

NIH Clinical Trials – Boilerplate Language

BACKGROUND

Certain pieces of the clinical trial information now required by NIH during the application process can be completed by using the following text. This document will be updated when/if new language is released by the UMMS Office of Regulatory Affairs.

Dissemination Plan

As Responsible Party, I will share information about this/these trial(s) via timely registration, updates, and results reporting in ClinicalTrials.gov in accordance with NIH policy.

The informed consent documents used for this/these trial(s) will include statements to inform participants that information about the trial will be posted in ClinicalTrials.gov.

The University of Michigan's Human Research Protections Program (HRPP) Operations Manual is the primary location where rules, policies, practices, and guidance pertaining to the University's HRPP are provided, including Part 11 (section II.H) which addresses the requirements to register trials and report results. Compliance with these provisions is monitored by designated components of the UM HRPP.

NOTE: This language would only be appropriate for grants submitted with proposed trials for which the UM PI is the initiator of the trial and there is no other IND/IDE holder for an investigative drug or device. An alternate version is provided below for UMCC (Cancer Center) trials.