

**Irish Council for Bioethics**  
*Comhairle Bitheitice na hÉireann*

**Minutes for Council Meeting**  
**Wednesday 9<sup>th</sup> March 2005**

**In the Chair:** Mr. Dermot Gleeson

**Present:** Prof. P. Cunningham; Dr. D. Dooley; Dr P. Flanagan; Prof. C. Kelleher; Prof. M. Lawlor; Dr. P. McKenna; Ms. M. Mulvihill; Prof. F. O’Gara; Prof. R. O’Regan; Mr. Asim Sheikh; Prof. P. Whittaker

**Apologies for absence:** Mr. M. Dempsey; Prof. P. Hannon; Prof. T. McGleenan; Dr. N. O’Brien; Prof. A. Scott; Prof. Sean Strain.

**Also present:** Dr. S. O’Sullivan; Ms E. de Grae; Dr. S. Dyke.

**1. Minutes**

The minutes from September and December 2004 were adopted and signed.

**2. Matters Arising**

There were no matters arising.

**3. Report from the scientific director**

Dr O’Sullivan informed members that two leading ethicists had been secured to speak at the 2<sup>nd</sup> Irish Council for Bioethics public lecture/debate on Wednesday 11<sup>th</sup> of May 2005. She told members that the speakers would be Professor John Harris (University of Manchester) and Professor Paul Schotsmans (University of Leuven) and that they would discuss the pros and cons of an open market in relation to organs for donation.

Dr O’Sullivan informed members that the Council had recently recruited two new staff members to the secretariat, Mr. Paul Ivory as a full-time research officer and Dr. Stephanie Dyke who would be dedicated to drafting the GMO report and who would work on a part-time basis.

Ms de Grae reported to the members on the NEC forum which took place in Amsterdam on the 21<sup>st</sup> and 22<sup>nd</sup> of December 2004. She stated that it was an extremely beneficial meeting, which discussed issues such as the use of ICT in the treatment of neurological disorders, the use of cost utility analysis in resource distribution in the public health service as well as the relationship between National Bioethics Councils and local research ethics committees. She informed Council that the next NEC forum would take place in Luxembourg in May.

Dr O'Sullivan updated members on the REC project, which the Council had been commissioned to undertake by the Department of Health & Children. She informed members that she and Ms de Grae were in the process of preparing a set of standardised documentation and a guidance booklet. She also informed the members that she and Ms de Grae would prepare a proposal for the training and auditing of research ethics committees.

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

Prof. Cecily Kelleher welcomed Dr. Peter McKenna to the working group and thanked him for volunteering his time and expertise. She stated that it would be desirable to have another member of the Council co-opted to the working group. Prof. Mark Lawler volunteered to join the group. Both Mr Gleeson and Prof. Kelleher thanked Prof. Lawler. It was suggested that it might be beneficial to have an ethicist comment on the draft opinion document. Various Council members suggested Dr David Smith as a possible candidate. Dr O'Sullivan agreed to contact Dr. Smith in this regard.

Prof. Kelleher informed members that the working group had decided on a framework for an opinion document. She noted that the document would emphasise the importance of the protection of research participants and the necessity of facilitating ethical research and consider other issues, such as the structure of RECs in Ireland and abroad and the establishment of a central authority for RECs reviewing non-clinical trials. She noted that Dr O'Sullivan would prepare a draft document for the working group's consideration over the following months.

#### **5. Report from Chairperson of the GMO Working Group**

Prof. Peter Whittaker told members that the working group had produced a framework for the opinion document and that members of the working group had previously written draft chapters. He told members that Dr. Dyke would set about drafting an Irish-centric opinion document.

It was suggested that the document should consider the issue of distributive justice due to Ireland's charitable links with developing countries. It was also suggested that the document should consider the issue of post release monitoring.

The point was raised that the working group should attempt to anticipate changes in the Irish situation with regard to GMOs so that the document would not become obsolete on the basis of new developments.

#### **6. Report from the Chairperson of the Human Biological Material Working Group**

Mr Gleeson asked members if they had any general comments to make on the draft report. Council members congratulated the working group on the draft. It was discussed whether it would be beneficial to have a peer review of the report however it was decided that due to the multi-disciplinary expertise of the Council and co-opted members this would not be necessary. It was widely agreed that the draft report was well written and would be accessible to all potential readers.

Council members were asked if they had any specific comments to make regarding the draft report.

The point was raised that Recommendation 1, which refers to research participants withdrawing their consent for their inclusion in research, might be redrafted in order to start the report on a more positive footing.

With regard to Recommendations 4 and 5 it was suggested that in order to clarify their meaning the conjunctions “and” “or” should be used at the end of each bullet point, where appropriate.

There followed a discussion on whether Recommendation 16 fell within the remit of the Council. It was decided that the recommendation should remain because there is a chapter on commercialisation, which discusses the issues of patenting and intellectual property rights and because there is a European Directive relating to those issues.

Mr. Sheikh thanked members for their comments on the recommendations.

Dr O’Sullivan informed members that at the last meeting of the working group three issues of major concern were raised with regard to consent.

The first issue was what type of consent should be recommended. Some members of the group had expressed an opinion that a broad/generic consent might be recommended and argued that so long as a person is competent then this would show respect for his/her right to autonomy. It was decided, however that the report would not change its current stance, which favours a layered consent as this displays respect for persons by allowing potential research participants to form a decision based on a list of options which would be accompanied by available relevant information. It was agreed that the report would refer to the public consultation recently undertaken by RCSI to support this stance.

The second issue was whether consent was deemed essential for auditing, quality assurance and teaching. It was decided that these practices were necessary for diagnosis and treatment and not related to research and therefore consent was not essential. It was agreed that the report would include an argument in support of this.

The third issue of concern related the use of material obtained for clinical purposes in unforeseen research. A lengthy discussion followed on whether the report should retain its current stance, which requires researchers to seek retrospective consent from patients for the use of their biological material in research or where this is “impracticable” to go to a research ethics committee and seek a waiver.

The alternative to this option was that researcher should seek prospective consent for the use of material obtained for clinical purposes in unforeseen research. Under this system a patient/potential research participant would be asked to sign a layered consent form. It was agreed that should this system be adopted then seeking consent would need to be carefully timed so that patients/potential research participants could fully understand the distinction between consent for a clinical procedure and consent for research.

It was decided that Dr O'Sullivan would prepare a briefing document outlining the two options and would circulate it to Council members that afternoon. Members were asked if they would forward their comments on this issue to Dr O'Sullivan before the next meeting of the working group on Friday 11<sup>th</sup> March 2005.

**7. Any other business**

Mr Gleeson noted that the current Council's term of office was coming to an end and asked Dr O'Sullivan if she might suggest possibly suitable candidates for the next Council to the Royal Irish Academy.

**8. Date of next meeting**

Thursday 9<sup>th</sup> June 2005 at 10.30am.

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