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|  | **Study involves:** | Language to add: |
|  | If the research meets the State of California's definition of a medical experiment[[1]](#footnote-1):  (a) 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; or  (b) The investigational use of a drug or device; or  (c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject. | California Experimental Subject's Bill of Rights  1. 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.]***  1. Whether or not you take part is up to you. 2. You can choose without force, fraud, deceit, duress, coercion, or undue influence. 3. You can choose not to take part. 4. You can agree to take part now and later change your mind. 5. Whatever you decide it will not be held against you. 6. You can ask all the questions you want before you decide. 7. 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.]*** 8. 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.]*** |
|  | Include the language when the research requires entry into Bridge and Electronic Medical Records (EMR) systems:  (a) All studies that investigate a drug or device;  (b) All studies which require items or services that result in any charge or billing component (including billing to a third-party insurance, study sponsor, or patient) in the Epic billing system; or  (c) All studies that include, as part of their protocol, any clinical intervention, including the invasion of any research participant (control or subject) body cavity (e.g. blood draw) when such an intervention takes place within a UC Davis Medical Center (UCDMC) licensed facility.[[2]](#footnote-2) | If you agree to participate in this research study, a signed copy of this consent document and the privacy authorization form may be filed in your electronic medical record (EMR) and your study participation may be added to your EMR. This information will be used for your care and treatment and for healthcare operations, which may include billing and payment. Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your EMR until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your research records. |
|  | If accessing identifiable health information ensure that you provide a copy of the UC Davis [HIPAA authorization](https://research.ucdavis.edu/wp-content/uploads/UC-Davis-Health-HIPAA-Authorization-Form-9.2017.pdf) form to the subject and include this language. | We will access protected health information (e.g., your medical record) for this study and you will be asked to sign a separate form, commonly referred to as a HIPAA authorization, to give your permission. ***[If applicable, include the following sentences.]*** Your medical records may become part of the research record. If that happens, your medical records may be looked at by the sponsor of this study and government agencies or other groups associated with the study. They may not copy or take your personal health information from your medical records unless permitted or required by law.  Federal law provides additional protections of your medical records and related health information. These are described in the UC Davis Health Notice of Privacy Practices (<http://www.ucdmc.ucdavis.edu/legal/privacy/>) and in an attached document. |
|  | Include the injury language when the research involves greater than minimal risk. | If you are injured as a result of being in this study, the University of California will provide the necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by the University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about compensation, you may contact the IRB Administration at (916) 703-9158 or [HS-IRBEducation@ucdavis.edu](mailto:HS-IRBEducation@ucdavis.edu).  [Include if applicable, otherwise delete.] If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number. This information will be used to check to see if you receive Medicare, and, if you do, report the payment they make to Medicare. The study sponsor will not use this information for any other purpose. |
|  | Include when the study has possible costs to subjects not covered by the research. | For more information about possible costs, please contact the research team. The research team can follow UC Davis Uninsured Non-Emergency Estimate Policy (Policy ID 1883) to work with their department and Decision Support Services to get you a cost estimate. |
|  | Include this language when the research collects, obtains or analyzes biospecimens and/or information derived from those specimens. | Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them. |
|  | Include this language when a member of the research team has a related financial interest or if the University of California has an institutional conflict. | ***[Name of Conflicted Party]***, a researcher on the study team, has a financial interest in [Sponsor], the company paying for this study. The company is paying ***[Name of Conflicted Party]*** for ***[describe the interest; or payment, e.g., consulting fee, salary]***. The [type of interest] income ***[Name]*** receives is in addition to their salary from the University of California. If you have questions, tell the study coordinator and they will put you in touch with someone to talk to. |

1. California Health and Safety Code § 24170 [↑](#footnote-ref-1)
2. UCD Health P&P 2317: Documentation of Research Patient Status in the Electronic Medical Record (EMR); UCD Health P&P 2306: Legal Medical Record Content/Core Elements [↑](#footnote-ref-2)