OVERVIEW: ROLES OF VA INSTITUTIONAL OFFICIALS

All information below is from the VHA Directive 1200.05(1), Version January 7, 2019 (amended March 3, 2020):

1. The HRPP is a comprehensive system to ensure the protection of human subjects participating in research. The HRPP consists of a variety of individuals and committees such as: the VA facility Director, Associate Chief of Staff (ACOS) for Research and Development (R&D), the Administrative Officer (AO) for R&D, the R&D Committee, the Institutional Review Board (IRB), other committees or subcommittees addressing human subjects protection (e.g., Biosafety, Radiation Safety, Radioactive Drug Research, Conflict of Interest), investigators, IRB staff, research staff, health and safety staff (e.g., Biosafety Officer, Radiation Safety Officer), compliance officers, information security officers, privacy officers, and research pharmacy staff. The objective of this system is to assist the institution in meeting ethical principles and regulatory requirements for the protection of human subjects in research.
2. The Institutional Official (IO) is the individual legally authorized as signatory official to commit an institution to an assurance. The IO is responsible for ensuring that the institution's HRPP functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The Principal Deputy Under Secretary for Health is the IO for VHA Central Office, and VA facility Directors are the IOs for local VA facilities. The IO serves as the official representative of the institution to external agencies and oversight bodies, and provides all written communication with external departments, agencies, and oversight bodies.
3. The R&D Committee is a committee responsible, through the Chief of Staff (COS) to the VA facility Director, for oversight of the facility's research program and for maintenance of high standards throughout that program (see VHA Directive 1200.05). The investigator must submit the protocol for initial review and obtain written approvals from the IRB, other applicable committees, and from the R&D Committee. In addition, the investigator must receive written notice from the ACOS/R&D that the research may commence before initiating the research.
4. Facility Directors, their administrative staff, COS, other facility senior administrators such as Associate or Assistant Directors or Chief Nurse, and NPC Administrative Staff may observe IRB meetings, but may not serve as voting or non-voting members of the facility's IRB. VA facility research office staff including, but not limited to, the ACOS for R&D, the AO for R&D, and IRB administrative staff may not serve as voting members of the facility's IRB. They may serve as ex officio, non-voting members; however, they and the IRB must be sensitive to any potential, actual, apparent, or perceived conflicts of interest and appropriately manage such conflicts. NOTE: Ex officio members are for purposes of this Handbook not allowed to be voting members of the IRB.
5. The VA medical facility Director certifies that the medical facility has sufficient expertise in women's health to conduct the proposed research (see guidance at http://www.research.va.gov/resources/policies/default.cfm).
6. VA is authorized to care for Veterans and to conduct research that supports the mission of VHA and that enhances the quality of health care delivery to Veterans. Therefore, research involving children must be reviewed carefully by the IRB for its relevance to VA and must not be greater than minimal risk. The VA medical facility Director must approve participation in the proposed research that includes children (see guidance at: http://www.research.va.gov/resources/policies/default.cfm)
7. If a research subject needs treatment in a medical emergency for a condition covered by this paragraph, VA medical facility Directors must provide reasonable reimbursement for the emergency treatment in a non-VA facility.
8. Before approving international research involving human subjects research, the IRB must ensure that human subjects outside of the U.S. who participate in research projects in which VA is a collaborator receive equivalent protections as research participants inside the U.S. (see OHRP guidance at http://www.hhs.gov/ohrp/international/index.html). NOTE: The VA medical facility Director must

approve participation in the proposed international research (see guidance at: http://www.research.va.gov/resources/policies/default.cfm).

All information below is from IRB SOPs:

1. SOP 201: Each IRB will have two or more compensated VA employees, as voting members. Officials in Research and Development administration including, but not limited to the Associated Chief of Staff for Research and Development and the Administrative Officer for Research and Development, do not serve as voting members of the IRB.
2. SOP 201: The Academic Senate, Vice President for Research and/or the Associate Vice President for Research Integrity and the VA Medical Center Director (for VA representation) in consultation with the IRB Chair and IRB Director have the authority to appoint members to the IRB. Members will be solicited from the University of Utah and greater Salt Lake communities. The VA Medical Center Director officially appoints VA IRB members and alternates in writing. The VA IRB member must be appointed for 3 years and may be re-appointed indefinitely.