



**Ministry
of Defence**

Joint Service Publication 536

**Ministry of Defence Policy for
Research Involving Human
Participants**

Version 2.0 – May 2014

This JSP has been equality and diversity impact assessed in accordance with departmental Policy. This resulted in a Part One screening only being completed (no direct discrimination or adverse impact identified / policy is a reflection of statutory requirements and has been cleared by a Legal Advisor).

Sponsored by:

Surgeon General

Ministry of Defence Policy for Research Involving Human
Participants

Document Description:

Research involving human participants undertaken, funded or sponsored by the Ministry of Defence (MOD) must meet acceptable ethical standards.

Scientific quality is upheld by review of research proposals by Scientific Assessment Committees. This Joint Services Publication (JSP) lays out the requirement for and process to achieve this review.

Ethical standards in research are upheld by the MOD Research Ethics Committee (MODREC). This JSP details the instructions for the ethical conduct and treatment of human participants in MOD research (both clinical and non- clinical) and the process of achieving ethical approval for research.

Version	Date	Description
1.0	23 Mar 2006	First issue
1.1	25 Jun 2010	Revisions Minor
1.2	21 Jan 2011	Revisions Minor
2.0	xx May 2014	Second Issue

This document will be subject to version control by:

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Introduction

1. The Ministry of Defence (MOD) is fully committed to operating to the highest national^{1,2} and international³ ethical research standards. The MOD has therefore decided to operate the process of ethical scrutiny and approval via an independent committee to ensure that decisions on acceptability are independent of the MOD. The Senior Responsible Owner (SRO) for the MOD Ethics Procedures for Research Involving Human Participants is the Surgeon General (SG).

Purpose

2. This Joint Services Publication (JSP) replaces the First Issue of JSP 536. It sets out the instructions for the ethical conduct of MOD research (both clinical and non-clinical) to ensure that participants⁴ are looked after to the highest ethical standards.

3. Specifically, this JSP sets out the MOD's process for the assessment and approval of research protocols involving human participants. It provides instructions and guidance for all involved in sponsoring, funding, managing, reviewing and utilizing research funded by MOD and/or involving MOD staff and/or MOD entitled dependants that involves human participants and details the scrutiny required.

4. Research involving human participants undertaken, funded or sponsored by the MOD must meet acceptable ethical standards. These instructions are founded in nationally and internationally accepted principles (including those in the Declaration of Helsinki) and guidance. Further information can be found on the MOD Research Ethics Committee (MODREC)⁵ website.

5. The MOD Research Review Process involves a two stage review with the initial stage being a scientific appraisal by a Scientific Assessment Committee (SAC) followed by an ethical review by MODREC. The SAC and MODREC will function in accordance with their respective direction and Terms of Reference detailed at Annexes I and J.

6. It is acknowledged that decisions relating to ethics are complex and that it is not possible to provide generic guidance that will cover all possible issues or eventualities. In all cases, advice and guidance can be obtained from MODREC via the Secretariat, which will seek guidance as necessary.

Scope

7. The procedures detailed in these instructions are designed to protect the participant, the investigator and the MOD and must be followed for any research project in which the researchers:

- a. Conduct research on human participants, including (but not limited to) administering substances, taking blood or urine samples, removing biological tissue, radiological investigations, or obtaining responses to an imposed stress or experimental situation.

¹ <http://www.hra.nhs.uk/>

² <http://www.rcplondon.ac.uk/sites/default/files/documents/guidelines-practice-ethics-committees-medical-research.pdf>

³ <http://www.wma.net/en/30publications/10policies/b3/index.html>; <http://www.isdbweb.org/en/publications/view/declaration-of-helsinki-draft-text-for-public-consultation/campaigns>

⁴ The definition of a human participant is: any person who volunteers to participate in MOD sponsored research as covered by the individual protocol submitted to and approved by MODREC.

⁵ The MODREC is a body of independent non-MOD experts (drawn from a wide range of disciplines) and lay members to ensure that the decisions on the ethical acceptability of the research proposals are independent of MOD.

- b. Conduct research to collect data on an identifiable individual, either directly (such as by focus groups or interviews) or indirectly (such as by questionnaire or observation).
 - c. For the purpose of research, use non-public domain records and papers that contain information that is private or personal and could identify an individual (or group of people) or has the potential to cause harm.
8. For any other instances requiring experimentation, where there is the potential for harm (physical, psychological or other) to a human participant and where investigators are unsure whether a review by an ethics committee is required, advice must be sought from MODREC via the Secretariat.
9. Researchers who are undertaking epidemiological or retrospective studies employing data originally obtained for purposes other than research need to ensure that their requirements are within the bounds of the Caldicott Principles^{6,7,8} and the Data Protection Act. In cases of doubt, advice and guidance, in relation to the Caldicott principles should be sought from the single Service (sS) Caldicott Guardians or via the Secretary of the Defence Medical Services Caldicott Guardians' Committee⁹ or via the Secretariat.
10. Advice and guidance on the requirements of the Data Protection Act can be sought from a Data Protection Officer or via the Secretariat.
11. When MOD becomes involved in multi-centre protocols where ethics review has been completed and approval given by another NRES recognised Research Ethics Committee (REC), research involving MOD personnel must be reviewed by MODREC. The MOD aspect of the study cannot commence until there is formal MODREC approval.

Exceptions

12. These instructions do not apply to:
- a. Personnel who are only testing or evaluating vehicles, equipment or materials, **unless**,
 - (1) the study is to determine the effect of these on the human participant,

or

 - (2) the equipment being tested is safety critical life support equipment¹⁰.
 - b. Personnel assessing the operability of commercially manufactured equipment which has formally approved Safety Standards and the military are using it for the purpose for which it was designed and approved, unless the study is to determine the effect of the equipment on the human participant.
 - c. Studies of new features and techniques/procedures during training, or field exercises, or operations following Standard Operating Procedures (SOPs) in which it is documented that the risk or stress to personnel is not increased beyond that which is expected and reasonable through the routine employment of that participant.

⁶ http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4068403

⁷ <https://www.gov.uk/government/publications/the-information-governance-review>

⁸ <http://systems.hscic.gov.uk/infogov/caldicott>

⁹ SO1 Medical Policy, HQ Surgeon General; email: SG ACDS StratPol-Med Pol SO1.

¹⁰ Simple assessments such as comfort of wear, ability to move or conduct tasks in the equipment are exempt.

d. Personnel carrying out standard operating procedures or undergoing routine operational training techniques¹¹. However, research on human participants to determine information not previously known involving the centrifuge would require ethics approval.

13. Where there is doubt any queries as to whether or not MODREC approval is required are to be addressed to the MODREC Secretariat, which will seek guidance from the SAC Chairman or MODREC Chairman, as appropriate.

Health and Safety

14. All appropriate UK legislative and MOD specific health and safety standards and regulations apply as a bare minimum to all aspects of the research study including the direct working environment in which the study is to be conducted and to all investigators and participants.

15. Within MOD, the Defence Safety and Environment Authority (DSEA) is responsible for the regulation of safety and environmental protection of individuals conducting Defence activity by the implementation of MOD regulatory regimes in all safety domains.

16. MOD requirements in relation to health and safety are detailed in the MOD Health & Safety Handbook, JSP 375¹², which provides a common structure for the organisation and arrangements of the day to day management of health and safety within the MOD.

17. In relation to studies involving human participants there is a specific requirement on the Chief Investigator (CI) to ensure that all of the health and safety issues have been identified and addressed or mitigated and specific risk assessments and trial plans (including risk management plans) that have been completed. It is expected that, where appropriate, these are complete (reviewed and signed off) prior to the submission of the protocol for scientific and ethical review. It should be noted that MODREC may require evidence of the completion of this process.

18. In addition to the health and safety responsibilities of the Chief Investigator there are also specific responsibilities for the Supervisor and the Line Manager to ensure that all of the requisite health and safety arrangements have been considered prior to the submission of a protocol for scientific and ethics review.

19. Safety Cases will not be subject to routine review by either the SAC or MODREC but must be cited as references if they are subject to DSEA approval. Furthermore, any concerns raised by the SAC and/or MODREC will be reported to the MOD Human Research Governance Board and the SRO for appropriate action prior to ethics approval.

Data Protection

20. All personal data collected from MoD human research under a MODREC approved protocol is subject to the requirements of the Data Protection Act¹³. This any information collected and/or collated in accordance with the provisions of the protocol. The protocol per se may not be subject to these requirements.

21. Any personal information collected should be stored appropriately and only utilised for the business purpose stated in the approved protocol.

¹¹ Military pilots undertaking centrifuge training.

¹² <https://www.gov.uk/government/publications/jsp-375-health-and-safety-handbook-safety-forms>

¹³ <http://www.legislation.gov.uk/ukpga/1998/29>

MOD Research Definitions

22. MOD does not undertake research involving human participants unless it is for the benefit of MOD or other Government Departments. In deciding whether a study requires ethics review a decision needs to be made as to whether it is a research project, audit or service evaluation. If it is a research study the following should be considered:

- a. The primary aim of research is to derive new knowledge.
- b. The aim of audit and service evaluation projects is to measure performance against a known standard or to measure the standard achieved.

23. Annex B gives guidance on the differences between research, clinical audit and service evaluation. Further information can be found in the National Research Ethics Service (NRES) section of the Health Research Authority (HRA) website¹⁴.

Ethical Standards for Research: General Principles

24. The following standards must be followed rigorously when there is human participation in a research project:

- a. The research project should be of potential benefit to the MOD or other Government Departments¹⁵.
- b. A risk benefit analysis must be undertaken and should demonstrate that the potential risk(s) associated with the design of the research has/have been assessed and any residual risks are deemed to be acceptable and in proportion to the expected benefit. This should be made available with the application for review if required.
- c. The research project shall be conducted to avoid all unnecessary physical and mental discomfort, suffering or injury and to avoid the misuse of the participant's time.
- d. Only the minimum number of individuals required to achieve statistically valid results should be recruited to participate in the study.
- e. The information required from the research project must not be already known, nor be determinable from studies other than those involving human participants.
- f. Adequate resources must be in place to utilise the outcome of the study appropriately.
- g. Wherever possible the participants of the study should normally be from a cohort that will benefit from the results of the study.
- h. Proper preparations must be made, and adequate facilities provided, to protect the human participant(s) against, and deal with, all foreseeable possibilities of distress, discomfort, injury, disability or death.
- i. Only persons having the requisite competencies¹⁶ should conduct the research project. All persons who participate in conducting the study must apply the highest degrees of skill and care during all stages of the study.

¹⁴ <http://www.hra.nhs.uk/>

¹⁵ Where the research study is not directly beneficial to the MOD but to the wider Government, the liability may rest with an Other Government Department (OGD).

¹⁶ Guidance on the expected competencies can be sought from the Chairman of the SAC and/or the MODREC Secretariat.

- j. All reasonable steps must be taken to ensure that the participants have no physical or mental conditions or previous exposures which may make participation in the research more hazardous for them than for other participants, unless such a condition is a prerequisite for the particular study.
- k. The Chief Investigator (CI), each member of the Investigative Team and the Independent Medical Officer (IMO) will be prepared and empowered to terminate any participant's involvement at any stage if they believe that continuation is likely to result in unnecessary distress, injury, disability or death.
- l. The importance of free and fully informed consent is paramount at every stage of research. Informed consent will be sought from all potential participants. Potential participants who possess capacity to give informed consent must be informed of the purpose of the study in writing in a manner that can be easily understood and where appropriate supported through meaningful discussion. This must include any risks associated with their participation and the fact that they are free to withdraw from the study at any time without consequence and without having to give a reason or explanation. There are particular difficulties caused by the involvement of subordinates as research subjects and also difficulties caused by conducting research on the CI's own patients and immediate staff – which must be addressed in the protocol, to demonstrate that these issues have been recognised and mitigated.
- m. Potential participants who lack capacity to give informed consent cannot be included in research unless the research is connected with the specific condition impairing the participant and research of equal effectiveness and relevance cannot be carried out in participants with capacity to give informed consent. Clinical trials on participants who lack capacity must conform to the Medicines for Human Use (Clinical Trials) Regulations 2004. Other intrusive research on participants who lack capacity must conform either to the Mental Capacity Act (2005) or to the Adults with Incapacity (Scotland) Act 2000, depending on where the research takes place. If practicable, the consent (for clinical trials) or advice (for all other intrusive research) of the patient's next of kin will be required before the patient is included in the research. If this is not practicable, for example if the research involves emergency treatment, then consent/advice must be sought from a medical professional who is not connected to the research and who is not the subordinate to anyone connected to the research. The CI must provide information for legal representative (clinical trials) or consultee (other intrusive research) in writing in a manner that can be easily understood and, where appropriate, supported through meaningful discussion. The CI must record in writing that they have been consulted/have consented. If participants' inability to make an informed decision is temporary, informed consent must be sought for their continuing participation in the study when capacity is regained. Patients who subsequently withdraw consent will no longer be part of the study. If participants withdraw from the study, consent will be sought to use data already collected. If this is also withdrawn then these data must be excluded from the study and the data destroyed.
- n. Participants aged 16-17 years must only be requested to take part in research studies that are being targeted for the benefit of that group or where there is a specific military justification for including this group¹⁷. Whereas in law those between 16 and 18 can be presumed to be able to consent to treatment and research, it is regarded as good practice to obtain consent from a parent or carer with parental responsibility in addition to obtaining assent/consent from the young person¹⁸ though this is not always practicable. The provision of an independent

¹⁷ MOD DHALI/B Initiative – Directorate of Operational Capability, House of Commons Defence Select Committee, Adult Learning Inspectorate and Nicholas Blake QC; <http://www.official-documents.gov.uk/document/hc0506/hc07/0795/0795.pdf>

¹⁸ <http://www.wma.net/en/30publications/10policies/b3/17c.pdf>; Declaration of Helsinki (1964) 59th WMA General Assembly,

advisor¹⁹ to discuss the study and the benefits and potential disadvantages of participation in a neutral venue is considered best practice with this group.

o. A sufficient period of time must be allowed for the participants to review the information before deciding to participate. This is usually a minimum of 24 hours, except for those 16 and 17 years of age where a period sufficient to allow them to discuss participation with parents/carers or an independent advisor should be given. If research is to be justified on military personnel who are under 18 years of age then there must be a specific reason for including this group.

p. Principle 3 of the UN (1982) Principles of Medical Ethics states that, "It is a contravention of medical ethics for health personnel to be involved in any professional relationship with prisoners or detainees, the purpose of which is not solely to evaluate, protect or improve their physical and mental health"²⁰.

q. Captured Personnel (CPERS)²¹ are not to be used as participants in research under any circumstances, except in the case of social surveys which are constructed so as to involve minimal risk, stress or intrusion, and are intended to improve their own conditions. These studies must be submitted and considered for ethics approval.

r. Individuals who volunteer to participate in research studies can be recompensed for the inconvenience of their taking part but the value or nature of the recompense should not serve as an inducement and/or encouragement to participate. Further guidance can be found at Annex E and via the MODREC Secretariat.

Individual Responsibilities

25. Research that involves human participants results in numerous responsibilities for all of those involved with developing, designing and conducting the study. These individuals include the Chief Investigator (CI), the MOD Line Manager/MOD Sponsor, the Academic Supervisor and where required the Independent Medical Officer (IMO). Not all individuals will be relevant for all individual studies.

a. Chief Investigator (CI)

The CI should ensure that:

- (1) The study is of potential benefit to the MOD;
- (2) The study is designed to provide the maximum benefit with the least number of participants;
- (3) The study will have adequate power to achieve the intended aim of the project;
- (4) The study has been reviewed by an appropriate subject matter expert;
- (5) The study has been reviewed and accepted by their MOD Line Manager and/or Supervisor, if appropriate.

Seoul, October 2008.

(http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1_Guideline.pdf) and The Children's Act 2004 (<http://www.legislation.gov.uk/ukpga/2004/31/contents>)

¹⁹ The independent advisor should be a medical or scientifically qualified person who understands the study but is not part of the investigative team.

²⁰ www.un.org/documents/ga/res/37/a37r194.htm

²¹ <https://www.gov.uk/government/publications/jdp-1-10-second-edition-captured-persons-cpers>

b. MOD Line Manager/MOD Sponsor

The MOD Line Manager/Sponsor should ensure that:

- (1) The study is of potential benefit to the MOD;
- (2) The study is appropriately financed and resourced;
- (3) A detailed risk assessment process has been conducted and any associated risks identified and reviewed;
- (4) Any health and safety concerns have been identified and addressed;
- (5) The study has been reviewed by an appropriate subject matter expert;
- (6) The study supervisor accepts that the study is appropriately designed.

c. Academic Supervisor

The Academic Supervisor should ensure that:

- (1) The study is worthwhile;
- (2) The researcher has the appropriate competencies to undertake the study;
- (3) The study is of potential benefit to the MOD;
- (4) The study is designed to address the questions/ hypothesis posed;
- (5) The study will utilize the minimum number of participants to produce statistically valid results;
- (6) The study will produce results that can be reproduced;
- (7) A detailed health and safety review has been completed and that any health and safety issues identified have been appropriately addressed.

d. Independent Medical Officer (IMO)

The Independent Medical Officer (IMO) should:

- (1) Be suitably qualified and experienced for the study in question;
- (2) Be independent of the Project Officer and the experimental team;
- (3) Recognize that their primary purpose is to safeguard the health, safety and well-being of the participants;
- (4) Confirm by medical examination and/or screening, as detailed in the protocol, that all participants are fit to participate in the research;
- (5) Be accessible to the participants during the study in accordance with the description in the protocol;
- (6) Modify or terminate a participant's involvement in the study, if appropriate;

(7) Make clinical records of adverse events, interventions, withdrawals and other medical matters, and ensure that these are retained with the records of any medical examinations in accordance with routine Data Protection requirements.

e. Volunteer Champion

The Volunteer Champion should:

- (1) Be suitably qualified and experienced for the study in question;
- (2) Be independent of the Project Officer and the experimental team;
- (3) Recognize that their primary purpose is to safeguard the health, safety and well-being of the participants;
- (4) Confirm that a medical examination and/or screening, as detailed in the protocol, has been conducted and that all participants are fit to participate in the research²²;
- (5) Be accessible to the participants during the study in accordance with the description in the protocol;
- (6) Modify or terminate a participant's involvement in the study, if appropriate.

Research Involving Medicines or Medical Devices

26. Research involving medicines is regulated under the Medicines for Human Use (Clinical Trials) Regulations (2004)²³. All interventional trials of medicinal products, including new therapeutic approaches using previously tested medicinal products on people, must be approved by the Medicines and Healthcare products Regulatory Agency (MHRA)²⁴ and by MODREC. There are statutory instructions for Good Clinical Practice in such trials. MHRA also regulates research involving both implantable and other medical devices. MODREC and MHRA approvals processes are interdependent and clinical trials cannot commence until approval has been obtained from both authorities.

International Research Collaboration

27. Through its formal international agreements and Memoranda of Understanding (MOU) with other nations, MOD conducts and participates in collaborative research programmes which, when they involve human participants, must undergo appropriate ethics scrutiny. Where UK MOD personnel/entitled dependants are recruited to participate in an overseas trial lead by a partner nation, that nation's research protocol must be sent, along with the written review of its own Research Ethics Committee (or equivalent), to the MODREC Secretariat for MODREC's consideration prior to any recruitment taking place. If MODREC does not approve the protocol, then UK MOD personnel/entitled dependents must not participate in the trial.

Ethics Review Process

28. Ethical issues must be considered at all stages during the preparation of experimental research proposals. The decision as to whether a research proposal requires scrutiny and approval by MODREC starts initially with the CI, their MOD Line Manager/MOD Sponsor or

²² If medically qualified and appropriately registered the Volunteer Champion may have access to medical information if necessary in line with Consent and Caldicott principles.

²³ www.legislation.gov.uk/uksi/2004/1031/contents/made

²⁴ Details regarding the Medicines and Healthcare Regulatory Agency can be found at www.mhra.gov.uk

Academic Supervisor, whose responsibilities are outlined above. All research proposals require oversight and assessment as part of the normal management process, for budgeting and health and safety requirements. All research proposals must be reviewed by the CI's MOD Line Manager²⁵, involving appropriate Subject Matter Experts (SMEs) as required prior to the submission of a formal protocol. Advice on submission requirements can be sought at any stage via the MODREC Secretariat prior to a formal submission.

29. All submissions for formal ethics review must be made through the MODREC Secretariat to ensure that due process is followed. The MODREC Secretariat will quality check the submitted protocol to ensure that all of the required information has been provided including a letter to confirm that the submitted protocol has been approved by the CI's MOD Line Manager/MOD Sponsor or Academic Supervisor. The MODREC Secretariat will then formally register the protocol with a MODREC reference number and date prior to forwarding to the SAC for scientific review.

30. All submitted protocols will be sent in the first instance by the Secretariat to the relevant SAC, the Terms of Reference for which can be found at Annex I, to be assessed for technical and scientific rigour, i.e. to ensure that the methods proposed in the application are well-designed and sufficiently robust to provide the information required.

Scientific Assessment Committee (SAC) Review

31. The SAC will review the protocol to ensure that the purpose, proposed methods and analysis of the data are scientifically robust. The SAC will also ensure that the study will not present an unacceptable risk to either the participants or the researchers. During this process, the SAC will actively engage with the CI to discuss any revisions required and the CI will be invited, and is expected to participate in, any formal review meetings, if necessary by teleconference.

32. The SAC will provide an initial decision on the protocol within 20 working days²⁶ of it being presented to the Committee which will be reported to the next MODREC meeting.

The possible SAC decisions are:

- a. The protocol is approved as presented (Approved);
- b. The protocol is approved subject to minor revision (Provisional Approval);
- c. The protocol requires major revision and a second SAC review by the same SAC (Second SAC Review);
- d. The protocol is rejected (Rejected).

33. Protocols referred back to the CI for revision will be monitored by the MODREC Secretariat which will contact the CI to hasten a response after 30 working days. After three hasteners the protocol will be registered as discontinued, and the submission of a revised protocol after this time period will be registered as a new protocol.

34. On receipt of the SAC's decision, the CI can contact the MODREC Secretariat to formally withdraw a protocol.

35. The MODREC Secretariat will only forward a protocol to MODREC for ethics review which has full SAC approval.

²⁵ The MOD Line Manager may be required to account for the progress of the MODREC protocol by the MOD Human Research Governance Board and/or the SRO.

²⁶ May be extended slightly to allow for Leave / Holiday periods.

MODREC Review

36. MODREC meets ten times during the year, although this can be increased if required, and CIs will be required to attend the review of their protocols to address any queries and/or concerns raised by MODREC.
37. The possible MODREC decisions are:
- a. The protocol is approved as presented (Approved);
 - b. The protocol is approved subject to minor revision and may be approved by the MODREC Chair once revisions are complete (Provisional Approval);
 - c. The protocol requires a major revision and a second MODREC review (Second MODREC Review);
 - d. The protocol requires major revision and a second SAC review prior to a second MODREC review (Second SAC Review);
 - e. The protocol is rejected (Rejected).
38. MODREC will provide a formal decision on the protocol as soon as practicable and provide formal feedback within 20 working days if required of it being considered at the meeting.
39. MODREC reserves the right to refer a protocol back to the SAC in light of its risk/benefit analysis.

MODREC Ethics Approval Process

40. The researchers are not permitted to commence their research until a research protocol has been approved by MODREC as ethically acceptable. The CI will be required to be in possession of formal written notification of approval prior to commencing the research including recruiting volunteers.

Approval Time Limit

41. The approval of a research project by MODREC is valid for a designated time period which is normally a maximum of three years. Any required variation to the normal time limit of approval by MODREC can be requested at the time of approval. If the research is to continue after MODREC's approval would expire, the protocol must be reviewed, updated, if required, and resubmitted to MODREC to ensure that it remains compliant with current legislation and guidance, prior to the formal expiry date. If research has not commenced under a specific protocol before the original MODREC approval has expired, then the protocol must be resubmitted prior to any research commencing. If the research study is a long term study then MODREC will require updates on an annual basis to ensure that the currently accepted best ethics standards are being employed. Updates and revisions can be submitted either as requested amendments or at the triennial review.

Amendments

42. Amendments are formal alterations to the approved MODREC protocol and are only expected to occur once the research has commenced and/or as a result of improved scientific understanding or unforeseen issues in the conduct of the study. Any changes made to a MODREC protocol must be approved by MODREC as a formal amendment.

43. The CI is required to notify MODREC, in advance, of any proposed changes to the MODREC approved research protocol. Requests for amendments are to be submitted to the MODREC Secretariat on the Amendment Request Form at Annex G together with the requested amendments marked as tracked changes on the amended protocol.

44. The amendment request will be considered at the next scheduled meeting of MODREC, or out of committee, as appropriate. A formal response should be given to the applicant within 30 working days from receipt of the amendment request. However, if the amendment is far-reaching, e.g. involving a change in the primary purpose, a significant change of methods or new types of investigation or intervention with research participants, MODREC can request that a complete protocol is submitted as a new application requiring re-examination by SAC and ethics review by MODREC as a new protocol.

45. No deviation from, or change to, the research protocol shall be initiated by the CI without the prior written approval of MODREC, unless this is necessary to eliminate immediate hazards to research participants ('urgent safety measures') or when the change involves only logistical or administrative aspects of the research. If any changes are made to a protocol due to unexpected safety concerns, the research should be halted as soon as safely possible and not restarted until MODREC has been informed and the required amendments formally approved. If there is any doubt as to whether MODREC approval is required, advice must be sought from MODREC via the Secretariat.

46. In the event of the requirement to take urgent safety measures, the MODREC Chairman and MODREC Secretariat must be informed as soon as practicably possible. The initial notification should be followed by formal written notification no later than three working days from the date that the urgent safety measures are taken.

47. The CI is responsible for ensuring that arrangements are in place to review significant developments as the research proceeds and to instigate any modifications/amendments to the design of the research protocol. These modifications must be submitted to MODREC as formal requests for amendments and approval obtained before implementation (except when there are immediate hazards to research participants).

Research Project Reporting

48. Following approval of the research study, MODREC is to be provided with regular updates on progress from the research team. It is the responsibility of the CI to ensure that progress reports are timely and accurate. The nature and periodicity of updates, which include Notification of Commencement of Research, Annual Reports and a Completion Report (see paragraphs 49-53 below), will be confirmed by the MODREC Secretariat. Templates for these reports can be found at Annex F. If these reports give rise to concerns about the progress of the research or the way in which it is being conducted, MODREC can withdraw its approval for the research.

49. **Commencement of Research Report.** Notification is required at the commencement of research under a specific protocol to ensure that the appropriate MODREC governance and oversight requirements are evoked. If the MODREC Secretariat has not been notified regarding the commencement of research within six months of formal MODREC approval, then the CI will be required to provide a note of explanation.

50. **Annual Reports.** The first Annual Report is due 12 months after receipt of MODREC approval. If this has not been received by the MODREC Secretariat within 90 days of its due date, the MODREC Chairman will be informed of this by the MODREC Secretariat and the CI will be required to provide a note of explanation in writing and/or in person.

51. **Completion Report.** A full report is required on the completion of individual research studies to enable MODREC to determine whether or not the submitted protocol achieved the desired outcome, together with a report and explanation of unexpected or adverse events and a note of any plans for publication of the results. This is to be submitted to the MODREC Secretariat no later than 90 days after completion of the study. If this has not been received by the MODREC Secretariat within 90 days, the MODREC Chairman will be informed and the CI will be required to provide an explanation in writing and/or in person.

52. **Termination Report.** In the event that a study is not undertaken or is terminated prior to completion, the CI is to submit a report to MODREC detailing the reason(s) that the study has not proceeded as expected, or has been terminated. The format to be used is at Annex F. The CI is required to notify the MODREC Secretariat of the decision to terminate the study as soon as possible after the decision has been made and to submit a formal termination report to the MODREC Secretariat no later than 30 working days after the decision not to proceed/terminate has been made. If the report has not been submitted to the MODREC Secretariat within 30 days, the MODREC Chairman will be informed and the CI will be required to provide an explanation.

53. The existence of all reports and/or the failure to submit a report will notified to the MOD Human Research Governance Board who will require a written explanation from the Line Manager.

Appeals Process

54. An applicant who has had their protocol rejected by either SAC or MODREC may appeal against the decision.

55. The MODREC Secretariat will staff the Appeal request to the MOD Human Research Appeal Board as the sole Appeals Authority. The Appeals Authority may call upon the advice of experts not associated with the research protocol and will provide a decision on whether the appeal should proceed within 30 working days of receiving it and a final decision as soon as is practicable.

SAC Appeal

56. A notice of intention to appeal, including the grounds for appeal, must be provided to the MODREC Secretariat within 30 working days of receipt of the SAC decision.

57. If the Appeals Authority allows the appeal, the protocol will be submitted to a second SAC as directed by the Appeals Authority.

58. The second review will be in accordance with the standard procedures for the review of any new application. The second SAC may consider the matters raised during the initial review but is not bound by them. It should consider carefully any representations made by the applicant. There can be no appeal against the decision of the second review.

59. If the second SAC review gives a favourable opinion then the MODREC Secretariat will be notified and the protocol will be submitted to MODREC for ethics review in accordance with normal procedures.

MODREC Appeal

60. A notice of intention to appeal, including the grounds for appeal, must be provided to the MODREC Secretariat within 60 working days of formal receipt of the decision for appeal against a MODREC decision.

61. If the Appeals Authority allows the appeal the Appeal Board will request the assistance of NRES²⁷ to have the protocol reviewed by a second NRES-approved REC as appropriate.

62. The second review will be in accordance with the standard procedures for the review of any new application. The second REC may consider the matters raised during the initial review but is not bound by them. It should consider carefully any representations made by the applicant. There can be no appeal against the decision of the second review.

63. If the second REC gives a favourable opinion then this NRES recognised committee rather than MODREC will assume the responsibility for the review and approval of any requested amendments although the responsibility for monitoring the research will remain with MOD; MOD no-fault compensation will still apply. However, the MODREC Secretariat will require copies of all correspondence between the CI and the second REC to ensure that MOD oversight of progress, via the MOD Human Research Governance Board, is maintained. Additionally, the normal MOD reporting procedures regarding annual reports, etc., will remain extant.

Governance

64. The MOD Ethics Review Process is owned and reviewed by the MOD Human Research Governance Board. This Board, which is chaired by the Surgeon General, has responsibility for the operation of ethics review policy and the maintenance of sound reporting standards to audit across the MOD, including an annual review of the performance of SACs, the MOD Secretariat and MODREC.

Compensation

65. MOD operates a no-fault compensation scheme, which applies to all appropriately recruited volunteers participating in all MODREC approved research activities covered by this JSP. More details of this scheme can be found at Annex H. Additionally, volunteers are also eligible to apply for a Service pension provision or for Civilian compensation, as appropriate. Volunteers recruited through the NHS will be eligible for compensation through the routine NHS Trust arrangements.

Document Retention

66. The purpose of the retention of the documentation related to the MODREC approved protocol is to ensure that MOD has the ability to provide the relevant data at a later stage to support the rights of the volunteers and comply with the UK Government record keeping requirements.

67. The MOD is fully compliant with Cabinet Office data handling requirements including the Data Protection Act and all CIs are expected to ensure that their researchers are compliant with these provisions.

68. On completion of research conducted under a specific MODREC protocol, the following information as hard copy is to be returned to the MODREC Secretariat for retention in accordance with extant UK legislation and MOD policy:

- a. Individual signed Consent Forms;
- b. Clinical data if not held under paragraph 69, below;

²⁷ The National Research Ethics Service (NRES) is the UK authority for recognition of NHS ethics committees which recognises MODREC as operating to the UK standards.

- c. Details of any adverse events and their management;
- d. Any completed Adverse Event Forms and/or Accident Report Forms (MOD Form 510 or equivalent);
- e. Any accident and incident investigations, including Service Inquiries/Boards of Inquiry and local investigations that relate to the study.

69. If the individual study teams wish to retain any of the data listed above then individual arrangements are to be made with the MODREC Secretariat to retain this information at a nominated site. If specific arrangements are made, then it is the responsibility of the CI to ensure that if these data are no longer required to be retained at the nominated site, they should either be forwarded to the MODREC Secretariat or the MODREC Secretariat is informed of where they are to be retained.

70. The documentation retained by the MODREC Secretariat in relation to each protocol will include:

- a. The MODREC approved protocol;
- b. All MODREC approved amendments and revised versions of the approved protocol;
- c. All MODREC reports inclusive of Annual Reports and Completion Reports;
- d. All signed Consent Forms;
- e. All Adverse Event Reports;
- f. Any recorded medical information;
- g. All Accident Report Forms;
- h. Any accident or incident investigations that relate to the study;
- i. Letter of approval from SAC;
- j. Letter of approval from MODREC.

71. The documentation will be retained in a secure archive holding accessible to the MODREC Secretariat. All requests by the research team to access their data will be assessed on the merits of the individual requests.

72. The normal retention period for all documentation will be 50 years, but this will be reviewed periodically on the basis of potential litigation liabilities.

Ministry of Defence Policy for Research Involving Human
Participants

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ANNEX A - MODREC SECRETARIAT CONTACT DETAILS

MODREC Secretariat
Dstl Governance
Bldg 005, G01
Dstl Porton Down
Salisbury
Wiltshire SP4 0JQ

Ethics Helpline: 01980 658849

Fax: 01980 613004

E-mail: ethics.sec@dstl.gov.uk

Website: www.science.mod.uk/engagement/modrec/modrec.aspx

ANNEX B - DEFINITIONS OF RESEARCH, CLINICAL AUDIT AND SERVICE EVALUATION²⁸

In summary, and as defined by the NHS National Research Ethics Service, the following table outlines key differences²⁹.

Research	Clinical audit	Service Evaluation
The attempt to derive new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted to produce information to inform delivery of best care.	Designed and conducted solely to define or judge current care.
Quantitative research – designed to test a hypothesis Qualitative research – identifies/explores themes following established methodology.	Designed to answer the question: “Does this service reach a predetermined standard?”	Designed to answer: “What standard does this service achieve?”
Addresses clearly defined questions, aims and objectives.	Measures against a standard.	Measures current service without reference to an external standard.
Quantitative research - may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.	Usually involves analysis of existing data but may include administration of interview or questionnaire.
Quantitative research - study design may involve allocating patients to intervention groups. Qualitative research uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.	No allocation to intervention groups: the health care professional and patient have chosen intervention before clinical audit.	No allocation to intervention: the health professional and patient have chosen intervention before service evaluation.
May involve randomization.	No randomization.	No randomisation.
Requires ethics approval (MODREC).	Does not require ethics approval.	Does not require ethics approval.

²⁸ <http://www.nres.nhs.uk/EasysiteWeb/getresource.axd?AssetID=355&type=full&servicetype= Attachment>

²⁹ The definitions in the table are guidelines for researchers but can not cover every eventuality exactly.

ANNEX C - DOES MY RESEARCH PROTOCOL NEED TO BE SUBMITTED TO MODREC?

Not all human research needs ethics review. For example, there would be no need for ethics approval of an anonymous questionnaire seeking opinion about canteen food. In the case of testing a new rifle, there would probably be no need for ethics approval unless the research involved studying the effect of the rifle on the individual, for example to assess the effect of the noise on hearing. On the other hand, assessment of a new protective suit in a hot environment would need ethics approval because of the risk of the participants becoming dangerously overheated. Research involving life support equipment whose failure could cause death also requires ethics approval.

In all cases the guidance given in JSP 536: *Policy for Research Involving Human Participants* must be followed. If you think that your protocol does not need ethics scrutiny it may be helpful to answer the following questions. If any of your answers fall into column A in the table below, it is likely that ethics approval of your protocol is required from MODREC. Further advice can be obtained from MODREC via the MODREC Secretariat.

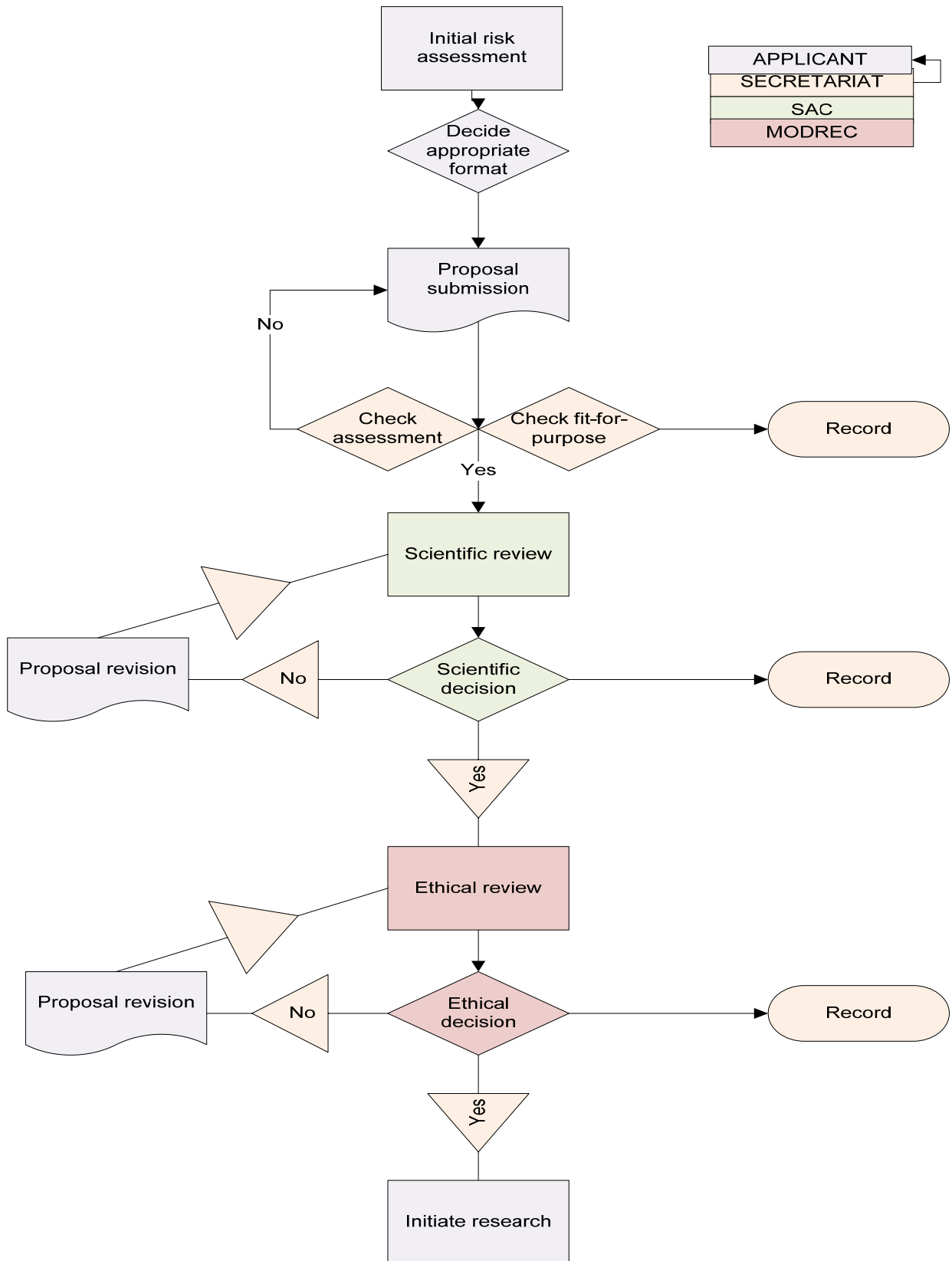
This checklist of questions is aimed at helping you decide if ethics scrutiny is needed. It cannot be totally comprehensive, so even if all your answers are in Column B, if you are in any doubt as to whether ethics approval is necessary please contact MODREC via the MODREC Secretariat for advice.

It is the responsibility of you and your MOD Line Manager to ensure that no research requiring ethics approval is started before MODREC approval has been obtained, this includes the commencement of the recruitment of volunteers.

Table C-1: Investigator's Decision Aid for Ethics Review Requirement.

	A	B
1. Are the risks to the research participants in any way greater than those to which they are exposed in the course of their normal peacetime duties?	YES	NO
2. Is there any psychological intrusion, for example personality questionnaires, psychometric tests, or recording of sensitive personal information?	YES	NO
3. Is there any physical intrusion, for example body fluid sampling or medical examination?	YES	NO
4. Will the psychological endurance of the research participants be tested beyond the limits inherent in their normal peacetime duties?	YES	NO
5. Will the physical endurance of the research participants be tested beyond the limits inherent in their normal peacetime duties?	YES	NO
6. Will any physiological monitoring be used, for example of body temperature, heart rate, ECG, breathing rates e.t.c, spirometry?	YES	NO
7. Will any drugs or other substances be administered?	YES	NO
8. If applicable, have all the unmanned tests and safety assessments been completed satisfactorily, to appropriate standards and throughout the ranges of environmental and physiological conditions in which human exposures are planned?	NO	YES
9. Will the research participants be paid extra for taking part in the study?	YES	NO
10. Will the research participants be drawn from a group which stands to benefit from the new equipment or technique?	NO	YES
11. If applicable, are Standard Operating Procedures available for the equipment or system?	NO	YES
12. Can the information collected be linked to individual participants?	YES	NO

ANNEX D - ETHICS REVIEW PROCESS FLOW CHART



ANNEX E - RECOMPENSE OF VOLUNTEERS

1. Individuals who volunteer to participate in research trials should do so of their own free will and should be free to withdraw from the study at any point without prejudice. The MOD reserves the right to recompense volunteers in recognition of any inconvenience or discomfort that might be caused by their participation. The recompense or reward provided should not be an undue inducement and/or enticement to encourage individuals to volunteer; therefore, it should not take the form of learning credits or prizes of any form.

2. For service personnel the payment is recognised as an Experimental Test Allowance (ETA) and is liable for both Income Tax and National Insurance Contributions which are automatically deducted from the volunteers' pay. In accordance with JSP 752³⁰, Tri Service Regulations for Allowances, Chapter 10 Section 3 ETAs are defined to include:

- a. Invasive procedures e.g. the use of monitoring instruments in the body;
- b. Provision of samples e.g. blood, urine or faeces;
- c. Exposure to stressful conditions e.g. experimental diving;
- d. Clothing and equipment e.g. accelerated-wearing trials and/or physiological tests for new equipment;
- e. Other tests approved by MODREC.

Rate of Payment

3. The value of the payment is advised annually by the Armed Forces Pay Review Body (AFPRB). The rate is detailed in JSP 752 Chapter 1 Section 6.

4. The details of the Experimental Diving Allowance are laid out in JSP 752 Chapter 10 Section 12.

³⁰ <http://defenceintranet.diif.r.mil.uk/Personnel/Military/Remuneration/Pages/JSP752.aspx>

ANNEX F – TEMPLATES FOR MODREC REPORTING

MODREC Annual Return

General Information

Protocol No:

Protocol Title:

Chief Investigator:

Organisation:

Date of Approval:

Specific Information

Date research started:

Date research completed (if in year):

No. of volunteers involved:

No. of under 18s involved:

Amendments required:

Date Amendments approved:

Adverse events:

Date of Adverse Event:

Progress of research:

Publications:

Additional Information:

MODREC Closure Report

General Information

Protocol No:

Protocol Title:

Chief Investigator:

Organisation:

Date of Approval:

Specific Information

Date research started:

Date research completed:

No. of volunteers involved:

No. of under 18s involved:

Amendments required:

Date Amendments approved:

Adverse events:

Results of research:

Publications:

Title of research report:

Location of research report:

Location of storage of study data:

Recommendations for further research:

Publications:

Additional Information:

MODREC Termination Report

General Information

Protocol No:

Protocol Title:

Chief Investigator:

Organisation:

Date of Approval:

Specific Information

Date research started:

Progress of research:

Date research terminated:

Reason for Termination of research:

No. of volunteers involved:

No. of under 18s involved:

Amendments required:

Date Amendments approved:

Adverse events:

Publications:

Additional Information:

Individual Adverse Event Report

General Information

Protocol No:

Protocol Title:

Chief Investigator:

Organisation:

Date of Approval:

Specific Information

Date research started:

No. of volunteers involved:

No. of under 18s involved:

Adverse Event

Date of Adverse event:

Nature of Adverse event:

Harm caused by adverse event:

Impact of adverse event:

Action taken following adverse event:

Impact on research:

Remedial action taken:

Action of Data Safety Monitoring Committee:

Follow-up action required:

Date of notification to MODREC:

ANNEX G – REQUEST TO AMEND A MODREC APPROVED PROTOCOL

Amendment Requests

General Information

Protocol No:

Protocol Title:

Chief Investigator:

Organisation:

Date of Approval:

Specific Information

Date research started:

No. of volunteers involved:

No. of under 18s involved:

Description of amendment required:

Rationale for Amendment:

Impact of Amendment not being approved:

Date Amendments approved/rejected (with reasons):

ANNEX H - COMPENSATION ARRANGEMENTS

Arrangements for the Payment of No-Fault Compensation to Participants in MODREC Approved Studies³¹

1. The MoD maintains an arrangement 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 Directorate of Judicial Engagement Policy, Common Law Claims & Policy (DJEP-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 they reasonably can to mitigate their 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/Study endorsed by MODREC. 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.

³¹ Section agreed with DJEP-CLCP Dep Hd 28/10/13.

Additional/Alternative Compensation Arrangements

Compensation for Service Personnel

9. Service personnel who took part in studies before 6 April 2005 and who consider that they may have suffered later harm or disability due to that study should contact MOD Service Personnel and Veterans Agency (SPVA) for consideration of a war disablement pension. The personnel who are entitled to make claims under the war disablement pension scheme are laid out on the SPVA website³², as are details of the claims process.

10. In the event of service personnel suffering injury or disability as a result of their participation in MODREC approved MOD research on or after 6 April 2005 then they may be entitled to compensation under the Armed Forces Compensations Scheme (AFCS). The details of the AFCS are promulgated on the MoD Intranet^{33,34} and are also available on the SPVA website³⁵. Claims should be made to SPVA following the instructions available on the MoD Intranet and SPVA website.

11. In the event of service personnel suffering injury or disability as a result of their participation in MODREC approved MOD research which is sufficiently serious for subsequent medical discharge from the services, their medical records will automatically be forwarded to the MOD Service Personnel and Veterans Agency (SPVA) for consideration of compensation and pension enhancements³⁶ in addition to whatever MOD pension/gratuity they are already entitled to by virtue of their service. Similarly, in the event of death as a result of their participation in MODREC endorsed MOD research, their dependants may be entitled to receive a supplemented pension.

12. However, if either a Service person or their dependants receive payment under the MOD 'no fault compensation' arrangements (or as the result of a common law compensation claim) for the same condition as that for which a pension is received, any pension entitlement may be reduced since compensation should not be paid twice for the same injury, disability or death.

Civilian Pensions

13. In the event of a civilian research participant suffering injury or disability as a result of their participation in MODREC endorsed MOD research sufficiently serious for them to subsequently suffer a loss in earnings capacity; they may be eligible for benefits under Section 11 of the Principal Civil Service Pension Scheme (PCSPS). Further details are available in the PCSPS booklet Injury at Work. Similarly, in the event of death as a result of participation in MODREC approved MOD research, their dependants may be entitled to receive benefits.

Common Law Compensation

14. If a research participant or their representative believes that injury, disability or death was caused by the negligence of the MOD or its staff, and do not wish to pursue the possibility of a 'no-fault' compensation payment, a common law claim for compensation should be submitted to Directorate of Judicial Engagement Policy, Common Law Claims & Policy (DJEP-CLCP) (at the address in Para 2 above) detailing the full facts

³² http://www.veterans-uk.info/pensions/wdp_new_index.html

³³ DIN <http://defenceintranet.diif.r.mil.uk/libraries/corporate/DINS%20Archive/2008/01102RestrictDINs.pdf>

³⁴ Armed Forces Compensation Scheme - Statement of Policy

http://defenceintranet.diif.r.mil.uk/libraries/library1/DINSJSPS/20110714.1/974_AFCS_Statement%20of%20policy4.pdf

³⁵ http://www.veterans-uk.info/pensions/afcs_new.html

³⁶ http://www.veterans-uk.info/pensions/med_discharge.html

of the claim and stating that common law compensation is being sought.

**Multinational/Multicentre Research and Research Involving Other Government
Departments**

15. When MODREC is involved in studies which involve Departments other than the MOD there may be a requirement for specific Compensation Arrangements on a study by study basis.

ANNEX I - SCIENTIFIC ASSESSMENT COMMITTEES (SACs)

1. This document lays out the principles by which the Scientific Assessment Committees (SACs) will operate. The SACs work for their relevant Principal Personnel Officer (PPO)³⁷ or Chief Executives (CEs)³⁸ (or equivalent); their formal Terms of Reference are set by those authorities.
2. It is the PPOs/CEs (or equivalents) that appoint the Chairs of the SACs, approve recommendations for the membership of the SACs and hold the SACs to account for the quality and timeliness of their outputs.

Purpose

3. The (SACs) are scientific review committees within the MOD Research Review Process. They are sS or organisation based committees responsible, through a nominated individual, to their relevant PPO, CE or equivalent.
4. The SACs are established to provide a timely and robust scientific and technical peer review function across MOD on the quality, design and suitability of individual studies involving human participants in research.
5. The SACs will assess the safety and well-being of the participants and the researchers involved in the study, ensuring that any proposed medical surveillance is appropriate.
6. It is not the SAC's role to commission research.

Operating Procedures

7. The key output of the SAC is to ensure protocols presented to the MODREC have been through an expert review of the scientific acceptability, quality and validity of the research.
8. The secondary role of the SAC is to provide independent assessment and advice to researchers on achieving best scientific practice.
9. The SACs will only review protocols formally submitted through the MODREC Secretariat. A protocol will not be reviewed by MODREC unless it has been formally approved by the SAC.
10. To ensure timeliness the SACs will provide a comprehensive response to the CI within 20 working days of the protocol being presented to the SAC. This will provide a clear decision on the acceptability of the protocol including guidance and advice on the requirement to revise a protocol and the requirements for further review by the SAC.
11. The Chairman of the SAC will notify the MODREC Secretariat of the views, recommendations and decisions of the SAC prior to MODREC ethics review of the protocol. The SAC will provide formally approved version(s) of the protocol(s) where appropriate.
12. If one of the members of the SAC is either the CI or a member of the Research Team of a protocol to be reviewed they should ensure that a formal declaration of interest is registered with the Chairman and that they absent themselves from any formal SAC

³⁷ The Royal Navy, Army and Royal Air Force SACs are work to their PPOs.

³⁸ The dstl SAC works to the dstl Chief Executive.

decisions.

Appeals Process

13. The appeals process against a SAC decision is laid down in Paras 56 – 59 of the main document.

Committee Structure

14. The PPOs/CEs (or equivalent) will direct the composition of the SACs. As guidance it is expected that the Chairman will be a senior Scientific or Medical officer and the committee must include a Senior Military Officer (OF 4 or higher) and a core of senior scientific or medical members of staff with specific expertise including medical, human factors research, psychology and statistics, for the review of individual protocols as necessary. To be quorate the SACs should consist of a minimum of four committee members in addition to the Chairman.

15. The SAC Chairman can appoint members to the Committee following agreement with the relevant PPO/CE. When appropriate, the Chairman has the right to co-opt additional expertise onto the committee as required and/or request advice through the Secretariat from specialist advisers on the DSAC/ISTA registers. It is desirable that the SAC draws from a wide scientific and clinical base to give credibility to their analysis, advice and decision.

Frequency of Reviews

16. The SACs are to review protocols as necessary to ensure that the scientific review has been completed in time for the next MODREC meeting. Additional meetings/reviews may be convened, as required, to consider issues arising from new tasking, particularly Urgent Operational Requirements (UORs) and/or Urgent Business Requirements (UBRs). UORs/UBRs require the formal endorsement of a 1*rank or above.

17. Where required for formally requested UORs/UBRs, an expedited review can be conducted within 3-5 working days by the Chairman and Officers of the SACs, together with any additional expertise deemed appropriate by the Chairman. Following this review, the decision will be notified to the next scheduled meeting of the SAC for ratification.

Reporting

18. The SACs should formally record its meetings and/or reviews and provide a report to the MODREC Secretariat detailing the decisions taken and advice provided within 10 working days of informing the protocol author of the decision.

19. The Chairman of the SAC will submit an Annual Report through the PPO / CE (or equivalent) to the Surgeon General summarizing the protocols reviewed and the decisions of the reviews. The report should also detail any issues experienced by the Committee that might have an effect on its ability to maintain its purpose and/or effectiveness and should detail common weak areas with a trend analysis.

20. The SAC report should cover the calendar year from 01 January to 31 December and be delivered to the MODREC Secretariat by 31 January the following year for formal review by the MOD Human Research Governance Board.

Resources

21. Whilst resourcing the SAC is a PPO/CE decision for smooth functioning it is

recommended that the SAC Chairman has the following resources:

- a. Vice-Chairman and Alternate Vice-Chairman, who shall be committee members and represent the Chairman at Committee meetings in his/her absence and to whom responsibility can formally be devolved;
- b. Access to the register of Independent Scientific and Technical Advice (ISTA) independents, and appropriate officials, to provide expert advice as required;
- c. Secretarial support for the Committee meetings to be determined by the Chairman under the auspices of their individual budget holder.

Governance

22. The SACs shall not act outside this defined remit, nor incur any expense not justified by its remit.
23. The MOD Human Research Appeal Board will serve as the sole Appeals Authority for the SACs.
24. The SRO and the MOD Human Research Governance Board will feedback on issues encountered and suggestions for improvements to the review process.
25. The MOD Human Research Governance Board will produce an overarching annual report detailing the activity and performance of the MOD Ethics Review Process.

ANNEX J - MINISTRY OF DEFENCE RESEARCH ETHICS COMMITTEE (MODREC)

1. MODREC is an independent committee to the MOD. The Committee advises Ministers and does not employ staff or incur expenditure on its own account.
2. MODREC is established to provide independent advice across MOD on the ethics of the involvement of human participants in research.
3. The Senior Responsible Owner (SRO) for the overarching Ethics Review Process within the MOD and the primary sponsor for MODREC is the Surgeon General, who will ensure the continuing independence of MODREC.
4. MODREC will act in accordance with the requirements of the National Research Ethics Service (NRES) and United Kingdom Ethics Committee Authority (UKECA) and wherever possible with the Government's Code of Practice (COP) for Scientific Advisory Committees (December 2001). This document provides details of how MODREC will operate.

Terms of Reference (TOR)

5. The role of MODREC is to provide:
 - a. Independent advice to the MOD on the ethical acceptability of the research protocols submitted;
 - b. Independent assessment and advice to researchers on achieving best ethics practice;
 - c. Independent assurance that the research studies reviewed meet both nationally and internationally accepted standards;
 - d. Assessment of the risk to benefit of the study and the acceptability of any residual remaining risk;
 - e. Advise SRO on ethics policy.
6. MODREC shall not act outside these terms of reference, nor incur any expense not justified by its remit.
7. It is not MODREC's role to provide scientific or technical advice to external suppliers of research or equipment, or to act as a provider or commissioner of research.
8. All advice under the auspices of MODREC may only be given by an independent member of MODREC. Officials are not permitted to represent the advice of MODREC.
9. MODREC reserves the right to remove ethics approval at any point.
10. MODREC may only be represented at fora or other meetings by an independent member.

Membership

11. In accordance with the recommendations made by the Royal College of Physicians and NRES, MODREC will have an independent Chairman, Vice-Chairman (Lay) and Alternate Vice-Chairman and an appropriate number of independent members to support its

activities. Independent members will be drawn mainly from the medical, academic and public sectors. There will be an appropriate balance of independent lay and specialist expertise on the Committee. The Vice-Chairman or Alternate Vice-Chairman will, in the Chairman's absence, chair MODREC.

12. Any MOD staff present will be in an advisory, non-voting, role only and be in the minority. This is to ensure the integrity of the impartiality of the Committee's discussions, thereby maintaining the independence of MODREC's advice.

13. All members will be selected in an open and transparent way in accordance with the Commissioner for Public Appointments (OCPA) code of practice for Ministerial Appointments to Public Bodies (of August 2005).

14. The MODREC Chairman and independent members will be appointed by the Surgeon General on behalf of the Secretary of State for Defence or their nominated representative for a period of 3 years. At the Secretary of State's discretion they may be reappointed for a further final term of 3 years.

15. A full list of Committee members will be placed on the MODREC website, with the agreement of the members.

16. The Chairman of MODREC is empowered to invite non-members to a meeting as expert advisors. It is desirable that MODREC draws from a wide scientific and clinical base to give credibility to its analysis and final decision.

17. In addition, the register of independents maintained by the Independent Scientific and Technical Advice (ISTA) branch within MOD will provide a pool of expertise, which can be drawn on by MODREC for specific advice.

18. MODREC will have the following resources :

- a. Secretariat support for the Committee meetings from MOD as sponsoring department;
- b. Secretariat, financial and other administrative support from the MOD in the production of reports and documentation.

19. MODREC will provide advice and guidance on ethics issues to the SRO as required.

20. Any requests for information, including requests under the Freedom of Information Act (2000) will be directed through the MODREC Secretariat.

MODREC Secretariat

21. The MODREC Secretariat will be provided by the MOD. It will ensure administrative and secretarial support to meetings of the Committee, and be responsible for the administrative processes associated with recruitment and payment of independents' fees and expenses. Other functions will be:

- a. To be proactive in ensuring feedback from the tasking Department to MODREC on the actions taken in response to MODREC advice;
- b. To provide MODREC with the information it requires from the MOD;
- c. To assist the Chairman in the production of the key annual planning and

reporting documents.

Frequency of Meetings

22. MODREC will meet as necessary to conduct its business. There will normally be ten meetings per year. Additional meetings may be convened, as required.

Reporting

23. The MODREC Secretariat should formally record MODREC meetings and/or reviews and provide a report detailing the decisions taken and advice provided within 10 working days of informing the protocol author of the decision. The minutes should be made available to the SRO and the SACs.

24. The MODREC Secretariat will produce a draft MODREC Annual Report to cover the period 01 January to 31 December, by 31 January the following year. The Report will detail the protocols reviewed, the decisions made, the adverse events encountered during the studies and the reasons for any of the studies being suspended. The report will be discussed by MODREC at its February Meeting and the Committee will raise any issues that have impaired the effectiveness of the MOD Ethics Review Process. Once the Annual report has been agreed by MODREC it will be submitted to the MOD Human Research Governance Board, by 31 March.

25. The public release of the Annual Report will be considered on a case by case basis by the MOD Human Research Governance Board and wherever possible an unclassified Annual Report will be placed on the MODREC website.

Working with Other RECs Internationally

26. Where organisations similar to MODREC exist overseas, an arrangement may be set up between MODREC and the overseas organisation, provided that an appropriate international instrument (such as a Memorandum of Understanding) exists.

Fees and Expenses

27. The MOD will provide and control the financial resource to support the fees and expenses for independent members on the Committee, together with resource for secretariat tasks.

28. Fees are set strictly on the basis of the appointment which an independent member is holding at the time.

29. Claims for fees and receipted expenses should be made within 3 calendar months of the earning or expense being incurred.

Governance

30. The MOD Human Research Governance Board will serve as the sole Appeals Authority for MODREC.

31. The MOD Human Research Governance Board will produce an overarching annual report detailing the activity and performance of the MOD Ethics Review Process.

ANNEX K – THE MOD HUMAN RESEARCH APPEAL BOARD

1. The Appeal Board will be the sole Appeals Authority for the MOD Ethics Review Process for the Scientific Assessment Committees (SACs) and MOD Research Ethics Committee (MODREC).
2. The process for appealing against SAC and MODREC decisions is laid out in Paras 54 - 63.
3. Appeals against the decisions of the SACs or the MODREC must be lodged with the MODREC Secretariat as laid out in Para 56 (SAC) and Para 60 (MODREC).
4. The Appeal Board will consist of:
 - a. Surgeon General (SRO) as Chair;
 - b. SG - Head of Medical Strategy and Policy;
 - c. SG - Medical Director;
 - d. The Chair may add additional MOD or external experts relevant to the research area or to the approval process.
5. The Chair of the appropriate SAC or the MODREC Chair shall be available to provide the Appeal Board with the reasoning for the decision being appealed against.
6. Where considered necessary by the Chair, the Chief Investigator may be asked to attend an Appeal Board meeting.
7. Any member of the Appeal Board who has a conflict of interest over the protocol or the appeal being considered must declare that to the Chair. The Chair will then decide if the member should take any further part in the appeal process.
8. Whilst the Appeal Board will normally conduct its business electronically any member may request that the Chair convene a formal meeting of the Board where they consider it impossible to resolve the appeal without such a meeting. It is the Chair's decision whether or not to accept this request.
9. Where there is an even split of responses the Chair shall have the casting vote.
10. The MODREC Secretariat shall collate all the responses to an appeal and produce a final response to the CI making the appeal, copied to the SAC or MODREC Chair involved within 10 working days of the Appeal Board final decision.
11. The Appeal Board's decisions are final and there is no further right of appeal.
12. The Appeal Board will produce an Annual Report covering appeals considered and the outcomes for the calendar year from 1 January to 31 December and to be delivered to the Senior Responsible Officer by 31 March the following year for formal review by the MOD Human Research Governance Board.

ANNEX L - MOD HUMAN RESEARCH GOVERNANCE BOARD

1. The Governance Board is not involved in the preparation of ethics advice or with discussion of the routine ethics advice provided by MODREC.
 2. The Governance Board supported by the Secretariat will provide the quality audit function of the MOD Ethics Review Process and review the effectiveness of the Process.
 3. The Governance Board will ensure that the overarching MOD Ethics Review Process is appropriately reviewed and all proposed revision and/or improvement tasks are costed in terms of manpower (both independent and official (where appropriate), secretariat support and expenditure on fees and T&S).
 4. The Governance Board will review the Annual Reports from both the SACs and MODREC then make any necessary recommendations.
 5. The Governance Board will ensure that members of MODREC are regularly informed about developments in the Government's policies and MOD programmes concerning human research.
 6. The Governance Board will assist MODREC by ensuring that members receive appropriate further training from NRES staff and others as appropriate.
 7. The Governance Board will comprise the following:
 - a. Surgeon General (Chairman);
 - b. Chairman, of MODREC, the 2 MODREC Vice Chairs and up to 2 other MODREC members;
 - c. SG - Head of Medical Strategy and Policy;
 - d. SG – Medical Director.
- SG SO1 Occupational Medicine will provide the secretariat function for the Governance Board.
8. Governance Board meetings will be followed by a wider plenary meeting with the following additional attendees:
 - a. The Principal Personnel Officers and Chief Executives responsible for the SACs:
 - b. The Chair of each SAC.
 9. There will be an annual meeting of the Governance Board, normally in April / May. Additional meetings may be convened, as required, to consider issues arising from new tasking.
 10. In addition SG - Head of Medical Strategy and Policy will chair a biannual meeting between the Chair of MODREC and the SAC Chairs.

ANNEX M - SENIOR RESPONSIBLE OWNER (SRO) FOR THE MOD POLICY FOR RESEARCH INVOLVING HUMAN PARTICIPANTS

1. The SRO is personally accountable to the Defence Board for overseeing the operation of the MOD Policy for Research with Human Participants.
2. The role and responsibilities of an SRO, as well as the relationship with Top Level Budget (TLB) Holders and Process Owners, are explained in the Department's Policy and Guidance for SROs. The SRO is expected to adhere to the guidance provided and clarification can be provided by the Defence Transformation Unit.
3. The SRO will provide particular attention to ensuring the proper governance, assurance and programme management arrangements are established and maintained throughout the life of the programme in line with best practice, including that published by the Cabinet Office (Efficiency and Reform Group)³⁹ and relevant MOD authorities.
4. The SRO is responsible for ensuring the appropriate reporting mechanism is in place to ensure the required oversight of the operation of the policy. This will include reports to the Defence Transformation Unit, the submission of business cases and reports to the Investment Approvals Committee.
5. The SRO will have attended the Defence Academy College of Management and Technology (DA-CMT) formal SRO training programme or have received the equivalent training.
6. The formally appointed SRO should notify the Defence Transformation Unit prior to any planned departure from the role to ensure that a suitable successor is appointed to manage the operation of the MOD's Policy for Research with Human Participants and the specific responsibility for the Independent MOD Research Ethics Committee.

³⁹ Formerly the Office of Government Commerce.