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Policy:
In addition to the Office for Human Research Protections (OHRP) regulations at 45 CFR 46 and Food and Drug Administration (FDA) regulations 21 CFR 50 and 21 CFR 56, along with University of California requirements, 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 may be directly relevant to human subjects research. *(References are included in text below rather than at the end as a citation for ease of reference.)*

I. **Abortion:** California Health and Safety Code (Sections 123420-123450, 123110 (a), 123115 (a), California Civil Code 56.10, 56.11)
   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.[1]
   B. The health care provider is not permitted to inform a parent or legal guardian without the minor's consent. The provider can only share the minor's medical records with the signed consent of the minor.

II. **Acquired Immune Deficiency Syndrome (AIDS) Immunization:**
   A. California Health and Safety Code (Sections 121280): States that it is in the interest of the people of California to develop a vaccine to prevent the HIV infection, and the process for the development of that vaccine, including the development of a prototype to be given to HIV negative people to determine toxicity and efficacy, the need for insurers to not withhold settlement or coverage and confidentiality measures.
   B. Section 121310: A manufacturer, research institution, or researcher shall, prior to the administration of an AIDS vaccine to a research subject, obtain that woman's informed consent, that shall comply with all applicable statutes and regulations.
   C. Section 121315 (a): A manufacturer, research institution, or researcher shall not be strictly liable for personal injury or wrongful death resulting from the administration of any AIDS vaccine to a research subject participating in the clinical trials described in this chapter.
   D. Section 121320 (a): No person shall be denied the opportunity to be a research subject because of the inability to pay for medical treatment.

[1] (*Highlight remains in this document intentionally*): American Academy of Pediatrics v. Lungren (1997) 16 Cal.4th 307. **A minor may consent to an abortion without parental consent and without court permission.** California Health and Safety Code remains unchanged.

III. **Assisted Oocyte Production**: California Health and Safety Code (Sections 125330-125355)

A. Prior to obtaining informed consent from a subject for assisted oocyte production (AOP) 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.

IV. **Children / Minors:** (California Family Code, Sections 6920-6929): Describes when minors (children) may consent for themselves in various scenarios where treatment may be provided.

A. Consent: Additional Guidance and Requirements:

1. Children - For subjects < 18 years of age, their parents or legal guardians are the legally authorized representatives who may grant permission for their participation in research.
2. Parents - Only the parents may grant permission for their child's participation in research. *Assent is to be sought from the child, only after permission has been obtained from the parents.* Grandparents and other relatives or caregivers may not grant permission unless they have been granted formal custody of the child by a court. In such cases, the LR must obtain a copy of the court order as evidence of that person's authority to grant permission for participation in research on the child's behalf.
3. Children in State Custody - According to the California Department of Children's Services' (DCS) applicable policies by virtue of the court order granting DCS legal custody of certain children (e.g., foster children) that Department is the agency that is authorized to grant permission for participation in research for children in their custody. The decision of whether to grant permission for research is made on a case-by-case basis by DCS. In such cases, the LR must obtain a copy of the court order from DCS.
4. Mature Minors or Emancipated Minors - In certain limited circumstances, it may be appropriate to allow a mature minor to consent to participation in a research study in the absence of the permission of a parent or legal guardian if the minor has the sufficient capacity to consent to the procedures involved in the research study.
5. The IRB will determine whether the inclusion of mature minors or emancipated minors in research activities in the absence of the permission of a parent or legal is appropriate. Further, each situation is judged on a case-by-case basis. *Legal counsel may be appropriate to consider as part of this decision.* Documentation of those decisions must be included in the research file.
6. The following information provides examples of circumstances under which California law combined with federal regulations permits individuals under 18 to enroll in research without permission from parent(s) or guardian(s):
    (1) Minors may consent for themselves to medical care related to the prevention or treatment of pregnancy, but not necessarily

to sterilization or abortion [California Family Code Section 6925; Health and Safety Code Section 123450 for abortion].[2]

(2) Minors 12 years of age or older have the legal right to consent on their own behalf, for:
   a) Mental health treatment or counseling on an outpatient basis or residential shelter services (in limited circumstances) [California Family Code Section 6924].
   b) Medical care related to the diagnosis or treatment of infectious, contagious, or communicable diseases that are required to be reported to the local health officer or a related sexually transmitted disease [California Family Code Section 6926].
   c) Medical care related to the diagnosis or treatment of the condition and collection of medical evidence about alleged rape or sexual assault [California Family Code Section 6927].
   d) Medical care and counseling related to the diagnosis and treatment of an alcohol or drug-related problem [California Family Code Section 6929].

(3) Self-sufficient minors who are:
   a) 15 years of age or older;
   b) living separately from their parents/guardians; and
   c) managing their own financial affairs have the legal right to consent on their own behalf to medical or dental care [California Family Code 6922].

(4) Emancipated minors, those who are:
   a) married or divorced
   b) on active duty in the U.S. armed forces ***or*** emancipated by the court; and
   c) have the legal right to consent on their own behalf to medical, dental, or mental health treatment. They also have extensive other rights to enter into legal and business arrangements, and so can consent to be included in other research (e.g., interviews, surveys) [California Family Code 7000-7143].

(5) Capacity to consent depends upon:
   a) The age, ability, experience, education, training, and degree of maturity and judgment of the minor. A minor between the ages of fourteen (14) and eighteen (18) may have such capacity, but a minor under the age of fourteen (14) would rarely have such capacity;
   b) The conduct and demeanor at the time consent is to be given;
   c) The totality of the circumstances;

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[2] (*Highlight remains in this document intentionally*): American Academy of Pediatrics v. Lungren (1997) 16 Cal.4th 307. **A minor may consent to an abortion without parental consent and without court permission.** California Health and Safety Code remains unchanged.

d) The nature of the proposed research procedures and their risks, probable consequences, benefits, and alternatives to the treatment; and
e) The minor's ability to appreciate the nature, risks, consequences, benefits, and alternatives of the proposed research procedures.

B. Emancipated Minors (California Family Code, Sections 7000-7002; 7050-7052; 7120-7123): Further defines an emancipated minor and rights of emancipated minors.

C. Experimental Use of Drugs and Consent for Minors Provision (California Health and Safety Code, Sections 111515– 111545): Minor consent is required prior to administering an experimental drug. Parental or legal guardian consent (permission) is required, and minor consent (assent) is required for children 7 years of age or older.

D. Mandatory Reporting of Child Abuse or Neglect (California Penal Code, Section 11164 -11174.3) Identifies who is a “mandated reporter" required to report known or reasonably suspected child abuse or neglect.

E. Parental Consent for Children to Participate in Research (California Education Code, Section 51513): 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).

V. **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.

VI. **Consent:**

A. **Anti-Kickback** (California Code of Regulations, Section 650): In relevant part, Section 650 provides as follows:

1. The offer, delivery, receipt, or acceptance by any person licensed under this division or the Chiropractic Initiative Act of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary

interest or co-ownership in or with any person to whom these patients, clients, or customers are referred is unlawful.

B. **Consent**

1. (California Administrative Code 4733): Except as provided in Sections 4734 and 4735, a health care provider or health care institution providing care to a patient shall do the following:
    i. Comply with an individual health care instruction of the patient and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the patient.
    ii. Comply with a health care decision for the patient made by a person then authorized to make health care decisions for the patient to the same extent as if the decision had been made by the patient while having capacity.
2. (California Code of Regulations, Section 50423): Describes specific consent criteria for release of confidential information or records, the need for consent only after appropriate IRB approval, that the information is provided to subjects (or their representative) in a language that is understandable, and that consent language must not appear to be exculpatory.
3. California Health and Safety Code 24173 further defines “informed consent” as the authorization given pursuant to Section 24175 to have a medical experiment performed after each of the following have been satisfied:
    i. The subject or subject’s conservator or guardian, or other representative, as specified in Section 24175, is provided with a copy of the experimental subject’s bill of rights, prior to consenting to participate in any medical experiment, containing all the information required by Section 24172, and the copy is signed and dated by the subject or the subject’s conservator or guardian, or other representative, as specified in Section 24175.
    ii. A written consent form is signed and dated by the subject or the subject’s conservator or guardian, or other representative, as specified in Section 24175.
    iii. The subject or subject’s conservator or guardian, or other representative, as specified in Section 24175, is informed both verbally and within the written consent form, in nontechnical terms and in a language in which the subject or the subject’s conservator or guardian, or other representative, as specified in Section 24175, is fluent, of the following facts of the proposed medical experiment, which might influence the decision to undergo the experiment, including, but not limited to:
        (1) An explanation of the procedures to be followed in the medical experiment and any drug or device to be utilized, including the purposes of the procedures, drugs, or devices. If a placebo is to be administered or dispensed to a portion of the subjects involved in a medical experiment, all subjects of the experiment shall be informed of that

fact; however, they need not be informed as to whether they will actually be administered or dispensed a placebo.

(2) A description of any attendant discomfort and risks to the subject reasonably to be expected.

(3) An explanation of any benefits to the subject reasonably to be expected, if applicable.

(4) A disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

(5) An estimate of the expected recovery time of the subject after the experiment.

(6) An offer to answer any inquiries concerning the experiment or the procedures involved.

(7) An instruction to the subject that he or she is free to withdraw his or her prior consent to the medical experiment and discontinue participation in the medical experiment at any time, without prejudice to the subject.

(8) The name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the experiment.

(9) The name of the sponsor or funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization, if any, under whose general aegis the experiment is being conducted.

(10) The name, address, and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment.

(11) The material financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment. For purposes of this section, “material” means ten thousand dollars ($10,000) or more in securities or other assets valued at the date of disclosure, or in relevant cumulative salary or other income, regardless of when it is earned or expected to be earned.

iv. The written consent form is signed and dated by any person other than the subject or the conservator or guardian, or other representative of the subject, as specified in Section 24175, who can attest that the requirements for informed consent to the medical experiment have been satisfied.

(1) ***At UCI, the researcher finalizing the consent process and signing the written consent form satisfies this requirement.***

v. Consent is voluntary and freely given by the human subject or the conservator or guardian, or other representative, as

specified by Section 24175, without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence.

C. **Disclosure** (Regents of University of California, 51 Cal.3d 120, 271 Cal. Rptr. 146, 793 P.2d 479 (Cal. 1990)): In obtaining a patient's consent to a procedure, a physician must disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment.

D. **Health Plan Coverage for Clinical Trials** (California Health and Safety Code 1370.6): States in part:

1. An individual or group health care service plan contract that is issued, amended, or renewed on or after January 1, 2020, shall not:
    i. Deny a qualified enrollee's participation in an approved clinical trial.
    ii. Deny, limit, or impose additional conditions on the coverage of routine patient care costs for items and services furnished in connection with a qualified enrollee's participation in an approved clinical trial.
    iii. Discriminate against an enrollee based on the qualified enrollee's participation in an approved clinical trial.

E. **No Profit from Referral** (California Health and Safety Code, Section 445): Prohibits any person from profiting from the referral of a person to a health-related facility as follows:

No person, firm, partnership, association or corporation, or agent or employee thereof, shall for profit refer or recommend a person to a physician, hospital, health-related facility, or dispensary for any form of medical care or treatment of any ailment or physician condition. The imposition of a fee or charge for any such referral or recommendation creates a presumption that the referral or recommendation is for profit.

F. **Protection of Human Subjects in Medical Experimentation Act** (California Health and Safety Code, Sections 24170– 24179.5): 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.

1. **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.
2. 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. Per Section 24172, those rights include that the subject:
    i. Be informed of the nature and purpose of the experiment.
    ii. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

iii. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
iv. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
v. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
vi. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
vii. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
viii. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
ix. Be given a copy of the signed and dated written consent form as provided for by Section 24173 or 24178.
x. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

3. The Subject' Bill of Rights is to be including for protocols involving patient care (e.g., Expanded Access, CA Right to try).
4. The Subject's Bill of Rights is not required for protocols involving Humanitarian Use Device/s.
5. To view the UCI Experimental Subjects Bill of Rights (available in 10 languages) go to the HRP Website, then click on "IRB Forms", then "Consent Forms": https://research.uci.edu/human-research-protections/irb-forms/

G. **Signatures:** Per Health and Safety Code Section 24170-24179.5, **holding an HHS Federal wide Assurance exempts UCI researchers from the requirement to obtain a signature on the California Bill of Rights. The requirement is to provide the Bill of Rights to all research participant s in medical experiments. This Bill of Rights is attached as necessary to the IRB approved Consent Form.**

H. **Surrogate Decision Maker** (California Health and Safety Code, Section 24178):

1. With respect to medical experiments that relate to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of adult research participants, investigators may obtain surrogate informed consent by following a specific hierarchy for nonemergency and emergency room environments. (See Policy # 30.)
2. Non-Medical Research: California law addresses surrogate consent in the context of medical research. The Office of the President has acknowledged that campuses may permit the same surrogates authorized by Section 24178 may also be considered in the context of non-medical research.

3. Per the Common Rule, for research that is no more than minimal risk, the IRB may approve a request to waive some or all of the required elements of informed consent under specific circumstances, and in such cases the need for surrogate consent may also be waived. (See Policy # 30.)

VII. **Controlled Substance Research / Illegal Drug Research -** Research Advisory Panel of California, CA Health and Safety Code (Section 11480-11481; 11212-11213; 11603)

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.

C. Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose of research, instruction, or analysis, may lawfully obtain and use for such purposes those substances classified in paragraphs (45) and (46) of subdivision (b) of Section 11054 of the Health and Safety Code , upon registration with and approval by the California Department of Justice for use of those substances in bona fide research, instruction, or analysis.
   1. That research, instruction, or analysis shall be carried on only under the auspices of the individual identified by the registrant as responsible for the research. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.
   2. The Department of Justice may withdraw approval of the use of such substances at any time. The department may obtain and inspect at any time the records required to be maintained by this section.

D. Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose of research, instruction, or analysis, may lawfully obtain and use for such purposes such substances as are defined as controlled substances in this division, upon approval for use of such controlled substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to Section 11480 and 11481 .
   1. Such research, instruction, or analysis shall be carried on only under the auspices of the head of a research project which has been approved by the Research Advisory Panel pursuant to Section 11480 or Section 11481. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.

E. The Attorney General, with the approval of the Research Advisory Panel, may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying

characteristics of individuals who are the subjects of the research. Persons who obtain this authorization are not compelled in any civil, criminal, administrative, legislative, or other proceeding to identify the individuals who are the subjects of research for which the authorization was obtained.

VIII. **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. **Embryos:** 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.

X. **Experimental use of Devices**: California Health and Safety Code (Section 109920): Defines a device as a: means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is any of the following:

1. Recognized in the official National Formulary or the United States Pharmacopoeia, or any supplement to them.
2. Intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease in humans or any other animal.
3. Intended to affect the structure or any function of the body of humans or any other animal and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals and that is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

XI. **Experimental Use of Drugs**: California Health and Safety Code (Section 111515-111545)

A. Under the California Health and Safety Code 111515, an “experimental drug” means a drug intended for investigational use under Section 111595.

1. Section 111595 indicates that Section 111550 does not apply to any 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:

i. 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.

ii. 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.

iii. 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.

iv. 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.

v. 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.

vi. 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).

vii. 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.

B. California Health and Safety Code (Section 111525) states that prior to prescribing or administering an experimental drug, consent to the use of the drug shall be obtained in the manner specified in Section 24170 (also known as the Protection of Human Subjects in Medical Experimentation Act).

C. The Right to Try Act is defined at Section 111548. (See Policy # 41.)

XII. **Hereditary Disorders:**

A. Hereditary Disorders Act: California Health and Safety Code (Section 1124975) States in part, that each person in California is entitled to health care commensurate with their needs, detection through screeding of hereditary disorders can lead to further understanding an accumulation of medical knowledge and carriers of most deleterious genes should not be stigmatized and discriminated against. Participation of persons in hereditary disorders programs in the State of California should be wholly voluntary, except for initial screening for phenylketonuria (PKU) and other genetic disorders treatable through the California newborn screening program. All information obtained from persons involved in hereditary disorders programs in the state should be held strictly confidential.

B. California Health and Safety Code (Section 124980) States that 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.

C. 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.

XIII. **Mandatory Reporting of Sexually Transmitted Disease:** (California Health and Safety Code, Section 120500 -120605): Describes the requirements for reporting sexually transmitted disease to CA Department of Health. **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.

XIV. **Prisoners in Biomedical and Behavioral Research** (California Penal Code, Section 3500 – 3523) (Section 3369.5 of Title 15 of the California Code of

Regulations) (See Policy # 37.) Describes the requirements for biomedical and behavioral research conducted in CA prisons.

XV. **Research Records involving 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.

I. (California Insurance Code Section 10145.2): Addresses coverage for a vaccine for AIDS approved by the FDA and as recommended by the US Public Health Service.`

XVI. **Special Populations:**

A. **Elder Abuse and Dependent Adult Civil Protection Act** (California Welfare and Institutions Code, Section 15600 - 15637) Describes the requirements for reporting harm and neglect to elder or dependent adults.

B. (California Penal Code 11160): A health practitioner 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.

C. 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.

D. In the event a health practitioner 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.

E. 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.

F. 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.

XVII. **Stem Cell Research and Cures Act**

A. On November 2, 2004 California voters approved Proposition 71, the California Stem Cell Research and Cures Act ("Act"), a $3 billion bond measure to advance stem cell research over the next ten years. The Act also created the California Institute for Regenerative Medicine (CIRM) and the Independent Citizens Oversight Committee (ICOC) which will govern the Institute, and make grants and loans for stem cell research and research facilities.

B. (Section 125290.35): Institute will develop its own standards for scientific and medical research.

C. (Section 125290.55): States a scientific and medical accountability standard working group will be established. The composition of the working group is specified.

D. (Section 125300): The policy of the State of California shall be that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells, including somatic cell nuclear transplantation, shall be reviewed by a stem cell research oversight committee.

XVIII. **Surrogate Decision Maker**: (California Health and Safety Code Section 24178) (See Procedure # 30C.)

XIX. **Women and Minorities**: California Health and Safety Code (Section 100238)

A. In conducting or supporting a project of clinical research, a grantee shall, except as provided in subdivision (b) or (e), do all of the following:

1. Ensure that women, including, but not limited to, women over the age of 40 years, are included as subjects in each research project.
2. Ensure that minority groups are included as subjects in each research project.
3. Conduct or support outreach programs for the recruitment of women and members of minority groups as subjects in projects of clinical research.
4. The requirement established in subdivisions (a) and (d) regarding women and members of minority groups shall not apply to a project of clinical research if the inclusion, as subjects in the project, of women and minority groups is inappropriate for either of the following reasons:
    i. With respect to the health and safety of the subjects.
    ii. With respect to the purpose of the research.

B. In the case of any clinical trial in which women or members of minority groups will, under subdivision (a), be included as subjects, a grantee shall ensure that the trial is designed and carried out in a manner sufficient to provide for a valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.

C. In any grant, or in any contract by a grantee under a grant, the grantee or contracting party shall acknowledge, agree to, and be bound by, the terms of this section.

If a grantee is in compliance with the 1993 National Institutes of Health guidelines, the grantee shall be deemed to be in compliance with this section

ADDITIONAL CALIFORNIA LAWS TO CONSIDER AS APPLICABLE:

XX. **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.

XXI. **Prisoners in Biomedical and Behavioral Research**

A. Penal Code (Section 3500 – 3523) (Section 3369.5 of Title 15 of the California Code of Regulations) (See Policy # 37.)

B. 15 California Code of Federal Regulations Section 1454 states expectations for conducting research on juveniles.

C. 15 California Code of Federal Regulations Section 3369.5 states expectations for conducting research on adult inmates and parolees including the approval of a research advisory committee.

XXII. **Research Conducted by or at State Hospitals, Regional Centers, or by Other Persons or at Places Subject to Section 4514 of the Welfare and Institutions Code** (17 Code of California Regulations 50403-50429**;** 50401-50429 includes definitions and rules for the conduct of research.)

XXIII. **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.

XXIV. **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. (See Policy # 27.)

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)
https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=LAB&sectionNum=1454.
UC Legal Health Research Advisory: Clinical Activities as Research, July 2020
Panetta J, Wetherell J, Mehok M. California Stem Cell Research and Cures Act: what to expect from stem cell research? J Biolaw Bus. 2005;8(4):3-12. PMID: 16619447.
Estanol, L. (2019). Post-Approval Investigator Responsibilities (PAIR) Worksheet. *UC Irvine: Human Research Protections (HRP), Education and Quality Improvement Program (EQUIP)*. Retrieved from https://escholarship.org/uc/item/2kc9373m
Moore v. Regents of the University of California
UCOP: Use of Specimens (Moore Clause) Disclosure in the Informed Consent Form