



LOYOLA MEDICINE

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Administrative team, *Bone Marrow Transplantation*

Re: Registration of Clinical Trial

This is in response to your recent e:mail that included the following:

2. Please provide us with the web address for the registry where your clinical trial is registered. Please be aware that the journal requires registration of all clinical trials. Registration must be with an appropriate public trials registry. These can be region or country specific such as those maintained by the Australian NZ Clinical Trials Registry, the US National Library of Medicine or Current Controlled Trials. Please upload all registration information on the submission form and title page of the manuscript. The journal follows the trials registration policy of the ICMJE (www.ICMJE.org) and considers only trials that have been appropriately registered before submission, regardless of when the trial closed to enrolment. Acceptable registries must meet the following ICMJE requirements:

- • be publicly available, searchable, and open to all prospective registrants**
- • have a validation mechanism for registration data**
- • be managed by a not-for-profit organization**

If your clinical trial has not been registered, please explain why not. (E.g. pre July 2005).

This trial began in April, 2006 as a separate non-treatment trial here at Loyola University Medical Center (non-for-profit). Thus it was not part of a larger treatment trial. It was IRB approved and has been tracked by them but received expedited review by the IRB and as the new ICMJE rules were not clear at the time, we were under the impression that it did not need to be registered as the patients received no therapy and would not benefit from the results on the research blood tests that we were doing.

In June 2007 the ICMJE adopted the WHO's definition of clinical trial: "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes." This led us further to believe that it did not need to be registered as there was not a health-related intervention on behalf of the participants.

While the issues are a bit more clear in 2012, I am still not sure if today we would need to register this trial, but to avoid confusion and risk non-publication we have decided to do

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so for all trials of this nature. However again in late 2005 when the trial was first conceived, this was not clear.

Sincerely,

A handwritten signature in black ink, appearing to read "Patrick J Stiff". The signature is written in a cursive style with a large initial "P" and "S".

Patrick J Stiff MD