South West Local Research Ethics Committees

Common Application Form

GUIDANCE NOTES

April 1999

INTRODUCTION

The Local Research Ethics Committees (LRECs) in the South West have agreed to adopt a common application form. This has been developed in conjunction with the Regional Research and Development Directorate working closely with the Chairmen and members of LRECs. A slimmed down version of this application form is available for student projects. No separate guidance notes are available for that form.

The application form applies to all LRECs throughout the region but a separate application has to be completed for every LREC in the districts in which the proposed research will take place. It is essential that there is a local research contact in each district to deal with the application in the case of multicentre studies. For details of LRECs in the South and West see Appendix 4 in the Guidance Notes. Applications to five or more LRECs should go to the Multicentre Research Ethics Committee.

The LRECs function is to independently examine all proposals for research which is to be carried out within the geographical boundaries of the Authority, within the NHS and which involves human participants. All research projects should be submitted even if thought to be of a trivial nature.

LRECs will not be concerned with studies that are strictly audit, but investigators should recognise that some audit studies have clear research components, and that some audit studies can be very intrusive to patients and raise major ethical issues.

Applicants should discuss and if necessary submit protocols about which there may be doubt to the Administrator or Chair of the LREC.

Completing the form

The application form and guidance notes are available from LRECs in hard copy or as a disc version (Word for Windows 6.0 only). The disc version contains sophisticated formatting designed to ensure that the form cannot be changed or altered in any way.

It is essential that you complete the checklist on the front of the application form and enclose the relevant documents. Forms must be typewritten. Incomplete forms may not be considered by the LREC.

Details of the appropriate number of copies of the form and enclosures required (see checklist) should be obtained from the secretary of the relevant LREC. Double sided photocopying is preferable if possible.

ANNEXE A	**Must be completed if the study involves the use of a new medicinal product or medical device, or the use of an existing product outside the terms of its product licence.**
ANNEXE B	**Must be completed if the study involves the use of ionising or non-ionising radiation, radioactive substances or X-rays.**
ANNEXE C	**Must be completed if the research is conducted in a general practice setting.**
APPENDIX 1	Contains guidance on consent forms.
APPENDIX 2	Contains guidance on patient information sheets.
APPENDIX 3	Contains a consent checklist for investigators.
APPENDIX 4	Contains a list of addresses of the current secretaries of LRECs in the South West.

A copy of the lead applicant's CV (on a maximum of two sides of A4) must be submitted. If an application has previously been made by the applicant in the last 12 months this requirement may be waived.

Notes on completing the application form

The application form should contain sufficient information for ethics review in plain English; the lay members of LRECs should be able to assess the significance of the research and the associated ethical issues.

A simplified application form is available for students conducting research as part of a degree or educational programme. Applicants studying for a higher degree (PhD, MD or Masters degree by research) should complete the standard application form.

The majority of the application form is straightforward to complete; notes are not therefore provided for every question.

Section 1 - Details of applicants

1. A short title (6 words only) and a full title should be given. The use of the short title is for ease in administration. A brief indication of the potential benefits of the study should be given.
2. Details of the main applicant, including relevant qualifications. A brief CV of lead applicant must be submitted with the application, unless one has been submitted to the committe within the last 12 months.
3. Please give a contact telephone number in case the assessor wishes to discuss aspects of the application.
4. The main applicant should sign, together with the relevant head of department or supervisor. Where appropriate the relevant clinical director should sign; in some Trusts this is required for the purposes of indemnity.

Section 2 - Details of project

It is intended that in general, members of LRECs should be able to review the project from the details given on the application form. It is not therefore sufficient to enter “refer to protocol”. However, one version of the complete protocol should be sent in as indicated on the Checklist in order that members can refer to this in cases of uncertainty.

5. Please state clearly the hypothesis which this research is intended to test, or the questions it is expected to answer.
6. A brief synopsis of the relevant research in this area should be given. A limited number of key references should be cited. This should indicate if research has been done in humans before, and if so, why it is necessary to repeat it; and if not, has it been done in animals and with what results.

9. Details should be given as to how the size of the study was determined; this should usually include a formal sample size calculation.

10. If the project is a being done by a student as part of a course requirement, or is a pilot study, or multi-centre study, this should be indicated. If it is a student project being done as part of a course a shortened application form is available.

12. **This section must be completed.** Details should be given of any payment or reward made to the investigator, including grants that have been secured or are being sought to conduct the work. Details should be given as to the level of funding secured or sought, and for what this will cover. If the payment is on a per capita basis, details must be given about the sum agreed per patient, and the total number of patients expected. An indication must be given as to who will control the funds, eg charitable Trust. These finances must be audited. Finally a statement should be made as to whether all the costs incurred by the institution will be covered by the grant.

13. If being conducted in a Trust the R&D lead in the Trust will wish to be informed about the project.

Section 3 - Recruitment of participants

14. If advertisements are to be used to recruit study participants, please enclose a copy.

Section 4 - Details of consent

20. It is normally expected that written consent will be obtained, although this may not be appropriate in a postal questionnaire or interview study. A copy of the consent form to be used must be enclosed. If no written consent is to be obtained a full explanation must be given. A draft model consent form has been developed under the auspices of the Chief Medical Officer's Review of Research Ethics Committees and is shown in Appendix 1. The General Medical Council has provided advice to doctors on obtaining consent in research in the publication '*Seeking patients' consent: the ethical considerations*'. The consent form should be on headed paper.

21. If a significant proportion of participants do not speak English as a first language, special arrangements should be made.

22. If there are problems with consent because the study groups falls into the listed categories, the relevant details must be provided.

23. It is expected that unless there are exceptional circumstances, patients should receive a written information sheet or letter. This must be in clear English. (Many studies have to be resubmitted as the information sheet is inappropriate.) The information sheet should be separate from the consent form so it can be retained by the patient. If appropriate, an information sheet should be prepared for parents, carers or relatives. Justification must be given if this is not to be done. Appendix 1 in the Guidance Notes gives advice on the preparation of an information sheet. This guidance has been prepared nder the auspices of the Chief Medical Officer's Review of Research Ethics Committees. The relevant number of copies of the information sheet should be enclosed as indicated on the Checklist.

Section 5 - Details of interventions

24. If the study involves the use of a new medicinal product or medical device, or the use of an existing product outside the terms of its product licence, ANNEXE A in the guidance notes must be completed and returned with the application form. Please note that many medical devices are subject to similar regulations to those of new drugs. All medical devices must meet the appropriate safety regulations.

25. If the study involves the use of ionising or non-ionising radiation, radioactive substances or X-rays, ANNEXE B in the guidance notes must be completed and returned with the application form. An application using radioactive substances cannot proceed without the ARSAC Certificate holder's signature.

26. If blood and/or tissue samples are taken, consideration must be given to whether they will be destroyed when the study is complete. If they are to be retained patients must be informed. Ethical approval will be needed for any further studies using these samples. Consideration should be given to anonymising the samples.

27. If additional tests or investigations are being used with revenue consequences for the NHS, it is essential that the head(s) of the relevant department(s) (chemical pathology, radiology etc.) signs this section.

Section 6 - Risks and ethical problems

28. Careful and realistic consideration must be given as to any potential hazards to patients, the likelihood of these occurring and the steps taken to deal with these issues. This will include side effects and adverse effects resulting from treatment.

29. Consideration must be given as to the potential discomfort or distress, psychological or physical, caused to participants.

30. It is normally expected that an information sheet will be given to the patients' general practitioners, particularly if a drug is given, or an invasive procedure is undertaken. The relevant number of copies must be enclosed with the application form as indicated on the Checklist. Guidance on the Patient Information Sheet is given in Appendix 2.

    If the study is on hospital patients, all consultants should formally be approached to give their consent (preferably written) prior to the study commencing. If the study is in general practice, all parties should give their (preferably witnessed) consent.

Section 7 - Indemnity and confidentiality

31. Arrangements must be made to ensure that indemnity is available to cover negligent harm to patients or participants during the course of the research project. This will normally be available through the Trust or Health Authority for individuals working for those organisations. Individuals are also advised to maintain membership of their relevant defence organisation. Cover is provided by local medical defence bodies for doctors in primary care. Cover for non-negligent harm for participants may be required by the local research ethics committees in some circumstances. This will usually be covered by the ABPI guidelines in a drug trial.

    The involvement of medical students in the project has implications for insurance. The signature of the clinical director (Q4) may be needed for the purposes of indemnity.

34. All studies where personal data is retained in manual or computerised systems must be reported to the Data Protection Officer. Please give details of any additional steps to be taken over and above the requirements of the Data Protection Act. The Data Protection Act has recently been revised (1998) and is expected to come into force in 1999.

    If medical records are to be examined, patients should be reassured that only information directly relevant to the study will be extracted.

35. Special precautions are needed in the case of the use of audio or video recording to ensure confidentiality and anonymity.

36. It is the responsibility of the main investigator to ensure that research workers outside the employment of the NHS are fully aware of the need for confidentiality of patient information.

Checklist

The Checklist on the front page MUST be completed prior to sending the completed form back with the relevant enclosures.

APPENDIX 1 Consent Form

(Form to be on headed paper.)

Centre Number:

Study Number:

Patient Information Number for this trial:

CONSENT FORM

Title of Project:

Name of Researcher:

[Name and number of independent person]

Please initial box

1. I confirm that I have read and understand the information sheet dated ..... (version .....) for the above study ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. ☐
3. I am willing to allow access to my medical records but understand that strict confidentiality will be maintained. The purpose of this is to check that the study is being carried out correctly. ☐
4. I agree to take part in the above study. ☐

Name of patient	Date	Signature
Name of person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

1 for patient; 1 for researcher; 1 to be kept with hospital notes

TAKING PART IN RESEARCH

Study No:

Study Title:

You are being invited to take part in a research project. Here is some information to help you decide whether or not to take part. Please take time to read the following information carefully and discuss it with friends, relatives and you GP if you wish. Ask us if there is anything you do not understand or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

1. You may or may not receive any direct benefit from taking part in the study. However, information obtained during the course of the study may help us to understand better your condition or illness. It may also help us in selecting treatment for future patients.
2. It is up to you to decide whether to take part or not. If you do decide to take part you will be given an information sheet and consent form. Even if you do decide to take part, you are free to withdraw at any time and without giving a reason. This will not affect the standard of care you will receive. Your doctor will not be upset if you decide not to take part.
3. You may be paid travelling expenses for taking part in this study. The study may require you to attend more frequently. You should ask the study doctor or nurse about this.
4. All the information collected about you during the course of the research will be kept strictly confidential. If the study is of a drug or new device we need your permission to allow representatives from drug companies or perhaps officials from Government or Health Boards/Health Authorities to look at your health records. This is to check that the study is being carried out correctly. Any information taken away by these officials will not have your name on it. Any published report of the research will not identify you.
5. Depending upon the type of study, your GP will normally be informed that you are taking part. If this is problem for you, you should discuss it with your study researcher.
6. Sometimes during the course of the study new information becomes available. Your study doctor will talk to you about this and discuss with you whether you want to continue in the study. If you decide to withdraw, the study doctor will make arrangements for your care to continue. If you decide to continue in the study you may be asked to sign an updated consent form.
7. If the study is about a medical treatment, the study doctor will tell you about the known side effects which are listed on the attached sheet. If you suffer from any of these or any other

symptoms you should tell the study doctor next time you meet. If you are at all worried you should contact the study doctor immediately.

8. Some tests could affect your ability to obtain insurance. You should be sure to ask your study doctor about this.

9. If you have private medical insurance you should let the insurers know that you intend to take part in a research project. They will be able to tell you if this will affect your medical insurance.

10 Consumers for Ethics in Research (CERES) publish a leaflet entitled ‘Medical Research and You’. This leaflet gives more information about medical research and looks at some questions you may want to ask. A copy may be obtained from CERES, PO Box 1365, London N16 0BW.

TAKING PART IN RESEARCH

INFORMATION FOR PATIENTS ABOUT THE STUDY

Notes to Researchers

Potential recruits to yor research study need to be given sufficient information to decide whether or not they want to take part. You should give them the attached sheet containing general information and an additional sheet with information specific to your study.

The sheet specific to the study should contain information under the following headings and in the order specified. It should be written in simple, non-technical terms and easily understood by a lay person. Use short words, sentences and paragaphs. 'The readability' of any text can be estimated by the applicatioon of standard formulae. Two examples are attached. Checks on readability are also provided in most word processing packages.

1. **Study Title**
   Is the title self-explanatory? If not a simplified title should be included. The patient information sheet should be dated and given a version number.

2. **What is the purpose of the study?**
   The background and aim of the study should be given here.

3. **Why have I been chosen?**
   You should explain how the subject was chosen and how many other subjects will be studied.

4. **Who is organising the study?**
   Where appropriate, the answer should include the organisation or company sponsoring or funding the study (e.g. Medical Research Council, Pharmaceutical Company, charity, academic institution). Also mention here the duration of the study.

5. **What will happen to me if I take part?**
   You should say how long the patient will be involved in the study, how often they will need to visit a clinic (if this is appropriate) and how long will these visits be. You should explain (if appropriate) that reasonable travelling expenses will be paid for taking part in this study. (They may need to attend more frequently.) What exactly will happen e.g.blood tests, X-rays, interviews etc.? Will their diet be restricted, will they be able to drive? Whenever possible you should draw a simple flowchart or plan indicating what will happen at each visit. What are the patient's responsibilities? Set down clearly what you expect of them.

   You should set out simply the research methods youintend to use – the following simple definitions may help:-

   Randomised trial:
   Because we do not know which treatment is best, we need to make comparisons. People will be put into groups and then compared. Which group they are in is chosen as if 'by the toss of a coin' but now often by computer. Each group has a different treatment and they are compared. (You should tell the patients what chance they have of getting the trial drug/teatment.)

   Blind trial:
   In a blind trial you will not know which treatment group you are in. If the trial is a double

blind trial, your doctor will not know in which treatment group you are in (although, if they need to find out they can do so).

Crossover trial:
In the cross-over trial the groups each have the different treatments in turn. There may be a break between treatments so that the first drugs are cleared from your body before you start the new treatment.

Placebo:
A placebo is a dummy treatment such as a pill which looks like the real thing but is not: it contains no active ingredient.

6. What is the drug/device? (if applicable)
You should include a short description of the drug or device and give the stage of development. Patients entered into drug trials should be given a card (similar to a credit card) with details of the trial they are in. They should be asked to carry it at all times.

7. Are there other ways of treating my condition?
For therapeutic research the patient should be told what alternative treatments are available.

8. Are there any disadvantages in taking part in this study?
You should explain to the subjects any likely known side effects. If they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact number for them to phone if they become in any way concerned.

9. What are the possible risks of taking part?
The known side effects should be listed in understandable, meaningful terms (e.g. 'damage to the heart' rather than 'cardiotoxicity'; 'abnormalities of liver tests' rather than 'raised liver enzymes'). For an unlicensed drug it should be explained that there may be unknown side effects.

For studies where there could be harm to an unborn child if the patient was pregnant or became pregnant during the study, the following (or similar) should be said:

> 'It is possible that if the teatment is given to a pregnant woman it will harm the unborn child. Pregnant women must therefore not take part in this study. Women will have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who plan to become pregnant during the study should not take part. Women who could become pregnant must use an effective contraceptive during the course of this study.'

Use the pregnancy statement carefully. In certain circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy.

There should also be an appropriate warning and advice for men if the treatment could damage sperm which might therefore lead to a risk of a damaged foetus.

If insurance status could be affected by taking part this should be stated if e.g. high blood pressure is detected. If the patients have private medical insurance you should ensure that they check with the company before agreeing to take part in the trial. They will need to do this to ensure that their participation will not affect their medical insurance.

You should state what happens if you find a condition of which the patient was unaware. Is it treatable? What are you going to do with this information? What might be uncovered?

10. What are the possible benefits of taking part?
It is important not to exaggerate the possible benefits to the particular patient during the course of the study e.g. by saying they will be given extra attention. That could be seen as coercive. It would be reasonable to say something similar to

> 'We hope that both (all) the treatments will (control your pain, reduce your blood pressure etc.). However, this cannot be guaranteed. The information we get from this study may help us to treat future patients with (name of condition) better.'

If the treatment will not be available to the patient after the study this should be explained.

Where there is no intended clinical benefit to the patient from taking part in this trial this should be stated clearly.

The following sentences (or similar) will usually be appropriate:

> 'You will be told if important new information about this study becomes available which might affect your willingness to continue taking part. If any any time the researchers consider it in your best interest, they will withdraw you from the study. They will explain the reasons and arrange for your care to continue.'

11. Is my doctor being paid for including me in the study?
This means payment other than that to cover necessary expenses (e.g. laboratory tests arranged locally by the researcher). You could say:

> 'The sponsors of this study will pay (name of hospital department or research fund) for including you in this study' or
>
> 'Your doctor will be paid for including you in this study.'

12. What happens when the trial stops?
What treatments are available to the patient once their participation in the trial is over? Patients should be told if they will no longer have access to the study drug.

13. Are there any restrictions on what I might eat or do?
Patients should be told about any dietary restrictions any any medication which should be avoided.

Should the patient refrain from giving blood?

14. What if something goes wrong?
Where there are no ABPI or other no-fault compensation arrangements, and the study carries risk of physical or significant psychological harm, the following (or similar) should be said:

> 'If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you have any cause to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you.'

Where there are ABPI or other no-fault compensation arrangements the following (or similar) should be included:

> 'Compensation for any injury caused by taking part in this study will be in accordance with the guidelines of the ABPI (Association of the British Pharmaceutical Industry). A copy of these guidelines are available on request.'

How are you going to deal with complaints from patients? Is there a procedure in place? You will need to distinguish between complaints from patients as to their treatment by members of staff (doctors, nurses etc.) and something serious happening during or following their participation in the trial i.e. a reportable serious adverse event.

15. Confidentiality – who will know I am taking part in the study?
You will need to obtain the patient's permission to allow restricted access to their medical records and to the information collected about them in the course of the study. You should explain that all information collected about them will be kept strictly confidential. A suggested form of words for drug company sponsored research is:-

> 'Your medical records may be inspected by the company sponsoring (and/or the company organising) the study for purposes of analysing the results. They may also be looked at by people from the company and from regulatory authorities to check that the study is being

carried out correctly. Otherwise your name will not be disclosed outside the hospital/GP surgery.

or for other research:-

'All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery will be anonymised so that you cannot be recognised from it.

16. GP Notification

You should explain that for studies not being conducted by a GP, the patient's GP will be notified of their participation in the trial. You should seek the patient's agreement to this. In some instances agreement from the patient that their GP can be informed is a precondition of entering the trial.

17. LREC Approval

You should give the name of the Local Research Ethics Committe which approved the study.

18. What will happen to the results of the study?

What arrangements have been made to inform the patients about the results of the research? Where can they obtain a copy of the published results? Will they be told which arm of the trial they were in?

19. Contact for further information

You should give the patient a contact point for further information. This can be your name or that of another doctor/nurse involved in the study.

It is a requirement of the EC directive on good clinical practice that the patient be given the name of an 'independent person' who can also provide advice/information to them (A definition of an 'independent person' has been sought from the Medicine Control Agency.)

Remember to thank your patient for taking part in this study!

APPENDIX 3 Consent Checklist for Investigators

Adapted from a document prepared by Christopher Hodges and Christine Bendall
McKenna & Co, Solicitors, London EC1A 4DD

To assist compliance with Good Clinical Practice in the European Union issued by the Committee of Proprietary Medicinal Products, 1990 and Reports of the Royal College of Physicians, 1990 and 1986 and Health Service Circular HC(90)22 and Health Service Guidelines HSG (91)5.

Questions marked with an asterisk (*) are relevant to research in patients only.

Research project name ..... No. ..... Date .....

Participant name..... Sex..... DOB .....

Name of investigator obtaining consent .....

1.	1.1	Have you given the participant an oral explanation of the proposed research project?	Yes / No
	1.2	Have you given the information sheet to the participant?	Yes / No
	1.3	Have you told the participant that he/she will be kept informed of all relevant information which becomes available during the course of the study?	Yes / No
2.		Did your oral explanation to the participant include:	
	2.1	that this is a research project?	Yes / No
	2.2	participation is voluntary?	Yes / No
	2.3	the aims of the project?	Yes / No
	2.4	the likely duration of the participant's involvement?	Yes / No
	2.5	the expected benefits to the participant* and/or others?	Yes / No
	2.6	the expected nature of the drug, device or intervention being tested?	Yes / No
	2.7	the procedures which will be involved in participation?	Yes / No
	2.8	that the participant may instead receive a reference treatment or placebo?	Yes / No
	2.9	what alternative standard medical therapy is available?*	Yes / No
	2.10	what risks[1], inconvenience, discomfort or distress may reasonably be anticipated for this participant: the level and the likelihood?	Yes / No
	2.11	that there may be some unforeseen risks?	Yes / No
	2.12	that a refusal to participate may be given without reasons and will not affect the care which will be given to the participant*?	Yes / No

[1] Healthy volunteers should know all, even remote, risks. Patients should as a minimum be made aware of all material risks.

2.13 that the participant may be withdrawn from the study if the investigating physician considers this is necessary in the best interests of the participant? Yes / No

2.14 that personal information may be scrutinised during audit by competent authorities and properly authorised people, but all personal information will be treated as strictly confidential and will not be made publicly available? Yes / No

2.15 that information generated by the study may be published but that no details will be divulged from which the participant could be identified? Yes / No

2.16 that some such information will be retained for a period after the end of the trial? Yes / No

2.17 what compensation arrangements are available? Yes / No

2.18 whom to contact in an emergency and how? Yes / No

2.19 what activities if any must be avoided during participation (e.g. driving, operating machinery, drinking alcohol, sport, pregnancy, breast feeding), after participation (e.g. blood donation, participation in another trial) and for what period? Yes / No

3. Has the participant given authorisation to approach his/her GP and for permission for the GP to disclose medical information? Yes / No

4. Is or has the participant been involved in any other research studies? Yes / No

5. Is or has the participant recently been taking, or does he/she intend to take, any other medicines or preparations? Yes / No

6. Have you allowed the participant sufficient time to consider the matter on his/her own, to discuss with others if wished, or ask you questions? Yes / No

7. In your opinion, has the participant understood and consented to take part in this research? Yes / No

APPENDIX 4 — LREC Secretaries in the South West and MREC Administrator

1. Cornwall and Isles of Scilly

Mrs Carmen Thomas, Ethics Committee Co-ordinator/Secretary, Clinical Directorates Office, Royal Cornwall Hospitals Trust (Treliske), Truro, Cornwall TR1 3LJ. Tel: 01872 74242

2. North and East Devon

Mrs Sandy Chivers, Exeter Local Research Ethics Committee Secretary, Department of Medical Affairs, Royal Devon and Exeter Hospital (Wonford), Barrack Road, Exeter EX2 5DW.
Tel: 01392 402369

Miss Wendy Elliott, North Devon Local Research Ethics Committee Secretary, North and East Devon Health Authority, 12 Boutport Street, Barnstaple, North Devon EX31 1RW. Tel: 01271 327779

3. Plymouth and Torbay

Mrs Sue Luscombe, Plymouth LREC Secretary, South and West Devon Health Authority, The Lescaze Offices, Chinner's Bridge, Dartington TQ9 6JE. Tel: 01803 861876

Miss Sarah Parsons, Secretary, Torbay LREC, South Devon Healthcare Trust, Hengrave House, Torbay Hospital, Lawes Bridge, Torquay TQ2 7AA. Tel: 01803 614567

4. Somerset

Miss Elisa Stanbury, West Somerset Ethics Committee Secretary, Research and Development Support Unit, Taunton and Somerset Hospital, Musgrove Park, Taunton TA1 5DA.
Tel/fax: 01823 342799

Mrs Carol Watkins, Ethics Committee Secretary, Postgraduate Centre, East Somerset NHS Trust, Yeovil District Hospital, Higher Kingston, Yeovil, Somerset BA21 4AT. Tel: 01935 707324

5. Avon

Mrs Sue Bowman, Southmead LREC Secretary, Southmead Health Services NHS Trust, Southmead Hospital, Westbury-on-Trym, Bristol BS10 5NB. Tel: 0117 9505050

Mrs Linda Owen, Mrs Ann-Marie Burrows, Weston Research Ethics Committee Secretary, Weston Area Health Trust, Weston General Hospital, Grange Road, Weston-super-Mare, BS23 4TQ.
Tel: 01934 636363 (Ext. 3343)

Mrs Kathleen Matthews, Research Ethics Committee Secretary, Frenchay Healthcare NHS Trust Headquarters, Beckspool Road, Frenchay, Bristol BS16 1JE. Tel: 0117 9701070 (Ext. 3507)

Mrs Naazneen Nathoo, UBHT Ethics Committee Secretary, United Bristol Healthcare Trust, Trust Headquarters, Marlborough Street, Bristol BS1 3NU. Tel: 0117 9283613

6. Gloucestershire

Mrs Hazel Moynihan, Clerk to Gloucestershire Research Ethics, Gloucestershire Health Authority, Victoria Warehouse, The Docks, Gloucester GL1 2EL. Tel: 01452 318864

7. Wiltshire

Mrs Sally Collier, Salisbury Research Ethics Committee, Wiltshire Health Authority, Southgate House, Pans Lane, Devizes SN10 5EQ. Tel: 01380 728899

Mrs Sally Collier, Swindon Research Ethics Committee, Wiltshire Health Authority, Southgate House, Pans Lane, Devizes SN10 5EQ. Tel: 01380 728899

8. Bath

Research Ethics Committee Administrator (c/o Peter Rudd, Chairman) Royal United Hospital Bath NHS Trust, Combe Park, Bath BA1 3NG. Tel: 01225 825725

9. Dorset

Mrs Rachel Hanson, Ethics Committee Secretary, East Dorset, Local Research Ethics Committee, Poole Hospital Trust, Longfleet Road, Poole BH15 2JB. Tel: 01202 448201

Ms R Wilkinson, Ethics Committee Secretary, West Dorset Local Research Ethics Committee, Trust Headquarters, Dorset County Hospital, Old School of Nursing, Princes Street, Dorchester DT1 1TS. Tel: 01305 254640

South West Multi-centre Research Ethics Committee

Linnie Price, Administrator, South & West Devon Health Authority, The Lescaze Office, Shinners Bridge, Dartington, Devon TQ9 6JE. Tel: 01803 861947 Fax: 01803 861914

MREC Website: http://dialspace.dial.pipex.com/mrec/