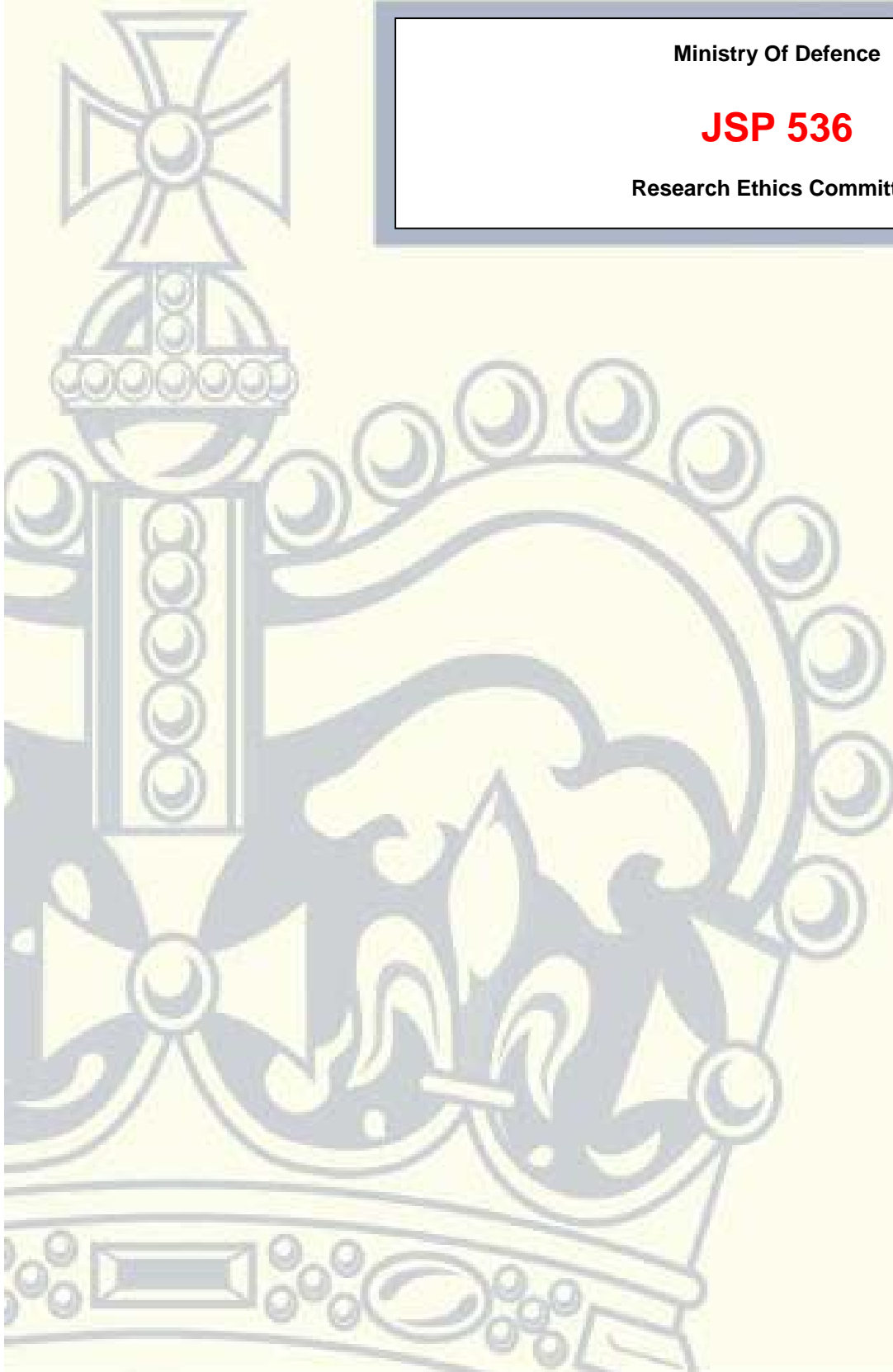


Ministry Of Defence

JSP 536

Research Ethics Committee



Document Description:

Research involving human participants undertaken, funded or sponsored by the Ministry of Defence (MoD) must meet acceptable ethical standards. Ethical standards are upheld by the MoD Research Ethics Committee (REC). This Joint Services Publication (JSP) sets out the MoD instructions for the ethical conduct and treatment of human participants in MoD research (both clinical and non-clinical).

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JSP 536: ETHICAL CONDUCT AND SCRUTINY IN MoD RESEARCH INVOLVING HUMAN PARTICIPANTS

Purpose

1 Research involving human participants undertaken, funded or sponsored by the Ministry of Defence (MoD) must meet acceptable ethical standards. Ethical standards are upheld by the MoD Research Ethics Committee (REC). This Joint Services Publication (JSP) sets out the MoD instructions for the ethical conduct and treatment of human participants in MoD research (both clinical and non-clinical). Specifically, this JSP sets out the MoD's process for assessment of research protocols.

2 This JSP provides instructions for all investigators conducting research involving human participants. Investigators and trials/project officers must be aware of the guidance provided in "MoD Guide to Research involving Human Participants", details at Annex A. The MoD REC will function in accordance with the terms of reference published in "MoD Research Ethics Committee for Research involving Human Participants", which includes the detailed roles and responsibilities of the Committee.

General

3 These instructions are based on nationally and internationally accepted principles and guidance (further information can be found on the Web Site, details are at Annex A). Ethical scrutiny must address the principles of the Declaration of Helsinki.

4 This JSP replaces DIN 07-006 of May 2005 'Interim Ethical Conduct and Scrutiny in MoD Research involving Human Participants'.

Scope

5 These instructions apply to research carried out on human participants.

6 The procedures detailed in these instructions must be followed for any research project in which the researchers:

- a. Conduct experiments upon the human participant (i.e. conduct research rather than treatment); including (but not limited to) administering substances, taking blood or urine samples, removing biological tissue, radiological investigations, or obtaining responses to an imposed stress or experimental situation.
- b. Conduct experiments to collect data on an identifiable individual's behaviour, either directly or indirectly (such as by questionnaire or observation).

- c. For the purpose of research, use non-public domain records and papers that contain information that is private or personal and could identify an individual (or group of people) and could cause harm.

7 For any other instances requiring experimentation, where there is the potential for harm to a human participant and where investigators are unsure whether a review by an ethics committee is required, advice must be sought via the MoDREC Secretariat.

Exceptions

8 These instructions do not apply to:

- a. Military operations, unless a research data gathering element is involved.
- b. Training and exercises, unless a research data gathering element is involved.
- c. Personnel who are testing or evaluating vehicles, equipment or materials, (e.g. experienced personnel assessing operability of commercially manufactured equipment that has established safety standards) unless the purpose is to determine the effect of an item on the human participant as part of a research project.
- d. Studies of new features or techniques during training or field operations following standard operating procedures in which the risk or stress to personnel does not exceed in any manner that which is inherent in the participant's daily life, occupation or field of service.
- e. Personnel carrying out standard operating procedures, undergoing acceptable, occupational training techniques for example military pilots taking centrifuge training. However experiments on protection involving centrifuge research on humans would require ethical approval even though both activities involve riding the human centrifuge.
- f. Epidemiological or retrospective studies employing secondary data from the public domain or obtained for purposes other than research where the use of such items cannot be linked or cannot cause harm or distress, to an individual or group of individuals.
- g. Cases where ethical oversight is a matter of course (e.g. where an MoD employee is a volunteer in a clinical research project at an NHS hospital), or where an MoD employee is acting in an entirely personal capacity.

Required Ethical Standards for Research (General Principles)

- 9 The following standards shall be followed rigorously when there is human participation in a research project covered by this JSP:
- a. The research project must form part of an official MoD programme and have reasonable prospects of yielding worth to the MoD.
 - b. The degree of risk should be commensurate with potential benefit and must be as low as possible.
 - c. Only the minimum number of participants should be involved so as to achieve statistically sound conclusions. However, the researcher should ensure that this minimisation of the number of participants is balanced against the risk of harm to the individual.
 - d. The research project shall be conducted so as to avoid all unnecessary physical and mental discomfort, suffering, injury and the misuse of the participant's time.
 - e. Sufficient knowledge must be acquired from reliable sources to give assurance of reasonable safety prior to any consideration of human participation; such sources include animal models, laboratory experiments and information from the scientific literature.
 - f. The results obtained from the research project must not be known to be obtainable by means of study other than those involving human experimentation.
 - g. Proper preparations must be made, and adequate facilities provided, to protect the human participant against, and deal with all foreseeable possibilities of distress, discomfort, injury, disability or death.
 - h. Only persons having the requisite scientific, technical and/or medical competencies shall conduct the research project. All persons who participate in the study will apply the highest degrees of skill and care during all stages of the study.
 - i. Reasonable steps, to include appropriate background checks, shall be taken to ensure that the participants have no physical or mental conditions or previous exposures which may make participation more hazardous for them than would be the case for a normal healthy person, unless such a condition is a prerequisite for the particular study.
 - j. The Principal Investigator, each member of the investigative team and the Medical Officer shall be prepared and empowered to terminate the participant's involvement at any stage if anyone has reason to believe that continuation is likely to result in unnecessary distress, injury, disability or death.

- k. The importance of free and informed consent will be recognised and promoted at every stage in the research. The participant should be informed in writing and where appropriate through meaningful discussion that they are free to withdraw from the study at any time without blame and without having to give a reason or explanation. Further information including guidance on the subject information sheet and consent form can be found in the “MoD guide to Research involving Human Participants”.
- l. There shall be no greater intrusion into the privacy of the participant than is absolutely necessary for the conduct of the study.
- m. Normally, no experiment will be initiated if there is any reason to believe that such experiments have been done previously and that no important new knowledge or benefit is likely to be obtained. However, replications may be made in exceptional circumstances, e.g. extending previous work where the purpose is to define boundary conditions for future extensions of a research project, or where the results of previous research are required but are not available to the MoD, e.g. because of corporate restrictions on data dissemination.
- n. Prisoners, either of war or any other, will not be used as participants under any circumstances except in the case of social surveys with minimal risk, stress or intrusion, intended to improve their own conditions. These may be submitted and will be considered for ethical approval.

Health & Safety

10 MoD must comply with the document “Safety, Health and Environmental Protection in the MoD, A Policy Statement by The Secretary of State for Defence” and all relevant, current Health & Safety legislation and provide working conditions that would ensure, as far as reasonably practicable, a healthy and safe working environment. Health & Safety criteria apply to all aspects of research and to investigators and participants.

Research Involving Medicines

11 Research involving medicines is regulated under the Medicines Act and the Medicines for Human Use (Clinical Trials) Regulations. All trials of new medicinal products, or new therapeutic approaches using previously-tested medicinal products, on people must be authorised by the Medicines and Healthcare Products Regulatory Agency (MHRA) (contact details can be found in the “MoD Guide to Research involving Human Participants”) who offer advice and undertake advisory inspections for such trials and the preparation of products used in them. There are statutory instructions for Good Clinical Practice in such trials. The same Agency regulates research involving new medical devices. Clinical trials will generally require approval

from a local NHS REC. Research protocols submitted to MHRA must also be submitted to MoDREC.

International Research Collaboration

12 Through its formal arrangements with other nations, MoD conducts some collaborative research programmes involving human participants. These collaborative programmes must undergo ethical scrutiny. Where UK MoD/Armed Forces personnel volunteer to participate in an overseas trial, the host nation's research protocol must be sent, along with the written review of its own ethics committee, to the MoDREC Secretariat for its consideration. No Fault Compensation must be available to MoD/UK Armed Forces personnel in overseas trials for ethical approval to be given.

Use of Schedule of Approved Procedures (SAP)

13 The Schedule of Approved Procedures (SAP) is a schedule of procedures that have been approved by the MoDREC as constituting the experimental limits for non-clinical research using human participants, which can be authorised by the MoDREC Chairman (Vice Chair). Clinical research will generally require approval from a local NHS REC.

14 However should the research proposal involve procedures which are either outside the limits of or not specified in the SAP it will be referred to the MoDREC for scrutiny. If the MoDREC approves the trial or study then the procedure may be added to the SAP at their discretion.

Review procedure to be adopted

15 It is generally acknowledged that decisions relating to ethics are complex and it is impossible to provide generic guidance that will cover all possible issues. The decision as to whether a particular research proposal requires scrutiny and approval by the MoDREC rests with line management who will be held accountable.

Stages of Ethical Review

Research experimenter/ investigator review

17 Experimenters or investigators are to consider ethical issues during the preparation of experimental proposals. However, investigators must not be the sole judges of whether their work conforms to ethical requirements. Advice can be sought via the MoDREC Secretariat.

Management review.

18 The proposal must be reviewed by line management, since research proposals will usually be assessed as part of the normal management process, for example for budgeting or Health and Safety reasons. Line Managers must seek assistance with this task from appropriate members of staff outside the line management chain. If ethical issues are identified within

research proposals then advice may be sought via the MoDREC Secretariat, before a formal submission is made.

Formal ethical review

19 Submission for formal review by the MoDREC should be via the MoD REC Secretariat. If Line Managers need further guidance then they should consult MoDREC Secretariat. All protocols will in the first instance be reviewed for technical rigour by an appropriate Scientific Advisory Capability, details of which will be given by the MoDREC Secretariat.

20 MoD operates a formal no fault compensation scheme, which applies to participating volunteers in research activities covered by this JSP. See Annex B for how to obtain details of the scheme.

Contact details of Secretariat

CSA's Secretariat: science | innovation | technology Secretariat
Poc: SIT Secretariat, MB, 1-K-49, London
e-mail: SIT-Sec or science@mod.uk
'phone: 0207 2182572 or MB 82572

Web Site Address for supporting documents:
<http://samis.defence.mod.uk/csaweb/csaweb/csa.htm>

Details of REC Secretariat to be confirmed.

ARRANGEMENTS FOR THE PAYMENT OF NO-FAULT COMPENSATION TO HUMAN VOLUNTEERS

1. This Annex sets out the arrangements for the payment of no-fault compensation to volunteers who suffer illness and/or personal injury as a direct result of participating as a non-patient (healthy) human volunteer in research conducted on behalf of the Ministry of Defence. The no-fault compensation arrangements only apply to volunteers (Military, Civilian, or non-Ministry of Defence) who participate in a Trial that has been approved by the MoD Research Ethics Committee.
2. A volunteer wishing to seek no-fault compensation under these arrangements should contact the Directorate of Safety & Claims (DS&C) St. George's Court, 2 -12 Bloomsbury way, London, WC1A 2SH who may need to ask the Claimant to be seen by a MoD medical adviser.
3. DS&C will consider reasonable requests for reimbursement of legal or other expenses incurred by volunteers 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 volunteer until the outcome is known and made available to the volunteer in order to inform his or her decision about whether to accept no-fault compensation or proceed with a common law claim. An interim payment pending any inquiry outcome may be made in cases of special need. It is the Claimant's responsibility to do all that he or she can to mitigate his or her loss.
5. In order to claim compensation under these no-fault arrangements, a volunteer must have sustained an illness and/or personal injury as a direct result of participation in a Trial. A claim must be submitted within three years of when the incident giving rise to the claim occurred, or, if symptoms develop at a later stage, within three years of such symptoms being medically documented.
6. The fact that a volunteer 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, DS&C, 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 DS&C 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. DS&C 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.