OFFICE OF RESEARCH ADMINISTRATION
MIAMI

National Institutes of Health (NIH) Policy on Dissemination of Clinical Trial Information
Office of Research Administration Guidance for Federal FY18 (Revised - 01/02/18)

The NIH Policy on Dissemination of Clinical Trial Information applies to applications submitted on or after January 18, 2017 that request support for the conduct of a clinical trial. This document provides guidance on NIH's review of the dissemination plan and terms of award.

Applicants are required to submit a plan for the dissemination of NIH-funded clinical trial information that will address how the expectations of this policy will be met. The NIH Human Subjects and Clinical Trials Information form is part of the FORMS-E package required for applications submitted for the January 25, 2018 due date and beyond. This form will include a "Dissemination Plan" as a required upload.

Since the FORMS-D application package does not explicitly request a dissemination plan, interim procedures are needed for NIH to obtain a Dissemination Plan from applicants submitting applications between January 18, 2017 and January 24, 2018. These interim procedures will be used for any clinical trial applications subject to the policy that are missing a dissemination plan.

Dissemination Plan

Applications subject to the policy that are submitted using FORMS-D will not have a designated upload area for the Dissemination Plan, and therefore it is likely that a Dissemination Plan was not included in the application. If a Dissemination Plan is not in the application, the NIH Institute/Center (IC) must request it from the applicant prior to award. The plan may be submitted through Just-in-Time, or via email from the Authorized Organizational Representative (AOR).

IF UM AOR is contacted by NIH requesting a Dissemination Plan, UM Pre Award will forward the request to Principal Investigator (PI) with cc to his/her department. PI should compile the Dissemination Plan consistent with the NIH Policy and information provided below and forward to mra@med.miami.edu. Pre Award will review the Dissemination Plan to ensure it meets NIH requirements and submit to NIH.

If UM PI is contacted by NIH requesting a Dissemination Plan, PI should compile the Dissemination Plan consistent with the NIH Policy and information provided below and forward to mra@med.miami.edu. Pre Award will review the Dissemination Plan to ensure it meets NIH requirements and submit to NIH.

The plan can be brief, but at a minimum it must contain sufficient information to assure that:

(1) the applicant will ensure that clinical trials under the award are registered and results information is submitted to ClinicalTrials.gov as outlined in the policy and according to the specific timelines stated in the policy ;
(2) informed consent documents for the clinical trial(s) will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov; and
(3) the recipient institution has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with policy requirements.

The Program Official (PO) will review the Dissemination Plan and verify that the minimum standards are met. If the plan is acceptable, the PO will document their approval via the PO checklist. The Grants Management Specialist will ensure that the approved Dissemination Plan and approval from the PO are included in the official grant file.

If the plan does not meet these minimum standards, or is otherwise not acceptable as determined by the IC, the grant award may not be issued until an acceptable plan has been submitted. If an award must be

made at the end of the federal fiscal year without an acceptable plan, a restriction must be placed on the award (see below).

Terms of Award

Once the Dissemination Plan has been approved by the IC, grants management will include the following two special terms and conditions in the Notice of Award:

1. The clinical trial(s) supported by this award is subject to the plan dated **[DATE]** submitted to NIH and the NIH policy on *Dissemination of NIH-Funded Clinical Trial Information.* The plan states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

2. This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:

   > In submitting this RPPR, the Signing Official (SO) (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

If an award must be made at the end of the fiscal year without an acceptable dissemination plan, the following restriction must be placed on the award:

> THIS AWARD CONTAINS GRANT SPECIFIC RESTRICTIONS. THESE RESTRICTIONS MAY ONLY BE LIFTED BY A REVISED NOTICE OF AWARD.
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> In absence of a plan for the dissemination of NIH-funded clinical trials information, all funds for this award are restricted **[add if Type 2 with ongoing clinical trial:** *with the exception of those costs associated with supporting currently enrolled patients***]**. Funds remain restricted until the **[NIH IC]** has received and approved a dissemination plan.
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> No funds may be drawn down from the payment system and no obligations may be made against Federal funds, **[add if Type 2 with ongoing clinical trial:** *except for those associated with patient care for currently enrolled patients,***]** prior to the **[NIH IC]**'s notification to the recipient via a revised Notice of Award that the identified issues have been resolved and this restriction removed.

IF ORA receives an award with the above-referenced restrictions, ORA Post Award will set up the award and restrict the funds, as well as alert PI and his/her department to this restriction. PI should compile the Dissemination Plan consistent with the NIH Policy and information provided above and forward to mra@med.miami.edu. Pre Award will review the Dissemination Plan to ensure it meets NIH requirements and submit to NIH. PI and ORA will monitor future awards to ensure this restriction is lifted based upon submission of the Dissemination Plan.