GUIDANCE FOR SUBMITTING MOUs, MOAs, AND OTHER WRITTEN AGREEMENTS TO ORD

DATE: July 25, 2017

SCOPE: This document describes ORD’s current position on how sites should implement the requirements outlined in VHA Directive 1200.02 concerning the submission of Memorandums of Understanding (MOUs); Memorandums of Agreements (MOAs); and other written agreements to the Office of Research and Development (ORD).

The following topics are covered in this guidance document:

1. Background
2. Types of Agreements that should be submitted to ORD
3. Agreements that should not be submitted to ORD
4. Submitting Agreements to ORD
5. Review of Agreements by ORD

1. BACKGROUND

Paragraph 5b(2)d of VHA Directive 1200.02, “Research Business Operations” stipulates that VA medical facilities conducting research must submit MOUs or other written agreements, including those for the use of the university affiliate’s IRB, IACUC, Safety Committee, and Biosafety Committee to ORD. Additionally, it specifies that these facilities must also submit MOAs that commit the VA medical facility’s research program and another entity to specific programmatic responsibilities, to ORD prior to the facility signing the agreement.

This guidance document will clarify which agreements need to be submitted to ORD, types of agreements that should not be submitted to ORD, how to submit the agreements to ORD, and what feedback you can expect to receive from ORD post-submission.

2. TYPES OF AGREEMENTS THAT SHOULD BE SUBMITTED TO ORD

Agreements that commit the VA facility’s research program and another entity to an ongoing programmatic relationship must be submitted to ORD for review prior to signature by the VA facility.

Examples of such agreements include the following:
   a. New Reliance agreements whereby a VA facility relies on a review committee of another entity, VA or otherwise (renewals do not need to be submitted to ORD);
   b. Shared space agreements;
   c. Interagency and Consortium agreements that cover multiple projects;
   d. Collaborative research agreements that cover multiple projects.

3. AGREEMENTS THAT SHOULD NOT BE SUBMITTED TO ORD

ORD does not need to see individual project specific agreements. Examples of agreements that do not need to be reviewed by ORD include the following:
   a. Data Use Agreements/Data Transfer Agreements;
   b. Material Transfer Agreements;
   c. Cooperative Research and Development Agreements (CRADAs) for specific research projects;
   d. Facility and Project-specific Service Agreements;
e. Facility and Project-specific Contracts and Subcontracts;
f. HR Agreements to include WOC and IPA agreements.

4. SUBMITTING AGREEMENTS TO ORD

Agreements qualifying for review per paragraph 2 of this guidance document should be submitted to ORD for review. Please upload the proposed agreement to the “VHA Directive 1200.02 Required Agreements” SharePoint site located here (copy and paste the following URL into your web browser):

https://vaww.vha.vaco.portal.va.gov/sites/comm/admin/Lists/VHA_Directive_120002_Required_Agreements/AllItems.aspx?InitialTabId=Ribbon%2EListItem&VisibilityContext=WSSTabPersistence&View=%7b80c1c06a-e2f6-4604-aa1e-ee746804548b%7d&SortField=_ModerationStatus&SortDir=Desc.

A brief summary describing the activity covered by the agreement should be included in the field labeled, “Submitter’s Comments”.

Instructions for uploading documents to the site can be found in the document titled, “Instructions for Submitting VHA Directive 1200.02 Required Agreements to ORD”, located on the ORD Policies and Guidance Documents webpage: https://www.research.va.gov/resources/policies/default.cfm.

If you are unsure whether an agreement needs to be submitted to ORD for review, please send an email to VHACOORDRegulatory@va.gov describing the nature of the agreement in question.

5. REVIEW OF AGREEMENTS BY ORD

An email acknowledging receipt of the submission will be sent to both the individual responsible for uploading the documents to the SharePoint site (the “creator”) and the individual listed as the VA POC. ORD will review the information submitted to evaluate applicable ORD policy issues relevant to the Agreement.

Once ORD has completed its review, both the creator and VA POC will receive an email from SharePoint instructing them to access the SharePoint site to check the review status of their agreement. The designated reviewer should be contacted directly by email if revisions or clarifications have been requested.

If feedback has not been received from ORD within 10 business days of uploading the initial documents to the SharePoint site, please send an email to VHACOORDRegulatory@va.gov requesting a status update on the review.

REGULATORY AND VHA POLICY REFERENCES: