d. assurances that research participants will receive information that becomes available during the course of the research relevant to their participation (including their rights, safety and well-being)

e. the provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.

9.18 *Community considerations*

a. the impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn

b. the steps which had been taken to consult with the concerned communities during the course of designing the research

c. the extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health needs

d. a description of the availability and affordability of any successful study product to the concerned communities following the research

e. the manner in which the results of the research will be made available to the research participants and the concerned communities.

Expedited review

9.19 RECs shall establish any procedures necessary for the expedited review of research proposals. *(See Section B).* These procedures, which should be described in full in the Standard Operating Procedures, should specify the following:

a. the nature of the applications, amendments, and other considerations that will be eligible for expedited review

b. the quorum requirements for expedited review

c. the status of decisions (e.g. whether requiring confirmation by the full REC or not)

Decision-making

9.20 In making decisions on applications for the ethical review of research, an REC should take the following into consideration:

a. a member should withdraw from the meeting for the discussion and decision procedure concerning an application where there arises a

conflict of interest; the conflict of interest should be indicated to the Chair prior to the review of the application, and recorded in the minutes

b. an REC should not review an application in which one of its own members is a named researcher; such applications should be submitted to another REC

c. by invitation of the Chair, independent experts or others may take part in the discussion of the proposal at the REC meeting; however, a final decision may only be taken when sufficient time has been allowed for review and discussion of an application in the absence of non-members (e.g. the investigator, representatives of the sponsor, independent experts) from the meeting, with the exception of REC administrative staff and approved observers

d. decisions should only be made at meetings where a quorum is present

e. the documents required for a full review of the application shall be complete and the relevant elements mentioned above should be considered before a decision is made

f. written comments from absent members shall be allowed to inform the discussion, but only those members who actually participate in the review by the committee at its meeting shall participate in the decision

g. there should be a pre-determined method for arriving at a decision; it is recommended that decisions be arrived at through consensus where possible. Where a consensus is not achievable, the REC should vote.

9.21 Advice that is not binding may be appended to the decision.

9.22 In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.

9.23 An unfavourable opinion on an application should be supported by clearly stated reasons.

10 Submitting an application

10.1 The application shall be submitted by the "principal investigator" who is the person designated as taking overall responsibility within the team of researchers for the design, conduct and reporting of the study. It follows that the applicant should be of adequate qualification and expertise to fulfil this important role.

10.2 Where a potential applicant is inexperienced, there should be an identified supervisor of adequate quality and experience who will counter-sign the application form, and then share the responsibility for the ethical and scientific conduct of the research. A current signed CV of the supervisor should be submitted with the application.

10.3 RECs should ensure that their requirements for submitting an application for review are described in an application procedure that is readily available to prospective applicants.

10.4 Research to be undertaken by students primarily for educational purposes (e.g. as a requirement for a University degree course) shall be considered according to the same ethical and operational standards as are applied to other research. In such cases the supervisor takes on the role and responsibilities of the sponsor. In reaching its decision, the REC will wish to consider the broader overall benefits gained by such research.

Application requirements

10.5 These shall be published by the REC and shall include the following:

a. the name(s) and address(es) of the REC secretariat to which the application is to be submitted

b. the application form

c. the format for submission

d. any additional documentation

e. the language(s) in which core document(s) are to be submitted

f. the number of copies to be submitted

g. the deadlines for submission of the application in relation to the review dates

h. the means by which the application will be acknowledged, including the communication of the incompleteness of the application

i. the expected time for notification of the decision following review

j. the time frame to be followed in cases where the REC requests supplementary information or changes to the documents from the applicant

k. the fee structure, if any, for reviewing an application

l. the application procedure for amendments to the protocol, the recruitment material, the potential research participant information, and the information or methods used to obtain consent

m. the process for addressing any disputed decisions.

The documentation

10.6 All documentation required for a thorough and complete review of the ethics of proposed research should be submitted by the applicant. This may include, but is not limited to:

a. signed and dated application form

b. the protocol of the proposed research (clearly identified and dated), together with supporting documents and references, and details of any previous scientific peer review

c. a summary, synopsis or diagram ("flowchart") of the protocol in non-technical language

d. a description of the ethical considerations involved in the research

e. diary cards and other questionnaires intended for research participants

f. when the research involves a study product (such as a pharmaceutical or device under investigation), an adequate summary of all safety, pharmacological, pharmaceutical and toxicological data available on the study product, together with the summary of the clinical experience with the study product to date (e.g. recent investigators brochure, published data, a summary of the product's characteristics)

g. the applicant(s)'s current curriculum vitae (updated, signed and dated).

h. material to be used (including advertisements) for the recruitment of potential research participants

i. a full description of the process to obtain and document consent

j. written and other forms of information for potential research participants (clearly identified and dated) in the language(s) understood by the potential research participants and, when required, in other languages

k. informed consent form (clearly identified and dated) in the language(s) understood by the potential research participants and, when required, in other languages

l. a statement describing any compensation for study participation (including expenses, and access to medical care) to be given to research participants.

m. a description of the arrangements for indemnity, if applicable

n. a description of the arrangements for insurance coverage for research participants, if applicable

o. a statement of agreement to comply with ethical principles set out in relevant guidelines, and the identity of such guidelines

p. all significant previous decisions (e.g. those leading to a negative decision or a modified protocol) by other RECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for previous negative decisions should be provided.

11 Glossary

11.1 Clarification is given here of the meaning of some of the terms as used in this document, and as used in the *Research Governance Framework for Health and Social Care*. These meanings are broadly compatible with their use in other regulatory documents. Sometimes such documents use alternative words.

11.2 For some definitions, a list of some *"Key responsibilities"* is also given where they are relevant to the role of Research Ethics Committees. It should be noted that the responsibilities as listed here are not comprehensive, and further reference should be made to the text of the *Research Governance Framework for Health and Social Care* where there is a complete description.

11.3 **Participants:** - patients, users, relatives of the deceased, professional carers or members of the public agreeing to take part in the study. In some legal and regulatory documents the term "subject" is used instead.

11.4 **Research Ethics Committee** – the committee convened to provide independent advice to participants, researchers, funders, sponsors, employers, care organisations and professionals on the extent to which proposals for the study comply with recognised ethical standards.

* *Key responsibilities*:

- ensuring that the proposed research is ethical and by so doing, protects the dignity, rights, safety and well-being of participants
- providing public reassurance of that protection

11.5 **Principal Investigator** - the person designated as taking overall responsibility within the team of researchers for the design, conduct and reporting of the study.

Researchers - those conducting the study at individual sites.

* *Key responsibilities:*

- developing proposals that are ethical and seeking research ethics committee approval
- conducting research to the agreed protocol and in accordance with legal requirements and guidance e.g. on consent
- ensuring participant welfare while in the study
- feeding back results of research to participants

11.6 **Funder(s)** - organisation(s) providing funding for the study through contracts, grants or donations to an authorised member of either the employing and/or care organisation.

Sponsor - the individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial. The sponsor takes primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting; the sponsor is usually, but does not have to be, the main funder.

* *Key responsibilities:*

- assuring the scientific quality of proposed research

- ensuring research ethics committee approval obtained
- ensuring arrangements in place for the management and monitoring of research

11.7 **Employing Organisation(s)** - the organisation(s) employing the principal investigator and/or other researchers. The organisation employing the principal investigator will normally hold the contract(s) with the funder(s) of the study. Organisations holding contracts with funder(s) are responsible for the management of the funds provided.

* *Key responsibilities:*

- promoting a quality research culture
- ensuring researchers understand and discharge their responsibilities
- taking responsibility for ensuring the research is properly managed and monitored where agreed with sponsor

11.8 **Care Organisation** - the organisation(s) responsible for providing care to patients and/or users and carers participating in the study.
Responsible Care Professional - the doctor, nurse or social worker formally responsible for the care of the participant while they are taking part in the study

* *Key responsibilities:*

- ensuring that research using their patients, users, carers or staff meets the standard set out in the RGF (drawing on the work of the research ethics committee and sponsor)
- ensuring research ethics committee approval obtained for all research
- retaining responsibility for research participants' care

11.9 **Favourable opinion** - the term used to describe the decision reached by a Research Ethics Committee that the proposed research complies with recognised ethical standards.

11.10 **Approval** – a term in common usage which merely affirms that the REC has given a favourable opinion. It should be noted that, by itself, such approval by an REC does not entitle a researcher to proceed with the research. All research taking place within the NHS additionally requires the "approval" of the host NHS organisation - this is an absolute requirement. To proceed without this would constitute research misconduct.
Certain types of research will also require the "approval" of other authorities (e.g. the Medicines Control Agency).

11.11 **Rejection** – the term used to describe the decision reached by a Research Ethics Committee that the proposed research does **NOT** comply with recognised ethical standards. Whatever other approval might have been gained, the research may **NOT** proceed within the NHS.

11.12 **Health Authority** - a body established by the NHS to oversee health matters for the population of a defined area. At present these are "District Health Authorities" but from April 2002, these will be replaced by "Strategic Health Authorities". The term "Health Authority" as used in this document refers to

the current organisations until April 2002, and subsequently to the Strategic Health Authorities.