HUMAN RESEARCH PROTECTION PROGRAM (HRPP)

MCP 011-019

San Francisco VA Health Care System
(SFVAHCS)
San Francisco, CA 94121

Rescinded Document:
See paragraph 7.

Effective Date:
August 20, 2021

Signatory Authority:
SFVAHCS Director

Recertification Date:
August 31, 2026

Responsible Owner:
Human Studies Coordinator/HRPP Manager

1. POLICY

This medical center policy (MCP) revises the local requirements for our Human Research Protection Program (HRPP), to assure the safety and welfare of all human subjects enrolled in research projects conducted or supported by this institution. All activities related to human subject research, regardless of funding source, will be guided by the ethical principles of respect for persons, beneficence and justice as outlined in the Belmont Report. The ethical conduct of research is a shared responsibility; it requires cooperation, collaboration and trust among the institution, investigators and their staff, the subjects who enroll in the research, and the members and staff of the HRPP.

2. JUSTIFICATION

This policy establishes local standards and requirements in addition to VHA Directive 1200.05, Requirements for the Protection of Human Subjects in Research.

3. RESPONSIBILITIES

a. **VA Medical Facility Director.** The VA medical facility Director, who also serves as the Institutional Official (IO), is responsible for ensuring overall VA medical facility compliance with this policy, and appropriate corrective action is taken if noncompliance is identified. The Research and Development Committee (R&DC) assists with these efforts. IO responsibilities are further discussed in VHA Directive 1200.05 and VHA Directive 1058.01.

b. **Human Studies Coordinator (HSC)/HRPP Manager.** The Responsible Owner is responsible for day-to-day policy oversight and providing guidance on behalf of the HRPP, with assistance from others on the HRPP team.

c. **Associate Chief of Staff for Research and Development (ACOS/R&D).** The ACOS/R&D administers the Clinical Research Program with the assistance of the Deputy Associate Chief of Staff for Clinical Research (D-ACOS/CR). The ACOS/R&D ensures that patent and royalty applications are reviewed and approved by ORD's

Technology Transfer Program Office before they are initiated. Upon notification of a PBM Safety Alert from the Chief of Staff, the ACOS/R&D will forward the Alert to the Human Studies Coordinator. ACOS responsibilities are further discussed in VHA Directive 1200.05.

d. **Clinical Research Office (CRO).** The CRO coordinates the HRPP and maintains access to all research protocols involving human subjects approved at the SFVAHCS. When advising researchers about the conduct of VA research, the CRO will incorporate applicable state and local laws governing human research. If there is a conflict between authorities, the CRO will consult with Office of General Counsel (OGC) and/or the OGC Specialty Team Advising Research (STAR) attorney to resolve the conflict. The CRO consists of the Human Studies Coordinator (HSC), HRPP Coordinator(s), HRPP Regulatory Assistant(s) and administrative support staff.

e. **Research and Development Committee (R&DC).** The R&DC provides the oversight of the HRPP to ensure regulatory compliance per VHA Directive 1200.01. The R&DC serves as the committee of record for initial review of exempt human subjects research.

f. **Clinical Research Workgroup (CRW).** The CRW of the R&DC provides the expertise to review clinical research. The CRW has been delegated the authority to conduct scientific review and recommend approval of clinical research by the Research and Development Committee (R&DC). Workgroup members are expected to demonstrate integrity and professional judgment and must recuse themselves when there is a conflict of interest. The chair of the CRW or designee has authority to clear conditions placed by this workgroup and has signatory authority for VA and other interagency documents to document approval of human subjects research.

g. **Institutional Review Board (IRB).** The designated IRB of record reviews studies before research can begin, conducts continuing review of previously approved research, and has the authority to require cessation of research activities after approval. The provision of services by the IRB is established through a memorandum of understanding or other written agreement that outlines the responsibilities of the SFVAHCS and the IRB. VA officials may not approve research that has not been approved by a designated IRB of record.

IRB review of VA research includes, as necessary, verification that the manufacture and formulation of investigational or unlicensed drugs or devices conforms to federal regulations. The IRB is responsible for confirming that such drugs or devices have the appropriate legal and regulatory approval (e.g., IND, IDE) or meet the exemptions for such approval, and confirms that the IND or IDE number is valid.

Each IRB works very closely with the CRO and provides timely reports and documentation to meet the requirements of the SFVAHCS HRPP and applicable VHA Handbooks and Directives. The IRBs will promptly notify the CRO should they identify issues that require reporting to ORO, OHRP and/or FDA.

SFVAHCS's IRBs of record are the UCSF IRB, the Veterans Affairs Central IRB (VA CIRB) and the National Cancer Institute's Central IRB (NCI CIRB). SFVAHCS may use other external IRBs of record, including commercial IRBs, for multi-site studies and cooperative research in accordance with signed MOUs/reliance agreements and VHA Directive 1200.05.

h. **University of California, San Francisco (UCSF) IRB.** The UCSF IRB serves as SFVAHCS's primary IRB of record, reviewing human subjects research proposals that are not under the purview of any another IRB of record.

The UCSF IRB has agreed to comply with VA requirements in reviewing VA research in accordance with a signed MOU. When reviewing international research, the UCSF IRB will ensure that it has the appropriate expertise and knowledge of the locale through IRB members or consultants.

UCSF's IRB also has an active role in the SFVAHCS Quality Improvement (QI) program through the auspices of their Quality Improvement Unit (QIU), which handles any participant or whistleblower complaints received by the IRB for any of the facilities for which it acts as IRB of record. QIU also processes post-approval events (e.g., reports of adverse events, non-compliance, and other research-related incidents), applying VA definitions and requirements where needed.

i. **UCSF Conflict of Interest Advisory Committee (COIAC).** The COIAC assists the IRB and the SFVAHCS's HRPP by reviewing any conflict of interest that may arise in human subjects' protocols reviewed by UCSF's IRB for SFVAHCS Principal Investigators who hold dual appointments as UCSF faculty.

j. **Financial Conflict of Interest (FCOI) Administrators.** The FCOI Administrators shall be appointed by the VA medical facility Director to review of conflicts of interest related to studies which are not overseen by UCSF IRB.

k. **Research Compliance Officer (RCO).** The Human RCO's primary responsibility is auditing and reviewing research protocols and committee processes relative to requirements for the protection of human subjects. To fulfill these responsibilities, the Human RCO conducts annual consent document audits and triennial regulatory audits on all active human research protocols and serves as a consultant to review committees or workgroups (e.g., R&DC, UCSF IRB, CRW) as needed to provide additional expertise in compliance with applicable regulations and VA policies. The RCO's activities may not be determined or managed by the Research Service, PIs, or any other research personnel. RCO responsibilities are further discussed in VHA Directive 1200.05 and VHA Handbook 1058.01.

l. **Human Studies Coordinator (HSC).** The HSC is responsible for the conduct of research within the HRPP, managing HRPP staff, and is responsible for monitoring changes in applicable policy and regulations, drafting policies, directing internal QI activities, filing required reports with regulatory authorities, assisting with regulatory

visits by outside auditors, and forwarding PBM Safety Alerts to the Research Pharmacist. The HSC serves as the principal liaison with UCSF's IRB and other IRBs of record. The HSC has no budget or fiscal control beyond recommendations for CRO budgets and implementation of fiscal activities approved by the Director of Research Operations/Administrative Officer and the ACOS/R&D.

The HSC serves as the point of contact for subjects with questions about their rights as a research subject or complaints about research at the SFVAHCS. The HSC will answer questions within his or her area of expertise or refer the subject elsewhere as appropriate. Complaints will be investigated and if appropriate, discussed with the CRW, the D-ACOS/CR, and/or the ACOS/R&D, and/or referred to the RCO, Office of General Counsel, and/or the facility Director.

m. **HRPP Coordinator(s) and Assistant(s).** The HRPP Coordinator(s) and Assistant(s) are the CRO analysts with primary screening, record keeping, reporting, communication, documentation responsibilities, and may have authority to clear conditions established by review committees. They may also serve as liaisons to the UCSF IRB or other IRBs of record.

n. **Information Systems Security Officer (ISSO) and Privacy Officer (PO).** The ISSO and the PO serve as *ex officio* (non-voting) members of the R&DC to ensure compliance with VA policies on data security and privacy, respectively, in accordance with VHA Directive 1200.01. The ISSO and PO also serve as consultants to the IRB per VHA Directive 1200.05.

o. **Research Pharmacist.** The Research Pharmacist is a member of the CRW as a consultant in the handling of research pharmaceuticals. He or she manages the research pharmacy and controls all investigational drugs. Upon being notified of a PBM Safety Alert, the Research Pharmacist will (1) notify the HSC if the research pharmacy has supplies of the investigational drug in question, and (2) notify any investigators who have prescribing privileges for that drug.

p. **Chief Pharmacist.** The Chief Pharmacist is responsible for oversight and control of investigational drugs, ensures appropriate pharmacy polices are current and that any requests for data extraction from Pharmacy Service or access to national dispensary databases for research purposes are cleared with the HSC or a designated member of the CRW.

q. **Service Chiefs.** The Service Chiefs are responsible for oversight and control of investigational drugs and devices used within their service, ensuring appropriate service level polices are current, investigational drugs and devices are stored in a manner to prevent unauthorized use, and any request for use of investigational drugs or devices has current IRB and R&D approval. A Service Chief's signature on the Request for R&D Committee Approval form indicates the chief's agreement to provide special handling of investigational products where required.

r. **Office of General Counsel (OGC) Specialty Team Advising Research (STAR).** OGC STAR provides the legal support and interpretation of regulations, policy and guidance as needed to support all facets of the SFVAHCS HRPP. Counsel reviews contracts, CRADAS, MOUs and other agreements as needed prior to execution.

s. **NCIRE - Veterans Health Research Institute.** NCIRE is the SFVAHCS's non-profit research and education corporation (NPC). NCIRE administers grants from non-VA sponsors and ensures that all such applications receive required reviews and approval. NCIRE monitors specific research training requirements for each Sponsor and ensures that the VA CITI modules contain the necessary elements.

t. **Principal Investigator (PI).** The PI is responsible for the conduct of the research as approved and must ensure that research is conducted in compliance with all applicable policies and regulatory requirements. The PI must attain and maintain the status of a SFVAHCS PI. If the research involves an investigational drug or device, the PI is responsible for ensuring that the drug or device is used only on an approved research protocol and that prescribing physicians are listed on that protocol. VA Investigator responsibilities are further discussed in VHA Directive 1200.05.

u. **All members of the research community** are required to ensure that all apparent serious or continuing non-compliance and unanticipated problems in research involving risks to subjects or others are reported promptly to the applicable IRB. Apparent serious or continuing non-compliance, serious unanticipated problems involving risks to subjects or others, and local unanticipated SAEs must be reported to the IRB in accordance with VHA Directive 1058.01 (within five business days of initial awareness); these reports are required in addition to other applicable reporting requirements (e.g., to the Sponsor under FDA requirements).

4. OTHER PARAGRAPHS

a. The SFVAHCS HRPP oversees all regulated research involving human subjects conducted on station or at any affiliated sites by SFVAHCS researchers while on official VA duty time. Individuals wishing to conduct such research are required to obtain R&DC approval prior to undertaking or continuing any research activities.

National VA regulations and guidance concerning human subjects research are available publicly at http://www.research.va.gov/resources/policies/default.cfm. SFVAHCS HRPP policies and procedures are published on the VA intranet (only available within the VA secure network). IRB guidance is available publicly online at the following links:

- UCSF IRB: http://irb.ucsf.edu/
- VA Central IRB: http://www.research.va.gov/vacentralirb/default.cfm
- NCI IRB: https://www.ncicirb.org/
- WCG IRB: https://www.wcgirb.com/how-to-submit/
- Advarra IRB: https://www.advarra.com/irb-services/

b. **Not Subject to HRPP Oversight:** Activities that do not constitute human subjects research (such as operations activities, program evaluation, quality improvement, case reports, and surveillance activities) in accordance with VHA Program Guide 1200.21 do not require oversight by the IRB or SFVAHCS HRPP.

If a researcher is unsure whether the planned activity constitutes human subjects research under this policy, the researcher should consult the IRB or the SFVAHCS HRPP. If a formal written determination is desired (e.g., as recommended by VHA Program Guide 1200.21 if the activities will be published in a peer-reviewed journal), the researcher may:

1) Submit a request to the authority for issuing such a determination (contact the SFVAHCS HRPP for more information).

2) If recommended by the CRO, request a not human research determination from the IRB. The IRB will provide written notification confirming the activity does not constitute human subjects research.

In addition, activities that have been granted a Humanitarian Device Exemption (HDE) by the IRB do not require SFVAHCS HRPP or R&DC oversight.

c. **Recruitment Flyers for non-VA Research:** may be posted and distributed with approval by a CRW member (or designee) and must include a disclaimer that the flyer is for information only and the research is not sponsored or endorsed by VA. The research must be relevant to Veterans and the mission of VA. Once an investigator obtains approval documentation from the CRW member or designee, the investigator must contact the VA Public Affairs office to request permission for posting. Approved flyers may be posted on any bulletin board that is not covered by glass.

d. **Requests for Exempt Certification:** Researchers are not permitted to make exempt determinations independently. All requests for exempt certification are subject to confirmation by the IRB and approval by the R&DC as the initial committee of record.

e. **VA Central Research Privacy Board (CRPB):** ORD has established and provided the management of a centralized Privacy Board to facilitate select VA research activities requiring a waiver of authorization if the criteria are met when an IRB is unable to provide the reviews and approvals. Investigators must submit applications for waivers of HIPAA Authorization to the CRPB via IRBNet. Refer to the VA CRPB Standard Operating Procedures for additional information including when the CRPB may be used, review processes and procedures, and timeframes for review.

f. **Initial Review:** All initial submission applications are subject to review and approval by the R&DC. Final approval to conduct human subjects research cannot be granted until the ACOS/R&D has received documentation of all necessary approvals from the IRB and other subcommittees or workgroups as applicable (e.g., CRW, PO, ISSO, biosafety subcommittee, radiation safety subcommittee, UCSF COIAC) that have

obligations to review and approve the proposed research.

Specific permission from the MCD or ORD, if required, will be sought after the study has received full approval from the IRB and the R&DC.

g. **Continuing Review:** Investigators must maintain approval of all appropriate committees, subcommittees, and workgroups for the duration of the study. Ongoing compliance is monitored through the IRB and SRS continuing review process, if required, and failure to maintain appropriate approvals may lead to delay or suspension of previously approved research.

Continuing review for research involving human subjects must be submitted and approved annually, as determined by the IRB of record. Studies regulated by the 2018 Common Rule Requirements (see 45 CFR 46) *may not require* annual continuing review by the IRB.

All applications for renewal are reviewed by the IRB and may require additional review by other subcommittees or workgroups (e.g., biosafety, radiation safety). Applications that include substantive changes in the VA portion of the study may require CRW review and approval. Research activities may resume once all approvals have been obtained.

h. **Informed consent forms** approved by the IRB are considered approved by SFVAHCS once initial R&DC approval of the associated project has been granted. ***Note**: After enrollment for a clinical trial has ended, the trial's informed consent form(s) must be posted on a publicly available website (e.g., clinicaltrials.gov).* For requirements related to the posting timeline and who is responsible for posting the consent forms, refer to VHA Directive 1200.05.

i. **Modifications:** All modifications to the IRB-approved protocol or documents must be submitted and approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the subject. Modifications involving changes to the VA HIPAA form or to the HIPAA determinations must be reviewed by the PO. ISSO review may be required for modifications which impact the study's data security plan.

j. **Adverse Events, Unanticipated Problems, Non-Compliance, and Suspensions or Terminations of Research by Outside Agencies** must be reported by researchers through the CRO following the guidelines for the IRB of record and in accordance with VHA Directive 1058.01. All reports will be reviewed by the HSC or an HRPP Coordinator or Assistant and the appropriate IRB and may be forwarded to other local committees or workgroups for discussion and/or action.

The IO is responsible for reporting a research problem or event to the appropriate authorities in the required manner within the time interval(s) specified.

The HSC is responsible for notification to the IO, internal committees, and other

necessary parties (e.g., the Research Pharmacist for PBM Safety Alerts). Where permitted by the appropriate authority, the HSC is responsible for filing follow-up reports (e.g., detailing any additional findings and appropriate remedial actions to the relevant ORO office at intervals and in a manner specified by that office).

The HRPP Coordinator or Assistant is responsible for communicating the outcome of the reviews to the researchers.

Where remedial actions involving a specific study or research team are required, the PI is responsible for ensuring that the actions are completed within the timeline set forth by ORO after the IRB's determination. Where remedial actions involving programmatic non-compliance are required, the ACOS/R&D is responsible for ensuring that the actions are completed within the timeline set forth by ORO after the IRB's determination, unless remediation requires substantial renovation, fiscal expenditure, hiring, or legal negotiations.

Current guidance on reporting problems, adverse events, local research deaths, and apparent serious or continuing noncompliance can be found at: https://www.va.gov/ORO/oropubs.asp.

k. **Conflicts of Interest:** After ORD notifies the ACOS/R&D of approval of patents and royalties, the ACOS/R&D will notify the IRB and R&DC through the CRO of a VA protocol with a potential institutional financial interest. The ACOS/R&D will also refer the PI to the Office of General Counsel or OGC STAR attorney, who will evaluate whether an institutional financial conflict of interest exists and consult with the appropriate committee, subcommittee, or workgroup for management strategies. The IRB has the final authority to grant IRB approval of the research associated with the patent and royalties through its review of submissions to the related research.

Investigators and research staff must disclose to the IRB of record any potential, actual, or perceived conflict of interest of a financial, professional, or personal nature that may affect any aspect of the research. They must also comply with all applicable VA and other federal requirements regarding conflict of interest.

PIs disclose potential financial conflicts of interest by completing the applicable section of the study application to the IRB. UCSF COIAC manages such conflicts for applications reviewed by UCSF IRB, while local FCOI Administrators manage such conflicts for applications reviewed by the VA Central IRB or other external IRBs. Approval may be withheld until identified conflicts are eliminated or until an acceptable plan is in place to manage conflicts. Management of potential conflicts is reported to R&DC through the minutes of each IRB or a separate workgroup report, as applicable.

l. **Cyber-Security and Data Incident Reporting:** Research staff must abide by the station's ISSO and PO policies for data security and privacy protection, and incidents implicating these policies must follow the procedures described therein. See Research Policy 151-26 for additional information.

m. **Education and Credentials:** ORD requires all investigators, research staff, and other personnel participating in, or reviewing, human subjects research to commit to an ongoing program of research education. Investigators, research staff, CRW members, VA representatives to the IRB and R&DC members are subject to this requirement.

Completion of CITI training is verified by SFVAHCS administrators. Researchers whose training is not current are not permitted to perform human subjects research, and their access to SFVAHCS computer systems may be suspended.

Research staff without clinical privileges, or whose privileges do not sufficiently encompass their research duties, are required to maintain a valid scope of practice document which outlines the tasks delegated to them by each SFVAHCS-approved PI for whom they work; nothing in this policy shall permit an individual to work outside of their credentials and/or privileging. Scopes do not expire, but PIs are responsible for reviewing the scopes of practice for all associated research staff at least annually and for submitting revised scopes as needed.

n. **HRPP Resources:** Resources (including, but not limited to, space, personnel, continuing education opportunities, and access to Regional Counsel) available to the HRPP are evaluated annually by the R&DC during its review of the program, continually by the D-ACOS/CR during regularly scheduled strategic planning and operational meetings of the CRO, and as needed by the ACOS/R&D in response to requests by the HSC or D-ACOS/CR.

The budget for the HRPP is submitted annually to medical center management through the DRO and the R&DC as part of the overall research budget. NCIRE augments the HRPP budget through salary and general fiscal support.

o. **International Research**

1) International research, as defined in VHA Directive 1200.05, is subject to the same policies, procedures, and processes as domestic research, including those for initial review, continuing review, review of modifications to previously approved research, and post-approval monitoring (including handling of complaints, non-compliance, and unanticipated problems involving risk to subjects or others). Except for CSP studies, all international research must also be approved by the Facility Director.

2) For CSP studies, PIs must obtain a waiver from the Chief Research and Development Officer (CRADO) prior to conducting international research. The PI must submit the required materials to the CRO for review by the ACOS/R&D. Following review by the ACOS/R&D, the CRO will request review and approval by the MCD on the PI's behalf and will forward the application to the CRADO. *For requirements related to the application for a waiver, refer to VHA Directive 1200.05.*

3) The PI must conduct the research in accordance with VA requirements and all other applicable federal requirements for protecting human subjects, tissue banking, use of databases, federal criminal laws, and the standards of ethical conduct for employees of the federal branch.

p. **Quality Improvement Plan**

1) The HRPP assesses its performance through:

a) annual reports to its accrediting body (if required), ORO, and the R&DC,

b) the results of the annual informed consent and triennial regulatory audits by the RCO,

c) metrics on HRPP processes (e.g., the volume of applications processed, the time interval between receipt of applications and final approval by the ACOS/R&D), and

d) periodic audits by ORO.

The HRPP endeavors to reduce the rate of reportable findings on the RCO audits while maintaining high customer satisfaction (quantified by number of serious complaints received by leadership annually).

5. DEFINITIONS

a. **Conflict of Interest.** Personal or professional relationships, including financial investments, service on boards or committees, or concurrent obligations, that may affect a researcher's ability to exercise independent judgment in the conduct of research.

b. **Collaborative Institutional Training Initiative (CITI).** The VA-approved human subjects protection and good clinical practice training provider.

c. **Collaborators.** Individuals not based at the San Francisco Veterans Affairs Health Care System (SFVAHCS) and have no direct or indirect authority to impact the research undertaken at this facility and are therefore not subject to VA policies and educational requirements. Examples include statisticians under contract, colleagues at other institutions with whom de-identified data is shared, and researchers who retain VA services under the auspices of a subcontract or MOU.

d. **HRPP.** Consists of the SFVAHCS CRO, the Research Compliance Officer (RCO), the Privacy Officer (PO) with responsibility for human research, the Information System Security Officer (ISSO) with responsibility for human research, the CRW, the Director of Research Operations (DRO), the Deputy Associate Chief of Staff for Clinical Research (D-ACOS/CR), the Associate Chief of Staff for Research (ACOS/R&D), and the Institutional Official (IO). Refer to VHA Directive 1200.05(2) section 5 for descriptions of responsibilities.

e. **Humanitarian Use Device (HUD).** A medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the U.S. per year. HUD devices are further discussed in 21 CFR 812.

f. **Institutional Conflict of Interest.** Business agreements or relationships that may compete or appear to compete for the same resources within the institution. An Institutional Conflict of Interest might occur when research involves patents or royalties as the VA retains a portion of the earned income from those sources.

g. **Investigational Drug.** A drug or biological product for which an investigational new drug application (IND) has been filed with the Food and Drug Administration (FDA). Investigational drugs are further discussed in 21 CFR 312.

h. **Investigational Device.** A device for which an investigational device exemption (IDE) has been filed with the Food and Drug Administration (FDA). Investigational devices are further discussed in 21 CFR 812.

i. **Local serious adverse events (SAEs).** SAEs occurring at SFVAHCS, at VA-leased space at UCSF Mission Bay, or at affiliated VA sites (e.g., CBOCs).

j. **Noncompliance.** Failure to adhere to the laws, regulations, or VA or University policies governing human research. Serious Noncompliance and Continuing Noncompliance are defined and discussed in VHA Directive 1058.01.

k. **SFVA Research sites.** While most research will be conducted at the SFVAHCS main campus, researchers may be engaged in research at one of our Community Based Outpatient Clinics (CBOCs), SFVA-leased space off-campus, or at another facility with the approval of the R&DC.

l. **SFVA Research staff.** Individuals who are engaged in research with human subjects that is approved (or pending approval) at SFVAHCS, regardless of type of employment (VA-paid, WOC or volunteer).

m. **Restricted Research and Vulnerable Populations.** Some research is prohibited at the VA or requires special permission or approval in accordance with VHA Directive 1200.05. Please contact VA HRPP (V21SFCHRPP@va.gov) for information on how to obtain medical facility Director certification where required.

n. **SFVA Research.** Any research involving SFVAHCS resources including VA time, equipment, or space owned, leased, or used by VA.

o. **VA Resources.** VA resources are used when the research:

(1) is sponsored by SFVAHCS,

(2) is conducted by or under the direction of any employee or agent of SFVAHCS in connection with his/her SFVAHCS responsibilities,

(3) is conducted on any property or within any facility of SFVAHCS,

(4) recruits Veteran subjects on SFVAHCS property; or

(5) involves the use of SFVAHCS's non-public information to identify or contact human research subjects or prospective subjects to use such data for research purposes.

6. REFERENCES

a. 18 U.S.C. § 201

b. 45 CFR 46 (Common Rule)

c. 38 CFR 16

d. 21 CFR 50, 56, 312, 361, and 812

e. 5 CFR 2635

f. VA Handbook 6500

g. VHA Directive 1200.01

h. VHA Directive 1200.05

i. VHA Directive 1058.01

j. VHA Handbook 1058.05

k. VHA Program Guide 1200.21

l. Federalwide Assurance (FWA) FWA00000280

m. MCM 119-08

n. Research Policy 151-26

o. VA/AFGE Master Agreement Articles 53 and 63.

7. RESCISSION

MCM 11-19, Human Research Protection Program, dated January 25, 2019 is rescinded.

8. REVIEW

This MCP must be reviewed at minimum at recertification and including when there are changes to the governing document, VHA Directive 1200.05.

9. RECERTIFICATION

This MCP is scheduled for recertification on or before the last working day of August 2026. This MCP will continue to serve as local policy until it is recertified or rescinded. In the event of contradiction with national policy, the national policy supersedes and controls.

10. SIGNATORY AUTHORITY

Bruce Ovbiagele, MD FRCP
San Francisco VA Health Care System Chief of Staff
Date Approved: August 20, 2021

NOTE: *The signature remains valid until rescinded by an appropriate administrative action.*

DISTRIBUTION: MCPs are available at: Medical Center Policies (MCPs) (sharepoint.com)