



University of California
San Francisco

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Human Research Protection Program Institutional Review Board (IRB)

Full Committee Approval

Principal Investigator

Dr. John A Gonzales, MD

Type of Submission: Submission Response for Initial Review Submission Packet
Study Title: Systemic and Topical Antivirals for Control of Cytomegalovirus Anterior uveitis: Treatment
Outcomes
Study Status: Active - Full Board
IRB #: 26-46387
Reference #: 466309
Reviewing Committee: Laurel Heights Committee
Study Risk Assignment: Greater than minimal

Approval Date: 05/02/2026 **Expiration Date:** 05/01/2027

Regulatory Determinations Pertaining to This Approval:

Valganciclovir & Ganciclovir: The IRB Committee agreed that an IND was not needed for the use of the drug/supplement in this study.

Individual Research HIPAA Authorization is required of all subjects. Use the Permission to Use Personal Health Information for Research form, the Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research (if the VA is a site) or the local HIPAA authorization for research form, if the study involves access to patient records outside UCSF.

A waiver of HIPAA Authorization is granted for the recruitment procedures to identify potential subjects. The recruitment procedures involve routine review of medical or other records, do not adversely affect the rights and welfare of the individuals, and pose minimal risk to their privacy, based on, at least, the presence of the following elements: (1) an adequate plan to protect the identifiers from improper use and disclosure; (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, or a health or research justification for retaining the identifiers was provided or such retention is otherwise required by law; (3) adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study,

or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule; (4) the research could not practicably be conducted without the waiver; and (5) the study recruitment could not practicably be conducted without access to and use of the requested information. Study participants will sign a consent form prior to participation in the study.

IRB Comments:

Important Information for the Principal Investigator (updated 6/20/2024):

- It is the Principal Investigator's responsibility to ensure that all study personnel are properly trained for their roles in the study.
- It is the Principal Investigator's responsibility to ensure that the list of personnel in the IRB application is current and those listed as Key Study Personnel maintain current CITI Human Subjects Protection Training. Information about CITI Human Subjects Training can be found on the [IRB website](#).
- It is the Principal Investigator's responsibility to report to the IRB any protocol violations, adverse events and other reportable events/items that meet the UCSF reporting requirements. Please review and follow the [Post-Approval Reporting Requirements Summary Sheet](#).
- Providing all updated Investigator's Brochures, protocols and pharmacy manuals to UCSF's Investigational Drug Service (IDS) to ensure relevant new drug information is available to the research pharmacists in a timely manner.
- If this study has collaborating sites with their own reviewing IRBs, it is the Principal Investigator's responsibility to ensure that the collaborating sites have current IRB approval prior to engaging with them in any research activities, including sharing UCSF data or samples with them.
- If the IRB has approved the study to enroll non-English speaking participants, the Principal Investigator must ensure that the consent method follows current UCSF guidelines based on the IRB-approved method ([Short Form Method vs. Preferred Method](#)).
- The UCSF IRB strongly encourages enrollment of diverse participants. UCSF's Clinical & Translational Science Institute (CTSI) Participant Recruitment Program and the CTSI Integrating Special Populations Core offer tools, services, and consultations to support recruitment of underrepresented populations. For more information and to request a consultation, see: [Bit.ly/UCSFRAGE](#)
- **NEW ITEM:** The UCSF IRB strongly encourages enrollment of people with disabilities. Please review the [Participant Accessibility Guidelines](#), prepared by the [UCSF Office of Disability Access and Inclusion](#). After reviewing the guidelines, if you have specific questions about accommodations, please [submit a consultation request](#) to UCSF CTSI Consultation Services.
- A security risk assessment by UCSF IT Security **AND** Data Transfer Agreement by the Office of Sponsored Research (OSR -- Industry Contracts Division) must be completed if

your 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, [UCSF Affiliated Institutions](#)) or individual.** For industry or federally sponsored clinical studies, the contract with the sponsor covers data access/sharing and hence a Data Transfer Agreement is not required for such studies. If data will be shared with or hosted by a vendor (e.g., cloud software services), a security risk assessment and UCSF procurement contract must be completed.

- 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 OSR, not to the IRB.**

- To determine if a Data Security Risk Assessment is required, contact the intake team at 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 Reviews: Visit <https://data.ucsf.edu/data-sharing> or email datasharing@ucsf.edu
- For information about establishing contracts for data sharing engagements: Visit <https://icd.ucsf.edu/material-transfer-and-data-agreements> or email mta@ucsf.edu

All changes to a study must receive UCSF IRB approval before they are implemented. Follow the [modification request](#) instructions. The only exception to the requirement for prior UCSF IRB review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103.b.4, 21 CFR 56.108.a). In such cases, report the actions taken by submitting a Protocol Violation/Incident Report in iRIS. (There is an option under Major Research-Related Incident -- Change in protocol necessary to immediately protect research participants or others.) If the change will be a permanent change to the study, you must also submit a Modification form.

Expiration Notice: The iRIS system will generate an email notification eight weeks prior to the expiration of this study's approval. However, it is your responsibility to ensure that an application for [continuing review](#) approval has been submitted by the required time.

In addition, you are required to submit a [study closeout report](#) at the completion of the project.

Documents Reviewed and Approved with this Submission:

Consent Documents

Study Consent Form			
Title	Version #	Version Date	Outcome
STACCATO Consent Trial II	Version 1.0	04/24/2026	Approved
STACCATO Consent Trial I	Version 1.0	04/24/2026	Approved
HIPPA Research Authorization	Version 1.0	03/24/2026	Approved

Other Study Documents

Study Document			
Title	Version #	Version Date	Outcome
citiCompletionCertificate_9262245_55551394	Version 1.0	04/24/2026	Approved
Valganciclovir package insert	Version 1.0	03/23/2026	Approved
Cytovene-IV_ Package Insert	Version 1.0	03/23/2026	Approved
UCSF Worksheet_FDA Drugs and IND Requirements_Valganciclovir	Version 1.0	03/23/2026	Approved
UCSF Worksheet_FDA Drugs and IND Requirements_Ganciclovir	Version 1.0	03/23/2026	Approved
ClinicalProtocol	Version 1.0	03/23/2026	Approved
IND Status	Version 1.0	03/23/2026	Approved

For a list of all currently approved documents, follow these steps: Go to My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

San Francisco Veterans Affairs Medical Center (SFVAMC): If the SFVAMC is engaged in this research, you must secure approval of the VA Research & Development Committee in addition to UCSF IRB approval and follow all applicable VA and other federal requirements. The IRB [website](#) has more information.