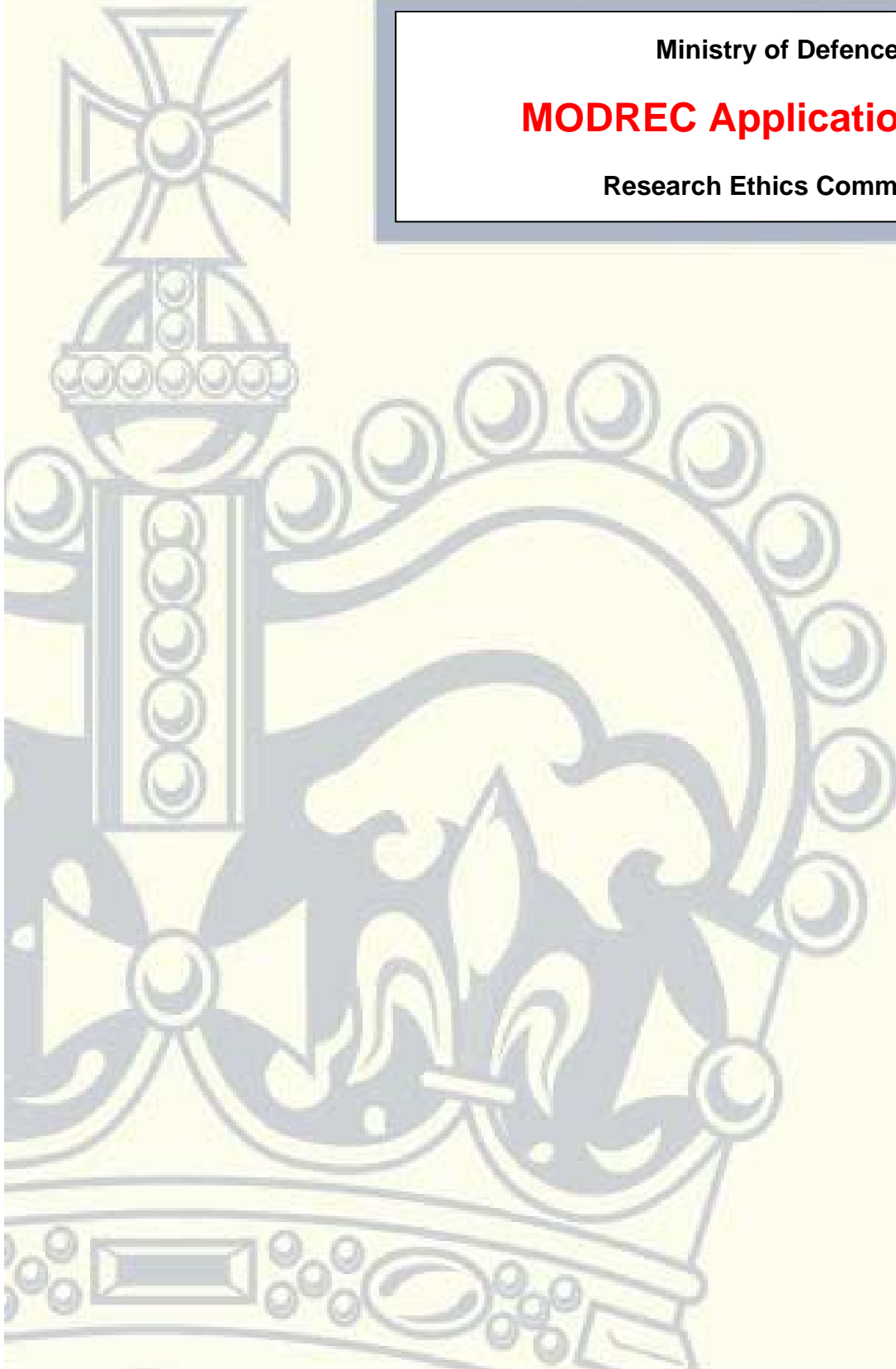


Ministry of Defence

MODREC Application Form

Research Ethics Committee



Document Description:

Application form for MODREC approval of human research

Version	Date	Description
1.0	19 Jun 2006	First issue
1.1	15 Oct 2007	Minor format & content changes
1.2	22 Oct 2009	Minor format & content changes
1.3	25 Jun 2010	Minor format & content changes
1.4	21 Jan 2011	Minor format & content changes

This document will be subject to version control by:

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MODREC Protocol No:



MINISTRY OF DEFENCE

Ministry of Defence Research Ethics Committee (MODREC)

MODREC APPLICATION FORM

*Please read the notes in the MoDREC Application Form Guide before completing this form.
Enter text in the grey boxes, which will expand automatically to encompass your text.
Please e-mail the completed form and any supporting documents to
ethics.sec@dstl.gov.uk*

1. TITLE OF STUDY

2. DATE/VERSION

Date	Version

3. NATURE OF PROJECT

4. INVESTIGATORS

4a. Chief Investigator

Name and Title:

Grade/Rank:

Post Title:

Department:

Establishment:

Address:

Telephone:

E-mail:

4b. Other investigators / collaborators / external consultants

4c. Name of the Independent Medical Officer (if applicable)

5. PREFERRED TIMETABLE

5a. Preferred start date:

5b. Expected date of project's completion:

6. SPONSOR / OTHER ORGANISATIONS INVOLVED AND FUNDING

6a. Department/Organisation requesting research:

6b. If you are receiving funding for the study please provide details here:

6c. Please declare any competing interests:

7. OTHER RESEARCH ETHICS COMMITTEE (REC) APPROVAL

Has the proposed study been submitted to any other REC? If so, please provide details:

8. PURPOSE OF THE STUDY

9. STUDY DESIGN, METHODOLOGY AND DATA ANALYSIS

10. SAFETY

10a. Has a Project Safety Committee been appointed? If so, please give the name and contact details of the chairman.

10b. How will the safety of the proposed research be managed?

10c. Is your application supported by a certificate of verification stating that the safety of the proposed research has been properly assessed and managed? (The certificate of verification should be attached to the application. If there is no certificate of verification this needs to be explained.)

10d. Who is the named person taking responsibility for the safety of the equipment to be used in the research?

10e. Who is the named person taking responsibility for the overall safety of the proposed research and who will be responsible for day-to-day safety?

10f. How will those conducting the research be made aware of:-

a) Their responsibilities for reporting any new issues as to safety which arise after the start of the project and

b) Their responsibilities for reporting adverse events in the conduct of the project?

10g. What other measures have been taken to ensure the safety of this research and minimize any risk to the participants?

11. ETHICAL CONSIDERATIONS

12. PARTICIPANTS TO BE STUDIED

Number of participants:

Lower age limit:

Upper age limit:

Gender:

Please provide justification for the sample size:

13. SELECTION CRITERIA

14. RECRUITMENT

14a. Describe how potential participants will be identified:

14b. Describe how potential participants will be approached:

14c. Describe how potential participants will be recruited:

15. CONSENT

15a. Please describe the process you will use when seeking and obtaining consent:

A copy of the Information for Participants and Consent Form must be attached to this application. For your convenience proformas are provided at the end of this document. These should be filled in, modified where necessary, and attached to the end of your application.

15b. Will the participants be from any of the following groups?

Under 18: Yes/No

Subordinates: Yes/No

Prisoners: Yes/No

Pregnant or nursing mothers: Yes/No

Mental Illness: Yes/No

Learning disabilities: Yes/No

How will you ensure that participants in the groups listed above are competent to consent to take part in this study?

15c. Are there any special pressures that might make it difficult for people to refuse to take part in the study? How will you address such issues?

16. PARTICIPANT INVOLVEMENT: RISKS, REQUIREMENTS AND BENEFITS

16a. What are the potential hazards, risks or adverse effects associated with the study?

16b. Does your study involve invasive procedures such as blood taking, muscle biopsy or the administration of a medicinal product? Yes/No

If so, please provide details:

16c. Please indicate the experience of the investigators in the use of these procedures:

16d. If medical devices are to be used on any participant, do they comply with the requirements of the Medical Devices Directives?

16e. Please name the locations or sites where the work will be done:

16f. Will group or individual interviews / questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting? If so, please list these topics and explain how you will prevent, or respond to, volunteer discomfort:

16g. Is it possible that criminal or other disclosures requiring action (e.g. evidence of professional misconduct) could take place during the study? If yes,

give details of what procedures will be put in place to deal with these issues:

16h. Please describe any expected benefits to the research participant:

16i. Under what circumstances might a participant not continue with the study, or the study be terminated in part or as a whole?

17. FINANCIAL INCENTIVES, EXPENSES AND COMPENSATION

17a. Will travelling expenses be given?

17b. Is any financial or other reward, apart from travelling expenses, to be given to participants? If yes, please give details and justification:

17c. If this is a study in collaboration with a pharmaceutical company or an equipment or medical device manufacturer, please give the name of the company:

18. CONFIDENTIALITY, ANONYMITY AND DATA STORAGE

18a. What steps will be taken to ensure confidentiality (including the confidentiality and physical security of the research data)? Give details of the anonymisation procedures to be used, and at what stage they will be introduced:

18b. Who will have access to the records and resulting data?

18c. Where, and for how long, do you intend to store the consent forms and other records?

19. INFORMATION FOR PARTICIPANTS AND CONSENT FORM

The Information for Participants and Consent Form should be composed according to the guidelines and submitted with this form.

The following, where applicable, are attached to this form (please indicate):

- Information for Participants**
- Consent Form**
- Appendix relating to medicines and/or healthcare products**
- Letter to general practitioners**
- Letter to parents/guardians**
- Letter of other research ethics committee approval or other approvals**
- Copy of e-mail recruitment circular/poster/press advertisement**
- Questionnaire/ topic guide/ interview questions**

- Evidence of permission from organisation (e.g. hospital) where research is to take place**
- List of acronyms**
- CVs of named investigators**
- CV of supervisor**
- CV of Independent Medical Officer**

Please list any other supporting documents:

Information for Participants

Study title

Invitation to take part

What is the purpose of the research?

Who is doing this research?

Why have I been invited to take part?

Do I have to take part?

What will I be asked to do?

What is the device or procedure that is being tested?

What are the benefits of taking part?

What are the possible disadvantages and risks of taking part?

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

Are there any expenses and payments which I will get?

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

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

What happens if I suffer any harm?

What will happen to any samples I give?

Will my records be kept confidential?

Who is organising and funding the research?

Who has reviewed the study?

Further information and contact details.

Compliance with the Declaration of Helsinki.

CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Title of Study:

Ministry of Defence Research Ethics Committee Reference:

- **The nature, aims and risks of the research have been explained to me. I have read and understood the Information for Participants and understand what is expected of me. All my questions have been answered fully to my satisfaction.**
- **I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and be withdrawn from it immediately without having to give a reason. I also understand that I may be withdrawn from it at any time, and that in neither case will this be held against me in subsequent dealings with the Ministry of Defence.**
- **I understand that the screening process to decide if I am suitable to be selected as a participant may include completing a medical screening questionnaire and/or a physical examination by a medical officer and I consent to this.**
- **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.**
- **I agree to volunteer as a participant for the study described in the information sheet and give full consent.**
- **This consent is specific to the particular study described in the Information for Participants attached and shall not be taken to imply my consent to participate in any subsequent study or deviation from that detailed here.**
- **I understand that in the event of my sustaining injury, illness or death as a direct result of participating as a volunteer in Ministry of Defence research, I or my dependants may enter a claim with the Ministry of Defence for compensation under the provisions of the no-fault compensation scheme, details of which are attached.**

Participant's Statement:

I _____

agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes

written above and the Information for Participants about the project, and understand what the research study involves.

Signed

Date

Witness

Name

Signature

Investigator's Statement:

I _____

confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the Participant.

Signed

Date

AUTHORISING SIGNATURES

The information supplied above is to the best of my knowledge and belief accurate. I clearly understand my obligations and the rights of research participants, particularly concerning recruitment of participants and obtaining valid consent.

Signature of Chief Investigator

.....

Date

Name and contact details of Independent Medical Officer (if appropriate):

Name and contact details of Chief Investigator:

APPENDIX: DETAILS OF MEDICINES AND/OR HEALTHCARE PRODUCTS

Please state name, dose, number of doses of the substances to be administered, and the route of administration.

Please state briefly the known pharmacology of any pharmacologically or physiologically active substances, including possible side effects. Please provide appropriate documentation.

REGULATORY STATUS

If the study involves the administration of medicinal products to participants, please indicate which of the following is applicable and append a copy of the relevant documentation or in the case of the exemptions, a copy of the letter from the Medicines and Healthcare products Regulatory Agency (MHRA) confirming exemption.

- a) Marketing Authorisation** (previously called a Product licence)
- b) Clinical Trial Authorisation (CTA)***

*The CTA replaces the CTC (Clinical Trial Certificate), CTX (Clinical Trial Exemption) and DDX (Doctors and dentists exemption scheme). Further information on this can be found on the Medicines and Healthcare Products Regulatory Agency website: <http://www.mhra.gov.uk>

The Committee will only give approval on presentation of the relevant certificate or letter confirming authorisation or exemption.

ARRANGEMENTS FOR THE PAYMENT OF NO-FAULT COMPENSATION TO RESEARCH PARTICIPANTS

1. This Annex sets out the arrangements for the payment of no-fault compensation to a person who suffers illness and/or personal injury as a direct result of participating in research conducted on behalf of the Ministry of Defence. The no-fault compensation arrangements only apply to research participants (Military, Civilian, or non-Ministry of Defence) who take part in a Trial that has been approved by the MOD Research Ethics Committee.
2. A research participant wishing to seek no-fault compensation under these arrangements should contact the DBR Common Law Claims & Policy (CLCP), Ministry of Defence, Level 1, Spine 3, Zone J, Whitehall, London, SW1A 2HB who may need to ask the Claimant to be seen by a MOD medical adviser.
3. CLCP will consider reasonable requests for reimbursement of legal or other expenses incurred by research participants in relation to pursuing their claim (e.g. private medical advice, clinical tests, legal advice on the level of compensation offered) provided that they have been notified of the Claimant's intention to make such a Claim.
4. If an injury is sufficiently serious to warrant an internal MOD inquiry, any settlement may be delayed at the request of the research participant until the outcome is known and made available to the participant in order to inform his or her decision about whether to accept no-fault compensation or proceed with a common law claim. An interim payment pending any inquiry outcome may be made in cases of special need. It is the Claimant's responsibility to do all that he or she can to mitigate his or her loss.
5. In order to claim compensation under these no-fault arrangements, a research participant must have sustained an illness and/or personal injury as a direct result of participation in a Trial. A claim must be submitted within three years of when the incident giving rise to the claim occurred, or, if symptoms develop at a later stage, within three years of such symptoms being medically documented.
6. The fact that a research participant has been formally warned of possible injurious effects of the trial upon which a claim is subsequently based does not remove MOD's responsibility for payment of no-fault compensation. The level of compensation offered shall be determined by taking account of the level of compensation that a court would have awarded for the same injury, illness or death had it resulted from the Department's negligence.
7. In assessing the level of compensation, CLCP, in line with common law principles, will take into account the degree to which the Claimant may have been responsible for his or her injury or illness and a deduction may be made for contributory negligence accordingly.
8. In the event of CLCP and the injured party being unable to reach a mutually acceptable decision about compensation, the claim will be presented for arbitration to a nominated Queen's Counsel. CLCP will undertake to accept the outcome of any

such arbitration. This does not affect in any way the rights of the injured party to withdraw from the negotiation and pursue his or her case as a common law claim through the Courts.