INFORMED CONSENT CLINICALTRIALS.GOV DISCLOSURE STATEMENT

Per FDA regulation, the following statement is required on Informed Consent Forms used in Applicable Clinical Trials:

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

NIH-funded trials also require the disclosure statement on informed consent forms. While additional explanation may be provided, the disclosure statement may not be modified.

Find more information about requirements for informed consent forms at: https://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm