UNIVERSITY OF CALIFORNIA, DAVIS

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OFFICE OF RESEARCH
IRB Administration
TELEPHONE: 916 703-9151
FAX: 916 703-9160

[CURRENT DATE]

PI FIRST NAME PI LAST NAME, PI DEGREE
Department:
Phone:
Email:

Dear Dr. Mr. Ms. [PI LAST NAME]:

On [EFFECTIVE DATE] the [BOARD NAME] reviewed the following protocol:

Type of Review:	IRBNet: SUBMISSION TYPE
Title:	Project Overview: PROJECT TITLE
Investigator:	Project Overview: PI LAST NAME, PI FIRST NAME, PI DEGREE
IRB ID:	IRBNET ID
Funding:	Project Overview: SPONSOR NAME
Grant ID and Title:	Initial Review Application: GRANT INFORMATION PAGE: GRANT ID Initial Review Application: GRANT INFORMATION PAGE: GRANT TITLE
IND, IDE or HDE:	Initial Review Application: DRUGS AND BIOLOGICS INFORMATION PAGE: IND NUMBER Initial Review Application: MEDICAL DEVICE(S) INFORMATION PAGE: IDE/HDE NUMBER
Approval Period and Continuing Review Requirement:	The IRB approved the protocol from [EFFECTIVE DATE] to [PROJECT EXPIRATION DATE] inclusive. Before [CONTINUING REVIEW DEADLINE DATE: CALCULATE 45 DAYS BEFORE THE EXPIRATION DATE] or within 25 business days of study closure, whichever is earlier, you are to submit a completed "FORM: Continuing Review (HRP-212)" and required attachments to request continuing approval or closure. If continuing review approval is not granted before the expiration date of [EXPIRATION DATE] approval of this protocol expires on that date.
Risk Determination:	[PROJECT RISK LEVEL]
Category:	Expedited *<If not applicable, delete this section.>*

This information comes directly from your IRBNet application. The information cannot be edited after IRB approval.

IRB approval expires on the project expiration date. To apply for another approval period you must submit an application for continuing review.

The IRB will determine if the research is Minimal Risk or Greater than Minimal Risk

If reviewed using the expedited procedure the expedited category will be listed.

IMPORTANT
The IRB lists comments or conditions that must be met when conducting this research here.

The IRB approves you to enroll up to this number of subjects or access this number of records. If need to increase the number submit a modification.

Look here for details about the IRB approved consent process and documentation determination or an IRB issued waiver or alteration thereof.

For research involving minors the IRB will make a determination for both parental permission and child assent. Look here for the IRB's determination.

Comments/Conditions:	In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103). *<If applicable, add to this section.>*
Subjects:	• The IRB approved enrollment of up to subjects. • The IRB approved enrollment participants who are unable to speak or read English. *<Delete if not applicable.>*
Record Review:	*[If not applicable, delete this section]* This study is approved to access up to records. The data that can be accessed include data entered into the record between _____ and _____.
Consent	*<Delete bullets that do not apply. When needed, list specific cohort>* • A written consent form signed by study participants. • IRB waiver of the requirements for a signed consent form. • IRB approved waiver of consent. You must use the most currently approved consent document(s). *<Delete if there are no consent documents.>*
Parental Permission	*<Delete bullets that do not apply. When needed, list specific cohort. If not applicable, delete this section.>* • Both parents, unless one parent is deceased, unknown, incompetent, or not available, or when only one parent has legal responsibility for the care and custody of the child. • One parent (or legal guardian). • Neither parent (nor guardian) as this research meets the requirements for a waiver of consent.
Assent	*<Delete bullets that do not apply. When needed, list specific cohort. If not applicable, delete this section.>* • Assent will be obtained from all children capable of assenting. • Assent will not be obtained from children who are too young to understand the research. • Assent will not be obtained from children because this research meets the requirements for a waiver of consent. • Assent will be documented by the person obtaining assent on the consent document. Children who can read will be given an Information Sheet about the study.

When research takes place at UCDMC and it involves PHI the IRB will make a determination about the requirements to comply with HIPAA. Look here for the IRB's determination

All researchers are notified of these University Policies at the time of IRB approval.

If the research involves an agreement for an IRB reliance this section will list additional information.

HIPAA:	*<Delete bullets that do not apply. When needed, list specific cohort. If not applicable, delete this section.>* • Signed HIPAA Research Authorization from the participant or the participant's legally authorized representative. • HIPAA Waiver of Authorization for participant identification and recruitment. • HIPAA Waiver of Authorization for the study.
Biological Use Authorization:	• If your research involves recombinant DNA molecules, human gene transfer, infectious agents, or biohazardous materials, please contact the Institutional Biosafety Committee to determine if a Biological Use Authorization is required.
UCDMC Laboratory Testing or Sample Retrieval:	• Studies involving laboratory testing or sample retrieval (including tissue specimens) through UCDMC must coordinate services with the Department of Pathology and Laboratory Medicine. Call 734-2112, or email hs-pathresearch@ucdavis.edu to coordinate the services as soon as possible to avoid delays or complications.
Reliance:	*<If not applicable, delete this section.>*
Documents Submitted:	[STUDY DOC LIST (HTML)]

The IRB letter will contain a list of items reviewed. The list is auto-populated with file names. The file name you use will appear on the IRB determination letter. The IRB will not be able to alter this information.

This Assurance, on file with the Department of Health and Human Services, covers this activity:

FWA No: 00004557
Expiration Date: December 22, 2020
IORG: 0000251

UCD's Federalwide Assurance (FWA) number is included. The Federal Policy (Common Rule) for the protection of human subjects requires that each institution "engaged" in Federally-supported human subject research file an Assurance with the Office of Human Research Protections. The assurance formalizes the institution's commitment to protect human subjects.