Ministry of Defence

JSP 536
Governance of Research Involving Human Participants

Part 1: Directive

Foreword

The MOD is fully committed to operating to the highest national and international ethical research standards[1]. The MOD therefore operates the process of ethical scrutiny and review via an independent committee to ensure that decisions on acceptability are independent of the MOD. The Senior Responsible Owner for the Governance of Research Involving Human Participants is the Director General (DG) of the Defence Medical Services. This JSP sets out the MOD's process for the assessment and review of research protocols involving human participants. It provides instructions and guidance for all involved in sponsoring, funding, managing, reviewing and utilising research funded by MOD and/or involving MOD staff and/or MOD entitled dependants that involves human participants and details the scrutiny required.

Director General, Defence Medical Services
Defence Authority for Healthcare and Medical

[1] Legislation and best practice guidelines are set out by Health Research Authority and other institutions including the Social Services Research Group, Economic and Social Research Council, the principles of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), Universities UK, and publications including the RESPECT Code of Practice, and the WMA Declaration of Helsinki (all accessed 5 Dec 19). Government best practice is set out in Ethical Assurance Guidance for Social Research in government, Government Functional Standard for Analysis & Research, Magenta Book: Central Government guidance on evaluation, The Aqua Book: guidance on producing quality analysis for government.

Preface

How to use this JSP

1. JSP 536 is intended as a publication which details the procedures required for the assessment, review and approval of research involving human participants. It is designed to be used by any person or organisation responsible for the conduct, sponsoring, funding, management, scrutiny and authorisation of all research on human participants funded by MOD and/or involving MOD personnel and/or MOD entitled dependents. This JSP contains the policy, direction and guidance on the processes to follow and the best practice to apply. This JSP will be reviewed at least annually.

2. The JSP is structured in two parts:

Part 1 - Directive, which provides the direction that must be followed in accordance with statute or policy mandated by Defence or on Defence by Central Government.

Part 2 - Guidance, which provides the guidance and best practice that will assist the user to comply with the Directive(s) detailed in Part 1.

Coherence with other Defence Authority Policy and Guidance

3. Where applicable, this document contains links to other relevant JSPs, some of which may be published by different Defence Authorities. Where particular dependencies exist, these other Defence Authorities have been consulted in the formulation of the policy and guidance detailed in this publication.

Related JSPs	Title
JSP200	Statistics
JSP 375	Management of Health and Safety in Defence
JSP 440	The Defence Manual of Security, Resilience and Business Continuity
JSP 441	Information, Knowledge, Digital and Data in Defence
JSP 462	Financial Management and Charging Policy Manual
JSP 525	Corporate Governance
JSP 539	Heat Illness and Cold Injury: Prevention and Management
JSP 752	Tri-Service Regulations for Expenses and Allowances
JSP 754	Tri-Service Regulations for Pay
JSP 822	Defence Direction and Guidance on Training and Education
JSP 831	Redress of Individual Grievances: Service Complaints
JSP 832	Guide to Service Inquiries
JSP 887	Diversity, Inclusion and Social Conduct
JSP 892	Risk Management
JSP 893	Policy on Safeguarding Vulnerable Groups

Further Advice and Feedback – Contacts

4. The owner of this JSP is the Head of Research and Clinical Innovation. For further information on any aspect of this guide, or questions not answered within the subsequent sections, or to provide feedback on the content, contact:

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MOD Research Ethics Committee	Visit MODREC website for details.	

Glossary of abbreviations

Glossary of abbreviations	
AFCS	Armed Forces Compensation Scheme
CE / CEO	Chief Executive / Officer
CLCP	Common Law Claims and Policy
CRO	Contract research organisation
CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Products
CV	Curriculum Vitae
DBS-Vets	Defence Business Services - Veterans
DEXA	Dual energy x-ray absorptiometry
DG DMS	Director General Defence Medical Services
DPA 18	Data Protection Act 2018
DSEC	Defence Scientific Expert Committee
DJEP	Directorate of Judicial Engagement Policy
GCP	Good clinical practice
HR	Human Resources
HRA	Health Research Authority
HFEA	Human Fertilisation and Embryology Authority
HTA	Human Tissue Authority
MHRA	Medicines and Healthcare Regulatory Authority
ICF	Informed Consent Form
IMO	Independent Medical Officer
ISTA	Independent Science and Technology Advice
MODREC	MOD Research Ethics Committee
NMEIT	No Material Ethics Issues Tool
PCSPS	Principal Civil Service Pension Scheme
PI	Principal Investigator
PIS	Participant Information Sheet
PPO	Principal Personnel Officer
PR	Proportionate review
R&D	Research and Development
REC	Research Ethics Committee
SAC	Scientific Assessment Committee
SOPs	Standard Operating Procedures
SPVA	Service Personnel and Veterans Agency

SRO	Senior Responsible Owner
SSAR	Suspected Serious Adverse Reaction
TLB	Top Level Budget
TORs	Terms of Reference
UKECA	United Kingdom Ethics Committee Authority
UOR / UBR	Urgent Operational / Business Requirement
VA	Volunteer Advocate

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1 Introduction and Background

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Context

1. The MOD is fully committed to operating to the highest national and international standards in human participant research.

2. This Joint Services Publication (JSP) replaces previous versions of JSP 536. It is modelled on the UK Health Departments' policy framework for health and social care research and Governance Arrangements for Research Ethics Committees. The policy describes MOD's commitment to an environment where:

a. Safer, more efficient or more effective treatments, care, equipment, operational procedures and other services are developed and tested through ethical and scientifically sound research.

b. Applying to do research is ideally simple, and getting a decision is quick, with predictable timelines.

c. Researchers find it straightforward to do high-quality, scientifically sound, ethical research.

d. Research projects get registered (where appropriate), the data and tissue they collect can be made available for future analysis, adequate consent and privacy safeguards are put in place, and research findings[2] are published and summarised as appropriate.

Purpose

3. This JSP sets out the principles and responsibilities of good practice in the management and conduct of MOD human participant research. The principles protect and promote the interests of participants by describing robust scientific and ethical conduct and proportionate, assurance-based management of human participant research. Chapter 3 'Responsibilities' defines who is responsible for ensuring principles are met.

4. Chapters 1 to 3 of this document set out the principles and responsibilities at a high level. They will be supported by operational arrangements and guidance in Part 2 of the JSP, working (where appropriate) in collaboration with the Health Research Authority (HRA) and other UK regulators to ensure a broadly consistent approach to co-ordinating and standardising regulatory practice.

5. Chapters 4 and 5 set out the specific governance arrangements for Scientific Assessment Committees (SACs) and the MOD Research Ethics Committee (MODREC) respectively.

[2] i.e. the findings that the research was designed to produce; for guidance on incidental and other health-related findings, see wellcome.ac.uk/sites/default/files/wtp056059.pdf (accessed 5 Dec 19).

Scope

6. This policy must be applied by anyone (including Service Personnel, MOD civil servants, UK civilians or foreign nationals) involved in any research project to be conducted in the UK, overseas or on operations, that meets all the following criteria:

a. The project is undertaken, funded or sponsored by the MOD, or involves MOD-employed staff and/or participants including cadets (and the work is relevant to their MOD role or activities).

b. The activity meets the definition of research as outlined at paras 8 to 11.

c. The research will involve human participants.

7. Research is within scope of this policy if any members of the research team or participants are funded wholly or in part by the MOD. This includes personnel conducting research as part of a post-graduate degree or course of study funded by MOD[3] or taking place during MOD-funded work time.

8. Research involving veterans or Service dependents / families is generally not included unless:

a. It is funded by the MOD or conducted by MOD-funded staff.

b. Comparisons are to be made to currently Serving personnel.

c. MOD funded services/sites/property are being analysed, assessed or used.

9. **Definition of research**. For the purposes of this policy, research is defined as the attempt to derive generalisable or transferable[4] new[5] knowledge to answer or refine relevant questions with scientifically sound methods[6].

10. Research **does** include:

a. All activities that are carried out in preparation for, or as a consequence of, the interventional part[7] of the research such as screening potential participants for eligibility, obtaining participants' consent and publishing results.

b. Non-interventional research (i.e. projects that do not involve any change in standard treatment, care or other services), projects that aim to generate hypotheses, methodological research and descriptive research.

c. Projects where the main purpose of the research is educational to the

[3] Refer to JSP 822 'Defence Direction and Guidance on Training and Education' Part 2 Chapter 6.2 'Postgraduate Education'.
[4] This definition involves an *attempt* at generalisability or transferability, i.e. the project deliberately uses methods intended to achieve quantitative or qualitative findings that can be applied to settings or contexts other than those in which they were tested. The *actual* generalisability or transferability of some research findings may only become apparent once the project has been completed.
[5] Including new knowledge about existing capabilities, procedures etc.
[6] Projects that are not designed well enough to meet this definition are not exempt from this policy framework
[7] This means the part of the research where a change in treatment, care or other services is made for the purpose of the research. It does not refer to other methodological 'interventions', e.g. issuing a postal survey.

researcher, either in obtaining an educational qualification or in otherwise acquiring research skills at post-graduate level[8].

d. Projects involving human cadavers. Though generally not considered by Research Ethics Committees and covered by the Human Tissue Act (2004), the sensitivities around such research carried out by Defence warrant MODREC review.

11. Research **does not** include:

a. Audits of practice i.e. the comparison of a current or previously conducted non-research process with a "gold-standard".

b. Service evaluation i.e. evaluating the effectiveness of a current or previously conducted non-research process. This includes evaluation of training.

c. Low risk service improvement (decision must be made by Research Sponsor).

12. This policy applies to all research involving human participants. Human participants include any persons of any age regardless of status (military, Civil Service, UK civilian or foreign national).

13. Human participants **do not** include:

a. Personnel that are testing or evaluating vehicles, equipment or materials, including assessment of the operability of commercially manufactured equipment that meets approved formal safety standards (and it is being used for the purpose for which it was designed and approved) unless:

(1) A key output of the study is to determine the effect of these on the human participant and human data will be collected (such as medical, behavioural, psychometric etc); or

(2) the equipment being evaluated is also being used for safety critical life support during the test (e.g. a diving regulator)[9].

b. Personnel involved in studies of new features of existing capability, or new techniques/procedures during training, field exercises, or operations providing they are following Standard Operating Procedures (SOPs) and the risk assessment has documented that the physical or psychological risk or stress to personnel is not increased beyond that which is expected and reasonable for the routine employment of that participant.

c. Personnel carrying out SOPs or undergoing routine operational training techniques.

14. Captured persons (CPERS) **must not** be used as participants in research under any circumstances, except in the case of social surveys which are constructed to involve minimal risk, stress or intrusion, and are intended to improve conditions for those CPERS.

[8] Not including taught Masters degrees

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

15. The inclusion criteria for research that is within scope of this policy and must be submitted for science and ethics review is summarised for research teams at Annex 1A in Part 2 'Guidance' of this JSP.

16. This document draws on relevant sources[10] but cannot exhaustively compile all the principles, requirements and standards that may be issued separately by individual bodies with an interest in research. In particular, it does not repeat requirements and expectations that apply generally, such as professional standards or legislation regarding age of legal capacity, equality, health and safety, data protection, Welsh language, whistleblowing etc. It remains the responsibility of those to whom relevant legal requirements and professional standards apply to ensure that they also meet those requirements and standards, in line with the guiding principles set out in this policy.

Implementation

17. This policy largely sets out what is (or should be) already happening. The intention is to remove unnecessary bureaucracy for researchers, both in what the policy expects of them directly and what it expects of others that then affects them. It is supported by guidance (Part 2 of this JSP), SOPs and operational platforms, including MODREC Website[11], that are developed separately.

[10] These sources include legislation and other publications about good research practice, such as the ADASS/SSRG resource pack for social care, ESRC Framework for Research Ethics, the principles of ICH GCP, the previous Research Governance Frameworks, RESPECT Code of Practice, UUK Concordat to support research integrity and WMA Declaration of Helsinki (all accessed 5 Dec 19).

[11] https://www.gov.uk/government/groups/ministry-of-defence-research-ethics-committees (accessed 5 Dec 19).

2 Principles

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Principles that apply to human participant research

1. The following statement of principles serves as a benchmark for good practice that the management and conduct of all human participant research is expected to meet.

Principle 1: Safety

The safety and well-being of the individual prevails over the interests of science and society.

Principle 2: Competence

All the people involved in managing and conducting a research project are qualified by education, training and experience, or otherwise competent under the supervision of a suitably qualified person, to perform their tasks.

Principle 3: Scientific and Ethical Conduct

Research projects are scientifically sound and guided by ethical principles in all their aspects.

Principle 4: Integrity, Quality and Transparency

Research is designed, reviewed, managed and undertaken in a way that ensures integrity, quality and transparency.

Principle 5: Protocol

The design and procedure of the research are clearly described and justified in a research proposal or protocol, where applicable conforming to a standard template and/or specified contents.

Principle 6: Legality

The researchers and sponsor familiarise themselves with relevant legislation and guidance in respect of managing and conducting the research.

Principle 7: Benefits and Risks

Before the research project is started, any anticipated benefit for the individual participant and other present and future recipients of the activity or device in question, are weighed against the foreseeable risks and inconveniences (once they have been mitigated) [1].

[1] A formal, structured risk assessment is only expected where identified as essential. The risk: benefit ratio will normally be sufficiently described and considered as part of review processes such as research ethics committee review.

Principle 8: Approval

A research project is started only if the research protocol / proposal (and any other relevant information) has received a favourable review of the scientific quality and the ethics. For certain research, additional relevant bodies may also need to approve the protocol. Within MOD, scientific quality is reviewed by a Scientific Assessment Committee (SAC) and ethics review is provided by the MOD Research Ethics Committee (MODREC).

Principle 9: Accessible Findings

The findings, whether positive or negative, are made accessible, with adequate consent and privacy safeguards, in a timely manner after the study has finished, in compliance with any applicable regulatory standards, i.e. legal requirements or expectations of regulators. The only exceptions are research for educational purposes, early phase trials and security sensitive research. In addition, where appropriate, information about the findings of the research is available to those who took part in it, in a suitable format and timely manner, unless otherwise justified.

Principle 10: Choice

Research participants[2] are afforded respect and autonomy, taking account of their capacity to understand. Where there is a difference between the research and the standard practice that they might otherwise experience, research participants are given information to understand the distinction and make a choice, unless MODREC agrees otherwise. Where participants' explicit consent is sought, it is voluntary and informed. Where consent is refused or withdrawn, this is done without reprisal.

Principle 11: Insurance and Indemnity

Adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project.

Principle 12: Respect for Privacy

All information collected for or as part of the research project is recorded, handled and stored appropriately and in such a way and for such time that it can be accurately reported, interpreted and verified, while the confidentiality of individual research participants remains appropriately protected. Data and tissue collections are managed in a transparent way that demonstrates commitment to their appropriate use for research and appropriate protection of privacy.

Principle 13: Compliance

Sanctions for non-compliance with these principles may include appropriate and proportionate administrative, contractual or legal measures by funders, employers, relevant professional and statutory regulators.

[2] Either directly, or indirectly through the involvement of data or tissue that could identify them.

2. In addition, the following principles apply to interventional research (where a change in treatment, care or other services is made for the purpose of research):

Principle 14: Justified Intervention

The intended deviation from normal treatment, care or other services is adequately supported by the available information (including evidence from previous research).

Principle 15: Ongoing Provision of Treatment

The research proposal or protocol and the participant information sheet explain the special arrangements, if any, after the research intervention period has ended (e.g. continuing or changing the treatment, care or other services that were introduced for the purposes of the research).

Principle 16: Integrity of the Care Record

All information about treatment, care or other services provided as part of the research project and their outcomes is recorded, handled and stored appropriately. This must be in such a way and for such time that it can be understood by others involved in the participant's care, and then accurately reported, interpreted or verified whilst maintaining the confidentiality of records.

Principle 17: Duty of Care

The duty of care owed by health and social care providers continues to apply when their patients and service users take part in research. A relevant health or social care professional[3] retains responsibility for the treatment, care or other services given to patients and service users as research participants, and for decisions about their treatment, care or other services. If an unmanageable conflict arises between research and patient interests the duty to the participant as a patient prevails.

[3] Who may or (particularly where the research team is not local to the research site) may not be a member of the research team.

3 Responsibilities

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Responsibilities of Individuals and Organisations

1. There must be clear designation of responsibility and accountability, with clear lines of communication, between all those involved in research. Communication pathways must be clear in terms of what, how, who, when and why, with documented[1] roles and responsibilities. Dialogue and collaboration have a central role within a research project. Clear, upfront discussion of issues and agreement of principles and procedures for each project are essential to its effective conduct and success, as well as mitigating some risks. All individuals and organisations with responsibilities under this policy should understand the value of research and recognise the importance of co-operation and shared endeavour as critical to its success. Those with experience of good practice in the management and conduct of research are encouraged to share their knowledge with novices.

Chief Investigators (CI)

2. The CI is the overall lead researcher for a research project and normally the lead author of the research protocol. In addition to their responsibilities in conducting aspects of the research if they are members of a research team, CI are responsible for the overall conduct of a research project including:

a. Satisfying themselves that the research proposal or protocol takes into account any relevant systematic reviews, other research evidence, and research in progress[2]; that it makes effective use of patient, service user and public involvement where appropriate; and that it is scientifically sound, safe[3], ethical, legal and feasible, and remains so for the duration of the research taking account of developments while the research is ongoing.

b. Satisfying themselves that the proposal has been submitted for review by, and obtained a favourable opinion from, the appropriate Scientific Assessment Committee (SAC), MODREC and any other relevant review or approval bodies (and any revisions to the proposal in light of those reviews have been made).

c. Satisfying themselves[4] that everyone involved in the conduct of the research is qualified by education, training and experience, or otherwise competent, to discharge their roles in the project.

d. Satisfying themselves that the information given to potential participants is in a suitable format and is clear and relevant to their participation in the research and, where consent is required, to their decision-making about taking part in the research[5].

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[1] Any documentation must be proportionate. Roles and responsibilities must be agreed and understood by all the relevant parties, but are not expected to be re-documented separately if their description for the purpose of review processes such as research ethics committee review is sufficient.
[2] Research studies may replicate previous research, but must acknowledge the reason for doing so.
[3] i.e. that the risk of harm has been minimised as much as possible and is not expected to outweigh the benefits.
[4] For multi-site projects, this may be delegated to the principal investigator (PI) at each research site.
[5] www.hra-decisiontools.org.uk/consent (accessed 5 Dec 19).

e. Adhering to the agreed arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after the research has finished[6].

f. Starting the research only once the Research Sponsor has confirmed that everything is ready for it to begin.

g. Adhering to the agreed procedures and arrangements for reporting (e.g. progress reports, safety reports) and for monitoring the research, including its conduct, the participants' safety and well-being and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments.

h. Adhering to the agreed arrangements for making information about the findings of the research available, including, where appropriate[7], to participants.

i. A duty to address and report research misconduct, any safety issues or unexpected events during the research, especially where this has the potential to affect compliance with prior SAC or ethics review.

j. Ensuring that results of projects are registered, disseminated and reported appropriately.

3. Students should not normally take the role of CI unless they are the sole PhD or masters student undertaking the research[8].

a. Relevant supervisors (or course leaders) should be encouraged to develop and lead research projects that individual students at Masters level and below can contribute to at different stages.

b. A research culture must be fostered amongst relevant undergraduate students by encouraging an awareness of health, psychology and social care research, research ethics and public involvement, and enabling them to develop skills in research methods.

c. Students from courses that are not primarily related to health, psychology and social care, such as business studies or IT, who wish to undertake research involving patients or service users, their data or tissue, or the public in a health or social care setting, must have a co-supervisor with relevant experience that will help them understand the context and the associated research process.

d. The contribution of students to the development, conduct and reporting of the research must be appropriately acknowledged like that of other contributors, e.g. in accordance with journal editors' authorship criteria.

4. Research must[9] be conducted in accordance with a research proposal or protocol – a document that describes clearly what will be done in the research. This is important so that

[6] Funders or others may set expectations about making data and tissue available.
[7] https://www.hra.nhs.uk/planning-and-improving-research/best-practice/publication-and-dissemination-research-findings/ (accessed 5 Dec 19).
[8] Exception may be made for experienced healthcare personnel undertaking educational qualifications or doctoral level studies whilst employed by a health and social care provider or whilst undertaking a fellowship.
[9] Or must, if there is a legal requirement, e.g. in the case of clinical trials of investigational medicinal products.

the research team can all understand consistently what they are supposed to do, and so that the research can be properly analysed and, if necessary, reproduced. Public involvement[10] plays an important role in research design and planning. Well-planned and well-written research proposals, protocols and procedures are key to carrying out research successfully. They help avoid subsequent amendments[11], which are time-consuming and costly for the funder, the researchers and the review/approval bodies. Not adhering to the research proposal or protocol has the potential for adverse impact and reputational risk to all parties involved. For research participants, this compromises any informed consent given; for the researcher, it creates a scientific risk that the research data (or their credibility) may be compromised; and for Research Sponsors there is often a financial and resource implication particularly where a suspension to recruitment or extensive investigation are involved.

5. Research proposals, protocols and procedures must be clear, comprehensive and easily accessible to the research team. Good document management and version control are essential so that the same single version of the research proposal or protocol is being followed in the same way by everyone involved. It is appreciated that there may be an expectation or requirement for documents to be revised and updated during the lifespan of study. It is important to ensure that changes to the research proposal or protocol are submitted as amendments for review by a SAC, MODREC and any other relevant review/approval bodies and, if they receive favourable opinion[12], that they are introduced uniformly across all relevant research sites.

Research Teams

6. The research team is the group of people involved in the conduct of a research project. It may include care professionals, academics, patients and service users, members of the public, research professionals, students and/or scientists. Research team members' accountability must be clearly agreed between them and their employer(s)[13] and documented, especially where multiple disciplines, collaborating organisations or patients are involved in a single research team. For multi-site research, a single research team led by the CI may undertake the activity at all the sites, or there may be different research teams at different sites, led either by the CI or by a PI who takes responsibility for the conduct of the research at that site. Research teams are responsible for:

a. Demonstrating to the CI and Research Sponsor their suitability to conduct the research.

b. Acquiring any particular knowledge and skills in order to conduct the research.

c. Conducting the research according to the most up to date approved research proposal or protocol and any complementary information in compliance with any applicable regulatory standards and guidance.

[10] i.e. involving patients, service users or the public in the design, management, conduct or dissemination of research.
[11] Where research deliberately entails modifying parameters or procedures during its course (e.g. adaptive clinical trials, iterative approaches in qualitative research), amendments should be avoided by the proposal or protocol specifying the adaptation schedule and processes up front.
[12] Or if they give effect to urgent safety measures.
[13] Or directly with the Research Sponsor, where this accountability does not arise in the context of their employment, e.g. in the case of research team members who are patients, service users or the public.

d. Providing information in a suitable format for potential participants that is clear and relevant to their participation in the research and, where consent is required, to their decision-making about taking part in the research.

e. Ensuring participants' safety and well-being in relation to their participation in the research (e.g. by asking questions about the patient's experience with the research intervention) and reporting adverse events where expected or required.

f. Addressing and reporting research misconduct.

7. Where consent is sought:

a. Potential research participants must be provided, normally by the research team, with the information they need to help them decide whether they wish to take part in research or not. Potential participants must be given reasonable time to reach their decision (normally a minimum of 24 hours). The information must be provided in a suitable format. Unless otherwise justified (e.g. by feedback from public involvement), the information should include a concise explanation of relevant research evidence and research in progress that shows why the proposed research is justified.

b. A permanent and accessible copy of any information sheet should normally be made available to all participants.

c. Consent must be documented and available for inspection by relevant regulators.

8. Proportionality must be applied to the provision of information to potential research participants. The more research deviates from established practice or otherwise detrimentally affects the balance between the anticipated risks and benefits, the greater the amount of information will need to be provided to potential participants. By the same token, the closer the research is to standard practice, the less need there is to provide patients and service users with detailed and lengthy information. For instance, pragmatic trials looking at the effectiveness of routinely used standard treatments should be facilitated so that patients can be recruited in a way that complies with the law but does not unduly burden either patients or the care professionals seeking their consent.

Funders

9. The funder is the organisation or group of organisations providing financial (or in kind) funding for the research project. The funder is normally the Research Sponsor in the case of commercial research. The funder is responsible for:

a. Ensuring the relevance of the research to the target population, the relevance of the research to the organisation and how it fits in with the organisation's research priorities and, if appropriate, the value for money of the research as proposed has been conducted.

b. Reviewing information about the attribution of costs to confirm that costs to all parties (including excess treatment costs) have been identified and described in

accordance with national guidance[14] where applicable, and that the costs are not disproportionate compared to the value of the output.

c. Considering (with advice if necessary) whether the research is really achievable within the settings as a whole in which it is intended to be carried out, particularly in view of the priorities and constraints in health, psychology and social care if the research will have an impact on care provision.

d. Making ongoing funding conditional on a Research Sponsor, and relevant approvals being in place, before the research begins (but not before initial funding is released, as some funding may be needed in order to put these in place).

e. Using contracts and conditions of funding to promote compliance with this policy.

Research Sponsors

10. The Research Sponsor is the organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. **All research has a Research Sponsor**. For MOD sponsored or co-sponsored research,[15] sign-off on behalf of the Research Sponsor (MOD) must be at the minimum of OF5/B2 level[16]. For non-MOD organisations the research sponsorship responsibilities must be accepted by an individual of appropriate seniority. TLBs are responsible for determining which individuals are authorised to sign-off the sponsorship arrangements for research.

11. The Research Sponsor[17] has overall responsibility for the research, including:

a. Ensuring appropriate scientific review through a SAC to identify and address poorly designed or planned research, or poor-quality research proposals, protocols or applications. Research Sponsors must seek SAC assurance that research proposals and protocols:

(1) Take into account systematic reviews of relevant existing research evidence and other relevant research in progress.

(2) Make appropriate use of patient, service user, research participant and public involvement.

(3) Are scientifically sound, safe, legal and feasible, and are expected to remain so for the duration of the research, taking account of developments while the research is ongoing.

[14] e.g. www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research (accessed 5 Dec 19).
[15] Either commercial or contracted.
[16] The employer of the chief investigator, or funder, is not automatically the research sponsor; they must explicitly accept the responsibilities of being the research sponsor.
[17] These commitments must be confirmed by a representative with sufficient seniority (i.e. OF5/B2) to confirm that they will be met. For clarity, while this individual is not the Research Sponsor (as this is normally an organisation e.g. MOD or a University), they are expected to have authority to represent the Research Sponsor.

b. Demonstrating, when asked, that the investigators, research team and research sites are suitable.

c. Ensuring that roles and responsibilities of the parties involved in the research and any delegation by the Research Sponsor of its tasks are agreed and documented.

d. Ensuring adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project.

e. Agreeing appropriate arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after the research has finished. Ensuring arrangements for information about the findings of the research are made available including, where appropriate, to participants[18].

f. Ensuring that, where expected or required, the research has a favourable opinion from a SAC, MODREC[19] and any other relevant review/approval bodies before it begins.

g. Ensuring that where the Research Sponsor is not MOD, research has explicit written approval at the minimum of OF5 / B2 level.

h. Verifying that regulatory and practical arrangements are in place before permitting the research to begin in a safe and timely manner.

i. Ensuring and keeping in place arrangements for adequate finance and management of the research project including its competent risk management and data management.

j. Ensuring that effective procedures and arrangements are kept in place and adhered to for reporting (e.g. progress reports, safety reports) and for monitoring the research, including its conduct and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments.

k. Ensure results of projects are registered, disseminated and reported appropriately.

12. Research Sponsors of clinical trials of investigational medicinal products have particular legal duties – see https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/#ctimps for details.

13. Universities and colleges normally accept the role of Research Sponsor for educational research conducted by their own students, unless the student is employed by a health or social care provider, or has a Military-based Research Sponsor, that prefers to take on this role. Research Sponsors of educational research must ensure that supervisors can and do carry out the activities involved in fulfilling this role. Where the academic supervisor cannot adequately satisfy the Research Sponsor's oversight responsibilities due to location or expertise, the Research Sponsor must agree co-

[18] For educational research, registration, accessibility of data and tissues, and dissemination may be limited to institutional arrangements.
[19] Whether outright or following a provisional opinion, resubmission or appeal.

supervision arrangements with a local care practitioner, a Military co-supervisor, or other suitably qualified individual.

Contract Research Organisations

14. A contract research organisation (CRO) is a person or an organisation (commercial, academic or other) contracted by the Research Sponsor to perform one or more of the Research Sponsor's activities. A Research Sponsor may delegate any or all of these activities to a CRO, but the ultimate responsibility (e.g. for the quality and integrity of the research data) resides with the Research Sponsor[20]. The CRO is responsible for implementing quality assurance and quality control in respect of the activities delegated to it. Any activity that is delegated to, and assumed by, a CRO must be specified in writing. Any activity not specifically delegated to, and assumed by, a CRO is retained by the Research Sponsor.

Research Sites

15. Research sites are the organisations with day-to-day responsibility for the locations where a research project is carried out. In health and social care research, they are often providers of health or social care and/or the employer of members of the research team. Within MOD research sites may include any parts of the Defence Estate, partner organisations sites or the deployed environment. Research sites are responsible[21] for:

a. Demonstrating to relevant approval bodies and Research Sponsors that the location is suitable for the research.

b. Being aware of all research activity being undertaken in or through the site.

c. Ensuring that the roles and responsibilities of individuals at the site and any collaborating parties are agreed and documented for individual research projects.

d. Satisfying themselves (e.g. by taking assurances from others in a position to give them) that, if expected or required, the research has been reviewed/approved by a SAC, MODREC and any other relevant bodies before research participants take part (including indirectly, through the involvement of data or tissue that is likely to identify them).

16. Research sites must have confidence in accepting assurances from other bodies about the compliance with relevant legislation and national standards of proposed research activities, without duplicating review of those proposals. Accepting assurances carried out to national standards reduces the organisation's risk of misunderstanding or misinterpreting its obligations. Organisations remain responsible, including through monitoring and training, for ensuring that the research activities are conducted in accordance with their applicable legal obligations.

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[20] This does not prevent appropriate CROs from acting as the Research Sponsor's legal representative – see www.hra.nhs.uk/resources/before-you-apply/roles-and-responsibilties/sponsors-legal-representative (accessed 5 Dec 19).

[21] Where the location of the research is wholly independent of any of the individuals and organisations with responsibilities under this policy framework (e.g. a public or private space that is not under contract for the research, such as a public library or a café), these responsibilities fall instead to the PI's employer.

17. Research funding must not be wasted, and the production of evidence to inform future care must not be hampered or delayed, by poor information or processes at research sites:

a. Research sites are expected to make information available about their capacity and capability to support different types of research so that Research Sponsors can tell quickly and easily where they should place their studies to best effect[22].

b. Research sites are expected to keep themselves in a position to be able promptly, efficiently and proportionately assess their ability to take part in an individual research project. Research sites must have good, up-to-date working knowledge of their research capacity and capability.

c. If a site needs to put in place additional arrangements to support a specific research project, that process must take into account the views of the Research Sponsor and research team about the timetable for starting the research at that location, particularly for multi-centre projects.

d. Research sites are expected to accept reliable assurances from others in a position to give them. This includes assurances about the ethics and safety of the research project, its compliance with the law and other standards (e.g. confidentiality), the suitability of contracts and costings and the competence, character and indemnification of members of the research team who are not substantively employed at the site, including patients, service users and the public. Decisions about research team members' suitability must not be based on inappropriate HR processes, such as disproportionate training expectations (e.g. Good Clinical Practice (GCP) or health and safety training for individuals, roles or projects that do not need it), irrelevant occupational health checks (e.g. vaccination history where there is no contact with patients or service users) or duplicative checks of character.

e. Research sites must take steps to avoid disproportionate 'one size fits all' processes and duplication of effort, especially in requesting and assessing information, e.g. when research sites are involved in multi-centre projects or when they do repeat business with CI, Research Sponsors etc. already known from previous projects.

f. Research involving participants who are subsequently transferred to another research site is expected to be facilitated by the transferring site,[23] who should provide all relevant information to the receiving site so as to support the continuation of the research.

g. Where there is an urgent need or small window of opportunity for relevant ethical research, such as public health emergencies, quick co-operation among relevant parties to facilitate the research is expected.

[22] e.g. http://www.nihr.ac.uk/about-us/CCF/policy-and-standards/rss-operational-capability-statement.html www.rcgp.org.uk/researchready (accessed 5 Dec 19).
[23] A transferring site will have been a research site for the project. Where an organisation is simply identifying participants for research taking place elsewhere, it does not count as a transferring site.

h. Research sites may designate staff to facilitate activities that fulfil their responsibilities under this policy. Such staff may act as a shared resource across more than one site.

Regulators of Professions

18. Regulators of professions such as the General Dental Council, General Medical Council, General Pharmaceutical Council, Health and Care Professions Council, and Nursing and Midwifery Council are responsible for professional standards and for ensuring compliance with these standards, e.g. by assessing fitness to practise. These standards normally apply to, and must therefore treat, the professionals' research activity in the same way as their provision of care, teaching etc. In cases where research misconduct also constitutes professional misconduct, the regulator of the relevant profession retains its responsibility for taking action alongside any action taken by other bodies such as other relevant regulators, the researcher's employer and the police.

Other Regulators

19. Regulators are statutory bodies that oversee particular activities according to their functions, which are set out in legislation. There are a number of regulators in the UK with a remit for activities related to health, psychology and social care research (the Health Research Authority (HRA)) or to health research only (the Human Fertilisation and Embryology Authority (HFEA), the Human Tissue Authority (HTA) and the Medicines and Healthcare products Regulatory Agency (MHRA)).

a. The HRA, HFEA, MHRA and the Administration of Radioactive Substances Advisory Committee all have a role in co-operating with each other to approve research, and with the HTA (which licenses storage of tissue for research, not the research itself). This co-operation is underpinned by agreements between these bodies which set out how they work together to improve and simplify the regulatory environment, or arrange for one body to perform functions on behalf of others.

b. The HRA and the Devolved Administrations work together to co-ordinate and standardise the regulation of health and social care research.

Employers

20. Employers are the organisations employing the CI and members of the research team[24]. The CI's employer is often the Research Sponsor. Employers may also be funders, research sites and/or care providers. Employers are expected to:

a. Encourage a high-quality research culture, including:

(1) Ensuring employees are supported in and held to account for conducting research in a professional manner, including research integrity.

(2) Ensuring effective management of employees and their work, including employees' safety, well-being, work environment and facilities.

[24] Excluding employers of people whose role in the research is not part of their employment, e.g. research team members who are patients, service users or the public.

(3) Ensuring financial management and calculation of costs in support of financial probity.

(4) Ensuring agreement with their partners[25] (e.g. funders, Research Sponsors, collaborators, commercial partners, network members, integrated board etc) and employees about accountability and division of responsibilities, including arrangements for any intellectual property arising from research.

b. Ensure researchers understand and discharge their responsibilities.

c. Follow good HR practice, including in the provision of assurances about researchers' suitability; provide written procedures, supervision and training that support accountability and effective collaboration; encourage care with financial resources; raise awareness of the wider environment within which health, psychology and social care research is conducted; and bridge any gap between employees' current competence and the competence needed for their work.

d. Take proportionate, effective action in the event of errors and breaches, or if misconduct or fraud are suspected.

21. Employers of research staff must ensure appropriate individual learning and competence. This includes acknowledging existing experience, qualifications and skills, rather than just giving training. Relevant training given should have measurable learning outcomes that are competence-based and directly linked to the competencies demanded by the employee's role and the procedures (such as SOPs) relevant to that role. It is important to confirm that individual members of the research team have an adequate level of awareness of the correct procedures, what those entail, and the importance of following them. It is also important to understand the wider context of any error or breach that does occur. Systems must be in place not only to enable the identification of failures or breaches but also to place responsibility with the relevant party. For instance, if an error or breach occurs owing to insufficient time to complete a number of tasks, providing training will not in itself solve the problem or reduce the risk of a repeat. Lessons learnt from experience must be identified and implemented, including through incorporation into training and personal development.

22. It is important to encourage open and honest reporting. It is widely recognised that a culture of openness and honesty encourages safety. Incident reporting is important in all research and is strongly encouraged so that lessons can be learnt and improvements made. Errors can only be rectified, and improvements made to reduce adverse impacts and increase the quality of research outcomes, if they are reported in a timely way. For this to be truly effective, a culture of openness and honesty is essential, with a focus on improvement rather than blame.

Health and Social Care Providers

23. Providers are organisations that provide health or social care. This includes organisations providing services under contract with NHS or local authority providers or commissioners[26], e.g. general practitioners, privately run treatment centres, care homes or

[25] This is particularly important for jointly funded posts and other dual employment, e.g. care professionals who also have a university role.
[26] Including purchasing of services undertaken directly by those receiving care or support, from their own resources or from their 'personal budgets', i.e. local authority funding managed by or on behalf of the service user.

magnetic resonance imaging (MRI) services. Providers' involvement in research is generally as research sites, when they may also be the employer of members of the research team, and/or when they have responsibility for research participants' care. A provider is normally the Research Sponsor for non-commercial research if it is the Chief Investigator's employer. Health and social care providers may also provide services to research sites, such as identifying potential participants or making information available for research elsewhere. In addition to any responsibilities they may have in their capacities as sites, employers and/or Research Sponsors, providers must recognise the importance of research in improving treatments, care and other services and their outcomes by:

a. Promoting opportunities to take part in health and social care research.

b. Retaining responsibility for the care of their patients and service users as research participants, including agreeing any associated excess NHS tariff treatment costs.

c. Having regard to this policy framework according to their legal duty under Section 111(7) of the Care Act 2014 and contributing to the fulfilment of their commissioners' legal duties to promote research under the Health and Social Care Act 2012.

Scientific Assessment Committees (SAC)

24. Each single Service and MOD Agency which conducts research is required to assess whether the amount of research it conducts requires the establishment of a SAC to undertake independent scientific review of research protocols. Where an organisation does not have a SAC, arrangements are to be made with an established SAC for the assessment of research proposals[27].

25. The SAC is convened under the authority of the Principal Personnel Officer (PPO) or CE of the organisation and reports its work and outcomes to the PPO / CE on an annual basis.

26. Working with the CI and Research Sponsor the SAC is responsible for ensuring that all research proposals:

a. Are properly designed and planned and that the design will not need significant change during the lifetime of the project. In designing the research, account must have been taken of relevant existing research evidence and other research in progress, including within MOD and its agencies.

b. Are safe, legal and feasible, and expected to remain so for the duration of the research, taking account of developments while the research is ongoing.

c. Are appropriate and have outputs that are relevant to the business of MOD, its partners or other Government Departments and is aligned to the relevant organisations research strategies.

[27] This may be done by either a permanent agreement or on an ad-hoc basis and the SAC selected should be one with knowledge either of the research area, research population or the research team.

d. Have participant information, questionnaires and study de-briefs that are readable and comprehensible within the proposed research subject group.

e. Are assessed to confirm whether proposed testing can be conducted in the environment or at the frequency proposed without detriment to military training or operations and that the proposed research subjects are not already involved in multiple other research proposals (research overload).

27. A SAC review is proportionate to the scale and complexity of the research proposed. Research proposals that present no material issues of research quality and low risk to participants may not warrant consideration at a full meeting of SAC. They must be identified on receipt in accordance with standard operating procedures so that the scientific review may be undertaken by a sub-committee of the SAC. SAC's opinion on such proposals may be given by the executive sub-committee.

28. On completion of the assessment, the SAC is to provide assurance to the Research Sponsor that the research meets the requirements above.

Ministry of Defence Research Ethics Committee (MODREC)

29. MOD convenes an independent, security cleared, research ethics committee called MODREC with the remit to protect the dignity, rights, safety and well-being of research participants and researchers by providing an independent ethical opinion on all projects that fall under this policy.

30. MODREC's role is to provide a point in time review of protocols to ensure they take account of the principles listed in Chapter 2 of this policy, along with all other relevant ethics considerations prior to the recruitment of research participants. MODREC is not able to further enforce (or ensure research adheres to) these principles, although does retain the right to withdraw a favourable ethics opinion. The individuals and organisations responsible for enforcing the principles and notifying relevant authorities of breaches are outlined earlier in this Chapter.

31. MODREC is an ethics committee not a scientific peer review committee. It may request further expert peer review if it is unhappy with any aspect of a protocol.

32. MODREC is recognised by United Kingdom Ethics Committee Authority[28] for the review of protocol under the relevant national and devolved legislation.

33. MODREC is supported by a secretariat and has its own governance (described in Chapter 5) and standard operating procedures based upon those developed by the HRA.

[28] https://www.hra.nhs.uk/about-us/partnerships/four-nations-and-united-kingdom-ethics-committee-authority/

Annex A: Relationship between principles and responsibilities

Responsibility for adhering to the principles as outlined in this policy depend on the nature and specific organisation of each piece of research, however in general they are as follows:

Principle	Responsibility								
	Chief Investigator	Research Team	Sponsor	Employer	Research Site	Funder	Regulators	Providers	SAC
1 – Safety	✓	✓	✓	✓	✓				✓
2 – Competence	✓	✓	✓	✓	✓				✓
3 – Scientific and Ethical Conduct	✓	✓	✓	✓	✓	✓	✓		✓
4 – Integrity, Quality and Transparency	✓	✓	✓	✓	✓	✓			✓
5 – Protocol	✓	✓	✓				✓		✓
6 – Legality	✓	✓	✓	✓	✓		✓	✓	✓
7 – Benefits and Risks	✓	✓	✓	✓	✓		✓		✓
8 – Approval	✓		✓		✓	✓	✓		✓
9 – Accessible Findings	✓		✓			✓			
10 – Choice	✓	✓							
11 – Insurance and Indemnity			✓						✓
12 – Respect for Privacy	✓		✓		✓	✓	✓		
13 – Compliance	✓	✓	✓	✓	✓	✓	✓		
14 – Justified Intervention	✓	✓	✓						✓
15 – Ongoing Provision of Treatment			✓		✓	✓		✓	
16 – Integrity of Care Record	✓		✓						
17 – Duty of Care	✓	✓	✓	✓	✓			✓	

4 Governance and arrangements for Scientific Assessment Committees (SACs)

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Introduction

1. SACs are the scientific review committees within the MOD Research Review Process. They are single Service or organisation-based committees responsible to the Director General/3* of that organisation.

2. This Chapter lays out the principles by which the Scientific Assessment Committees (SACs) will operate. The formal Terms of Reference are set by the SAC appointing authority. Guidance on submitting a protocol for Scientific Review can be found in JSP 536 Part 2 Chapter 2.

Purpose

3. The SACs are established to provide a timely and robust scientific and technical peer review function across the MOD on the quality, design and suitability of individual studies involving human participants in research. This will include ensuring reviews are proportionate to the level and complexity of individual proposals.

4. The SACs will assess proposals to ensure the safety and well-being of the participants and the researchers involved in the study, and that any proposed medical surveillance and / or intervention is appropriate.

5. It is not the SAC's role to commission research.

Committee structure

6. The PPO / CE is to appoint the Chair of the SACs and direct / approve recommendations by the SAC Chair for the membership of the SACs. The PPO / CE holds the SAC to account for the quality and timeliness of their outputs.

7. It is expected that the Chair will be a senior Scientific or Medical Officer and the committee must include a senior military officer (OF4 or higher) and a core of senior scientific or medical members of staff with specific expertise including medicine, human factors research, psychology and statistics, for the review of individual protocols as necessary.

8. To be quorate the SACs should consist of a minimum of four committee members in addition to the Chair.

9. When appropriate, the Chair has the right to co-opt additional expertise onto the committee as required and / or request advice through the MODREC Secretariat[1] from

[1] Contact details are available on the MODREC Website.

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.

10. **Declaration of interest**. If one of the members of the SAC is a member of the Research Team of an application to be reviewed, they should ensure that a formal declaration of interest is registered with the Chair and that they absent themselves from any formal SAC decisions.

Key Outputs

11. The key output of the SAC is to provide assurance to the Research Sponsor and Chief Investigator (CI) that protocols presented have been through an expert review of the scientific acceptability, quality and validity of the proposed research.

12. The secondary role of the SAC is to provide independent advice to researchers on achieving best scientific practice.

Operating procedures

13. The SACs will formally review protocols submitted to them by the CI normally in preparation for presentation to the MODREC. SACs can provide advice on research quality to any researcher and whether their protocol requires MODREC review or not.

14. Except where the protocol meets the criteria for proportionate or expedited review, SACs will provide a comprehensive response to the Research Sponsor and 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 an application and the requirements for further review by the SAC.

15. The Chair of the SAC will notify the Research Sponsor and the CI of the views, recommendations and decisions of the SAC prior to submission of the protocol by the Chief Investigator for MODREC ethics review or assessment by an external regulatory body. The SAC will provide the Research Sponsor with formally approved version(s) of the protocol(s) where appropriate.

16. 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 ofHd Research and Clinicial Innovation.

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

18. **Proportionate review**. The SACs are to provide a proportionate review process which allows for a rapid (10 day) turn-around of protocol where there is low risk to the subjects or experimenters, and minimal burden and intrusion to the participants. These

applications are likely to be ones with low scientific impact[2]. They are likely to include MSc protocols that have already been reviewed by a University Supervisor.

Reporting

19. The SACs should formally record its meetings and/or reviews in case of future challenge or the occurrence of unexpected events during the conduct of the research. The PPO / CE has the right to see and review these records.

20. The Chair of the SAC will submit an Annual Report to the PPO / CE[3] (or equivalent) summarising 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. The PPO / CE (or equivalent) should raise any concerns not resolvable within their organisation to the Director General DMS as Senior Responsible Owner (SRO).

Resources

21. While resourcing the SAC is a matter for the PPO / CE, it is recommended that the SAC Chair has the following resources available:

a. A Vice-Chair and Alternate Vice-Chair, who shall be committee members and represent the Chair 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 PPO / CE are responsible to the SRO for the governance of the SAC. They may request assistance from the SRO in assessing and resolving any specific governance issues that they are unable to resolve within their own organisation.

24. The PPO / CE and the SRO will feedback on issues encountered and reported and provide suggestions for improvements to the review process.

[2] See also the criteria for proportionate ethics review as outlined in Chapter 5 para 10.
[3] Normally covering 1 January to 31 December unless otherwise required by the PPO / CE.

5 Governance arrangements for the Ministry of Defence Research Ethics Committee (MODREC)

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Introduction

1. This Chapter covers the principles, requirements and standards for MODREC, including its remit, composition, functions, management and accountability. It applies to the review of all research falling under the scope of this JSP (as described in Chapter 1 paras 6-9).

2. At the request of the Research Sponsor, Chief Investigator (CI) or host organisation, MODREC may agree to consider applications or research proposals that fall outside the normal scope of this JSP if the proposal raises material ethical issues. When MODREC does this, the principles, requirements and standards set out in this document will apply.

3. When acting as a medical care provider, MOD owes a duty of care to users of its services. When providing care, MOD is responsible for ensuring that ethical issues and risks in the course of the care are considered. MODREC is not expected to consider applications in respect of activities that are not research, for example clinical practice, audit, service evaluation and health surveillance. Guidance on differentiating such activities from research is contained in JSP 536 Part 2 Chapter 1 Annex A and is also available from research governance offices and from the Health Research Authority (HRA). MODREC members who give advice on the ethics of such activities must make it clear that they are not doing so in their capacity as a MODREC member.

4. As described in Chapter 3, employers owe a duty of care to their employees. MODREC is not expected to assume employers' responsibilities or liabilities, or to act as a substitute for employers' proper management of health and safety in the workplace. It is for employers to ensure that they are fulfilling their duties as employers when their employees take part in research.

5. 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 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 (REC) or equivalent, to MODREC for consideration prior to any recruitment taking place.

Role of MODREC

6. Whatever the research context, the interests of participants come first. Their dignity, rights, safety and well-being must be the primary consideration in any research proposal, as well as in MODREC review. MODREC must be assured that there are proportionate safeguards to protect people taking part in research.

7. The interests of researchers and research are always secondary to the dignity, rights, safety and well-being of people taking part in research. MODREC also takes into account the interests and safety of the researchers, as well as the public interest in reliable evidence, and enables ethical and worthwhile research of benefit to MOD, participants or to science and society.

8. The benefits and risks of taking part in research, and the benefits of research evidence for improved health, psychology and social care, occupational and operational processes and procedures and equipment should be distributed fairly among all social groups and classes. Selection criteria in research protocols must not unjustifiably exclude potential participants, for instance on the basis of economic status, culture, age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation. MODREC must take these considerations into account in reviewing the ethics of research proposals, particularly those involving under-researched groups.

9. In accordance with definitions described in its standard operating procedures, MODREC will review a research project and reach one of the following decisions:

a. Favourable.

b. Unfavourable.

c. Provisional with request for further information.

Proportionate Scrutiny

10. MODREC review is proportionate to the scale and complexity of the research proposed. Research proposals that present no material ethical issues do not warrant consideration at a full meeting of MODREC. They must be identified on receipt in accordance with standard operating procedures so that the ethics review may be undertaken by an executive sub-committee of MODREC. MODREC's opinion on such proposals may be given by the executive sub-committee.

Independence and impartiality

11. MODREC must be independent and impartial. Its opinion must be free, and must be seen to be free from conflicts of interest. This includes freedom from pressures of:

a. Political influence;

b. Institutional affiliation;

c. Trades union or profession-related interests;

d. Direct or indirect financial inducement or any impression thereof;

e. Coercion;

f. Strategic concerns;

g. Market forces; and

h. Agency-, discipline- or topic-related bias.

12. The protection of research participants and the enabling of ethical research are best served by co-operation and communication between all those who share responsibility for the research. Except when it would compromise their independence, MODREC must collaborate with regulators, actual and potential research participants, researchers, funders, Research Sponsors, employers, organisations providing care and care professionals. MODREC must also collaborate with other RECs if required, for example to share relevant information from previous applications or expertise in reviewing particular types of research.

Competence and Efficiency

13. MODREC review must be competent, timely and authoritative. The membership, ongoing training and performance management of MODREC, as well as the operational and administrative support it receives, must be arranged to maximise the quality, rigour and promptness of reviews, and the efficiency of the decision-making processes. MODREC should give its opinion within sixty working days of receipt of a valid application. The sixty-day period excludes the time an applicant may take to supply additional information requested by MODREC.

14. MODREC must operate according to the law in the conduct of its business, for example by following due process and complying with its own standard operating procedures. MODREC must also have regard to statutory provisions for ethical review of particular types of research, e.g. the requirements for a favourable opinion of a clinical trial under the Medicines for Human Use (Clinical Trials) Regulations 2004 or for approving research involving adults lacking capacity under the Mental Capacity Act 2005 or the Adults with Incapacity (Scotland) Act 2000. Guidance on the application of this legislation to ethical review and REC operating procedures is provided in collaboration with the HRA.

15. It is not the role of MODREC to offer a legal opinion on research proposals, but it may advise the researcher, Research Sponsor or host organisation whenever it considers that legal advice might be helpful to them. Researchers, Research Sponsors and organisations where the research is carried out remain responsible for making sure the research is conducted in accordance with the requirements of law, relevant regulators and guidance, e.g. the Data Protection Act 2018, the Codes of Practice issued under the Mental Capacity Act 2005 and Human Tissue Act 2004, or recognised standards of Good Clinical Practice. Further details are provided in Chapters 3 and 4.

Compliance and Enforcement

16. If MODREC review is required, sponsoring organisations must ensure that the research they host has a favourable opinion. The research may not begin until a favourable MODREC opinion has been received.

17. The CI is the researcher who takes primary responsibility for the design, conduct and reporting of the research. The CI is responsible for the content of the MODREC application and for the scientific and ethical conduct of the research as outlined in Chapter 3.

18. Although MODREC must be assured about the planned ethical conduct and anticipated risks and benefits of any proposed research, it is not responsible for enforcement if the research turns out to be unsafe or is not carried out as agreed. This responsibility rests with the relevant regulators or comparable bodies, as well as with the researchers' employer and Research Sponsor, and with the care organisations where the research takes place (or through which the researchers have access to participants, or their tissue or information) or where the researchers have contracts.

19. MODREC must agree channels of communication with the relevant bodies in order to exchange advice. MODREC must use these channels to alert the bodies responsible for enforcement if they have grounds to suspect that enforcement action is warranted.

20. Proposed changes to a research protocol (including duration of the study) must be submitted, following any required scientific assessment, to MODREC as a project amendment in accordance with MODREC's standard operating procedures. Changes must not be implemented until the amendment has been formally approved.

21. MODREC must receive reports about the progress of the research if any developments affecting participants' dignity, rights, safety or well-being occurs. MODREC must reconsider its favourable opinion in light of pertinent information that comes to its attention. If MODREC would not have reached a favourable opinion if given the additional information during its initial review, it must notify the relevant statutory enforcement authorities. Where the law does not specify the responsibility for enforcement, MODREC must notify the Chief Investigator and the Research Sponsor that its opinion is no longer favourable.

Composition and Membership

22. The membership of MODREC must allow for a sufficiently broad range of experience and expertise so that the rationale, aims, objectives and design of the research proposals that it reviews can be effectively reconciled with the dignity, rights, safety and well-being of the people who are likely to take part.

23. MODREC is expected to reflect current ethical norms in society as well as its own ethical judgement. MODREC members may come from groups associated with particular interests but they are not representatives of those groups. MODREC members are appointed in their own right to participate in the work of MODREC as equal individuals of sound judgement, relevant experience and adequate training in research ethics and REC review.

24. MODREC must contain a mixture of people who reflect the currency of public opinion ('lay' members), as well as people who have relevant formal qualifications or professional experience that can help the REC understand particular aspects of research proposals ('expert' members)[46].

25. The appointing authority should make reasonable attempts to ensure that MODREC reflects the diversity of the adult population of society, taking account of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race,

[46] The term 'professional member' can imply someone whose job is to be a REC member (rather than an unpaid volunteer drawn from the care professions etc), so 'expert member' is used instead. For this reason, 'experts by experience' are counted as lay members.

religion or belief, sex and sexual orientation. This applies to both the lay and expert membership. When new appointments are made, efforts must be made to publicise the work of MODREC and encourage applications for membership from groups who are under-represented.

26. Appointment of members must be by an open and fair process, compatible with the Nolan standards. Vacancies must be filled following public advertisement in the press, and/or by advertisement via local professional and other networks as most appropriate to the vacancy to be filled. Potential candidates must be required to complete an application form and be interviewed. There must be standard written procedures for application and selection, which must comply fully with equality and human rights legislation.

Types of Members and Quorum

27. MODREC must have security cleared expert members to ensure methodological and ethical expertise. This expertise must be appropriate to the types of research proposals that MODREC reviews.

28. Lay members are people who are independent of care services, either as employees or in a non-executive role. Their primary professional interest is not care-related research. At least a third of MODREC membership should be lay. At least half the lay membership should comprise people who have never been care professionals, researchers in a care field, or chairs, members or directors of care service bodies or organisations providing care. Lay members must also hold appropriate security clearance.

29. MODREC may review and publish more precise definitions of expert and lay membership in accordance with standards agreed by the Health Research Authority.

30. MODREC may appoint security cleared specialist military and/or ethics advisors to ensure that the committee is appropriately briefed on the context of research projects. No more than four advisors should be present at any one time, and advisors must not be considered committee members for voting purposes.

31. For the purpose of effective debate, MODREC should normally have no more than 18 members in total. A quorate meeting is one attended by no fewer than seven members, including:

a. The chair or other officer.

b. At least one expert member.

c. At least one lay member who is not, and never has been, a care professional or a chair, member, director, officer or employee of a care service body.

d. At least one special advisor (in a non-voting capacity).

32. MODREC must be constituted so that it can function quorately during the protocol review part of its scheduled meetings.

33. Where other membership, composition or attendance criteria are specified, e.g. in law, when reviewing certain types of research proposals, guidance to convene in

accordance with the requirements set out in this document as well as the additional specifications is available from the HRA.

Officers

34. MODREC must have a chair, a vice-chair and an alternate vice-chair. If all three are unavailable, another member will be acting chair. These officers are appointed by the MODREC appointing authority, after consulting MODREC.

35. Candidates for office are expected to have at least one year's experience as a member of a REC (either MODREC or a HRA REC). Appointees must receive any necessary supplementary training (e.g. in chairing skills).

36. Officers are appointed for a specified period. An acting chair's appointment ceases when one of the other officers becomes available again or when his or her term as a member expires, whichever is sooner.

37. Officers may resign from office at any time. They may continue as members of MODREC, subject to the disqualification and resignation procedures of its appointing authority.

Referees

38. MODREC may seek advice from specialist referees on any aspects of a research proposal that fall beyond the members' expertise. MODREC may seek referees' advice at their discretion or because the law requires them to do so. Referees' advice must only be sought on issues material to MODREC's review of the research proposal, i.e. issues of research ethics.

39. Terms of reference and the advice required for referees must be established for each protocol referred. If attending a meeting to give their advice Referees do not count towards the quorum or vote on decisions. They are not involved in any MODREC business apart from advising on the issues put to them. Their advice is recorded in the minutes of the relevant MOREC meeting.

Observers

40. MODREC meetings are not public meetings. External observers may attend subject to appropriate security clearance and following a written invitation stating the terms and conditions of attendance. Attendance must be agreed in advance by the chair of MODREC and minuted accordingly.

41. Observers play no part in the deliberations of MODREC.

Advice to Applicants

42. MODREC must take steps to facilitate communication with potential or actual applicants. MODREC may designate a point of contact for more detailed discussion. This includes advice about whether a proposed activity requires MODREC review, or the content, submission or review of an application. The point of contact may be any of the REC's members (including those appointed as officers) or administrative staff.

Delegation

43. MODREC may appoint sub-committees consisting of its members. Executive sub-committees may exercise any of MODREC's functions on its behalf, in accordance with standard operating procedures. In particular, executive sub-committees may review and give an opinion of:

a. Research proposals that present no material ethics issues.

b. Information further to earlier review in full committee.

c. Substantial amendments.

d. Progress reports.

e. Proposals of a particularly security sensitive nature (as agreed by MODREC chair).

44. If MODREC issues a provisional opinion reached in full committee, it may delegate the responsibility for determining its final opinion to the chair or other officer, or to an executive sub-committee of specified members.

45. Responsibilities of MODREC officers may be delegated to administrative staff where the matters are administrative, in accordance with standard operating procedures. In particular, office staff may check evidence provided by applicants in response to requests for further information and issue letters confirming MODREC's opinion.

Conditions of Membership

46. Written terms of appointment for REC members must include the following:

a. Duration of appointment.

b. Renewal policy.

c. Disqualification[47] and resignation procedures.

d. Policy concerning declaration of interests.

e. Details of allowable expenses.

47. MODREC members are appointed for fixed terms not exceeding five years. Appointments may be renewed following appraisal. Members should not normally serve more than two consecutive terms of five years unless the member has rare expertise that is essential for the work of MODREC, in which case the appointment may continue to be renewed.

[47] The Chair may advise the Appointing Authority of issues that require the removal of a member form the Committee.

48. Former members of MODREC may be reappointed no sooner than two years after the end of their last term.

49. Attendance at meetings of HRA RECs as a co-opted member, referee or observer is encouraged, in the interests of training and consistency.

50. Simultaneous membership of more than one REC is permitted with the approval of the appointing authorities concerned, as is deputy membership of other RECs.

51. MODREC members are normally required to attend in full at least two thirds of all scheduled meetings in each year, barring exceptional circumstances. Attendance at scheduled sub-committee meetings should be taken into account.

52. MODREC members may resign at any time.

53. MODREC members must allow publication of their full name and, if applicable, their profession and institutional affiliation. In the interests of transparency and probity, any potential conflict of interest must be recorded and published with these personal details.

54. 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.

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

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

57. As a condition of appointment, MODREC members must agree to take part in relevant (normally annual) training appropriate to their role.

58. MODREC members must maintain confidentiality regarding applications, meeting deliberations, information about research participants and related matters. MODREC members must also be cognisant of their legal responsibilities under relevant security classifications and/or regulations.

59. Each MODREC member must be supplied with a personal statement regarding the indemnity provided by the appointing authority and its conditions.

60. The meetings and proceedings of MODREC and its sub-committees are conducted in accordance with standard operating procedures (see JSP 536 Part 2).

Requirements of MODREC review

61. The need for a MODREC review can be assessed using Annex A to Chapter 1 within JSP 536 Part 2. There is a standard process for submitting a research protocol for review by MODREC. MODREC also reviews applications in accordance with published standards.

Applying for MODREC review

62. Applications to MODREC must be made in accordance with a process set out in JSP 536 Part 2 and in written guidance for applicants hosted on the MODREC Website. This process covers the application from submission to opinion and on to subsequent notification of substantial amendments, progress reporting etc.

63. The MODREC secretariat are prepared to offer accurate advice and guidance to potential and actual applicants. This includes being able to answer queries about whether MODREC review is required, the application process (including the requirements for a valid application) and the review process (including the issues MODREC is likely to consider before reaching an opinion).

Requirements for a favourable opinion

64. MODREC gives a favourable opinion if it is assured about the ethical issues presented by the proposed research. These issues may vary, depending on the research in question. MODREC members receive training and guidance about the issues they should consider, both in general and in particular cases. The training and guidance reflect recognised standards for ethical research, such as the Declaration of Helsinki, and take account of applicable legal requirements.

Principles of Research Ethics Committee Review

65. MODREC receives training, guidance, standard operating procedures and quality assurance (including appraisal and accreditation) in order to support the identification and consideration of relevant issues.

66. MODREC also receives guidance on the wider regulatory and governance environment for research and its reliability in order to assess the assurances they receive. MODREC will accept credible assurances that others will do what is expected of them:

a. MODREC need not reconsider the quality of the science, as this is the responsibility of the Research Sponsor and will have been subject to review by one of the SACs. MODREC will be satisfied with credible assurances that the research has an identified Research Sponsor and that it takes account of appropriate scientific review.

b. MODREC can expect to rely on established mechanisms for ensuring the proper conduct of the research in accordance with the principles and responsibilities outlined in Chapters 2 and 3. Other standards assurance processes, such as inspection or accreditation of sites by regulators, may also be adequate for MODREC to be assured about the suitability of those sites.

c. Where others have a regulatory responsibility, MODREC can expect to rely on them to fulfil it. If the law gives another body duties that are normally responsibilities of MODREC according to this document, MODREC need not duplicate them. For example, the Medicines and Healthcare products Regulatory Agency has the primary legal responsibility for considering the safety of the research it regulates.

Expedited and Proportionate Review

67. There may be exceptional circumstances where, as a matter of public policy, or in the national interest, it is essential that an application should be reviewed urgently to allow a study to commence as quickly as possible. All such requests must fall under the definition of an Urgent Operational or Business Requirement and be endorsed by Head, Research and Clinical Innovation. The process for submission and assessment under an expedited review are laid out in JSP 536 Part 2 Chapter 3 (paras 21-24).

68. Some research requiring MODREC review in accordance with para 10 may be suitable for Proportionate review. The criteria for a proportionate review and the process of conducting the review are found in JSP 536 Part 2 Chapter 4.

MODREC Standard Operating Procedures

69. Standard operating procedures are essential to an efficient, consistent and accountable review service. They take into account applicable laws and national guidance, advice, exemplars, relevant internationally recognised principles and other developing standards. In doing so they provide the operational detail for meeting the principles, requirements and standards set out in this document.

70. MODREC standard operating procedures are published in JSP536 Part 2, and further clarifications are available on the MODREC website.

MODREC Annual Report

71. MODREC's annual report to its appointing authority shall include at least the following:

a. MODREC name, address and other contact details.

b. Details of any recognition by UKECA and/or designation by the Research Ethics Service for review of certain types of research proposal.

c. Details of the officers and staff.

d. Details of the membership, including for each member their occupation, expert/lay status, initial date of appointment, and where applicable the date on which the term of membership expired or the member resigned.

e. The current register of members' interests.

f. The attendance record of each member during the year.

g. A list of full meetings held during the year, including their dates and the number of members attending.

h. The training record of each member and deputy member.

i. A list of the applications reviewed during the year, including the final decision reached on each application and the time taken to complete the review (or the current status of the review).

j. A report by the Chair on MODRECs work during the year should be provided to the appointing authority.

MODREC Appointing Authority

72. The Director General, DMS is the MODREC appointing authority and acts on behalf of MOD to ensure:

a. MODREC policy (JSP 536) is kept up to date and fit for purpose.

b. Ensuring appropriate funding and administrative support is sourced from within MOD to ensure that MODREC can perform its function as outlined in this JSP

c. The Chair, officers, advisors and members of MODREC are appointed and managed using appropriate methods

73. Where the MODREC appointing authority delegates administrative support to the committee, the administering organisation will ensure:

a. Administrative support (including the appointment of administrative and other staff) for MODREC to perform its function as outlined in this JSP

b. Providing MODREC with such accommodation and facilities as it considers necessary (including arrangements for such administration, maintenance, cleaning and other services)

c. Funding for MODREC in each financial year equal to the amount of expenditure which it considers may be reasonably incurred by MODREC in that year for the purpose of performing its function

d. Administration relating to the appointment and management of MODREC members including ensuring appropriate security clearances

c. Ensuring there is a rotation system of members (e.g. staggered tenure) to achieve business continuity, development and maintenance of expertise, and the regular refreshment of debate.

e. Ensuring standard practice, a consistent approach, and timely consideration of complaints for the benefit of researchers and MODREC alike

f. Liaising with the HRA and UKECA to ensure that MODREC maintains its legal status, and follows good practice in its conduct of ethics reviews.

6 Arrangements for the payment of no-fault compensation to participants in studies reviewed by MODREC

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MOD No-Fault Compensation Arrangements

1. 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 MOD. The no-fault compensation arrangements only apply to research participants (military, civilian, or non-MOD) who take part in a Trial that has been given a favourable opinion by the MODREC.

2. A research participant wishing to seek no-fault compensation under these arrangements should contact the Directorate of Judicial Engagement Policy, Common Law Claims and 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 given a favourable opinion by MODREC. A claim must be submitted within 3 years of when the incident giving rise to the claim occurred, or, if symptoms develop at a later stage, within 3 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.

Additional/Alternative Compensation Arrangements

9. Compensation for Service Personnel (SP). SP 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 Defence Business Services–Veterans (DBS- Vets) 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 website, as are details of the claim's process.

10. In the event of service personnel suffering injury or disability as a result of their participation in work given a favourable opinion by MODREC 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 and are also available on the DBS-Vets website. Claims should be made to DBS-Vets following the instructions available on the MOD Intranet and DBS-Vets website.

11. In the event of service personnel suffering injury or disability as a result of their participation in research having gained a favourable opinion from MODREC which is sufficiently serious for subsequent medical discharge from the services, their medical records will automatically be forwarded to DBS-Vets for consideration of compensation and pension enhancements 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 SP 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.

13. **Civilian Pensions**. 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 endorsed research, their dependants may be entitled to receive benefits.

14. **Common Law Compensation**. If a research participant or their representative believes that injury, disability or death was caused by the negligence of 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 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 MOD there may be a requirement for specific Compensation Arrangements on a study by study basis.