



January 3, 2018

**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. The [attached 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.

Prior to January 25, 2018, the FORMS-D application package was in effect and does not explicitly request a dissemination plan. As a result, NIH may need to obtain a Dissemination Plan from applicants who submitted applications between January 18, 2017 and January 24, 2018. The attached document identifies interim procedures which will be used for any clinical trial applications subject to the policy that are missing a dissemination plan.

The [Dissemination Plan](#) is also available on the [Clinical Research page](#) of the Office of Research Administration (ORA) [website](#).

In order to better understand the various policy changes regarding human subjects research and clinical trials, the National Institutes of Health (NIH) created a 15-minute video entitled, [Overview of NIH Policies on Human Subjects Research and Clinical Trials](#), which provides a succinct explanation of the various policy changes.

Resources:

[NOT-OD-16-149 - NIH Policy on the Dissemination of Funded Clinical Trial Information](#)

[NOT-OD-15-015 – Notice of Revised NIH Definition of "Clinical Trial"](#)

[NIH Clinical Trials Policy Page](#)

