disclosure of the implications of the law is required for legally effective informed consent.

XXI. Responsibilities of Legal Counsel

A. In general, the IRB will apply the most stringent law when federal law and other applicable laws apply. However, legal counsel, as needed, will provide assistance to resolve conflicts between federal law and other applicable laws.

B. Legal counsel will provide assistance, as needed, when applying state and local laws that govern research involving human subjects, including when the research is conducted outside State of California.

References:

California Health and Safety Code - Section 11480-11481
California Health and Safety Code - Section 24170-24179.5
California Health and Safety Code - Sections 24185-24187
California Health and Safety Code - Section 102231 – 102232
California Health and Safety Code - Section 111515-111545
California Health and Safety Code - Section 120500-120605
California Health and Safety Code - Section 121075-121125
California Health and Safety Code - Sections 123420-123450
California Health and Safety Code - Sections 124320-125300
California Health and Safety Code - Section 124980
California Health and Safety Code - Sections 125330-125355
California Penal Code - Section 3500 – 3520
California Penal Code - Section 11164-11174.3
California Education Code - Section 51513
California Welfare and Institutions Code - Section 15601
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)