

# Irish Council for Bioethics

*Comhairle Bitheitice na hÉireann*

## Proceedings of the National Research Ethics Committees 23<sup>rd</sup> March 2004

1. The morning Session was chaired by Dr. Margaret Fitzgerald and consisted of two presentations. The first presentation was an *Overview of the National Situation regarding Ethics Committees* by Professor Cecily Kelleher. The first part of the lecture covered topics such as legislation and regulation in Ireland i.e. the Control of Clinical Trials Acts, Data Protection Act and EU Directive 2001/20/EC. The second part of the lecture focused on the results of a survey undertaken by the Irish Council for Bioethics' working group on ethics committees, which examined the current structure and composition of research ethics committees (RECs) in Ireland.

Dr. Siobhán O'Sullivan gave an *Overview of International Best Practice*. The lecture consisted of a definition of the principles of ethical conduct as well as the function of RECs. Dr. O'Sullivan reviewed international best practice with respect to current operational procedures e.g. recruitment, review processes, study structures, documentation and archiving and follow-up procedures. Finally, the presentation examined issues such as informed consent, confidentiality and community considerations.

Presentations were followed by a group discussion and a summary of the points raised are outlined below:

- ◆ A large proportion of the work carried out by RECs is not restricted to clinical trials and increasingly research studies are becoming inter-disciplinary in nature and currently RECs tend to be constituted and focused on reviewing clinical trial protocols. In view of this RECs would need to become more flexible and develop a broader remit to accommodate these needs.
- ◆ The issue of patient/research participant rights with regard to autonomy was addressed:
  - The point was raised that the function of RECs was two-fold i.e. to protect the rights of patients/research participants and to facilitate researchers who wished to undertake high quality research
  - The autonomy of patients/research participants must be protected, however, some weight would have to be given to community considerations
  - RECs should be mindful of the phenomenon of over-researching particular groups.
- ◆ With regard to procedural issues of RECs there was a need for the establishment of explicit formal structures.

2. The second session consisted of three break-out groups to discuss issues such as: composition of RECs, appointment of members, review process, decision/appeal process, archiving procedures, multi-centre research and funding.

A rapporteur was appointed from each group to report to the meeting as a whole. A number of issues emerged from discussions in the break-out groups:

- ◆ The establishment of a national supervisory body was broadly welcomed. It was agreed that there would need to be a coherent national framework for RECs. However, it was deemed essential for an appropriate balance to be struck between the autonomy of local/regional RECs and ethics committees providing a “single opinion” on multi-centre trials.
- ◆ As well as ethical considerations, ethos would have to be taken into account particularly on a local/regional level. It was agreed that ethics committees would need to take a pragmatic approach to how research protocols were dealt with.
- ◆ The recruitment of lay participants was fully endorsed. However, the optimal manner of enrolment and retention of lay members would need further consideration.
- ◆ There was a broad consensus that members should not be paid for their work on RECs as this may result in conflicts of interests. However, it was agreed that travel and subsistence expenses etc. should be recompensed.
- ◆ There was overwhelming support for a formalised structure for the training of REC members. It was suggested that there might be one or two education days per annum for any new members and a provision for the ongoing training for existing members to keep them up to date with best practice and new developments.
- ◆ Challenges facing RECs included: concerns about the implementation of the Clinical Trials Directive and its repercussion on RECs, training, resources and volume of work.

3. The final session of the day was chaired by Professor Cecily Kelleher and consisted of two presentations. The first of these *Implications of the Clinical Trials Directive on Ethics Committees: The Northern Ireland Response*, was given by Mrs. Stephanie Harcourt. The presentation outlined the comprehensive restructuring of ethics committees in Northern Ireland to meet the requirements of the Clinical Trials Directive. The newly established RECs are accredited to review all research protocols not just protocols relating to clinical trial studies.

Dr. Tom McGuinn delivered the second presentation, *Implementation of Directive 2001/20/EC on Good Clinical Practice in the conduct of clinical trials on medicinal products*. The talk outlined the current position with respect to the

implementation of the Clinical Trial Directive with specific mention made to RECs.

There followed an in depth general discussion. Many of those present expressed their disappointment and frustration that the Department of Health had not made progress regarding a number of key issues raised at previous stakeholder meetings.

Dr McGuinn stated that the Department of Health would have the final legislation prepared by mid-April. However, he acknowledged that given the timelines it was unlikely that the proposed supervisory body would have accredited RECs to review clinical trial protocols by 1<sup>st</sup> May.

A number of key points emerged from the discussion:

- ◆ The proposed supervisory body would in the short to medium term be housed within the Department of Health under the auspices of the Minister for Health. However, as yet it remains unclear how this body will operate.
- ◆ The Department of Health was currently consulting its lawyers with respect to transitional arrangements for ongoing trials whose protocols were approved by RECs prior to 1<sup>st</sup> May.
- ◆ The liability of individual REC members was being considered in the context of the Enterprise Liability Scheme.
- ◆ It was stressed that RECs who do not routinely review clinical trial protocols would be unaffected by changes to meet obligations under the new Clinical Trials Directive.