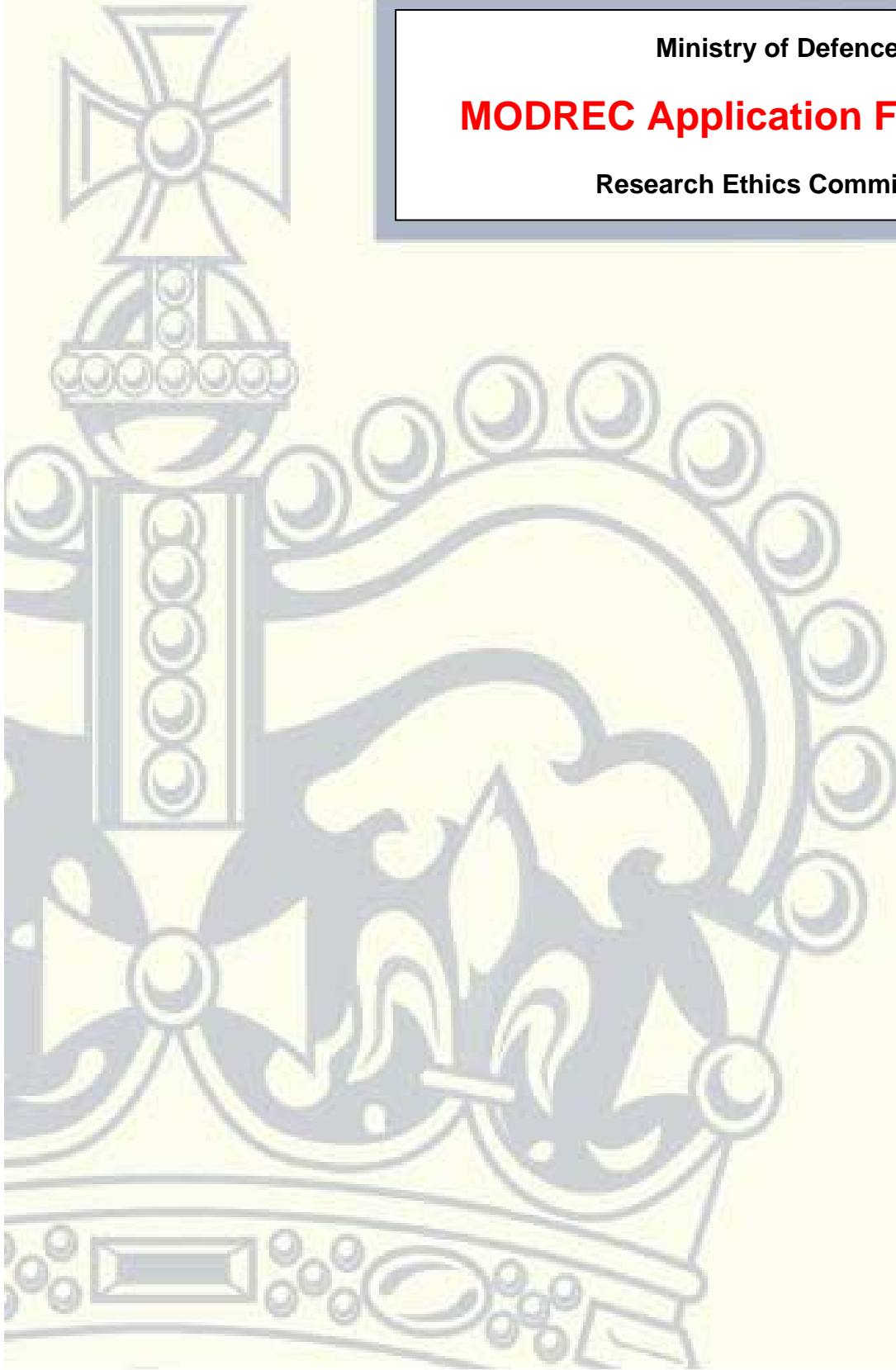


Ministry of Defence

MODREC Application Form Guide

Research Ethics Committees



Document Description:

Researcher guide to the procedure for obtaining ethical approval from the ministry of defence research ethics committee (MODREC) for research involving human participants.

Version	Date	Description
1.0	19 Jun 2006	First issue
1.1	15 Oct 2007	Minor format & content changes
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This document will be subject to version control by:

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MINISTRY OF DEFENCE

Ministry of Defence Research Ethics Committee (General)

Please read the following instructions carefully, before completing the application form.

GENERAL GUIDANCE

- **Please complete all sections of the form and mark 'N/A' those which do not apply to your study.**
- **Please be clear and concise throughout (particularly in the Information for Participants).**
- **If your project involves a number of sections and/or research methodologies you should ensure that each section is clearly defined and considered under each relevant question. Serious consideration should be given to the submission of more than one application for particularly long/complex projects.**

1. TITLE OF STUDY

This should be the same wherever it appears e.g. on Information for Participants, Consent Form.

2. DATE/VERSION

Please give the date of the most recent version and increase the version number each time a revised protocol is submitted. When making alterations please do so in a different font colour.

3. NATURE OF PROJECT

Please specify the nature of the research project, e.g. pilot study, original research.

Please also indicate whether this is a student project and, if so, the type of qualification sought, e.g. MSc, PhD.

4. INVESTIGATORS

Generally, all correspondence about the application will be sent to the Chief Investigator.

CVs are required for the Chief and other named Investigators.

Contact details provided must be external. Please provide external e-mail address and civilian telephone number.

Some research may require the involvement or supervision of an Independent Medical Officer (IMO), in which case include their brief CV.

5. PREFERRED TIMETABLE

The study, including recruitment, should not start until ethical approval has been given and this should be reflected in the preferred start date. However, under exceptional circumstances it may be possible for a project to be given urgent consideration. If you wish to apply for urgent review, please arrange for a 1* letter to be sent to the MODREC Chairman explaining why this is necessary.

6. SPONSOR / OTHER ORGANISATIONS INVOLVED AND FUNDING

- 6a. Please indicate the department/organisation requesting this work and provide contact details of any external companies or organisations involved.
- 6b. You should provide details of any funding provided for this study.
- 6c. Please declare any competing interests.

7. OTHER RESEARCH ETHICS COMMITTEE (REC) APPROVAL

If your study has been, or will be, reviewed by another REC please give details here.

8. PURPOSE OF THE STUDY

In this section of the form you should:

- 8a. Explain what the principal research question is, the specific objectives of the study and where appropriate the hypotheses to be tested.
- 8b. Provide the scientific justification and background of the study within the context of present knowledge and state the anticipated benefits and worth to the MoD of the proposed research.

9. STUDY DESIGN, METHODOLOGY AND DATA ANALYSIS

Please describe and justify your project's overall design and the method of data collection you have chosen.

Provide a brief summary of the nature of the participants' involvement. For instance, it should be clear to the Committee exactly what will happen to the research participants, e.g. they will complete two questionnaires; they will have 10 ml of blood taken etc. It should also be clear why it is necessary, where the interaction will take place, how long each session will take, how many sessions they will have to attend and how long the intervals between sessions will be.

Describe the statistical methods and/or any other relevant techniques (e.g. for qualitative research) to be used in the analysis of the results and state from whom data analysis advice has been sought.

If the study is collaborative or incorporates the involvement of another organisation the responsibilities of each party should be explained.

10. SAFETY

Safety is of the utmost importance, hence the inclusion of these questions which refer to physical risk. If they are not relevant to your protocol please mark each question as N/A.

11. ETHICAL CONSIDERATIONS

Please outline any ethical issues that might arise from the proposed study and how they are to be addressed. You might want to refer to issues such as recruitment in the workplace or in other contexts where there is already a relationship between researcher and potential participant, informed consent, the degree of confidentiality that can be assured and circumstances in which confidentiality might be breached (see section 15 below), anonymisation procedures, protection from harm, right to withdraw, the storage of sensitive data etc.

Please note that all research projects have some ethical considerations, even if these only relate to how confidentiality will be maintained, so please do not leave this section blank.

12. PARTICIPANTS TO BE STUDIED

Investigators must be able to demonstrate that they can justify the numbers of participants they plan to recruit, the age range and gender mix.

If the study design has been informed by statistical power calculations, please indicate how these were done.

13. SELECTION CRITERIA

Specify inclusion and exclusion criteria. If you are excluding participants on the basis of age, sex, ethnicity or any other factor, please explain why.

14. RECRUITMENT

How will potential participants in this study be (i) identified, (ii) approached and (iii) recruited? If you will be advertising, a copy of the advertisement/poster/recruitment e-mail should be included. Recruitment literature (e.g. recruitment letter or web pages) should also be submitted. See Appendix A for further guidance.

15. CONSENT

Written consent from participants will be required for all studies except those that are exclusively based on questionnaires, in which case submitting a completed questionnaire implies consent (this should be stated on the Information for Participants or introduction to the questionnaire). You should refer to and amend the consent form contained at the back of the application form.

To ensure compliance with the Data Protection Act 1998 participants must be informed what information will be held about them and who will have access to it (this relates to personal, identifiable information).

Research participants must have the right to choose whether or not they will participate in research, and obtaining informed consent is central to the ethical conduct of all research involving human participants. Fully informed consent in this context means consent freely given with proper understanding of the nature and consequences of what is proposed.

15a. The following process is recommended to ensure that this is in place:

1. Each participant should be given an oral explanation;
2. Each participant should then be given the 'Information for Participants' explaining in simple, non-technical terms, the procedures, any potential risks and hoped-for benefits;
3. The participant should be given reasonable time to consider this information and to consult others as necessary;
4. Except in the case of questionnaire based studies the participant should be asked to sign a consent form (which should be witnessed).

15b. Important special considerations relate to research projects involving children: please refer to the guidance produced by the Medical Research Council

www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002430

15c. Where the relationship between recruiter and potential participant might be influential, this must be acknowledged. Please also provide an explanation of how you will deal with predictable problems resulting from the prior relationship (i.e. how will the researcher counteract a perceived pressure to participate on the part of the volunteer, how will the risk of potential confidentiality/anonymity breaches be minimised and what level of anonymity can realistically be guaranteed).

16. PARTICIPANT INVOLVEMENT: RISKS, REQUIREMENTS AND BENEFITS

16a. Describe the potential hazards, risks and adverse effects, specifying the probability and seriousness in each case. Explain methods employed to reduce these risks.

16b. If your study involves invasive procedures, please provide details such as: where the procedures will take place and what facilities will be available, what volume of blood / size of sample will be taken/dose will be administered, where samples will be stored, how they will be identified and who will have access to them.

16c. For further information about medical devices see the Medicines and Healthcare products Regulatory Agency (www.mhra.gov.uk).

16d. The Information for Participants should make it clear under which circumstances action may be taken by the researcher.

16e. Please give an account of the circumstances in which participants might discontinue the study, and when the study as a whole would be stopped.

Communicating with General Practitioners

Sometimes it may be advisable or necessary to communicate with a research participant's GP about his/her involvement in your study. If so, you must obtain permission from the participant to write to his/her GP. Please include a copy of any letter you plan to send alerting a GP to his/her patient's participation and/or explain under what circumstances you might ask the participant's permission to divulge your findings to his/her GP.

17. FINANCIAL INCENTIVES, EXPENSES AND COMPENSATION

Payments may be made to participants for reimbursement of travelling, out-of-pocket expenses and compensation for time. An investigator who wishes to make any other payment must state his/her reasons for wishing to do so. Payments must be for inconvenience caused by participation rather than compensation for undergoing risk beyond what is normal for that person.

Non-patient research participants who suffer illness and/or personal injury as a result of taking part in a research project, which has been approved by MODREC, are covered by the MOD No Fault Compensation Scheme. A statement to this effect has been added to the pro-forma Information for Participants.

18. CONFIDENTIALITY, ANONYMITY AND DATA STORAGE

Confidentiality

Those involved in research owe an ethical and legal obligation to respect the confidences of research participants. The obligation extends to all personal information, medical or otherwise. A participant may, of course, consent to information being disclosed.

If researchers plan to share data with another party this must be stated on the Information for Participants. In circumstances where the researchers anticipate that they will wish to re-contact participants regarding the use of data for purposes other than those specified in the Information for Participants or to invite them to participate in further studies, participants must give their consent to be re-contacted regarding this on the consent form.

Ordinarily the application should refer to the need to obtain express permission if confidential information is to be used in a manner which will identify the research participant. Similarly, the researchers should also consider, and disclose in the application, any action that would need to be taken if circumstances were discovered which would give rise to concern (e.g. indication of a health issue, suggestion of professional misconduct).

If it is possible that information may come to light during the study which should be passed on to a third party (e.g. evidence of professional misconduct, information that should be passed on to the participant's GP), the participant should be advised of this possibility in the Consent Form and/or Information for Participants.

Details concerning confidentiality must be accurate and not capable of misleading potential participants.

The Information for Participants or Consent Form should state clearly if participant details are to be passed to any other organisation.

There are exceptions to the obligation of confidentiality which justify disclosure. All such disclosures must comply with the Data Protection Act and include:

Public interest

There may be circumstances where the right to confidentiality must be weighed against the public interest where there is a real or serious risk that another, or the public at large, may be put in danger by the participant.

Research Records

Chief investigators must ensure that proper records are kept throughout the active period of research. Records of personal details (names, addresses, telephone numbers) must be kept in a secure place along with any information of a medical nature (e.g. health screening questionnaire, details of drug usage). These records should be kept separately from research records, which should ideally be identified by a code number rather than by name. In tables of data, participants must only be identified by number not by initials or name.

Filing and Storage of Documents

A copy of the Information for Participants must be given to the participant to keep. The signed copy of the Consent Form should be retained, along with all other paperwork relevant to the project, in a secure location, accessible for inspection if required for at least **100 years** after the work is completed.

Responsibility lies with the Chief Investigator to produce, when required, evidence that informed written consent has been obtained.

At the end of the research the following records should be collated into one file and stored securely for 100 years:

- A copy of the research protocol;
- A copy of the application to MODREC;
- A copy of any correspondence with MODREC;
- Where appropriate a list of participants' names, dates of birth, addresses and their GPs' names and addresses;
- All correspondence relating to adverse reactions, and where appropriate, the records for each participant's involvement in the research and the record of any adverse reaction(s);
- Where appropriate a copy of the code which links participant names to research data;
- Copy of the data/results;
- Where appropriate a copy of any publications arising from the research.

Data Protection

All research participants have a right to inspect the record of their participation in your research project. Please ensure that your records are kept in a systematic, easily retrievable form during the active research phase and once filed for storage. Please ensure that non-essential records are shredded at the conclusion of the work, and that you do not keep records of personal or medical data in any location other than in those which are well-indexed, easily retrievable and securely stored.

Audit

You may be required to open your records for inspection for internal audit purposes either during the active research phase or during the period of storage.

19. GUIDANCE FOR PREPARATION OF INFORMATION FOR PARTICIPANTS

General Principles

The information needs to be brief and clear taking into account the educational level of the target audience. Please use simple words, requests rather than commands and a personal approach (e.g. 'we', 'you' rather than 'it', 'they').

This document provides guidance to completing the template (in the Application Form) which provides the same list of headings and questions. You may need to add, delete or modify some headings/questions to make the information appropriate to your study.

Please use your institution's letter heading at the top of the Information for Participants.

Study title

Give the title that appears in the protocol plus the MODREC reference number. Any acronyms must be spelled out.

Invitation to take part

You need to explain that you are inviting the person to take part. For example:

'We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please read the following information carefully and talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information.

Take time to decide whether or not you want to take part'.

You might wish to include one or two sentences explaining the study here.

What is the purpose of the research?

This is an important consideration for participants and must be presented clearly.

Who is doing this research?

State who is doing it, naming both the main investigator(s) and institution(s).

Why have I been invited to take part?

Explain briefly why and how the potential participant was chosen to be invited to take part and how many others will be in the study.

Do I have to take part?

Explain that taking part in the research is entirely voluntary. The following is an example:

'It is up to you to decide. We shall describe the study and go through this Information for Participants, which we will then give to you. You will have the opportunity to ask questions and in private if needed. The following day, after you have had time to consider this information, we will invite you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This will not affect your Service career in any way'.

What will I be asked to do?

To answer this question, try to put yourself in the participant's shoes.

You might include information about:

how long the participant will be involved in the research;

when it will start and where it will take place;

how often the participant will need to attend;

how long these visits will be;

what exactly will happen e.g. access to personal information, questionnaire, interview, discussion group, measurements, sample collection, blood test, x-rays, etc;

any pre-study requirements, such as avoiding alcohol for at least 24 hours, lifestyle or dietary restrictions etc; state that these details will usually be explained in the oral briefing;

when the results of the research will be known and whether the participants will be sent a report;

whether you may wish to contact the participants again in the future;

whether you may wish to use the data as part of a further study.

Use the most appropriate format (tables, diagrams, photos etc). The detail required will depend on the complexity of the study. It may help if the information is displayed in a simple flowchart or grid indicating what will happen at each stage of the study, rather than as lengthy lists in the text.

If the study will involve video/audio-taping or photography, you should explain what is intended, including the confidentiality issues. Specific consent will be needed if material of any sort that identifies the participant will be published and a statement needs to be included that the participants can at any time ask for the recording to be destroyed.

What is the device or procedure that is being tested?

You should include a short description of the device or procedure and give the stage of its development.

What are the benefits of taking part?

Explain these. It is important not to exaggerate the possible benefits. It would be reasonable to say something similar to:

‘The study will not benefit you directly, but the information we get will help to reduce the risks of diving’.

What are the possible disadvantages and risks of taking part?

Any risks, discomfort or inconvenience should be briefly outlined.

State what will happen if there is a problem during the test.

Explanation of risk is notoriously difficult so you should consider carefully how to explain any risk in your study.

Can I withdraw from the research and what will happen if I don't want to carry on?

Explain that the participants can withdraw at any stage. Explain what they can and cannot expect if they withdraw. The position on retention/destruction of data/samples on withdrawal must be made clear.

Are there any expenses and payments which I will get?

You should say whether expenses (e.g. travel, meals, etc) are available.

Details of payments for participation must be clearly stated.

Will my taking part or not taking part affect my Service career?

Make it clear that whether or not they take part will have no effect on their career.

Whom do I contact if I have any questions or a complaint?

The names, telephone numbers and e-mail addresses of the researcher(s) must be given. The researcher may try to solve the problem in the first instance. However, a participant may not wish to

complain to the researcher if he/she is the object of the complaint and so the contact details of the MODREC secretariat should be provided. (e-mail: ethics.sec@dstl.gov.uk ; telephone: 01980 658849).

What happens if I suffer any harm?

For healthy participants give details of the MOD No Fault Compensation scheme (these are provided in the MODREC Application Form). You could say:

‘If you suffer any harm as a direct result of taking part in this study, you can apply for compensation under the MOD’s ‘No-Fault Compensation Scheme’ (see details attached)’.

This scheme does not apply to patients.

What will happen to any samples I give?

It should be made clear whether:

- new samples will be taken e.g. blood, tissue, specifically for this study;
- samples excess to a clinical procedure will be asked for;
- access to existing stored samples will be asked for;
- material will be kept stored after the end of the study and if so for how long.

The same type of information, as for data, is needed. This should include:

- the secure procedures for collecting, using and storing samples;
- any possible intended use in the future for research that cannot yet be specified;
- who will have access;
- whether the samples can be linked to the individuals;
- provision for destruction;
- whether samples will be transferred outside the UK.

Will my records be kept confidential?

You should explain how confidentiality will be safeguarded during and after the study.

You may wish to tell the participants how your procedures for handling, processing, storage and destruction of their data match the Caldicott principles and the Data Protection Act 1998. If they could arise, you should also say how you will deal with situations where the study reveals previously unknown health problems, criminal activity or professional negligence.

It should be made clear:

- how the data will be collected;
- that it will be stored securely;
- whether the data will be anonymous or, if not, how confidentiality will be ensured;
- what it will be used for;
- if the data is to be retained for use in future studies and whether further REC approval will be sought;
- who will have access to view identifiable data (authorised persons such as researchers, sponsors, regulatory authorities);
- how long the data will be retained and that it will be disposed of securely.

Who is organising and funding the research?

Give details of sponsors and sources of funding.

What will happen to the results of this study?

Say whether the study will be written up as a PhD/MSc thesis, published as an internal report or in a professional journal etc.

Who has reviewed the study?

Mention MODREC and any other REC that has given ethical approval for the protocol. You might say:

‘All research on MOD/Service personnel is looked at by an independent group of people, called a Research Ethics Committee which has been engaged to protect your safety, rights, well-being and dignity. This study has been reviewed and approved by the MOD Research Ethics Committee’.

Further information and contact details.

Participants may want further information.

You should give the participant an appropriate contact point in order to obtain this. This could be information from documents or websites or from one of the members of the research team or from the Independent Medical Officer.

You should also provide a contact number if a subject had any concerns during the study, if this is different. For some studies an emergency contact number (which will be manned out-of-hours), if different, should be given and clearly displayed.

In a multi-site trial, the number must be appropriate for each site.

Compliance with the Declaration of Helsinki.

Include the statement:

‘This study complies and at all times will comply with the Declaration of Helsinki¹ as adopted at the 52nd WMA General Assembly, Edinburgh, October 2000 and with the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, (Strasbourg 25.1.2005).

¹World Medical Association (2000) Declaration of Helsinki. Ethical principles for medical research involving human subjects. 52nd World Medical Association General Assembly, Edinburgh, Scotland October 2000’.

MODREC is grateful to the National Research Ethics Service for providing information used in preparation of this guide to producing Information for Participants.

CONSENT FORM

The Committee acknowledges that each study has different requirements and that researchers need to communicate with a wide variety of potential participants. Although you are asked to retain the substance of the relevant paragraphs in the consent form provided, you are free to modify the language if it is in any way inappropriate for the intended participants. You should also ensure that the title of your project and its MODREC protocol number, once assigned, are added to the consent form.

Optional Clauses

Depending on the nature of your study and the participants you wish to recruit you should consider including the following clauses on the consent form:

- Please inform the researcher if you are currently involved or have been involved in any other research studies in the last 12 months;

- Please note you should not participate in this research if you become or are likely to become pregnant;
- I understand that I must not take part if... [list exclusion criteria];
- I agree to be contacted in the future by the researchers who would like to invite me to participate in follow up studies to this project, or in future studies of a similar nature;
- I agree that my GP may be contacted if any unexpected results are found in relation to my health;
- The information you have submitted will be published as a report and you will be sent a copy. Please note that confidentiality and anonymity will be maintained and it will not be possible to identify you from any publications.

This is not an exhaustive list and you should consider whether you need to amend any of these statements or design different ones that are more applicable to your research.

There may be occasions when a written explanation signed by the participant will be inappropriate, difficult or even impossible to obtain. Where this is the case, the applicant should inform MODREC of how (s)he will attempt to obtain fully informed consent and how it will be recorded.

Witness Signature

The witness should not be one of the investigators, but may be one of the other research participants or other independent person.

AUTHORISING SIGNATURES

The Chief Investigator should sign the consent form where indicated.

APPENDIX A: REQUIREMENTS AND GUIDELINES FOR THE PRODUCTION OF POSTERS, LEAFLETS AND E-MAILS FOR PARTICIPANT RECRUITMENT

Recruitment of research participants should be undertaken in such a way that participation is truly voluntary and there is no coercion, either explicit or implicit. MODREC prefers the use of indirect approaches rather than face-to-face individual requests to potential volunteers. Ideally, individuals should be able to take a positive step to participate rather than have the discomfort of declining a direct approach. Posters and leaflets may be used to recruit participants. The material can fall into several categories:

- a) Posters displayed locally and intranet notices
- b) Leaflets
- c) Advertisements in Service magazines
- d) Signals
- e) E-mails

Care should be taken when writing copy to consider the nature of the target group, ensuring that appropriate terminology is used. This is especially important for material likely to be seen by vulnerable groups and especially for advertisements that are to be published in large circulation magazines etc.

Characteristics of a good poster/leaflet or advertisement

The material should be visually attractive with a short clear heading in the form of an invitation and may include illustrations. Sufficient information should be given for potential participants to know roughly what is involved. Adequate information for making contact should be given.

Requirements

The Committee requires that all posters/leaflets meet the following requirements:

They must carry identification to allow reference to the records held by the Committee;

The minimum requirement is: MODREC ref no ***(***= protocol number);

A copy of the poster must be sent to the Committee to be deposited with the application papers, for review by the Committee and must be approved before use;

No details of any payments to be made to research participants should be included in the recruitment material.

Recruitment e-mails

Circular e-mails should satisfy all requirements in guidelines for posters. Additionally, they should be short, the subject box should contain a word or two about the study followed by ' – circular', and the e-mail should start with the sentence:

'Circular e-mail for use for recruitment of volunteers for study ref xx/cc, approved by the Ministry of Defence Research Ethics Committee. You are under no obligation to reply to this e-mail, however if you choose to, participation in this research is voluntary and you may withdraw at anytime.'

Proposed e-mails should be provided to MODREC along with justification for using this means of participant recruitment, and proposed target mail lists. Before an e-mail can be circulated it must be approved by MODREC.

These guidelines will be revised from time to time – please ensure that you have the most up-to-date version, which can be downloaded from the website.