The Procedure for the Ethical Review of Protocols for Clinical Research Projects in the European Union

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EU Directive 2001/20/EC sets out a number of measures intended to increase the harmonisation of ethics review of clinical research proposals. However, Directives allow different interpretations to be made by Member States when implementing them into national legislation. The provision for ethics review is not immune to this issue, and there are subtle differences between the implementations in each member state, and the practical transitions from previous systems to full compliance. However, when planning a multi-national study it is imperative to have understanding of these differences and their impact on how and when to make applications in different member states.

This excellent report compiles the results of a survey conducted in 2006 of the ethics review systems in 26 European countries (ie, the 25 EU member states at the time [with Luxembourg covered by the results for Belgium], plus Switzerland and Norway). The survey asked 35 questions, including:

- What laws or regulations apply to an application for conducting a clinical trial in [a country]?
- How is a 'single opinion' achieved for multi-site studies?
- How many members serve on an EC?
- What are the training requirements for members of ECs?
- Is there an appeal mechanism?

The report publishes, for the first time, a snapshot of the systems and processes in place in these countries; the operational value of this information alone will make it a valuable addition to the library of anyone planning multi-national clinical research within the EU. On another level, cross-referencing these results also highlights the level of diversity in systems, which will be great interest to policy-makers wishing to learn from their peers in other countries and increase the level of harmonisation, and to strategic planners looking ahead to ethics review systems of the future.

Several of the main areas of difference between countries have already been discussed at the EFGCP Annual Conference, which was held in January 2007, and will be reported in a future issue of CRfocus. A final section of the report provides an index of the appropriate websites in each country

The systems examined in this report are in constant evolution, and respond to developments in other countries. As such, the authors have proposed to provide regular updates via the EFGCP website (from the latter part of 2007) and to extend its scope to the countries covered by the WHO definition of Europe. This will further enhance the value of what is already an extremely useful report, and on behalf of ICR, I would like to offer my congratulations and thanks to the team, led by Frank Wells and Ingrid Klingmann, that conducted the survey.

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