Medicines for Human Use (Clinical Trials Regulations) 2004

Membership of research ethics committees

1. This note summarises the provisions for membership of recognised ethics committees set out in Schedule 2 to the Medicines for Human Use (Clinical Trials Regulations) 2004 as amended, and provides basic guidance on interpretation.

2. Any queries about the guidance should be sent to queries@nres.npsa.nhs.uk. Where complex questions of interpretation arise, NRES will seek further advice from the Government legal advisers responsible for drafting the Regulations.

Scope of the statutory provisions

3. The provisions came into effect on 1 May 2004. They apply to all NHS Research Ethics Committees that are "recognised" by the United Kingdom Ethics Committee Authority (UKECA) for the review of clinical trials of investigational medicinal products. The statutory requirements supersede the membership provisions in section 6 of the Governance Arrangements for NHS Research Ethics Committees (GAfREC, published by the Department of Health in July 2001) *where any conflict arises between them*.

4. The provisions of Schedule 2 also apply to the Independent Ethics Committees outside the NHS, which are recognised solely for the purpose of reviewing Phase 1 clinical trials in healthy volunteers.

5. Schedule 2 makes no provision for disqualifying any person from membership of an ethics committee on grounds of potential conflict of interest. This remains an issue for guidance to appointing authorities (see paragraph 5.4 of GAfREC). The guidance in this note deals only with the statutory provisions on membership.

6. The provisions of Schedule 2 do not apply in law to "authorised" (or non-recognised) NHS RECs. However, the guidance from NRES is that the provisions should be applied to authorised RECs in the same way.

Size and composition of an ethics committee

7. The Regulations provide that a committee shall have no more than 18 members. This reflects paragraph 6.1 of GAfREC.

8. At least one third of the total membership must be lay members. This follows paragraph 6.5 of GAfREC. However, the definitions of "expert" and "lay" member in the Regulations differ from those in GAfREC.

9. At least half of the lay members must meet additional criteria described below. Lay members who do not meet these criteria are referred to in this note as **"Lay"** and those who do as **"Lay+"** (see paragraphs 20-22).

10. It should be noted that the statutory definitions apply only to the ethical review of medicinal trials. The terms "expert" and "lay" may have a different meaning in other professional and organisational contexts.

Expert members

11. Under the Regulations, an expert member means a member who:

    (a) is currently a registered "health care professional" (see paragraph 11 below)

    (b) has professional qualifications or experience relating to the *conduct of, or use of statistics in clinical research*, unless those professional qualifications or experience relate only to the ethics of clinical research or medical treatment (see paragraphs 13-15 below)

    (c) is not a health care professional, but has previously been a registered medical practitioner or a registered dentist. *(Note: No time limit is specified, so this applies where a person has been registered at any time in the past.)*

12. *"Health care professional"* is defined in the Regulations and includes the following:

    - a doctor
    - a dentist

- a nurse or midwife
- a pharmacist
- an ophthalmic optician registered under section 7 of the Opticians Act 1989
- a registered osteopath as defined by section 41 of the Osteopaths Act 1993
- a registered chiropractor as defined by section 43 of the Chiropractors Act 1994
- a person registered by the Health Professions Council under the Health Professions Order 2001, which provides for registration of the following:

    - arts therapists
    - chiropodists
    - clinical scientists
    - dietitians
    - medical laboratory technicians
    - occupational therapists
    - orthoptists
    - paramedics
    - physiotherapists
    - practising psychologists
    - prosthetists and orthotists
    - radiographers
    - speech and language therapists.

13. The *"conduct of, or use of statistics in, clinical research"* is not defined in the Regulations. The guidance from NRES is that "clinical research" should be interpreted comprehensively for this purpose, and includes any research involving:

    - interventions, procedures, tests or analyses undertaken as part of the diagnosis, treatment or care of patients in the clinical setting, including monitoring and follow-up
    - tests or analyses to evaluate the safety or efficacy of methods of diagnosis, treatment or care of patients in the clinical setting, including quality of life outcomes
    - tests or analyses to develop new methods of diagnosis, treatment or care of patients in the clinical setting.

14. This definition means that, in addition to health care professionals, some non-health care professionals with clinical research experience may also qualify as expert members, for example:

- statisticians
- data managers
- academic scientists, e.g. biochemists, molecular biologists, immunologists, geneticists
- medical devices experts
- laboratory staff.

15. However, persons whose only involvement with clinical research relates to the management or monitoring of such research should not be regarded as having experience in the "conduct" of such research. For example, the following would not qualify as expert members under this criterion:

- project managers, clinical research associates and trial monitors employed by or under contract with pharmaceutical companies, medical device companies or CROs
- research managers or monitors employed by non-commercial research bodies
- administrative and secretarial staff of clinical researchers.

Lay members

16. A lay member is a person who does not qualify as an expert member and is eligible for appointment as a lay member.

17. A person is not eligible for appointment as a lay member if, in the course of his employment or business, he:

(a) provides medical, dental or nursing care

(b) conducts clinical research.

18. For this purpose, "conducting clinical research" may be defined in the same way as in paragraphs 13-15 above.

19. Generally speaking, members who are not eligible to be lay members will meet one of the criteria in paragraph 11 above and will therefore be eligible for appointment as expert members. There may however be some people who are not eligible for appointment at all to an ethics committee. This would be the case where, for example, a person provides medical, dental or nursing care in the course of his/her business (e.g. as a hospital manager) but is neither a health care professional, a former doctor or dentist, or a person with professional qualifications or expertise relating to the conduct of, or use of statistics in, clinical research.

20. At least half of the lay members must meet additional criteria described below. Lay members who do not meet these criteria are referred to as "Lay" and those who do as "Lay+".

21. A **Lay** member is a person who:

(i) has previously been a registered health care professional (see paragraph 12) - except for previously registered doctors or dentists who still qualify as expert members (see paragraph 11(c));

(ii) is or has been "a person involved in the conduct of clinical research other than as a research subject" (see paragraph 23) - except for persons covered by paragraph 11(b) who qualify as expert members;

(iii) is or has been a chairman, member or director of a health service body or any other body providing health care (see paragraph 24).

22. A **Lay+** member is therefore a person who is not and never has been any of the following:

(i) a health care professional;

(ii) a person involved in the conduct of clinical research other than as a research subject;

(iii) a chairman, member or director of a health service body or any other body providing health care.

23. There is no definition in Schedule 2 for *"a person involved in the conduct of clinical research*" (see paragraphs 21(ii) and 22(ii)). The term is wider than "conducting clinical research" (see paragraphs 13-14), which may be regarded as focusing specifically on clinical procedures, testing and analysis. Persons involved in the management of monitoring of clinical research (see paragraph 15) may be considered to be "involved in" its conduct. Where such persons are members of an ethics committee, they would be Lay but not Lay+.

24. Under paragraphs 21(iii) and 22(iii), "membership" of a health service body means for example a Board member. Therefore any executive or non-executive director or Board member of a NHS body or private health care organisation would be Lay but not Lay+. "Membership" does not mean any employee. People employed by NHS Trusts, Health Boards or other health care organisations in administrative, clerical or technical posts, auxiliary services, or in health care services not covered by the definition of health care professions, would be Lay+. Hospital chaplains would also be Lay+.

Summary

25. The table in the Annex shows how typical members of ethics committees might be classified under the Regulations. However, account should always be taken of the individual background of the member concerned, with reference to the detailed guidance above, before assuming that they fit into a certain category.

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ANNEX

Experts	Lay	Lay+
Hospital doctors	Previously registered health care professionals (other than doctors/dentists)	Members of the general public
Medical academics	Board members and directors of Trusts, Health Boards, SHAs, etc [2]	Social care professionals
GPs	Research managers and administrators at pharmaceutical companies or other clinical research bodies, e.g. project managers, CRAs, monitors, trials unit managers [2]	Sociologists
Psychiatrists	Research secretaries (if involved in management of clinical trials) [2]	Statisticians with no clinical trials experience
Dentists		Academic ethicists
Nurses and midwives		Lawyers
Pharmacists		Chaplains
Other currently registered health care professionals		NHS administrative, technical and support staff (not involved in management of clinical trials)
Previously registered doctors/dentists		
Clinical research data managers		
Clinical research statisticians		
Any other person with professional qualifications or experience of conducting clinical research [1]		

Notes:

(1) See paragraph 13.

(2) In practice, potential conflicts of interest would need to be taken into account by the appointing authority before such persons could be appointed as members of an ethics committee, but this is a separate issue from the classification of membership as expert/lay/lay+.