

NEW FDA FINAL RULING FOR MANDATORY LANGUAGE REGARDING CLINICALTRIALS.GOV FOR INFORMED CONSENTS

The Food & Drug Administration (FDA) has amended the current informed consent regulations (21 CFR 50.25) to require that informed consent documents and processes for **applicable** drug (including biological products) and device clinical trials include a specific statement that clinical trial information will be entered into ClinicalTrials.gov.

ClinicalTrials.gov is the clinical trial registry databank maintained by the NIH National Library of Medicine (NLM) which was created by statute, the Food and Drug Administration Amendments Act of 2007 (FDAAA). The submission of clinical trial information to ClinicalTrials.gov is also required by this statute.

This amendment to the informed consent regulations is required by FDAAA and is designed to promote transparency of clinical research to participants and patients.

The final rule can be found at <http://edocket.access.gpo.gov/2011/pdf/2010-33193.pdf>.

TO DETERMINE IF A STUDY IS AN APPLICABLE CLINICAL TRIAL:

http://grants.nih.gov/ClinicalTrials_fdaaa/ACTs_under_FDAAA.htm

DAIDS IMPLEMENTATION

AS OF **DECEMBER 1, 2011**, FOR NEW PROTOCOLS GOING THROUGH REGULATORY REVIEW, THE FOLLOWING LANGUAGE **MUST** BE INCLUDED IN THE SAMPLE INFORMED CONSENT (SIC) **ONLY** FOR APPLICABLE CLINICAL TRIALS:

“A description of this clinical trial will be available on 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.”

NOTES:

- Language cannot be modified
- Can be translated
- Only for applicable clinical trials
- SICs for ongoing studies do not need to be revised
- Participants do not need to re consent
- Not required to be in any specific location of the SIC

THE MANDATORY LANGUAGE IN THE SIC WILL BE CHECKED FOR APPLICABLE CLINICAL TRIALS DURING REGULATORY REVIEW WHEN NEW PROTOCOLS ARE SUBMITTED TO THE DAIDS REGULATORY SUPPORT CENTER (RSC). THE DAIDS PROTOCOL REGISTRATION OFFICE (PRO) WILL ALSO CONFIRM THE LANGUAGE IS IN EVERY SITE SPECIFIC IC DURING PROTOCOL REGISTRATION.

IF THE LANGUAGE IS MISSING IN THE SIC THERE MAY BE POTENTIAL DELAYS IN DAIDS APPROVAL OF THE PROTOCOL. IN ADDITION, THERE MAY BE DELAYS IN PROTOCOL REGISTRATION IF LANGUAGE IS MISSING IN THE SITE SPECIFIC IC.