

Summary of responses to the Consultation: Implementing the Recommendations of the Report of the Ad Hoc Advisory Group on the operation of the NHS Research Ethics Committees

Introduction

On 20 January 2006 the National Patient Safety Agency (NPSA), via its Central Office for Research Ethics Committees (COREC), launched its consultation on the plan to implement the recommendations of the *report of the ad hoc advisory group on the operation of NHS research ethics committees* (DH, June 2005).

The Department of Health and Social Services, Public Safety (DHSSPS) in Northern Ireland, along with the devolved administrations in Scotland and Wales, has also agreed to consult with its stakeholders and secure comments on the NPSA Implementation Plan. The consultation in Northern Ireland was limited to Sections 4.1, 4.1.1, 4.1.2, and 4.1.3. 4.1.4. 4.1.5. 4.2 and 4.4, Appendices C, E and F. The responses are to inform subsequent consideration of whether Northern Ireland should adopt some of or this entire proposal; and will inform wider discussions to establish consistent arrangements throughout the UK. The consultation in Northern Ireland closed on 28 April 2006 with 15 responses from a wide range of stakeholders, which included individual HPSS Research Ethics Committee (REC) members, entire HPSS RECs, HPSS Trusts, and individual academics. A list of all those who responded to the consultation can be seen at the end of this document.

An 'Implementation Plan Roadshow Northern Ireland' event was held specifically to engage the HPSS REC community during the consultation period. The DHSSPS is grateful to all of those who took the time and effort to make their views known.

Scope

The responses focus on recurrent themes emerging from the implementation plan proposals. This document summarises responses around each of these themes. Where opinion varied somewhat on the proposals, we have tried to reflect this accurately.

Some comments were received on amendments to GAfREC, outlined in Annex C. The DHSSPS shall review these separately in conjunction with DOH in England and UKECA.

Action

The results from the consultation will be used by the Department to inform decisions on the future operation of HPSS RECs in Northern Ireland and in the UK as a whole.

Dr Tracy Power

Theme	Comments from	General Comments
Section 4.1	1,2,3,4,5,6,7,8,9,10	<p>The principle of introducing proportion of review generated the majority of responses expressing opposition and concern about the principle and scepticism that its implementation would add value or make the service more efficient. However there was consensus on use of the term 'Research Ethics Service' to encapsulate the whole service as currently provided, in terms of support from the ORECNI office and its staff, central support from COREC and support to the research community from the HPSS RECs. In addition there was consensus for efforts to improve the standard of the submissions by discussions with the applicant prior to application to a REC. There was consensus also on screening out studies falling outside GafREC 3.1. Apart from one individual member of the academic community, there was universal opposition to studies of no material ethical issues being reviewed outside the full Research Ethics Committee. There was a strong view that Research Ethics Advisors, particularly National Research Ethics Advisors, would be seen as expanded administration. There was also cynicism that an individual could make an ethical decision and that the lay/ public gatekeeper role in such a decision would be absent.</p> <p>There were mixed views on the REC service commenting on scientific quality before a REC meeting, with most viewing that this was a matter for the sponsor, and that the REC Service would be criticised for invalidation of an application on the basis of perceived poor scientific quality.</p> <p>There was support for the proposal to identify through screening the small number of complex studies on which a REC requires expert review before a decision can be made, but some uncertainty expressed as to the practicality of implementation.</p>
Section 4.1.1 and Appendix C	1,2,3, 4, 5, 7,8, 9,10,11,12,13	<p>There was diversity of opinion ranging from acceptance all proposed amendments to rejection of some of the changes to GafREC.</p>

Section 4.1.2 and Appendix F

The summary of comments provided with Section 4.1 is also pertinent here.

In addition to objections on principle there were questions raised as to practicality of implementation in Northern Ireland given its combined Health and Personal Social Services context.

There was support for proposals to ensure early identification of studies that require further development before a REC can provide an opinion. However caution was expressed about judging scientific quality within the REC Service. There was also concern that if the REC Service filtered out applications on the basis of poor scientific quality there should be recourse to proper appeals arrangements for applicants. It was agreed that the adequacy of the Peer Review was best judged by the combined experience of the full REC. Peer review itself should remain the responsibility of the Research Sponsor.

There was consensus that student applications often had significant ethical issues particularly with the Northern Ireland Social Care context. These applications should not be triaged to a Research Ethics Advisor. There was however agreement with 'student application' committees to be flagged within the UK REC service. Student applications should be handled by dedicated RECs. Caution was also expressed regarding treatment of student applications and the need to take the educational context into account.

There was support for the proposal to screen out at an early stage applications not falling within GafREC 3.1.

There was also support for the proposal to identify through screening the small number of complex studies on which a REC requires expert review before a decision can be made, but some uncertainty expressed as to the practicality of implementation.

Apart from one individual member of the academic community, there was universal opposition to studies of no material ethical issues being reviewed outside the full Research Ethics Committee. There was a practical suggestion that 'low risk studies' should be completed on a

Section 4.1.3, Section 4.1.4 and Appendix E	1,2,3,4,5,6,7,8,9,10,12,15	<p>simpler application form. Also one of the HPSS Trusts' suggested that the decision as to whether a study had no material ethical issues should not be made by a Research Ethics Advisor within the REC Service but should lie with the sponsor, informed by national guidelines.</p>
Section 4.1.5	1,2,3,4, 6,7,8,10	<p>There was consensus on use of the term 'Research Ethics Service' to enshrine the whole service as currently provided, in terms of support from the ORECNI office and its staff, central support from COREC and support to the research community from the HPSS RECs. The majority of responses opposed the National Research Ethics Advisor role. There was support for the principle of a Local Research Ethics Advisor, although practically due to the current size of the REC service within Northern Ireland this role may not be required. There was a strong view that there was some scope for improvement in R & D Management, arrangements in Trusts and in peer review arrangements by sponsors. There was considerable concern that the introduction of Research Ethics Advisors would create confusion and increase timelines.</p> <p>There was broad support for the intention to reduce the volume of provisional opinions by providing early advice and improved guidance and feedback to applicants to ensure greater understanding of the expectation of a REC.</p> <p>Some within the REC community questioned the rationale for reducing provisional opinions on the grounds that the issue of a provisional opinion and subsequent favourable opinion demonstrated the value the REC was adding to the research. Introducing a 'conditional favourable opinion' was mostly not supported. There was also opposition to a Local research Ethics Advisor being able to review follow-up from an applicant to a REC's provisional opinion, and disbelief that such a role could review safety reports.</p>
Section 4.2	1,2,3,5,6,8,10,11,14,15	<p>There was no consensus on the proposal to pay non-NHS lay members. Of those who did support payment, some supported all</p>

		<p>members being paid with reservations about the implications of receiving payment, e.g. such as the impact on those receiving benefits or salary. Others who supported payment either wished lay members only to be paid or alternatively only members who were personally out-of-pocket.</p> <p>Northern Ireland has never historically paid a Chair's honorarium.</p>
Section 4.4	1,2,3,5,6,10,12	<p>With the exception of one individual REC member transfer of site-specific assessment to R &D was supported.</p>
EQUALITY IMPLICATIONS	7	<p>The only concern expressed surrounding equality implications includes the statement on Section 75 of the Northern Ireland Act 1988 concerning "due regard to the need to promote equality of opportunity"... between persons of different religious beliefs...". The concern was that it may be necessary to restrict some research studies to people of the same or similar religious beliefs as members of the research ethics committee.</p>

Respondents to the consultation

1. Dr G. W. Cran (Expert member HPSS REC 3, Senior Lecturer in Medical Statistics)
2. HPSS REC 2 (Vice-Chair Dr Ronald Atkinson)
3. HPSS REC 1
4. HPSS REC Administrators
5. Mr. Paul Davidson (Lay Member HPSS REC 3)
6. Dr John Trinder (Chair HPSS REC 3 on behalf of REC 3)
7. Greenpark Healthcare Trust
8. Dr Karola Dillenburger, Chair School research Ethics Committee, School Sociology, Social Policy, and Social Work, Queen's University of Belfast
9. RH Academic
10. Dr Martin Dempster, School of Psychology, Queen's University Belfast.
11. Dr Rosemary Kilpatrick, Director, Institute of Childcare Research, Belfast
12. Prof. Ian Young R&D Director, Royal Group of Hospitals Trust
13. DRH Academic
14. Mr. Mark Miskelly (Lay Member, HPSS REC 3)
15. Prof. D. R. Hadden, Consultant Physician, Honorary Professor of Endocrinology

