Department of Veterans Affairs

Memorandum

Date: July 29, 2020

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

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

To: Medical Center Directors (00)
Associate Chiefs of Staff for Research (151)

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. I signed formal memoranda on April 19, 2019, August 19, 2019, and January 16, 2020, concurring with continuance of ORO's discretionary enforcement of requirements related to the following three *specific* policy areas addressed in the Directive: establishment of Research & Development Committee Conflict of Interest Committees; Information System Security Officer (ISSO) and Privacy Officer (PO) reviews of proposed VA research; and use of Material Transfer Agreements (MTA) for transfer of biospecimens from VA in collaborative research activities. The extensions of the discretionary enforcement period were necessary to allow ORD additional time to coordinate with other VHA offices to publish guidance and supporting documents for these policy areas so as to ensure practicable and effective implementation by VA facility personnel.

3. As of the date of this memorandum, ORD continues to work with multiple program offices to address policy and implementation issues pertaining to the three policy areas. The specific provisions in Directive 1200.01 for which ORD continues to work toward resolving implementation issues and updates on resolving said issues are as follows:

   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 continues to work with the Office of General Counsel Ethics to issue a new Directive separate from VHA Directive 1200.01 establishing the policy and procedures for filing of the financial disclosure forms (Alt-450s) by VA Investigators and the review of Alt-450s at VA Facilities in conjunction with the Department's Government Ethics program. 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, including filing of the Alt 450s by VA Investigators conducting VA research.

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 revise policy language through submission of a proposed technical amendment. It is anticipated that the technical amendment will be published within the next 3 months. *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 on approval for revised MTA templates and a policy revision describing the individuals and program offices that must review MTAs prior to execution.

4. ORD and ORO both recognize that in the absence of pending policy revisions and 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 until January 31, 2021 the period in which it will refrain from making VA facility-level noncompliance findings pertaining to, and enforcing compliance with, the three policy areas described above unless ORD publishes policy revisions and/or establishes processes that enable the policy areas to be practicably implemented sooner. 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 implement policy and process changes that practicably enable VA research programs to comply with the aforementioned policy areas.

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