

Section C: Element-by-Element Review

DOMAIN I: ORGANIZATION

Standard I-1: The Organization has a systematic and comprehensive human research protection program with appropriate leadership.

Element I.1.A: The Organization has a written plan for its HRPP appropriate for the volume and nature of the research involving human participants conducted under its auspices.

Document 1 FWA (page 2) indicates the VAMC follows the Belmont Principles and elects to follow the Common Rule and its subparts for all human subjects research regardless of funding.

Document 2 MOU describes the relationship between the VAMC and the University in the protection of human subjects. Doc 2 describes the components for oversight and how they work together to protect participants.

Document 3 MCM 151-01 (page 1 Definitions) describes when the VAMC is engaged in research and who is considered a VA investigator (including agent of the VAMC). Doc 3 describes the oversight components at the VA and the components work together. Required approvals prior to commencement of research are described on page 4 (Section e. (3) & (8)).

Document 4 MCM 151-03 (page 1 Policy & Definitions) describes the goal, principles, and applicable laws governing the VAMC's protection of human subjects in research. Pages 2-4 (Section 4. a.-g.) describes the roles and responsibilities of the components of the HRPP. Page 4 (Section g.) reiterates that the PI cannot commence research until he/she has R&D approval. Pages 5-6 (Section i) describes the types of research and categories of participants typically covered by the HRPP. Attachments A1-1 and A1-2 describe the overall structure.

Document 5 MCP 151-05 describes the VAMC's plan to maximize compliance with regulations and policies.

Document 6 HRPP Policy (pages 2-3) describes the structure and roles/responsibilities of the HRPP components. Pages 4-5 describe when FDA regulations apply and applicable state laws.

Document 7 The University IRB SOPs (pages 1-2, Section III) describes the basic principles that govern the conduct of research.

Document 8 The Investigator Handbook (pages 5-7, Section 3, Part A-D) describes the responsibilities of the Investigator and study staff.