Department of Veterans Affairs

Memorandum

Date: August 19, 2019

From: Deputy Under Secretary for Health for Discovery, Education, and Affiliate Networks (10X)

Subj: Delay In Implementation of Three Policy Areas for VHA Directive 1200.01, Research and Development Committee

To: Medical Center Directors and Associates Chiefs of Staff for Research (ACOS/R&)

Thru: Executive Director, Office of Research Oversight (10R)

1. VHA Directive 1200.01, "Research and Development Committee," was signed and published on January 24, 2019. On January 29, 2019, the Office of Research and Development (ORD) notified the Department of Veterans Affairs (VA) research community that the Office of Research Oversight (ORO) would use its discretion with regards to enforcing certain provisions in Veterans Health Administration (VHA) Directive 1200.01 to enable VHA facility personnel adequate time to practicably update and implement their policies to be in compliance with the revised Directive. Specifically, until May 1, 2019, ORO agreed to refrain from making research program noncompliance findings with regard to: (a) new requirements introduced by the Directive; (b) substantive alterations of prior VHA Handbook 1200.01 requirements that were incorporated into the Directive; and (c) Research and Development (R&D) Committee policies and practices being inconsistent with those new and substantively altered requirements of the Directive.

2. On April 19, 2019, Dr. Carolyn Clancy, Deputy Undersecretary for Health for Discovery, Education, and Affiliated Networks and the signatory for VHA Directive 1200.01, signed a formal memorandum concurring with the continuance of the discretionary enforcement of requirements until September 1, 2019 related to three specific policy areas addressed in the Directive. The extension was necessary to allow ORD additional time to publish guidance and supporting documents for these policy areas so as to ensure practicable and effective implementation by VA facility personnel. These three areas in VHA Directive 1200.01 are the following:

   a. Paragraphs 5.h.(9); 5.i., and 5.l.(3) – Establishment of Research & Development Committee Conflict of Interest Committees for review of the OGE Form 450 Alternative – VA, Research Financial Conflict of Interest Statement. ORD is working with the Office of General Counsel Ethics Specialty Team to resolve issues. VA Facilities should continue following their procedures developed prior to the release of the revised VHA Directive 1200.01 for identifying and managing financial conflicts of interest for VA Investigators.
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b. Paragraphs 5.h.(6), 5.j, and 5.k – Completion of Information System Security Officer (ISSO) and Privacy Officer (PO) review before any VA study is given final approval. ORD is working with the Office of Information Security and VHA Privacy to resolve issues. NOTE: All VA human subjects studies (including exempt research) must continue to have an ISSO and PO review prior to the study receiving final R&D Committee approval, and such reviews must be documented. This requirement will continue to be enforced by ORO.

c. Paragraph 10.c. – Use of Material Transfer Agreements (MTA) for transfer of biospecimens from VA in collaborative research activities. ORD is working with the Office of General Counsel and the Technology Transfer Program to resolve issues and obtain approval for the templates developed to support the policy.

3. ORD continues to work with multiple program offices to address implementation issues pertaining to the three policy areas in VHA Directive 1200.01 referenced above. Because these issues have yet to be fully resolved, implementing guidance has not been forthcoming. ORD and ORO both recognize that in the absence of implementing guidance, the requirements in Directive 1200.01 pertaining to these policy areas cannot be effectively implemented by VA facility personnel. As such, ORO has agreed to extend the period in which it will refrain from making VA facility-level noncompliance findings until January 20, 2020 pertaining to, and enforcing compliance with, the three policy areas described above. All other new requirements and/or substantive alterations of prior requirements introduced by the issuance of Directive 1200.01 are expected to have been complied with starting May 1, 2019. ORD will continue to provide ORO with periodic updates on the actions being taken to be able to issue the necessary guidance to the field so that VHA facilities can comply with the requirements of Directive 1200.01 pertaining to these three areas.

Carolyn M. Clancy, M.D.