



Department of Health

**FOR
REFERENCE ONLY**

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25 February 1997

Dear Colleague

**MULTI-CENTRE RESEARCH ETHICS COMMITTEE FOR
SCOTLAND**

Summary

1. This circular sets out the arrangements for the ethical appraisal of multi-centre research which will come into effect on 1 April 1997.

Background

2. Previous arrangements for ethics committee review of multi-centre research required every aspect of each proposal to be considered by every Local Research Ethics Committee covering participating centres. Although this mechanism reflected the importance of local review it was a fragmented and time consuming procedure.

3. In order to streamline the arrangements for the ethical appraisal of multi-centre research, Multi-Centre Research Ethics Committees (MRECs) are being established across the country, one in Scotland, one in each of the English regions, one in Wales and one in Northern Ireland.

4. The membership of the MREC for Scotland is attached.

5. For the purposes of the MREC system, research will be regarded as 'multi centre' if it is being undertaken within 5 or more LREC geographical boundaries.

6. The MREC for Scotland will receive applications from 1 April 1997.

7. From 1 April, therefore, all applications for ethical appraisal where the principal research worker is based in Scotland, and which cover 5 or more LREC geographical areas, should be submitted to the MREC for Scotland.

Addressees:

For action:

General Managers,
Health Boards
Chief Executives,
NHS Trusts

For information:

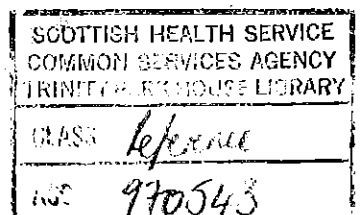
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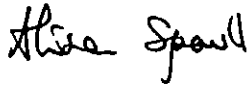


8. Application forms can be obtained from Mr Peter Reith, Secretary, Multi-Centre Research Ethics Committee for Scotland, Lothian Health Board, Deaconess House, 148 Pleasance, Edinburgh EH8 9RS (Tel: 0131-536 9021).

Action

9. General Managers are invited to draw this circular and the attached implementation document to the attention of their Local Research Ethics Committee and to circulate it widely within their Health Board.

Yours sincerely



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Director
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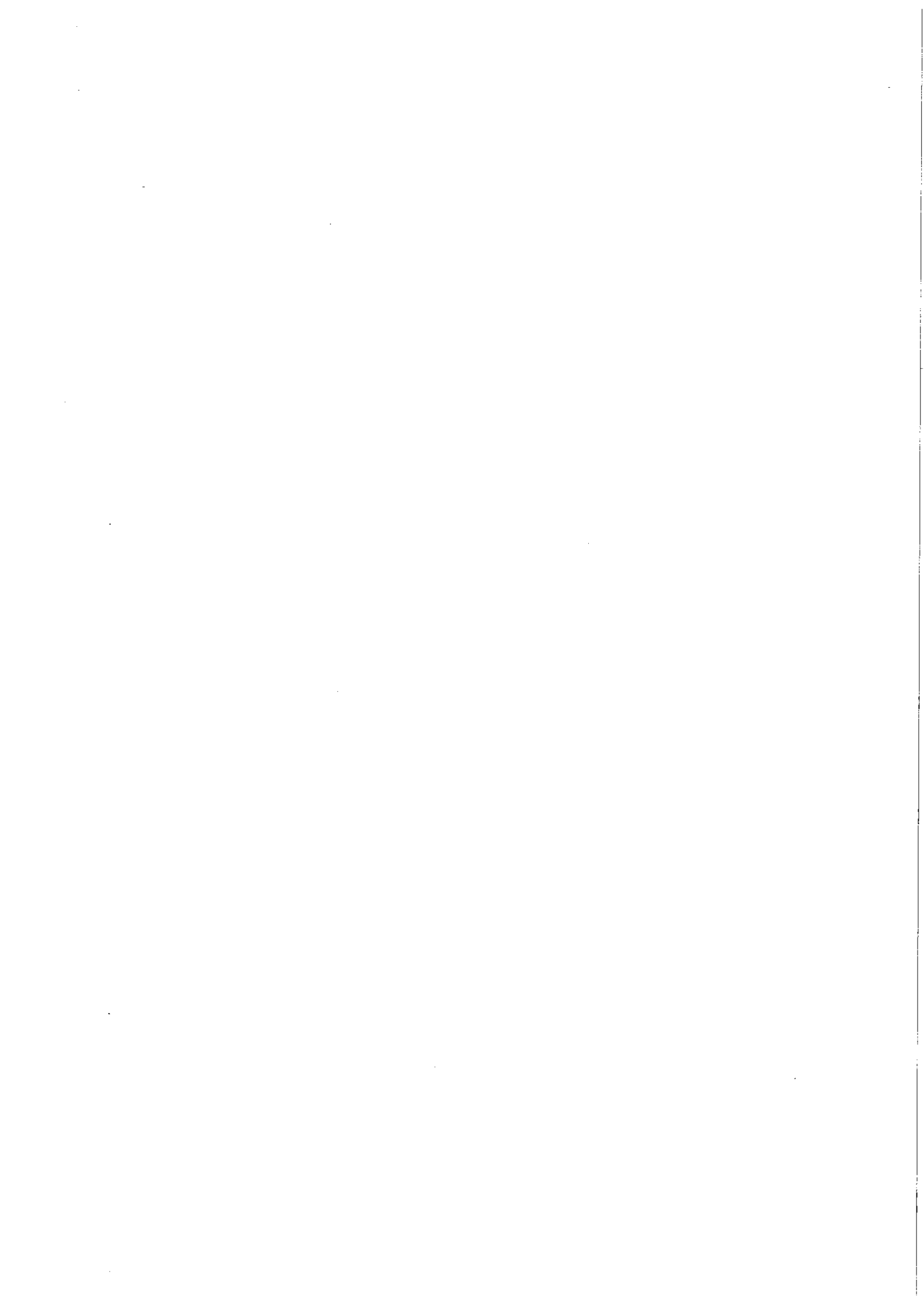
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**THE ESTABLISHMENT OF A MULTI-
CENTRE RESEARCH ETHICS
COMMITTEE FOR SCOTLAND**

CSO

Chief Scientist Office

Management Executive for the Scottish Health Service



MULTI-CENTRE RESEARCH ETHICS COMMITTEE FOR SCOTLAND

Implementation Paper

Introduction

1. This paper describes the new system of ethical appraisal of multi-centre research in Scotland. It should be read in the context of current guidance on Local Research Ethics Committees (LRECs) in Scotland set out in circular 1992(GEN)3¹ issued in March 1992 and takes account of comments made on the consultation document circulated in May 1996. This document sets out the arrangements being made in Scotland. Similar arrangements are being made to establish one multi-centre research ethics committee in each of the English regions, one in Wales and one in Northern Ireland.
2. Previous arrangements for ethics committee review of multi-centre research required every aspect of each proposal to be considered by every LREC covering participating centres. Whilst reflecting the importance of local review, it was also a fragmented and time-consuming approach, which could significantly delay the emergence of potentially important human research findings. Problems for research workers included the time, expense and inevitable frustration which resulted from requests for different - often incompatible - amendments to protocols, and differences in the forms and procedures employed by different LRECs.
3. The more co-ordinated approach set out in this document will still ensure that LRECs have autonomy and continue to receive full information on which to base advice relating to their local populations. It will also reduce time-consuming duplication of work.
4. These arrangements will cover all multi-centre research in the NHS including clinical trials; records-based, qualitative and Health Services economic research and surveys; and be able to advise on health-related non-NHS research.
5. Local Research Ethics Committees will retain autonomy in recommending whether the research should go ahead locally and will remain accountable to Health Boards for decisions affecting their local populations.

The New System²

6. One Multi-Centre Research Ethics Committee (MREC) will be established in Scotland, one in each of the English NHS regions, one in Wales and one in Northern Ireland. An MREC will be an advisory body set up to provide independent advice on the science and general ethics of multi-centre research proposals. The scope of MRECs consideration of

¹ This will be revised in due course to take account of the new multi-centre arrangements.

² See also the flow chart at Annex A.

research proposals will be consistent with guidance to LRECs. (*Local Research Ethics Committees* Chapter 3).

7. Each multi-centre research protocol will be considered by one MREC only - usually the one in which the principal researcher is based.^{3 4} The advice of that MREC will be given to LRECs in every locality involved, not just those within its host region or country.

8. Once MREC approval has been obtained, LRECs in every locality involved will have the opportunity to accept or reject the protocol for local reasons but will not be allowed to amend it. LRECs may occasionally need to seek locally applicable amendments which do not affect the integrity of the protocol, for example information sheets and consent forms in minority languages. They should do so only when essential. LRECs will be asked to notify their decisions to the designated MREC within a specified timescale and in particular to give reasons if they refuse a proposal. Thus the system will incorporate an additional safeguard which could bring to the attention of an MREC any major points that had possibly been missed in its consideration of the scientific and wider ethical aspects. The MREC will be obliged to consider any such points.

9. The system will involve rigorous scrutiny of each protocol by the relevant MREC, including, where necessary, detailed discussion with the principal researcher and/or expert advisers. It will allow LRECs scope to discuss local matters pertaining to MREC-approved protocols with the local and/or principal researcher (where the latter can help expedite clearance).

10. MRECs will expect to receive protocols which have already been subject to scientific assessment (although exceptions will be permitted if there is a satisfactory explanation). They will be required to take account of such assessments.

Definition of Multi-centre Research

11. For the purposes of the MREC system research will be regarded as “**multi-centre**” if **undertaken within 5 or more LREC geographical boundaries**. LRECs may still make voluntary arrangements whereby one may review research involving 2 to 4 centres on behalf of them all. (*Local Research Ethics Committees para 2.18*).

MREC Membership

12. The MREC membership requires to reflect a broad range of experience and expertise. Nominations for members were thus sought from a wide range of bodies representing hospital medical staff, nursing staff, general practitioners, other NHS professional staff and lay persons. Experienced LREC members were expected to be likely candidates. At least a third (but no more than half) of the membership can be lay. Simultaneous membership of an MREC and an LREC is permissible.

³ Subject to special circumstances described in para 18.

⁴ These proposals would not affect existing arrangements whereby gene therapy research proposals are considered by the UK Gene Therapy Advisory Committee.

13. There was a good response to the call for nominations and members for the MREC for Scotland were selected from those nominated by an appointments panel comprising chief professional officers within the Scottish Office Department of Health and representatives of consumer interests.

14. The chairman and vice-chairman, one of whom is to be lay, have been appointed by the Chief Medical Officer.

15. MREC members have been appointed initially for a period of 2 years. Thereafter terms of membership will be reviewed. The composition of the MREC is set out at Annex B.

Accountability and Evaluation

16. The MREC in Scotland is accountable to the Secretary of State. In practice this function has been delegated to the Chief Medical Officer. The formal mechanism for achieving accountability will be an annual report.⁵ This report will be sent to all LRECs in Scotland, and to other LRECs on request. It will also be available for public inspection.

17. There will be periodic meetings of MREC Chairmen to exchange views and share experiences.

MREC Cross Referrals

18. If the MREC in Scotland is heavily loaded it could, by agreement between secretariats, pass work to other MRECs. Proposals could similarly be passed on to another MREC if it has developed acknowledged expertise in a particular specialised area. Swift and efficient networking will be essential.

19. The MREC's role will not include hearing 'appeals' against the decisions of LRECs or other MRECs. Any differences of view between a research worker and an MREC should be resolved through continuing discussions between them. Should it prove impossible to come to an agreed outcome, referral to another MREC would be permitted, but only with the agreement of **both** the initial MREC and the research worker. The advice of the second MREC will be final.

Common Application Form, Standards and Procedures

20. To facilitate the system, a common application form has been developed. Local Research Ethics Committees are strongly encouraged to accept local applications on the agreed form, supplemented with local details as set out on the supplementary form. LRECs are still free to request further details if they think it necessary. The main and supplementary forms will be subject to review in the light of experience.

⁵Minimum details required set out in Annex C.

21. All MRECs will be expected to meet the same Standards commended to LRECs in the Standards Framework and will be asked to draw up agreed standing orders (or standard operating procedures - SOPs). It will be for LRECs to consider whether they should adopt procedures consistent with those of MRECs. It will be especially helpful to research workers if, unless there are strong reasons to the contrary, a consistent approach is taken on follow-up procedures eg frequency of asking research workers for progress reports.

Funding

22. The Chief Scientist Office is providing the initial funding for the MREC in Scotland for 1996/97 and 1997/98. When the national Support Fund is fully operational for 1998/99 costs of the MREC will be charged to it.

23. Responsibility for supporting LRECs in Scotland will remain with Health Boards.

Training

24. Training for MREC members and administrators will be provided as required. Initial training of LREC chairmen and members, in the new system, will also be provided.

Legal Liability

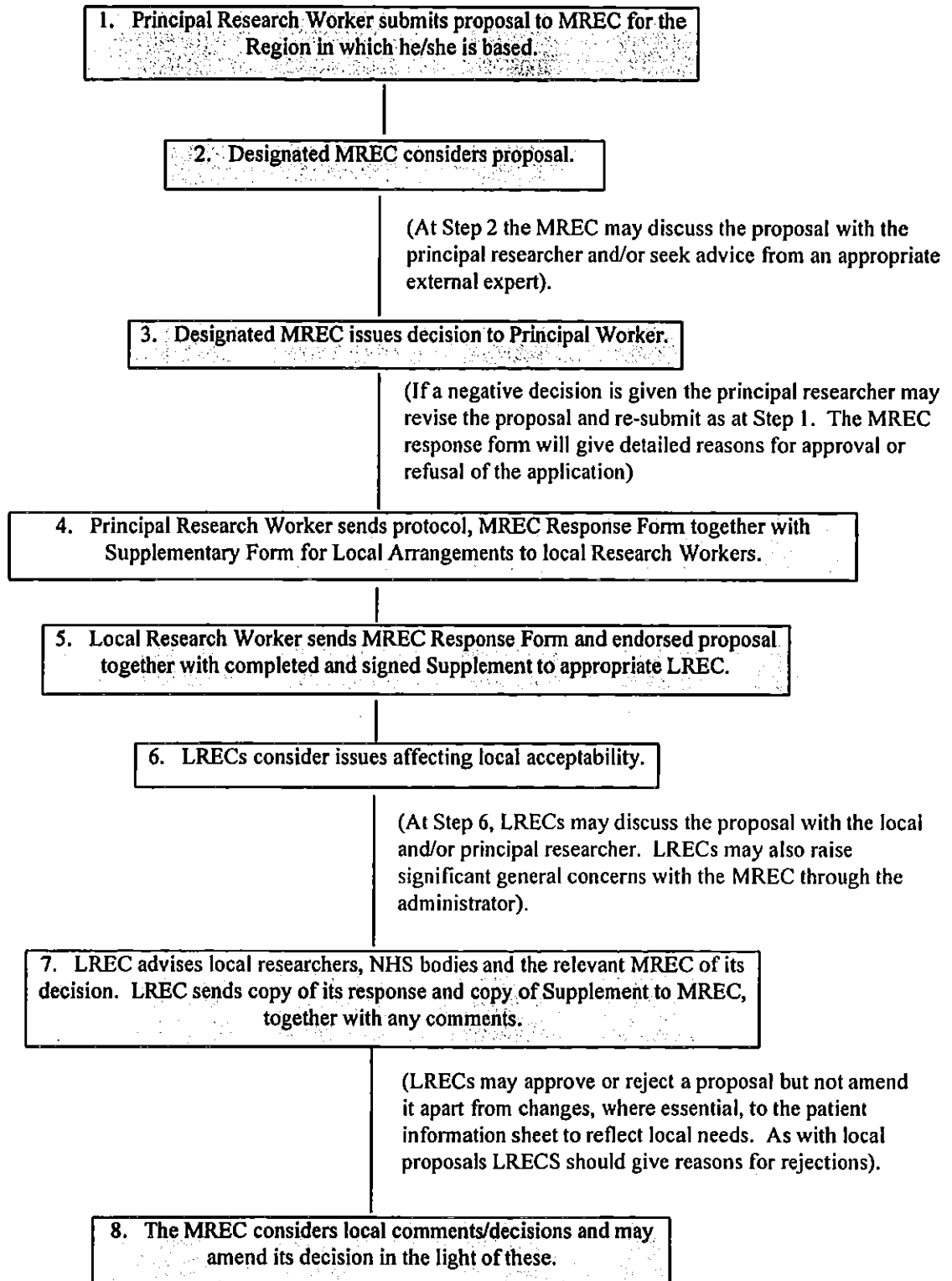
25. In the unlikely event of a claim being brought against an MREC member, the Department will bear any costs, provided that the member notifies it and assists it in all reasonable ways. Legal advice available to the Department is that there would be little prospect of a successful claim against an MREC member for personal injury arising from research approved as ethical by an MREC. Any negligence claim would lie principally against the research worker and the NHS body under whose auspices the research took place.

26. The legal liability of LREC members should similarly continue to be covered by the Health Board (see *Local Research Ethics Committees*, paragraph 2.11⁶).

⁶ Circular 1992 (GEN)3, March 1992.

MULTI-CENTRE RESEARCH ETHICS COMMITTEE SYSTEM: FLOWCHART

MRECs/LRECS should ensure that all stages of the process described below are undertaken in a timely and efficient manner.



MREC MEMBERSHIP

The table below sets out the composition for the MREC for Scotland. In practice variations of composition within agreed parameters will be permissible.

<u>Description</u>	<u>Maximum No.</u>	<u>Minimum No.</u>
General Practitioner	2	1
Nurse/Midwife	2	1
Professional Allied to Medicine	1	1
Clinical Pharmacologist/Pharmacist	2	1
Hospital Consultant	3	3
Public Health Physician/Epidemiologist	1	1
Lay Person	6	4
Total:	<u>17</u>	<u>12</u>

CONTENT OF MREC ANNUAL REPORT

The minimum details for the annual report are set out below.

Structure

Names of chairman, vice-chairman and all MREC members.

Disciplines covered by MREC membership.

Name, address and telephone and FAX numbers of principal administrative contact.

Number and dates of meetings held.

List of proposals considered, detailing in each case:

- when received, when considered and when the decision was notified;
- name of principal researcher
- whether transferred in from another MREC;
- whether approved, approved after amendment, approved subject to amendment, rejected or withdrawn;

List of proposals transferred out, with reason.

Training: any training needs identified or training undertaken.

