**NIH Clinical Trial Dissemination Plan**

This is **suggested** language to include in NIH grant applications**.** There is no one-size fits all dissemination plan as a plan should be specific to an individual study. The content below should be considered an outline of what the PI and/or study staff should do at a minimum.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.*

**Suggested language to include in NIH grant applications:**

As Principal Investigator of this grant application and clinical trial, I will comply with the clinical trial information dissemination expectations of the [NIH](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html)) policy and [FDA/DHHS Final Rule](https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission) to register and submit summary results at [ClinicalTrials.gov](http://www.clinicaltrials.gov/).  Consistent with the terms and conditions of NIH funding, I will ensure the submission and updating of registration and results information for this clinical trial in the timeframes established by the Final Rule. Registration and results reporting in ClinicalTrials.gov will be completed within the following timeframes:

* Registration of the trial at ClinicalTrials.gov no later than 21 days after enrolling the first participant
* All submitted information will be updated at least once a year.
* Any apparent errors, deficiencies, and/or inconsistencies identified by NIH as part of the quality control review process and any other errors identified will be addressed by the responsible party.
* Corrections to submitted information will be made within 15 days for registration information and 25 days for results information.
* Trial results will be submitted no later than one year after the primary completion date.

Informed Consent Documents for the clinical trial will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov.The UNC IRB has template language explaining that the study will be posted on clinicaltrials.gov that investigators are required to include in the consent document for the trial.

As PI, I will work closely with the UNC-CH Office of Clinical Trials (OCT), which serves as the university’s internal PRS. The OCT has responsibility for ensuring that clinical trial registration and reporting occurs in compliance with NIH policies. The OCT has support staff to facilitate the process of registration and results reporting to ClinicalTrials.gov and I will work closely with them to register this trial and to submit summary results to the website in a timely manner, in keeping within the required timeframes. Once data collection is complete, I will work with my statistician to prepare and submit trial results no later than one year after the primary completion date.