

April 27, 2005

I have reviewed the Ottawa statement and strongly support its importance and the general idea. I just have one cautionary note, which I would implore you to consider.

The statement is crafted with the model of a trial of a new medication or procedure in mind, particularly those that are sponsored by industry. It must also be kept in mind, however, that individual physicians may test a licensed medication on a sample of 2 or 3 patients with a rare condition that is poorly responsive to existing therapy, a medical student may conduct a small project involving a new procedure, or a nonphysician may conduct a pilot study of a new educational module on an at-risk group to determine its potential for usefulness on a larger scale. These individuals should have a very simple and quick registration process that does not include all of the components outlined in your statement, or else the adoption of your statement would have an inhibitory effect on the conduct of this type of small scale but often important exploratory research. For these types of projects the process should be very quick for a busy student or academician without secretarial support to complete, and, of course, free of monetary cost.

I do hope you keep this in mind as you move forward.

Sincerely,
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