## 4.7 Dissemination Plan

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***Guidelines***

1. *Required for clinical trials*
2. ***Format:***
   1. *No page limit*
   2. *Margins min. 0.5”*
   3. *NIH-recommended fonts: Arial, Georgia, Helvetica, Palatino Linotype*
3. ***Content:***
   1. *If application has multiple studies, only one Dissemination Plan is required*
      1. *Upload to each Study Record with unique file names OR attach a file that refers to the Dissemination Plan in another study record*
   2. *Follow all instructions below*
   3. *Contact* [*ctsiora@mednet.ucla.edu*](mailto:ctsiora@mednet.ucla.edu) *for additional guidance*
4. *When the form is complete:*
   1. *Remove this box*
   2. *Save file as “4.7 Dissemination Plan”*

**Instructions:**

1. Explain briefly your plan for the dissemination of NIH-funded clinical trial information and address how the expectations of the policy will be met.
2. The plan must contain sufficient information to assure the following:
   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;
   2. Informed consent documents for the clinical trial(s) will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov;
   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.

**Note:** Below is **suggested** language to include in NIH grant applications regarding UCLA’s registration process. There is no one-size fits all dissemination plan, this can be considered an outline what PIs and/or study staff should do at a minimum:

*Dissemination of study results through ClinicalTrials.gov registration and reporting at a minimum will include the following components:*

*X (insert name or role, can be a designee) will be responsible for handling ClinicalTrials.gov requirements for this project under the PI’s oversight. S/he will register the trial prior to enrolling the first subject. Once a record is established, s/he will confirm accuracy of record content; resolve problems; and maintain records including content update and modifications. S/he will also be responsible for aggregate results reporting and AE reporting at the conclusion of the project.*

* 1. *Add specifics related to this trial.*

**Note:** Do not include informed consent documents in your application.

**Note:** If your human subjects study meets the definition of “Delayed Onset,” include the dissemination plan in the delayed onset study justification.