OLIVE VIEW-UCLA MEDICAL CENTER
POLICY & PROCEDURE

NUMBER: 321
VERSION: 3

SUBJECT/TITLE: **HUMAN SUBJECT RESEARCH**

POLICY: All human subject research conducted at Olive View-UCLA Medical Center that involves human participants shall follow the established procedure outlined by the Olive View-UCLA Medical Center Education and Research Institute (ERI).

Prior to being initiated, all human subject research must be approved by the Institutional Review Board (IRB). The IRB shall be appropriately established and constituted, and its activities conducted in compliance with all applicable federal and state regulations.

The IRB shall meet monthly and maintain permanent records of its proceedings and actions. The records of the IRB's activities shall be reported, at least quarterly to the OVMC's Professional Staff Association (PSA) and the ERI Research and Education Operations Committee (REOC).

All human subjects who are asked to participate in a research project shall be provided with informed consent that includes the information described below under Section IV, "Informed Consent Process".

PURPOSE: To ensure the protection of human subjects who participate in biomedical research at Olive View-UCLA Medical Center.

DEPARTMENTS: All

DEFINITIONS: **Research**: Systematic investigation, including research development, testing, and evaluation that is designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research whether or not they are conducted or supported under a program that is considered research for other purposes.

Human Subject Participant: A living individual about whom an investigator (whether professional or student) conducting research obtains: 1) data through intervention or interaction with the individual or 2) identifiable private information.

PROCEDURE: I. **IRB Authority and Responsibilities**

IRB authority is granted by the Director of the Los Angeles County Department of Health Services, in accordance with the Bylaws of the Olive

View-UCLA Medical Center Professional Staff Association. The IRB approves and monitors research in accordance with regulations and requirements set forth by the federal Department of Health and Human Services, Office of Human Research Protection, Food and Drug Administration (FDA), and National Institutes of Health. Human subject research must adhere to the ethical principles contained in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* and the *Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*. The IRB is responsible for ensuring that:

- Risks to participants are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk, and, whenever possible, utilize clinical procedures that are already being performed for diagnostic or treatment purposes.
- Risks to participants are reasonable in relation to anticipated benefits (if any) to participants and the importance of knowledge associated with the expected results.
- Selection of subjects is equitable.
- Informed consent, specific to each research project and written in the language the participant or his/her legally authorized representative understands, is obtained and documented.
- Where appropriate, data collection is monitored to ensure the safety and privacy of participants and the confidentiality of the data.
- Appropriate safeguards are put into place to protect the rights and welfare of participants who are members of defined vulnerable populations.
- Findings and actions are reported to the investigator and institutional officials.
- Unanticipated problems involving risks to participants, serious or continuing non-compliance with IRB requirements, or termination of IRB approval are to be reported to institutional officials, and to institutions providing research oversight (such as the NIH or FDA) when appropriate.
- Central files of research documents are to be maintained for at least three years after completion or termination of a research project.

II. Facility/Institutional Authority and Responsibilities

The Olive View-UCLA Medical Center Chief Executive Officer, or designee, shall be a voting member of the IRB and support IRB activities through the participation and support of attending physician and hospital staff and the provision of space to support the IRB administrative

functions. Research approved by the IRB is subject to further review and approval or disapproval by the hospital administration, as appropriate. Hospital officials are not authorized to approve any research that has not been approved by the IRB.

III. Principal Investigator Responsibilities

Principal investigators are responsible for:

- Ensuring that the conduct of research and actions of project personnel are in compliance with the IRB-approved protocol, hospital policies and procedures, facility requirements, and all applicable federal, state, and local regulations.
- Ensuring that valid informed consent/assent has been obtained from all research participants or their legally authorized representatives, using a current IRB-approved informed consent document or script for recruiting research subjects.
- Ensuring that all project personnel involved in the process of consent/asset are properly trained and fully aware of their responsibilities relative to obtaining informed consent/assent according to IRB guidelines and applicable federal and state laws and regulations.
- Informing the IRB of any unanticipated serious adverse event or injury no later than two business days following the time it becomes known that a participant has suffered a serious adverse event/injury.
- Refraining from initiating any change in protocol without IRB approval, except when necessary to reduce or eliminate a risk to the participant(s), in which case the IRB is to be notified as soon as possible.
- Maintaining all required research records for review by the IRB and other authorized reviewers.
- Informing the IRB immediately of any significant negative change in the risk or benefit relationship of the research as originally presented in the protocol and approved by the IRB.
- Recognizing that IRB approval is valid for a maximum period of one year, with continuing review by the IRB required at least annually in order to maintain approved status.
- Refraining from entering any participants into a study prior to IRB approval or, after expiration of the IRB approval, obtaining approval of the IRB to continue participants on drug trials.
- Informing the IRB immediately upon becoming aware of any violations of federal Department of Health and Human Services (DHHS) or FDA regulations or IRB policies and procedures for the protection of human participants.
- Recognizing that failure to comply with all applicable DHHS or FDA

regulations, IRB policies and procedures, and the provisions of the protocol as approved by the IRB may result in suspension or termination of the project, notification of appropriate governmental agencies by the IRB, and/or suspension of the investigator's freedom to present or publish results.

- Providing a copy of the current IRB-approved protocol and stamped informed consent document to hospital officials as requested.
- Complying with the Health Insurance Portability and Accountability Act (HIPAA), California Health and Safety Code, and all other applicable laws, regulations, case law, DHS and Olive View-UCLA Medical Center policies, and the latest edition of the California Hospital Association Consent Manual guidelines related to the privacy of protected health information.

IV. Informed Consent Process

Consent for participation in a research study must be obtained under circumstances that provide the prospective participant or legally authorized representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The participant shall be informed of the following:

- Full explanation of the research purpose, design, duration, size, and subject (patient) criteria in language and terms he/she can understand
- Procedures of the study and any experimental drug or device to be used
- Potential benefits
- Potential discomforts and risks
- Reporting of events or new findings that may influence the participant's willingness to participate
- Description of alternative services that may be available based on the participant's medical condition and the associated benefits and/or risks
- A statement that refusal to participate will not compromise the individual's access to future medical services
- Financial responsibility for participation in the research and in availability of medical treatment should complications arise in the course of the study
- Voluntary participation and the right to withdraw
- Circumstances under which participation may be discontinued without the participant's consent
- Measures to safeguard privacy of protected health information
- Name of contact person(s) for questions about the study, research-related injury, or rights of research participants
- Compensation, if any, to the participant
- Investigator's financial relationship to sponsor or drug/device

manufacturer, including any apparent or action conflict of interest
- California Bill of Rights for Research Subjects
- Other information as stipulated by the IRB

Informed consent for research is in addition to informed consent required for medical treatment and must be written specifically for each research protocol. The consent document signed by a study participant or legally authorized representative must be an exact copy of the form that is approved by the IRB and must bear the appropriately dated stamp of the IRB.

Authorization for release of protected health information, as defined by HIPAA, must be documented separately from the informed consent using the attached form.

The signature original of the informed consent must be maintained by the Investigator and scanned into the research participant's electronic medical record. One copy must be given to the research participant.

Neither the informed consent document nor the process may include use of exculpatory language through which the participant or legally authorized representative waives, or appears to have waived, the participant's legal rights, or releases, or appears to release, the researcher, sponsor, or institution or its agents from liability for negligence. Research investigators must submit to the IRB, in writing, requests for changes to research activities, including the informed consent document. The only exceptions are changes necessary to eliminate an immediate hazard to the research participant, in which case the IRB shall be promptly notified.

V. Waiver or Alternation of Informed Consent Process and Documentation

The IRB may, under certain circumstances specified by federal law and regulation, alter the informed consent process, provided the IRB finds and documents that:

- The research or demonstration project is to be conducted by, or is subject to, the approval of state or local government officials and is designed to study, evaluate, or otherwise examine public benefit or service programs, procedures for obtaining benefits or services under these programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits under those programs; and
- The research could not practicably be carried out without the waiver or

alternation.

The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of the information consent, or waive the requirements to obtain consent, provided the IRB finds and documents that the research involves no more than minimal risk to participants, the waiver or alteration will not adversely affect the rights and welfare of the participants, the research could not practicably be carried out without the waiver or alteration, and whenever appropriate, the participants will be provided with additional pertinent information after participation.

The waiver or alteration of informed consent requirements shall not preempt applicable federal, state, or local laws that require additional information to be disclosed in order for informed consent to be legally effective. The decision as to whether to approve waiver of information consent rests with the IRB, not the investigator or the facility with the research takes place.

VI. Emergency Exemption from Prospective IRB Approval

FDA regulations allow for one emergency use of a test article (drug, device or biological) in an institution without the prospective IRB review and approval, provided such emergency use is reported to the IRB within five working days after such use. It is advised that physicians contact the IRB for guidance prior to such use. (Refer to FDA definition of emergency use at www.fda.gov.)

VII. HIPAA Privacy Rule Requirements

The IRB will review each study in accordance with the HIPAA Privacy Rule to determine whether or not a HIPAA authorization or waiver of HIPAA authorization is applicable. The investigator is required to provide a brief description of the protected health information for which use or access has been determined necessary by the IRB.

VIII. Procedure Documentation

Refer to the Olive View Education and Research Institute Policies and Procedure for procedure documentation requirements and standards.

References:
Title 45, CFR 46 (Department of Health and Human Services, Protection of Human Subjects)
Title 21, CFR 50 (FDA, Protection of Human Subjects)
Title 21, CFR 56 (FDA, Institutional Review Boards)
Title 21, CFR 312, Subparts A, B, C (FDA, New Drug Application)
Title 21, CFR 312, Subparts D, E (FDA, Responsibilities of Sponsors and Investigators)
Title 812 (FDA, Investigational Device Exemptions)
Title 34, CFR 99 (Family Educational Rights and Privacy Act)
P.L. 103-403 (Research on Transplantation of Fetal Tissue)
National Institutes of Health Guidance and Policy
Office for Human Rights Protections (OHRP) Guidance
FDA Guidance
45 CFR, Parts 160, 164; Section 164.512
California Health and Safety Code, Sections 24170-24179.5 (Protection of Human Subjects in Medical Experimentation Act)
California Code of Regulations, Title 22
Bylaws of the Olive View-UCLA Medical Center Professional Staff Association
Olive View Education and Research Institute Policies and Procedures
The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research
Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
Nuremburg Code
Declaration of Helsinki

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