

Irish Council for Bioethics
Comhairle Bitheitice na hÉireann

Minutes for Council Meeting
Thursday 9th December 2004

In the Chair: Mr. Dermot Gleeson

Present: Mr. M. Dempsey; Dr. M. Fitzgerald; Dr P. Flanagan; Mr. K. Kearon; Prof. C. Kelleher; Prof. M. Lawlor; Dr. P. McKenna; Ms. M. Mulvihill; Dr. N. O'Brien; Prof. R. O'Regan; Mr. Asim Sheikh; Prof. P. Whittaker

Apologies for absence: Prof. P. Cunningham; Dr. D. Dooley; Prof. P. Hannon; Prof. T. McGleenan, Prof. F. O'Gara; Prof. A. Scott; Prof. Sean Strain.

Also present: Dr. S. O'Sullivan; Ms E. de Grae; Mr P. Dempsey.

1. Minutes

Certain members pointed out that their apologies had not been noted and requested that this be done. It was also pointed out that Prof. Mark Lawler's resignation from the Human Biological Material working group should be added to the minutes. Once these changes are made the minutes will be adopted and signed.

2. Matters Arising

It was noted that the Department of Health and Children had requested the Irish Council for Bioethics to undertake a commissioned piece of work to standardise the application process for research ethics committee review of clinical trials on medicinal products for human use. It was pointed out that the Council could lend its expertise in the area of research ethics to this project but that a dedicated researcher should be recruited in order to carry out the task and that this would be funded by the DOHC. All agreed that this project would be independent from the work of the Council.

3. Report from the scientific director

Dr O' Sullivan reported on a research ethics committee (REC) meeting, which she facilitated on 8th September 2004 (before the DOHC request was made). The aim of the meeting was to provide a forum for RECs to discuss the operational aspects of reviewing clinical trial protocols under the new regulations (S.I. 190 of 2004). The meeting was attended by the administrators from RECs which were in the process of or hoping to seek recognition from the DOHC to review clinical trials. Issues discussed included application procedures, allocation of application to RECs and the role of Local Research Ethics Committees (LRECs) in multi-centre clinical trials. Dr. O'Sullivan stated that there

was overwhelming agreement that in order to assist both researchers and RECs, such aspects should be standardised and that the REC administrators should write to the DOHC requesting for this standardisation to be put into practice.

Dr O'Sullivan informed Council that she had attended the Global Summit of National Ethics Committees held in Australia in November. She stated that it was an extremely beneficial meeting, which discussed issues such as advanced directives, living organ transplantation and stem cell research.

Dr O'Sullivan also updated members on the situation between the EGE and NEC forum. She announced that the confusion between the roles of both organisations had been rectified and that there would be joint meeting of the two groups held in Amsterdam on the 21st and 22nd of December.

4. Report from the Chairperson of the Research Ethics Committee Working Group

Members heard with regret that Mr. Kenneth Kearon had resigned from the working group and the Council (effective end of 2004) in order to take up his new position as secretary general of the new Anglican Communion. Mr. Dermot Gleeson thanked Mr. Kearon for all his valuable contribution and wished him every success for the future. All members and the secretariat repeated these sentiments.

Prof. Kelleher was pleased to announce the working group's *Operational Procedures for Research Ethics Committees; Guidance 2004* had received very positive feedback and that there had been great demand for the booklet.

Prof. Kelleher informed Council that the working group was planning an opinion document on RECs reviewing both clinical and non-clinical research in order to adhere to its terms of reference. She informed Council that it had been agreed that the secretariat would examine the minutes from previous working group minutes to ensure that the opinion document would reflect the discussions of the group. Prof. Kelleher stated that his document would be quite short (5-10 pages).

In order that the working group would be in a position to achieve this aim it was suggested that they should co-opt Council members Dr Peter McKenna kindly volunteered to join the working group.

5. Report from Chairperson of the Human Biological Material Working Group

Mr. Asim Sheikh informed the council that the Biological Material Working Group had a meeting on Wednesday 1st December 2004 to discuss the first draft of the groups report on the use of human biological material in research. Mr. Sheikh explained that the Working Group had had a wide-ranging discussion on the issue of consent particularly in the context of archival material being used in research. Mr Gleeson invited members to comment on recommendations 17 and 18, which deal with archival material. There followed a lengthy discussion on the issue of consent for the use of archival biological material in research. Certain options were suggested and it was agreed that these options would be discussed in the final report.

Mr. Sheikh stated that a draft of the report would be circulated to Council before the next meeting, giving members sufficient time to prepare comments.

6. Any other business

It was decided that the GMO working group would meet in January in order to reestablish momentum and to decide on the final format of their opinion document.

It was decided that although the current Council's term of office would come to an end in May there would be a final meeting in June to tie up any possible loose ends.

7. Date of next meeting

Thursday 10th March 2005 at 10.30am.
