

# University of Kentucky guidance for the dissemination of NIH funded clinical trial information

## FORMS-E, section 4.7

The University of Kentucky does not have an official policy or template for the dissemination of this information. Instead, we provide guidance to investigators to draft a dissemination plan based on the three core components as part of NIH Guide Notice NOT-OD-16-149.

1. The applicant will ensure that clinical trial(s) 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:

**Suggestions: Indicate that the study will be registered with ClinicalTrials.gov no later than 21 days after the first patient is recruited. One copy of the consent form and the study results will be made available according to policy.**

2. Informed consent documents for the clinical trial(s) will include a specific statement related to posting of clinical trial information at Clinicaltrials.gov.

**The informed consent template provided by ORI includes, in the “What else do you need to know” section, the following statement:**

***“A description of this clinical trial will be available on [ClinicalTrials.gov](https://www.clinicaltrials.gov) as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.”***

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 University of Kentucky Policy for trials registration can be found on the UK OSPA website at: <https://www.research2.uky.edu/office-sponsored-projects-administration/clinicaltrials.gov>**