

Department of
Veterans Affairs

Memorandum

Date: APR 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 Associate 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 VA research community that the Office of Research Oversight (ORO) would use its discretion with regards to enforcing certain provisions in 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 regarding: new requirements introduced by the Directive; substantive alterations of prior VHA Handbook 1200.01 requirements that were incorporated into the Directive; and R&DC policies and practices being inconsistent with those new and substantively altered requirements of the Directive.

2. As the end of the discretionary enforcement period of May 1 approaches, there are three areas within VHA Directive 1200.01 that require additional time for ORD to resolve in order to publish guidance and supporting documents for the VA research community. These three areas in VHA Directive 1200.01 are the following.

3. 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 and anticipate resolution by Sep 1, 2019. 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.

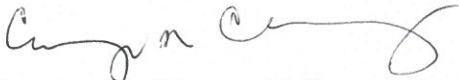
4. Paragraphs 5.h.(6), 5.j, and 5.k – Completion of Information System Security Officer (ISSO) and Privacy Officer (PO) review before any VA study is given final approval. ORD is working with the Office of Information Security and VHA Privacy to resolve issues and anticipate resolution by Sep 1, 2019. NOTE: All VA human subjects studies (including exempt research) must continue to have an ISSO and PO review prior to the

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study receiving final R&D Committee approval, and such reviews must be documented. This requirement will continue to be enforced by ORO.

5. 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 we expect resolution by July 1, 2019

6. ORD and ORO have discussed the necessity for resolution of the aforementioned issues before the associated policy requirements can be practicably implemented. As such, ORO has agreed to exercise its discretionary enforcement and refrain from making noncompliance findings pertaining to the three policy areas described in this notification until September 1, 2019. All other new requirements and/or substantive alterations of prior requirements introduced by the issuance of Directive 1200.01 are expected to be complied with starting May 1, 2019.

A handwritten signature in cursive script, appearing to read 'Carolyn M. Clancy'.

Carolyn M. Clancy, M.D.