This document is intended for use by the reviewing external IRB. The information provided is intended to provide the reviewing external IRB with local context, laws and policies affecting human subjects research at this institution. Additional supporting documents, referenced laws, and policies can be accessed online:

* Experimental Participants Bill of Rights: <https://irb.ucsf.edu/experimental-subjects-bill-rights>
* UCSF Office of Research / Department of Pathology Research Tissue Acquisition Policy: <https://bios.ucsf.edu/sites/g/files/tkssra1661/f/wysiwyg/Research_Tissue_Acquisition_Policy_2022_01_31_final_BSP.pdf>
* UCOP Guidance: Moore Clause: <https://researchmemos.ucop.edu/php-app/index.php/site/document?memo=UlBBQy0xNy0wNA==&doc=3715>
* UCOP Guidance: Surrogate Consent: <https://researchmemos.ucop.edu/php-app/index.php/site/document?memo=UlBBQy0yMS0wMQ==&doc=3789>
* Adolescent Working Group Guidance: Adolescent Confidentiality Toolkit: <http://www.publichealth.lacounty.gov/dhsp/Providers/toolkit2.pdf>
* UCSF Template Consent Documents: <https://irb.ucsf.edu/consent-and-assent-form-templates>
* UCSF Template HIPPA Authorization for Research forms: <https://irb.ucsf.edu/hipaa>
* UCSF HRPP Guidance for Minors in Research, including self-sufficient minors: <https://irb.ucsf.edu/children-and-minors-research>
* California Law Search: <http://leginfo.legislature.ca.gov/faces/codes.xhtml> California Code of Regulations: <https://govt.westlaw.com/calregs/Index?transitionType=Default&contextData=%28sc.Default%29>
* University of California Office of the President Human Subjects Policy and Guidance:

<http://www.ucop.edu/research-policy-analysis-coordination/policies-guidance/human-subjects/index.html>

Questions, comments, concerns regarding this should be sent to [irb@ucsf.edu](mailto:irb@ucsf.edu).

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# FWA

The University of California, San Francisco has unchecked the box.

# Communication

The preferred communication dynamic is noted below:

* UCSF Reliance Team irb@ucsf.edu
* UCSF PI: via their UCSF email address
* Edward Kuczynski, IRB Director: Edward.Kuczynski@ucsf.edu
* Erin Coons, Associate Director: Erin.Coons@ucsf.edu

# Integrity in Research

UCSF conducts random and for cause audits of research through the HRPP Quality Improvement Unit. Should your institution’s IRB require an audit of a UCSF study or investigator, please contact the UCSF QIU Team.

# Submission to the External IRB

The UCSF investigator, or appropriate party designated by the external IRB may submit to the external IRB after the study has been pre-screened. For WCG and Advarra an acknowledgement letter will be issued through iRIS. For all other reliances a stipulation will be sent through iRIS to the UCSF study team to instruct them to submit to the external IRB.

# Ancillary Committee Approvals

* Prior to IRB Approval: Detailed information is available on-line at <https://irb.ucsf.edu/new-study>
* Prior to Study Startup: These will be identified at screening. The UCSF IRB will inform the PI of these additional requirements.

## Research Advisory Panel of California (RAP of C) for Schedule I or II Controlled Substances

California law requires proposed research projects using certain opioid, stimulant, and hallucinogenic drugs classified as Schedule I and Schedule II Controlled Substances as their main study drug(s), to be reviewed and authorized by the Research Advisory Panel of California in the Attorney General's Office: <https://oag.ca.gov/research>

The investigator is responsible for securing RAP of C approval prior to securing IRB approval. 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.

California Health & Safety Code § 11480 & 11481

# Institutional Approvals

Additional approvals or clearance may be required prior to commencing research at UCSF. The Investigator is responsible for seeking and obtaining the appropriate approval or clearance. The UCSF IRB will remind the PI of these additional requirements.

## Data Storage: Cloud Services

Certain data may not be stored in cloud services. The following website provides information about the service and allowable uses: <https://data.ucsf.edu/cdrp/research>

The Investigator may need to undergo an IT Security Risk Review from UCSF IT Security to storing human subjects research data. The PI is responsible for consulting with the applicable IT departments as needed.

## IT Evaluation for Clinical Research

A Data Security Risk Assessment by UCSF IT **AND**Data Sharing Review by the Office of Sponsored Research (OSR -- Industry Contracts Division) must be completed if the study involves: **the collection, transmission, or storage of information when that data will be** **shared with or be accessible to any non-UCSF entity (e.g., pharmaceutical companies,** **NIH,**[**UCSF Affiliated Institutions**](https://irb.ucsf.edu/ucsf-affiliated-institutions)**) or individual.** This includes the use of third-party or vendor-hosted applications. UCSF or department-hosted applications may also need to be assessed, particularly if they are new applications or have never been reviewed by UCSF IT Security.

* Third-party or vendor-hosted applications include cloud-hosted applications and applications hosted by collaborating institutions
* UCSF or department-hosted applications include any application managed by UCSF or developed by the department

These requirements apply for both identifiable and de-identified data for funded and unfunded research. **Questions about these policies must be directed to UCSF IT and Office of Sponsored Research, not to the IRB.**

* + To determine if a Data Security Risk Assessment is required, the UCSF study team must contact the intake team at [datasecurity@ucsf.edu](mailto:datasecurity@ucsf.edu). More information about the assessment process is available at <https://it.ucsf.edu/service/it-security-risk-assessment>

* + For information about Data Sharing Review: <https://data.ucsf.edu/edrp> and <https://icd.ucsf.edu/material-transfer-and-data-agreements>

## Student Records

UCSF investigators wishing to access identifiable UCSF student records must contact the Registrar’s Office at [registrar@ucsf.edu](mailto:registrar@ucsf.edu) to confirm their research plan is consistent with university policy.

UCSF procedures for accessing student records are available from the [Registrar's website.](https://registrar.ucsf.edu/faculty-staff/ferpa-privacy) Assessing student records generally requires the student’s consent. A [sample consent form](https://registrar.ucsf.edu/faculty-staff/ferpa-privacy/sample-consent) is available.

## Specimens: Submission of Tissue to Pathology

Investigators must submit all specimens to pathology for examination, unless it is specifically listed as exempt in the [UCSF Research Tissue Acquisition Policy](https://bios.ucsf.edu/sites/g/files/tkssra1661/f/wysiwyg/Research_Tissue_Acquisition_Policy_2022_01_31_final_BSP.pdf). Investigators may obtain the sample for research use after Pathology has examined the specimen, classified the specimen as “excess,” and determined that it may be released for research purposes.

An exception to policy may be obtained on a case-by-case basis. The investigator is required to apply for an exception through the UCSF Department of Pathology Medicine: <https://pathology.ucsf.edu/>

## Conflict of Interest (COI)

UCSF investigators are required to report COIs to the Conflict of Interest Advisory Committee (COIAC) and the reviewing external IRB. The COIAC reviews the COI and develops a management plan, which is shared with the IRB. The IRB reviews the COI and the management plan. The IRB may accept the plan or require a higher level of management.

<https://compliance.ucsf.edu/financial-conflict-interest-research>

## Disclosure of COI in the Consent Document

An individual undergoing a medical procedure must be advised of any personal interests of the physician/investigator unrelated to the individual’s health, such as a research interest, that may affect the physician’s medical judgment. The reviewing external IRB must consider an appropriate plan for management of the identified Conflicts of Interest.

RPAC Memo No. 11-05 "Summary Statement of Principles and Policies on Institutional Conflict of Interest in Research"

## Radiation Safety / RDRC

Studies requiring Radiation Safety or Radioactive Drug Research Committee (RDRC) review must be approved by the respective UCSF committee prior to submission to the IRB.

## Institutional Biosafety Committee

Studies requiring Institutional Biosafety Committee (IBC) review must be approved by the UCSF Institutional Biosafety Committee prior to submission to the IRB.

## Human Gamete, Embryo and Stem Cell Research Committee

Studies using human embryonic stem cells (hESCs), induced pluripotent stem (iPS) cells, human embryos, human gametes, or other pluripotent cells must be approved by the UCSF Human Gamete, Embryo, and Stem Cell Research (GESCR) Committee prior to submission to the IRB.

# Local Demographics

## San Francisco Bay Area, California

<https://data.census.gov/cedsci/profile?g=0600000US0607592790>

This site provides current data for multiple sets of demographics for the region and for specific areas/cities within the region. When applicable, the IRB is should take into consideration the region’s demographics when conducting a review, such as:

|  |  |  |
| --- | --- | --- |
| * Age and Gender * Race and Ethnicity * National Origin | * Ancestry * Languages * Household Income | * Food Stamps * Educational Attainment * School Enrollment |

## Languages Spoken in the Region

The City of San Francisco is comprised of individuals with diverse linguistic background. About 43% (approximately 360,000) of residents in the city speak a language other than English at home. Language diversity data for the city of San Francisco is available at <https://sfgov.org/ccsfgsa/oceia/language-diversity-data>

## Fresno, California

<https://data.census.gov/cedsci/profile?g=0500000US06019>

## Oakland, California

<https://data.census.gov/cedsci/profile?g=1600000US0653000>

## Undocumented Immigrants

The Public Policy Institute of California estimates that nearly ¼ of the country’s undocumented immigrants reside in California (approximately 2.5 million individuals or 6% of the state’s population). Research targeting the immigrant population should provide sufficient provisions to secure the confidentiality of the subject’s data, such as obtaining a NIH Certificate of Confidentiality, DOJ Privacy Certificate, or similar.

Public Policy Institute of California – Undocumented Immigrants in California: <http://www.ppic.org/main/publication_show.asp?i=818>

# Informed Consent

## UCSF Guidelines

Investigators are expected to follow UCSF guidelines for consent process and documentation of informed consent process, unless otherwise described in the IRB application in iRIS. Additional information for the standard consent process at UCSF is available at: <https://irb.ucsf.edu/consent-form-guidelines-and-suggested-wording>

## Informed Consent Document

The UCSF Consent Template should be used to ensure compliance with State and Local requirements.

If the UCSF consent template is not used, the UCSF Consent Form Checklist must be used to ensure compliance with state and local laws. Only the UCSF logo should appear on the consent form. If desired, the logo of the lead site, coordinating center, cooperative group, trial network, consortium, etc. may also appear in addition to the UCSF logo. The following additional elements of the informed consent document are required for the State of California:

1. If a placebo is to be administered or dispensed to a portion of the subjects involved in a medical experiment, all subjects of such 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. The name, institutional affiliation, if any, and address of the person(s) actually performing and primarily responsible for the conduct of the experiment;
3. The name of the sponsor/funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization under whose aegis the experiment is being conducted; and
4. 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.

## Informed Consent Document Boilerplate Language

If the UCSF template consent document is not used, the approved consent must incorporate the local boilerplate language: <https://irb.ucsf.edu/consent-form-guidelines-and-suggested-wording#wording> .

### Experimental Subjects’ Bill of Rights

The Experimental Subjects’ Bill of Rights must be provided before consent is obtained. The Subject’s Bill of Rights is required if the study is a “Medical Experiment” as defined by California Law. If the study does not meet the definition of “Medical Experiment” the Bill of Rights is not required.

The UCSF template consent document incorporates the Subject’s Bill of Rights into the section titled “What should I know about a research study?”

The Bill of Rights must be:

1. In a language for which the subject or legally authorized representative is fluent.
2. Signed and dated by the subject or legally authorized representative. (If the Bill of Rights is incorporated into the consent document, the signature at the end of the consent document satisfies this requirement.)

“Medical Experiment” under California Law means:

* The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, 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;
* The investigational use of a drug or device; or
* Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.

**Note:** Waiver of documentation of consent is not permitted if the research meets the definition of a medical experiment in California.

The investigator may use the Bill of Rights language as a separate stand-alone document or add the language to the first page of the consent document:

**California Experimental Subjects Bill of Rights**

* Someone will explain this research study to you, including:
  + The nature and purpose of the research study.
  + The procedures to be followed.
  + Any drug or device to be used. **[*Delete if there are no drugs and devices used.]***
* Any common or important discomforts and risks.
* Any benefits you might expect.
* Other procedures, drugs, or devices that might be helpful, and their risks and benefits compared to this study. ***[Delete for research involving no alternatives.]***
  + Medical treatment, if any, that is available for complications. [***Delete for research involving no more than minimal risk.]***
* Whether or not you take part is up to you.
* You can choose without force, fraud, deceit, duress, coercion, or undue influence.
* You can choose not to take part.
* You can agree to take part now and later change your mind.
* Whatever you decide it will not be held against you.
* You can ask all the questions you want before you decide.
* If you agree to take part, you will be given a signed and dated copy of this document. ***[Delete if the consent process will not include obtaining signatures on the consent document.]***
* If you agree to take part, you will be given a copy of this document. ***[Delete if the consent process includes obtaining signatures on the consent document.]***

California Health and Safety Code § 109920; 109925; 111590; 111595; 24170-24179.5

Electronic Consent

In California, if research involves obtaining electronic consent from participants, the subjects must agree to the following in writing:

“**What are my rights when providing electronic consent?**

* California law provides specific rights when you are asked to provide electronic consent:
* You have the right to obtain a copy of the consent document in non-electronic format
* You have the right to provide consent in a non-electronic format.
* If you change your mind about electronic consent, you have the right to request your electronic consent to be withdrawn and you can then provide consent in a non-electronic format; however a copy of your electronic consent will be maintained for regulatory purposes.  If you wish to withdraw your electronic consent please tell the study team
* This agreement for electronic consent applies only to your consent to participate in this research study.”

## Documentation of Informed Consent: Digital Signatures

The University of California is defined as a “public entity” which must comply with digital signature requirements. A digital signature must be created by an acceptable technology. The California Secretary of State provides information about acceptable signatures and maintains a list of acceptable technologies: <http://www.sos.ca.gov/administration/regulations/current-regulations/technology/digital-signatures/>

California Code of Regulations § 22000-22005

### Compensation for Injury and Availability of Treatment for Injury

Use the boilerplate language for injury language. If sponsors ask that the wording of this statement be altered, please refer them to the [Treatment and Compensation for Injury Statement](https://irb.ucsf.edu/treatment-and-compensation-injury) page. Very few changes to the statement are allowed, and these requests will delay referral to the external IRB.

Boilerplate language and UCSF requirements for Treatment and Compensation for Injury are available from the [HRPP website](https://irb.ucsf.edu/treatment-and-compensation-injury).

## Documentation of Informed Consent: Non-English speakers

[**Preferred Method**](https://irb.ucsf.edu/consenting-non-english-speakers#preferred)**:**

The preferred method is to provide consent forms written in the participant’s language. The researcher obtains and submits written translations of the IRB-approved consent form(s) after the study is approved.

[**Short Form Method**](https://irb.ucsf.edu/consenting-non-english-speakers#short)**:**

This method only should be used for the **occasional and unexpected enrollment**of a non-English-speaking participant in a study for which there is no translated consent form in the participant’s language. Instead of signing the English-language consent form (which the participant does not understand), the participant signs a "short form consent" — the [Experimental Participants Bill of Rights](https://irb.ucsf.edu/experimental-subjects-bill-rights) in his/her language. **Routine use of this method is strongly discouraged. UCSF requires full translation of the consent once two participants of any one language have been enrolled.**

**When the short form method is used, UCSF-contracted interpreters are not required to sign either the full English consent form or the short form and therefore do not usually act as the witness. The signature block must include a signature line for the witness but not the interpreter.**

### Specimens

Use the following text if your protocol involves the research collection of non-exempt tissue derived from clinical specimens. The additional UCSF IRB approved consent form language is not required for studies collecting designated research biopsies.

“**Risk of inadequate specimens for diagnostic purposes**:

Providing parts of your surgically-removed tissue for research could, in rare cases, result in too little tissue being available for your doctors to make a clinical diagnosis (or complete other clinically important tests). To minimize this risk, a Pathologist (or a pathology designee) carefully evaluates every tissue specimen at the time of surgery to decide if it can safely be provided for research. With this process in place, we believe the risk of negatively impacting your clinical care through providing tissue for research is extremely small (below 1%).”

### Specimen Property Rights

Add the below paragraph to the consent form if bodily specimens will be taken from the subject and if there is a possibility that the results of the research may have commercial value:

“Your specimens may be used for commercial use. If this happens, you will not share in any profits.”

RPAC Guidance Memo No. 14-07 "Use of Specimens (Moore Clause) Disclosure in the Informed Consent Form "

Filing of Consent in Electronic Medical Record

If the research includes any procedures at UCSF Health, include the following language:

" Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records and may be added to your medical record. Your personal information may be given out if required by law.

### Confidentiality statement for studies conducted at a UCSF Clinical Research Services site

At certain sites, including CRS sites, every research participant is required to have a medical record. Use a confidentiality statement such as the following (adapted as appropriate):

“Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. A UCSF medical record will be created because of your participation in this study. Your consent form and some of your research test results will be included in this record. Therefore, your other UCSF doctors may become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.”

## Accessing Protected Health Information

This institution is a covered entity under HIPAA, specifically a Hybrid. If recruitment activities requires access to medical information in order to identify and contact eligible subjects, a waiver of HIPAA Authorization for this activity must be approved and the investigator must have a copy of the IRB’s Documentation of the Waiver prior to accessing the medical records.

If the investigator will be accessing identifiable health information, they must either:

Obtain a UCSF HIPAA Authorization form from the subject. Due to California and University of California specific requirements (such as a minimum of 14-point font), investigators are required to use the standard UCSF template HIPAA Authorization form. Templates are available from the [HRPP website](https://irb.ucsf.edu/hipaa). The following language must be included in the consent:

" You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you."

OR

Obtain a waiver of HIPAA authorization from the UCSF privacy board.

The UCSF IRB acts as their own privacy board when relying on an external IRB. HIPAA determinations are documented in the acknowledgement letter the UCSF study team receives from the UCSF IRB.

# Legally Authorized Representative

The UCOP Guidance for Surrogate Consent (attached) includes specific guidance for the IRB.

The state law uses the terms “surrogate decisionmaker” or simply “surrogate” to refer to the legally authorized representative. The University of California Office of the President (UCOP) issued guidelines for following the law and designed a form for surrogates to self-certify their eligibility. UCSF investigators are required to follow the UCOP guidelines and use the Self-Certification of Surrogate Decision Makers for Potential Subject's Participation in University of California Research form.

Of special note:

* No surrogates may be asked for consent unless the IRB has specifically approved the use of surrogates for consent for the specific study.

UCOP Guidance for Surrogate Consent

California Health and Safety Code §24178

# Children and Minors

Age of Majority in California is 18 years old.

## Minors Who are Not Children

These are circumstances where children may consent to their own participation in research:

* Emancipated – An Emancipated Minor is a person who is under 18 years old and:
  + Has entered into a valid marriage, whether it has been dissolved or not;
  + Is on active duty with the armed forces of the US; or
  + Has received a declaration of emancipation from the court.
* Self-Sufficient Minor – A Self-Sufficient Minor is a person fifteen years or older living away from home and managing their own financial affairs. The investigator should obtain documentation of self-sufficient minor status.
* Minors 12 years old or older in certain cases\*:
  + Mental Health treatment or counseling on an outpatient basis (not including convulsive therapy, psychosurgery or psychotropic drugs), or residential shelter services, if the minor is twelve or older and mature enough to participate intelligently and either (a) the minor is an alleged victim of incest or child abuse or (b) there is danger of serious physical or mental harm to the minor or others without such treatment. (The treating physician must contact and involve the parents unless the physician believes such contact would be inappropriate.)
  + Contagious Disease: Medical care related to the diagnosis or treatment of reportable infectious, contagious, or communicable/sexually transmitted diseases.
  + HIV Tests: The performance of an HIV test.
  + Rape: Medical care related to the diagnosis or treatment of the condition and collection of medical evidence with regard to the alleged rape.
  + Drug or Alcohol Abuse: Medical care and counseling relating to the diagnosis and treatment of a drug- or alcohol related problem (only if the treating physician deems and documents that parental involvement is inappropriate), excluding narcotic replacement drugs.
  + Pregnancy and care related to pregnancy, Contraception and Abortion: Minors Seeking treatment of pregnancy may consent for themselves to medical care related to the prevention or treatment of pregnancy, but not to sterilization.
* Sexual Assault – Any Age: Care related to the diagnosis or treatment of sexual assault for a minor, but the treating physician must attempt to contact the child’s parents or legal guardian unless the physician “reasonably believes” that the parent or guardian committed the sexual assault.

\*The California Family Code includes more restrictions and exceptions than can be summarized here. Consult the relevant sections of the law. Contact the UCSF IRB office for assistance in interpreting the law.

California Family Code §6920-6929; & 7000-7143

Adolescent Health Working Group Guidance: Understanding Confidentiality and Minor Consent in California (Adolescent Confidentiality Toolkit)

## Assent

UCSF IRB follows the federal regulations for obtaining consent/assent from minors.

# Prisoners

The [California Penal Code (Sections 3500; 3501-3509.5, 3521)](https://leginfo.legislature.ca.gov/faces/codes_displayexpandedbranch.xhtml?tocCode=PEN&division=&title=2.1.&part=3.&chapter=&article=) outlines provisions for research involving prisoners within the state.

## Biomedical Research

California law prohibits all biomedical research on prisoners ([Section 3502](https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=PEN&division=&title=2.1.&part=3.&chapter=2.&article=)). However, prisoner participation in investigational new drug (IND) research may be allowed under certain circumstances:

* The treatment protocol or treatment IND meets the regulatory requirements in 21 CFR 312, regulations enforced by the FDA; and
* The treatment is deemed to be in the prisoner's best medical interest [Section 3502.5(a)], and
* The prisoner-participant has given informed consent [Section 3521].

“Biomedical research” means research relating to or involving biological, medical, or physical science. Biomedical research does not include the accumulation of statistical data in the assessment of the effectiveness of non-experimental public health programs or treatment programs in which inmates routinely participate.

## Retrospective Medical Chart Review

Retrospective Medical Chart reviews (existing data) without prospective interaction with the subject is permissible. However, the use and disclosure of the individually identifiable information requires;

* Approval from the research advisory committee established to oversee research activities within the department (e.g. Department of Corrections and Rehabilitation); and
* The prisoner’s written authorization or a Waiver of Authorization from the IRB

## Behavioral Research

Prisoners are permitted in Behavioral Research only if the research is 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.

Behavioral modification techniques are allowable only if such techniques are medically and socially acceptable means by which to modify behavior and if such techniques do not inflict permanent physical or psychological injury.

“Behavioral research” means studies involving, but not limited to, the investigation of human behavior, emotion, adaptation, conditioning, and response in a program designed to test certain hypotheses through the collection of objective data. Behavioral research does not include the accumulation of statistical data in the assessment of the effectiveness of programs to which inmates are routinely assigned, including, but not limited to, education, vocational training, productive work, counseling, recognized therapies, and programs that are not experimental in nature.

Informed consent is not required for participation in behavioral research when the department (e.g. Department of Corrections and Rehabilitation) determines that it would be unnecessary or significantly inhibit the conduct of such research. In the absence of such determination, informed consent is required.

The Informed Consent Process must meet all conditions:

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:
   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. An offer to answer any inquiries concerning the applicable biomedical or behavioral research procedures.
   6. An instruction that the person is free to withdraw his consent and to discontinue participation in the research at any time without prejudice to the subject.

Compensation: the amount must be comparable to that which is paid to non-prisoner research subjects in similar research.

California Code of Regulations § 3369.5

California Penal Code § 3500-3524

# HIPAA Authorization

Due to California and University of California specific requirements (such as a minimum of 14-point font), investigators are required to use the standard UCSF template HIPAA Authorization form.

California Civil Code §56.11

# Other Requirements or Factors Affecting Research at UCSF

## Epic Care Everywhere

UCSF has not opted-in to the use of Epic Care Everywhere for research purposes, and therefore does not allow the use of non-UCSF data from Care Everywhere. The only exception is for research directly related to treatment, testing, or vaccine development for an active national public health emergency.

## Sponsor access to Protected Health Information

UCSF allows for industry sponsors to access Protected Health Information for monitoring purposes and to the extent required for adverse event reporting to the FDA. UCSF generally does not allow sponsors to retain PHI in Case Report Forms (CRFs / eCRFs) or other research records. In most cases direct identifiers must be removed and replaced with a code before UCSF will release data to sponsors.

## Compensation: Lottery/Raffle/Drawing

The University of California interprets California State Law prohibiting lotteries as also prohibiting compensation to research participants through a drawing. A lottery occurs when the individual included in the drawing provides something of value in return for their inclusion. In cases where research participants are entered into a drawing, the individual's consent and participation is something of value. So, if an individual can be included in the drawing only if they participate, the drawing meets the California definition of “lottery.” One way around this prohibition is to open the drawing to everyone, regardless of their participation. You can revise the protocol to include a mechanism for those who do not participate to enter the drawing. For example, you could add the following language to the invitation:

"Everyone can be entered in the drawing regardless of participation. If you do not want to participate but want to be included in the drawing, please email the study team at xxxxx.”

## Data Safety Monitoring Plan for Clinical Investigations

A Data Safety Monitoring Plan (DSMP) must be developed for all clinical investigations conducted at UCSF regardless of funding source. The DSMP must contain, at a minimum, a plan for safety monitoring, reporting of AEs and/or unanticipated problems involving risks to subjects, descriptions of interim safety reviews, and the procedures for communicating these results to the IRB, study sponsor (when applicable) and federal regulatory authorities (when applicable).

## Data Storage and Collection: Mechanical Turk

The use of the online service Mechanical Turk is acceptable when conducting human subjects research only if the data collected is non-sensitive.

Mechanical Turk may not be used if the data collected could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation, or is covered by HIPAA.

Internal Memo to IRB Directors from the University of California Office of the President

## Human Cloning

Cloning a human being or engaging in human reproductive cloning is prohibited. The purchase or sale of an ovum, zygote, embryo, or fetus for the purpose of cloning a human being is prohibited.

California Health and Safety Code § 24185-24187

## Investigational Drugs and Biologics

All investigational drugs and biologics must be stored and distributed by the UCSF Investigational Drug Service, unless a waiver is granted by the UCSF Investigational Drug Pharmacist.

University of California, San Francisco Department of Pharmaceutical Services Internal Policy

All research involving the use of biologics must comply with [California Department of Public Health Licensing Requirements](https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/FacilityLicensingHome.aspx).

## Oocytes for Research

California Law requires IRB approval for all research involving Assisted Oocyte Production (AOP) and egg extraction for research. The procedures for procuring oocytes must comply with state law, even if the procurement occurred outside of California.

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.

California Health and Safety Code § 125330-125355

## Privacy Laws

Article 1 of the California Constitution identifies privacy as an inalienable right. To this end, there are over 90 laws regulating privacy rights. The State of California Department of Justice summarizes these laws at <https://oag.ca.gov/privacy/privacy-laws>. Contact UCSF IRB at [IRB@ucsf.edu](mailto:IRB@ucsf.edu) for assistance in the interpretation of these laws in the context of research.

## Recruitment: Cold Call Recruitment

Cold calling/recruitment of subjects by members of the research team who are not involved in the patient’s care is allowed only under limited circumstances. The IRB must approve a telephone script, and the IRB application must explain why the study cannot be done unless the researchers approach subjects directly.