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Consultation response to the Scottish Executive – Health Department

Report of the *ad hoc* advisory group on the operation of the NHS Research Ethics Committees: Summary of Conclusions and Recommendations

The **Scottish Council on Human Bioethics** (SCHB) is an independent, non-partisan, non-religious registered Scottish charity composed of doctors, lawyers, psychologists, ethicists and other professionals from disciplines associated with medical ethics.

The principles to which the Scottish Council on Human Bioethics subscribe are set out in the ***United Nations Universal Declaration of Human Rights*** which was adopted and proclaimed by the UN General Assembly by resolution 217A (III) on 10 December 1948.

The SCHB is very grateful to the **Health Department** of the **Scottish Executive** for this opportunity to respond to the consultation on the ***Report of the ad hoc advisory group on the operation of the Research Ethics Committees: Summary of Conclusions and Recommendations***. It welcomes the Committee's intent to promote public consultation, understanding and discussion on this topic.

In addressing the consultation, the SCHB has formulated the following responses:

Conclusion 1: Report references 3.1, 4 (no. 1)

It should remain the role of research ethical review to safeguard the rights, dignity, safety and welfare of potential human research participants by providing an independent opinion on the ethical implications of a research proposal. Vigilance must be applied at all stages to preserve the independence of the RECs' decisions from political, research or management interests.

SCHB: The Council very much agrees with the above. However, not only should the opinion be independent but it should also be multidisciplinary.

Recommendation 1: Report reference 5 (no. 1)

The remit of NHSRECs should not include surveys or other non-research activity if they present no material ethical issues for human participants. COREC should develop guidelines to aid researchers and committees in deciding what is appropriate or inappropriate for submission to RECs.

SCHB: Agrees.

Conclusion 2: Report reference 4 (no 2)

Research of relevance and good quality is essential to underpin further developments in health and social care. This gives Research Ethics Committees a secondary role - to facilitate ethical research.

SCHB: Agrees.

Conclusion 3: Report references 3.1, 4 (no 3)

In addition to research in the NHS and Social Care, there is now a need also to provide for the requirements for ethical review set out by the new statutory and regulatory environments, such as for human tissue and mental capacity.

SCHB: Agrees.

Conclusion 4: Report references 3.9, 4 (no 4)

There has been a major improvement in the efficiency of the process of ethical review in the very recent past that has not yet been fully appreciated. COREC and the RECs are to be warmly congratulated, but some problems still remain.

SCHB: Agrees. The very positive work of RECs should also be emphasised and made public. This will then counter the sometimes negative images of RECs which exist amongst the research community.

Conclusion 5: Report references 3.2, 4 (no 5)

RECs should deal with ethical rather than scientific review.

SCHB: Agrees.

Recommendation 2: Report reference 5 (no 2)

RECs should not reach decisions based on scientific review. In the unusual situation of a REC having reservations about the quality of the science proposed, they should be able to refer to COREC for scientific guidance.

SCHB: In the unusual situation of a REC having reservations about the quality of the science proposed, they should send the proposal back to COREC which should seek scientific guidance. The RECs should never be in a position to have to make a decision relating to the science of a proposal. RECs are neither qualified nor often capable of making such decisions!

Recommendation 9: Report references 5 (no 9), Annex 3

We propose the creation of "Scientific Officers" in COREC to support the work of committees. They might undertake much of the preliminary assessment required, and review reports. Chairs, for whom it is a major burden, currently undertake this work.

SCHB: The Scientific Officers should work with the relevant scientific committees in the NHS, Universities etc. to assess the scientific merit of research proposals.

Conclusion 6: Report references 3.1, 4 (no 6)

Much research, such as surveys, service evaluation and research on NHS staff, does not require ethical review.

SCHB: Agrees.

Recommendation 1: Report reference 5 (no 1)

The remit of NHSRECs should not include surveys or other non-research activity if they present no material ethical issues for human participants. COREC should develop guidelines to aid researchers and committees in deciding what is appropriate or inappropriate for submission to RECs.

SCHB: Agrees.

Conclusion 7: Report references 3.3, 4 (no 7)

The REC operating system is perceived to be bureaucratic and should be better described and presented. The procedure for site-specific assessment (SSA) is cumbersome.

SCHB: Agrees.

Recommendation 3: Report references 5 (no 3), Annex 3

The recently introduced managed operating system has been well received. Its use of IT points the way to further efficiency and quality improvements. We believe that responsibility for site-specific assessment should be transferred to NHS hosts as soon as acceptable mechanisms for quality assurance are in place.

SCHB: Agrees.

Conclusion 8: Report references 3.3, 4 (no 8)

The IT system that underpins the operating system is generally successful, and the recently introduced combined approach with R&D is to be welcomed. Further opportunities for linkage of information supply amongst ethics committees, R&D departments and other regulatory bodies should be kept under constant review.

SCHB: Agrees.

Conclusion 9: Report references 3.4, 4 (no 9)

The application form attracts frequent criticism. Much of it is related to earlier electronic versions or because of the use of paper versions of what is designed as an on-line form. Nevertheless, the form could be more intuitive and a more easily usable paper version developed.

SCHB: Agrees.

Recommendation 4: Report references 5 (no 4)

The application form and application process call for improvement. The form should take more explicit account of differences between types of research and should also give more space and attention to ethical issues.

SCHB: Agrees.

Conclusion 10: Report reference 4 (no 10)

The current operating system, requiring as it does comprehensive information to be supplied "up front" for the RECs, has exposed a very variable level of understanding of ethical issues within the research community. We feel this is at the heart of some of the criticisms of the form itself. It reveals a need for researchers and health professionals to have access to information, support and training. This may aid the ability of researchers to identify and consider the ethical issues arising out of their proposed research. Consequently, they might be better able to describe, in their submissions to RECs, the ethical arguments in favour of their proposed research project (whilst acknowledging potential harms and how they propose to minimise the risks involved).

SCHB: Agrees.

Conclusion 11: Report references 3.6, 4 (no 11),

There is over-capacity in current NHSRECs. It is timely to rationalise further the number of RECs, with more intense operation for the smaller number resulting.

SCHB: In Lothian there does not seem to be over-capacity.

- RECs should only meet 1-2 times a month (otherwise the normal duties of members in their work would be undermined).
- RECs should only meet 2-3 hours (otherwise members would become tired and not function as effectively). This may mean that only 6-7 proposals should be considered at each meeting.
- RECs should not decrease the multidisciplinary nature nor the number of its members (and especially lay

members). This enables quality decisions to be taken.
- REC members often welcome a reduced number of research proposals over the holiday months since they are themselves often busy during these times.

Recommendation 6: Report references 5 (no 6), Annex 3

We believe that a smaller number of RECs - perhaps one for each Strategic Health Authority, with a limited number of exceptions - would be more appropriate. Their operations would be more intense than at present, with a greater use of electronic communications. The time commitment required of members and support staff for training should be more formally recognised, as should the time taken in committee hearings and preparation. This implies paying REC members appropriately, either directly or through compensating their employers.

SCHB:

- RECs should only meet 1-2 times a month (otherwise the normal duties of members in their work would be undermined).
- RECs should only meet 2-3 hours (otherwise members would become tired and not function as effectively). This may mean that only 6-7 proposals should be considered at each meeting.
- In a way, the paying of REC members is already being addressed through the possibility for members of recuperating any ‘loss of earnings’ in the expenses forms.

Conclusion 12: Report references 3.7, 4 (no 12)

We believe that the totally voluntary system of RECs may not be sustainable and, indeed, may no longer be appropriate. It is likely that it inhibits application for membership by sections of society that should be better represented.

SCHB: If some members want to remain voluntary, either because they are retired and already receiving a pension or otherwise, this should remain a possibility. There should be flexibility in this.

Recommendation 7: Report reference 5 (no 7)

Research Ethics Committees must represent the public interest as well as patient perspectives on research. This means that membership needs to be drawn from a wider mix of society and that all members need to be supported by appropriate training. We believe that our recommendation that we move towards a system of fewer, paid RECs will support this objective.

SCHB: RECs should never be over-worked.

Conclusion 13: Report references 3.8, 4 (no 13)

There appears to be some inconsistency amongst committees that cannot be explained by the necessary judgemental aspect of ethical review.

SCHB: Agrees.

Recommendation 8: Report reference 5 (no 8)

The issue of excessive inconsistency amongst committees should be addressed by concentrating on the provision of appropriate training, and on capturing and sharing good practice where issues and arguments have been already explored. The newly introduced system of quality assurance by peer review amongst committees and their members should assist this process and should be further developed.

SCHB: Agrees.

Conclusion 14: Report references 3.9, 4 (no 14)

The scale of the changes in operation that have recently been required of RECs should be acknowledged. The Chairs, members and support staff have responded magnificently.

SCHB: Agrees.

Conclusion 15: Report references 3.10, 4 (no 15)

DH officials and colleagues in the other UK countries should look imaginatively at pursuing more harmonisation of governance arrangements, given that there are moves for harmonisation across Europe.

SCHB: Agrees.

Observing international legislation

In order to harmonise regulations in biomedical research across Europe, the SCHB is of the view that the Scottish Parliament should ensure that RECs respect the following Council of Europe legislation:

Convention on Human Rights and Biomedicine [1],

the new ***Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research*** (CETS No.: 195) [2].

And as with the <**i>Hague Convention on the International Protection of Adults** [3], the SCHB would like to see the United Kingdom ratify, as soon as possible, the above Council of Europe legal instruments on behalf of Scotland.

Other remarks:

The chairperson of a REC should not be the most senior member of the REC since this may lead to undue influence with respect to REC decisions. Unfortunately, it is often the case that the Chairperson of a REC is the only professor of medicine or something similar on the REC with other members 'just' being lay, or more junior healthcare professionals. Sometimes these persons use their professional positions to bulldozer through their own views with others being unsure whether the whole REC is in agreement.
On the Scottish Ethics Advisory Group it is also noted that the most senior member (Chief Scientist) is the chairperson. However, this may be acceptable since it is not a REC and its remit and responsibilities are different.

It might also have been appropriate for SEAG to have more than just one lay representative.

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1. Convention on Human Rights and Biomedicine, http://conventions.coe.int/Treaty/en/Treaties/Word/164.doc - Entered into force on 1 December 1999 - Legally binding if ratified by a country - The United Kingdom has not signed nor ratified this Convention

2. Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research http://conventions.coe.int/Treaty/EN/Treaties/Word/195.doc - Adopted on 21 January 2005 but has not yet entered into force - Legally binding if ratified by a country - The United Kingdom has not signed nor ratified this additional Protocol

3. Convention on the International Protection of Adults, http://www.hcch.net/index_en.php?act=conventions.text&cid=71- Legally binding if ratified by a country - Adopted on 13 January 2000 but has not yet entered into force - The United Kingdom has ratified the Convention on 5 November 2003 (but for Scotland only) - http://www.scotland.gov.uk/health/mentalhealthlaw/millan/Report/rnhs-37.asp