Food and Drug Administration (FDA) Final Rule on New Required Element for Informed Consent (21 CFR 50.27)

**Disclosing that trial will be registered on ClinicalTrials.gov**

The final rule, issued January 2011 by FDA, amends consent regulations by requiring that informed consent documents for “applicable” clinical trials include a statement that information about the trial will be or has been submitted for inclusion in ClinicalTrials.gov trial registry.

Registration of applicable clinical trials has been a requirement since 2007 per the FDA Amendments Act FDAAA, 42 U.S.C. 282(j)(1)(A), section 402(j)(1)(A) of the PHS Act. With an impetus of promoting transparency, result databases provide public disclosure of ongoing research and results for key trial endpoints. Hence, it seems logical that investigators inform trial participants that this resource exists for obtaining information and results from the clinical trials in which they were involved.

**What does this mean for clinical researchers at UK?**

The UK IRB is in the process of revising the informed consent template to include the FDA required statement:

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``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."
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**When is inclusion of the statement in consent forms going to be mandatory?**

The effective date for the revised regulation is this month, so clinical investigators may begin including the statement in consent form documents for applicable clinical trials now if they choose to do so.

However, the compliance date of the final rule is **March 7, 2012**, so the addition will only be mandatory for trials initiated after that date. (For purposes of this rule, a trial is “initiated” if the sponsor/investigator has had any informed consent documents cleared or approved by an IRB).

**For studies ongoing before March 7, 2012, will investigators be required to re-consent subjects with revised consent forms including the additional statement?**

The requirement will be applied prospectively. Re-consent of subjects of trials initiated before the compliance date solely for the new requirement will not be required. Inclusion of the statement in cases where revision and re-consent is being done for other reasons is permitted but not required.

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Will FDA allow investigators to edit the required informed consent statement?

No. FDA wants a consistent message to be communicated to research participants. However there is nothing in the final rule that prohibits providing a separate information sheet about clinicaltrials.gov to a research participant as part of the informed consent process.

What if the IRB approves a ‘waiver of documentation’ of informed consent under 21 CFR 56.109?

If an IRB waives the requirement for a signed written consent form for an applicable study and requires the investigator to provide participants with a written statement regarding the research, that document “must include the new statement”. An example of such a document would be a cover letter for a survey study regarding tolerability of an investigational medication.

To find out more:


NONMEDICAL IRB NEWS

♦ **New Deadline:** If you are submitting a protocol for review by the nonmedical IRB, you will need to submit the application by the **Wednesday** deadline in order to have your protocol reviewed at the next scheduled meeting.

♦ **New Location:** The new location for Nonmedical IRB Meetings is Room 107 Breckinridge Hall.


Questions or comments? E-mail us at belinda.smith@uky.edu. To remove your name from our mailing list, please click here.