

From: Peter C. Gotzsche
Sent: Monday, February 20, 2006 7:28 AM
To: OHRI, OttawaGroup
Subject: Part 2 Comments

2.3.2 As part of a quality assurance mechanism prior to assigning a Unique ID, the organization should obtain and maintain a linked record of basic protocol information to identify duplicate ID requests for the same trial. (what exactly is basic protocol information? Isn't there a risk that trials get confused if there is not access to the full protocol?)

The registered information must be presented at least in English and also preferably in the major language(s) of the region where the main study is located.

(drop "preferably" and write "may also be presented in..." In many cases, it would be a waste of resources to use local languages in addition to English)

a.

§ All fields must be completed at point of registration, except for date of ethics approval, which may be submitted at a time of approval. (I would suggest: ethics approval first, at least in the first country for a MC trial, and then registration. If a trial is unethical, it may never be done, and very often, ethics committees require changes to the protocol)

bw

Peter G
Peter C. Gøtzsche
Director
The Nordic Cochrane Centre
Rigshospitalet, Dept 7112
Blegdamsvej 9
DK-2100 Copenhagen Ø
Denmark

Visiting address: Tagensvej 18 B, DK-2200 Copenhagen N

<http://www.cochrane.dk/>