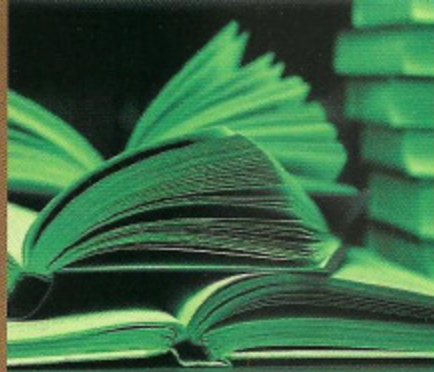


BOOK REVIEWS



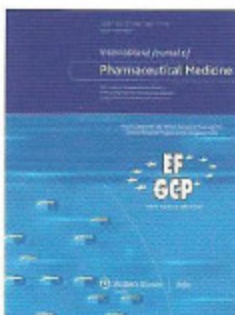
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THE PROCEDURE FOR THE ETHICAL REVIEW OF PROTOCOLS FOR CLINICAL RESEARCH PROJECTS IN THE EUROPEAN UNION. A report on the structure and function of research ethics committees across Europe.

EFGCP WORKING PARTY – CO CHAIRED BY DRs FRANK WELLS AND INGRID KLINGMANN.

IJPM 2007;21(1):1-113



I know this isn't a book but a special issue of the IJPM and as such you may think it odd that it is included in our Book Reviews section. The response is short: this is too important a publication to all of us to allow it to slip under the radar.

I can't begin to imagine the enormous amount of work that has gone into the investigation underpinning the report and of course the drafting of the report itself but it has clearly been a mammoth undertaking. And was it worth it? Yes.

The European Forum for Good Clinical Practice (EFGCP) seeks to promote European values and principles in ethics across Europe and further afield. The standards are based on the Declaration of Helsinki, the International Conference on harmonisation process as applied to GCP and now included in the GCP directives etc. These key documents all reference the structure and function of the ethics committees responsible for reviewing clinical trial protocols.

The EFGCP paused to consider how consistent the ethical review process was across the European Union and whether differences might interfere with the aims of the Directives themselves. An EFGCP subgroup therefore set out to examine the structure and function of ethics committees across the EU, Switzerland and Norway. The report is the output of this exercise.

Each country was systematically reviewed using a standard suite of 35 questions ranging from a summary of the laws and regulations applicable to conducting a clinical trial in a particular country; how long the process takes; what is the web address of the organisation issuing guidance on ethical review of an IMP; and through to the mechanisms by which ethics committees ensure that they are adequately trained and ensure quality assurance.

Working through the publication, country by country which was surprisingly easy to do, it became clear that despite everyone's best efforts to date, there are considerable variations in how countries approach the ethical review of clinical trial protocols, including such fundamentals as for example, whether it is the Sponsor or Investigator who should submit the protocol. These are things that we need to know.

Clearly processes are constantly changing and the report provides a database freeze view of what was happening at the time of the survey (2006); nonetheless, the information contained is very useful indeed to clinical researchers running studies in more than one country and looking for

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