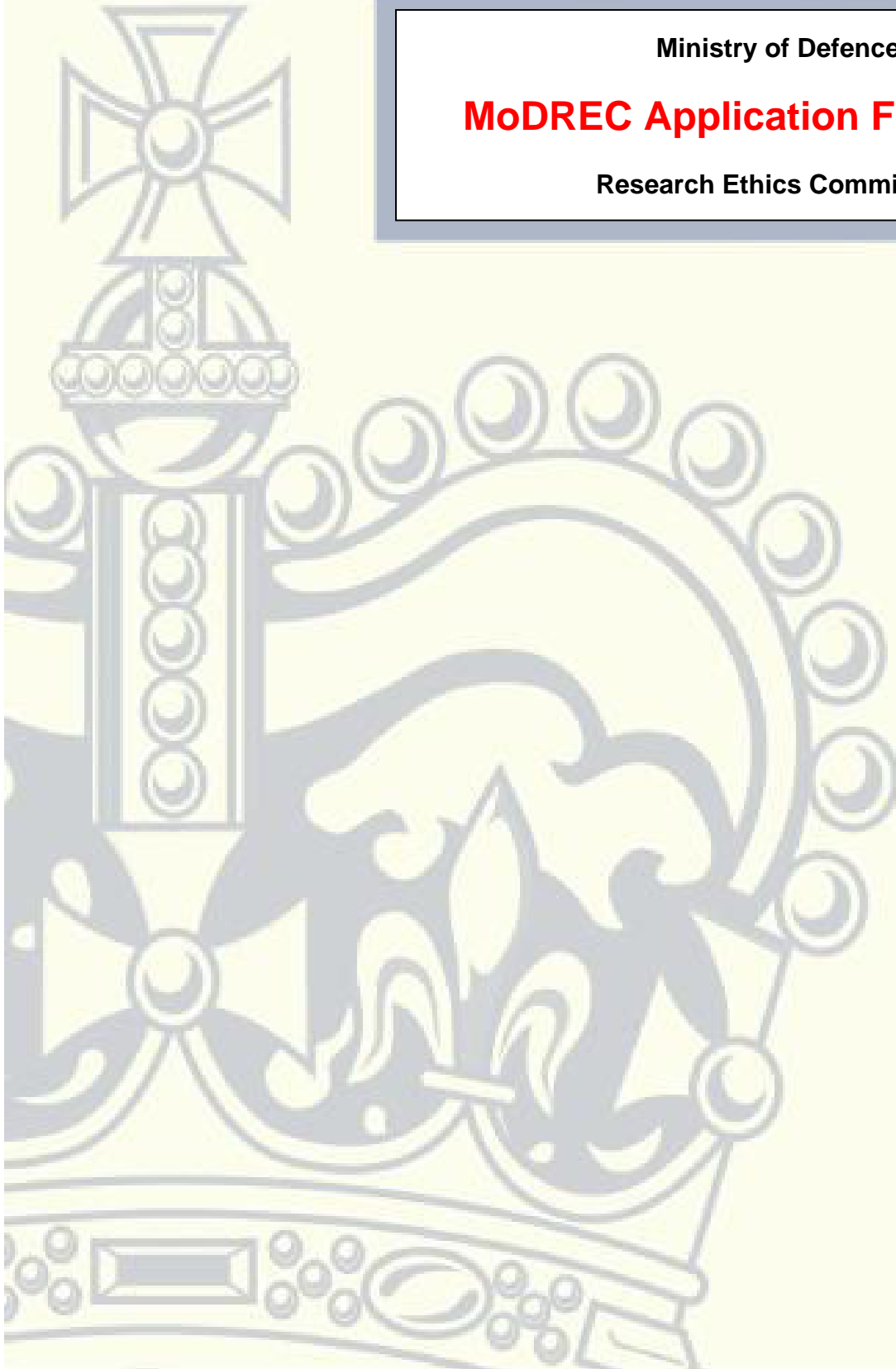


Ministry of Defence

MoDREC Application Form Guide

Research Ethics Committees



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

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MINISTRY OF DEFENCE

Ministry of Defence Research Ethics Committee

PROCEDURE FOR OBTAINING ETHICAL APPROVAL FROM THE MINISTRY OF DEFENCE RESEARCH ETHICS COMMITTEES (MoDREC) FOR RESEARCH INVOLVING HUMAN PARTICIPANTS

Please read through these guidelines carefully before completing the application form. Failure to complete all appropriate sections of the form adequately may delay your project

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.

About the Committee

The Ministry of Defence Research Ethics Committees (MoDREC) are responsible for ensuring that all research involving human participants undertaken, funded or sponsored by MoD personnel conforms to the highest ethical standards. There are two committees which work in parallel – MoDREC (General) and MoDREC (Personnel, Protection and Effectiveness). MoDREC (PPE) reviews protocols that cover personnel protection, such as optical and acoustic countermeasures, less than lethal weaponry (LLW), individual protective equipment (IPE), body armour and chemical and biological medical countermeasures as well as those studies employing strategic gaming to look at cognitive effects on performance. MoDREC (General) reviews protocols which generally fall outside these categories. Details of the Committee membership are available from the MoDREC Secretariat (see MoDREC contact details page 2) and on the MoDREC web pages (on the science|innovation|technology intranet website):

www.science.mod.uk/Strategy/MODrec.aspx

Which projects need MoDREC approval and which should be reviewed by an NHS Committee?

Not all human research needs ethical scrutiny e.g. anonymous, voluntary questionnaires which do not include intrusive questions. For further information to help you decide if ethical review is needed, please see ‘When does research require ethical approval?’ under ‘Frequently asked questions’ at the above address.

If you are in any doubt at all as to whether ethical review is required please get advice via the Secretariat.

When ethical approval is required, it must be obtained before recruiting research participants. All studies, including undergraduate and postgraduate projects, questionnaire-based projects or those which analyse personal data in any way, should be submitted for ethical review as specified in JSP536.

In addition it may be necessary to submit your project to an NHS Local Research Ethics Committee (LREC) if it involves any of the following:

- Patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient's or user's past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions;
- Individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above;
- Access to data, organs or other bodily material of past and present NHS patients;
- The use of, or potential access to, NHS premises or facilities;
- NHS staff - recruited as research participants by virtue of their professional role.

(From Governance Arrangements for Research Ethics Committees section 3.1 - <http://www.dh.gov.uk/assetRoot/04/05/86/09/04058609.pdf>)

Please check the National Research Ethics Service website (www.nres.npsa.nhs.uk) for further information.

If you are unsure which committee should review your application, please contact the MoDREC Secretariat (details below).

Clinical Trials of Investigational Medicinal Products (IMP)

MoDREC (Gen) and MoDREC (PPE) have recognition from the United Kingdom Ethics Committee Authority (UKECA) to review proposed Phase 1 trials. The UKECA's recognition relates only to the review of trials of investigational medicinal products as defined by the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended, and is limited to clinical trials in the United Kingdom. Note though in order for medicinal products and medical devices to be licensed, all stages of licensing process, including ethical approval of trials needs to be carried out in accordance with Good Clinical Practice (GCP) guidelines. As MoDRECs do not currently have GCP status these protocols will invariably be approved by other ethics committees (usually within the NHS) but MoDREC does need to be aware of protocols being submitted for approval to these committees in advance.

Also see Section 7 of these guidelines.

How do I go about applying?

All protocols (security permitting) should be e-mailed to the MoDREC Secretariat (see contact details below). In the case of classified material please contact the Secretariat. You will receive an e-mail giving you a protocol reference number (please enter this in the box at the top of the first page of the application form and be sure to quote this number in all future correspondence) and telling you to which Scientific Advisory Committee (SAC) we will send the application. The Chairman of that SAC will confirm to you and to the relevant MoDREC that they have received your protocol. They may contact you again during the

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scientific review process. When this is complete, the SAC Chairman will send the protocol to MoDREC (via the Secretariat) and e-mail you to inform you that it has been sent for ethical review. You may find it helpful to get informal advice from the appropriate SAC at an early stage of preparing your protocol, in which case please contact the MoDREC Secretariat.

MoDREC contact details

Any queries about the application form, or approval procedures in general, should be directed in the first instance to the MoDREC Secretariat:

Ministry of Defence Research Ethics Committee Secretariat
science/innovation/technology
01.K.47
Main Building
Whitehall
London SW1A 2HB
Office Tel: 0207 218 2512
Office Fax: 0207 218 9948
E-mail: ethics@mod.uk

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 Participant Information Sheet).**
- **If you have already given the information requested it is acceptable to give a reference to the appropriate section.**
- **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 the Participant Information Sheet and the 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 being sought, e.g. MSc, PhD.

4. INVESTIGATORS

Generally, all correspondence about the application will be sent to the Principal Investigator. The supervisor of a student protocol must be the Principal Investigator.

CVs are required for the Principal 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

- 5a. The study 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 appeal for urgent review, please submit a covering note with 1* support explaining why this is necessary.
- 5b. It should be noted that ethical approval is normally given for one year, after which an extension to approval should be sought: this does not necessitate the re-submission of a full application and can normally be done by Chairman's action. There will be exceptions to this rule for example where a protocol identifies that the start date is likely to exceed this one year period and in such instances the Chairman will need to take this into account when considering the protocol.

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

- 7a. To check whether your study is likely to require NHS LREC approval, see pages 1 and 2 of these notes.
- 7b. If your study has been, or will be, reviewed by another REC or any other associated body please give details here.

8. PURPOSE OF THE STUDY

In this section of the form you should:

1. Explain what the principal research question is, the specific objectives of the study and where appropriate the hypotheses to be tested.
2. 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. 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 and anonymity that can be assured and circumstances in which confidentiality might be breached (see Section 17 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.

11. 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.

12. 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.

13. 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.

14. 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 Participant Information Sheet 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 1988, participants must be informed of what information will be held about them and who will have access to it (this relates to personal, identifiable information). Explicit consent must be obtained for questionnaire studies in which sensitive data will be collected (see Section 18 for further information and possible wording).

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.

14a. 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 a Participant Information Sheet 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).

14b. Important special considerations relate to research projects involving children: please refer to the guidance for researchers produced by the National Children's Bureau '**National Children's Bureau Guidelines for Research**'.

The web address is:

http://www.ncb.org.uk/dotpdf/open%20access%20-%20phase%201%20only/research_guidelines_200604.pdf

14c. 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).

15. PARTICIPANT INVOLVEMENT: RISKS, REQUIREMENTS AND BENEFITS

15a. Describe the potential hazards, risks and adverse effects, specifying the probability and seriousness in each case. Explain the methods employed to reduce these risks. Please state if there is a risk assessment team, and if so, provide details of the members and their relationship to the MoD.

15b. If your study involves invasive procedures, please provide information such as: where the procedures will take place and what facilities will be available, volume(s) of blood to be taken, details of other samples, where samples will be stored, how they will be identified and who will have access to them.

15d. For further information about medical devices see the Medicines and Healthcare products Regulatory Agency (website: <http://devices.mhra.gov.uk>).

15g. The Participant Information Sheet should make it clear under which circumstances action may be taken by the researcher.

15i. 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.

16. 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 is included in the pro-forma Participant Information Sheet.

17. 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 Participant Information Sheet. 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 Participant Information Sheet or to invite them to participate in further studies, participants must give their consent to be re-contacted regarding this on the consent form.

The researchers should 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 Participant Information Sheet.

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

The Participant Information Sheet 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

Principal investigators must ensure that proper records are kept throughout the active period of research. Records of personal details (names, addresses, and 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 Participant Information Sheet 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 Principal 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.

18. PARTICIPANT INFORMATION SHEET

The Participant Information Sheet and the Consent Form comprise the last part of the Application Form. The Information Sheet is vital and must be completed carefully following the guidelines given below and using the proforma Participant Information Sheet included in the Application Form as a guide.

The Consent Form and Participant Information Sheet should be written clearly, the writer should use:

- * Simple words;
- * Requests rather than commands;
- * The active voice, e.g. we will book rather than the passive voice, e.g. appointments will be booked;
- * A personal approach, e.g. we, you, rather than the impersonal, e.g. student, subject, they, those, he or she.

Jargon and acronyms should be avoided or accompanied by a clear explanation in everyday language.

Please note that the Committee will only accept Participant Information sheets that address the following points:

- a. Indicate the Title of the Study and MoDREC protocol number;
- b. Provide a clear statement that this is a study in which the volunteer is being requested to participate and that such participation is entirely voluntary. This paragraph has been inserted

into the proforma Participant Information Sheet for your convenience, but may be amended where necessary;

- c. Provide a non-technical description of the nature and aims of the research project;
- d. Give a clear description of what will happen to the volunteer if (s)he agrees to take part and how much time it will take;
- e. Give details of any exclusion criteria which apply in order to avoid inappropriate recruitment;
- f. Give a description of any risks, inconvenience or discomfort that may reasonably be anticipated;
- g. Confirm anonymity or describe how confidentiality of personal information will be maintained. To ensure compliance with the Data Protection Act 1998, participants must be informed of what information will be held about them and who will have access to it (this relates to information that is identifiable or could potentially be linked back to an individual);
- h. Include explicit consent for data processing when collecting information classified as 'sensitive personal data' (see footnote below *) which is identifiable or could potentially be traced back to an individual. ('Explicit consent' is normally considered to be specific, written consent). As such, participants will need to give explicit consent for researchers to process sensitive data and permission for this should be sought on the consent form (sentence provided on standard consent form template). In the case of questionnaires where no consent form is to be used, the following statement should be included in the body of the questionnaire:

I consent to the processing of my personal information for the purposes of this research study. I understand that such information will be treated as strictly confidential and handled in accordance with the provisions of the Data Protection Act 1998.'

If the study is questionnaire based but is not seeking sensitive personal data it should be stated on the Participant Information Sheet that submission of a completed questionnaire implies consent to participate;

- i. Explain, where necessary, research procedures such as randomised control trial, anonymisation, etc. in non-technical terms;
- j. Give the name, telephone number and e-mail address of whom to contact in an emergency and whom to contact to obtain further details about the study;

*The Data Protection Act, 1998 classifies sensitive personal data as consisting of information as to '(a) the racial or ethnic origin of the data subject, (b) their political opinions, (c) his religious beliefs or other beliefs of a similar nature, (d) whether he is a member of a trade union (within the meaning of the Trade Union and Labour Relations (Consolidation) Act 1992), (e) his physical or mental health or condition, (f) his sexual life, (g) the commission or alleged commission by him of any offence, or (h) any proceedings for any offence committed or alleged to have been committed by him, the disposal of such proceedings or the sentence of any court in such proceedings'. (<http://www.legislation.hmso.gov.uk/acts/acts1998/19980029.htm>)

k. State what compensation arrangements are available in the event of injury;

l. In the case of non-patient research participants, include the statement *'In the event of your suffering any adverse effects as a consequence of your participation in this study, you will be eligible to apply for compensation through the MoD's No Fault Compensation Scheme'*;

m. Detail any payments in the form of an inconvenience allowance that are to be made to research 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 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 intend 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 or 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 Principal 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’;

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- 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.