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Human Research News v5, n7: Clinical Trials Registration Requirement

Date: 2005-09-29

As you may be aware, there is a new industry standard (though not a regulation or law) set by the ICMJE regarding the registration of clinical trials for publication. The Dean's Office of the School of Medicine issued the notice below on Monday, September 12, 2005.
CLINICAL TRIALS SHOULD BE REGISTERED TO RETAIN THE ABILITY TO PUBLISH!
The International Committee of Medical Journal Editors (ICMJE) has stated that they "will consider a trial for publication only if it has been registered before the enrollment of the first patient." Furthermore, the journal editors have specified deadlines for compliance with this policy. Failure to properly register a trial will preclude future publication of the results of those trials in major medical journals.
Deadlines Ongoing Trials: September 13, 2005 New Trials: Before enrollment of the first patient
Whose responsibility is it to register a trial?
All individuals who anticipate publishing papers about a trial have an interest in assuring that the trial is properly registered.
Please note that Phase I Clinical Trials Do Not Require Registration.
The following is general guidance on who will register clinical trials by key types:

- Special Attention For PIs Who Hold An IND or IDE:
    - For trials where a PI holds an IND or IDE with the FDA, the PI is considered the sponsoring entity and is expected to register the trial.
    - UCLA PIs conducting NIH and other Federally sponsored clinical trials may also be responsible for registering clinical trials if they hold the IND or IDE, although in some instances the awarding agency may handle the registration.
- PI Initiated Trials (Funded by Industry or Other non-Federal Sponsor): The PI should ensure proper registration of the trial. In some such cases an industry sponsor will register such trials, but this should be verified.
- Industry Initiated and Sponsored Trials: In most cases, the industry sponsor will register the trials. However, registration by the sponsor should be verified. For new studies, the Industry Contracting Unit will include language requiring an industry sponsor to assume responsibility for proper registration in all clinical trial contract agreements.
- NIH/Federally Sponsored Trials: Most NIH and other Federally sponsored clinical trials will be registered by those agencies. However, PIs should still verify registration.

Where should a trial be registered?
The site for registration is www.ClinicalTrials.gov/ Several internal clinical research units have registered their own sites (e.g., NPI). In addition, as a service to faculty the Office of Clinical Trials (OCT) can assist with trial registration upon request. Please contact Juliet Burnett at 310-794-8782, for OCT registration assistance.
Action you should take now:

- Search on www.ClinicalTrials.gov to check if your trial is registered. If not, contact your sponsor to determine if and when they will register your trial. Register your trial if the sponsor will not.
- If you are a PI who holds an IND or IDE, you are responsible for registering the trial. If you hold an IND or IDE for a federally sponsored trial, check with the awarding NIH Institute or Federal agency to ensure proper registration.
- If you have a PI-initiated study (regardless of sponsorship) and you do not hold the IND, complete Action #1.

For additional information:

- ClinicalTrials.gov: How to register trials with ClinicalTrials.gov
- Journal Editors: Is This Clinical Trial Fully Registered? (May 2005)
- Journal Editors: Clinical Trial Registration September 2004)

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