

MODREC Frequently Asked Questions

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1. Does my research protocol need to be submitted for ethical approval by MODREC?

Not all human research needs ethical scrutiny. For example, there would be no need for ethical approval of an anonymous questionnaire seeking opinion about canteen food. In the case of trialling a new rifle, there would probably be no need for ethical approval unless the research involved studying the effect of the rifle on the individual, for example to assess the effect of the noise on hearing. On the other hand, assessment of a new protective suit in a hot environment would need ethical approval because of the risk of the participant becoming dangerously overheated.

In all cases the guidance given in ‘JSP 536: Ethical conduct and scrutiny in MOD research involving human participants’ must be followed. If you think that your protocol does not need ethical scrutiny it may be helpful to answer the following questions. If any of your answers fall into column A, then you should get advice via the MODREC secretariat as to whether the protocol should be submitted to MODREC.

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

It is the responsibility of you/your line manager to ensure that no research requiring ethical approval is started before that approval has been given; this includes recruiting research participants.

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

the new equipment or technique?		
11. If applicable, are Standard Operating Procedures available for the equipment or system?	NO	YES
12. Can the information collected be linked to individual participants?	YES	NO

If the answers to any questions fall into column A, or if you are in any doubt as to whether ethical approval is necessary, please contact the MODREC secretariat for advice.

2. When can I start the research?

It is very important that the research, including recruitment of participants, does not start prior to ethical approval being given by MODREC. This is in order to conform to accepted ethical principles and because the MOD No-Fault Compensation scheme does not apply until the protocol has been approved by MODREC.

3. What is the Schedule of Approved Procedures?

If the proposed research procedures fall within the scope of the Schedule of Approved Procedures (SAPs) and the participants are not less than 18 years old, ethical approval can be given on behalf of MODREC by its chairman or vice-chairman following scrutiny by the appropriate Scientific Advisory Committee. Ex-committee approval of such protocols will be reported at the next MODREC meeting.

This system allows low risk protocols to be approved more quickly than if they had to wait for the next MODREC meeting. The SAPs are reviewed annually by MODREC and so it is important to be sure you have downloaded the most recent version, as procedures may be added to or subtracted from the list.

4. What is the MoD No-Fault Compensation scheme?

Under the MOD No-Fault Compensation scheme (NFC) no-fault compensation is paid to volunteers who suffer illness and/or personal injury as a direct result of participating as a non-patient (healthy) volunteer in research conducted on behalf of the Ministry of Defence. The NFC arrangements only apply to research participants (Military, Civilian, or non-Ministry of Defence) who take part in a study that has been approved by MODREC, so it is very important that research (including recruitment of participants) requiring ethical approval does not start before this approval has been obtained.

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.

Note that NFC only applies to healthy volunteers and so is not available to patients taking part in clinical protocols. NFC is not routinely available to patients taking part in research within the NHS. For clinical research you need to consider whether other compensation arrangements should be made.

5. Are researchers covered by the no-fault compensation arrangement?

No, researchers are not covered by no-fault compensation agreement

6. In the case of clinical protocols do I need to get NHS REC approval as well?

1. Both MODRECs have authority to undertake phase I, II and III Clinical Trials of Investigational Medicinal Products (CTIMPS) involving participants recruited through the Armed Forces.
2. The MODRECs are considered by the UK Health Departments to be an appropriate source of ethical review for other health and social care research involving participants recruited through the Armed Forces.
3. Where such research has received a favourable opinion from MODREC, there is no requirement for separate ethical review by a REC within the UK Health Departments' Research Ethics Services where research procedures continue within care organisations for which the UKHDs are responsible, for example following the transfer of wounded service personnel to NHS care.
4. The MODRECs are already authorised to review device trials. Medical device trials only fall under the Medical Devices Regulations where there are investigations conducted by the manufacturer to produce data on safety and performance for CE (Conformité Européene) marking purposes, or where the manufacturer has modified the device or plans to use it for a new purpose which would alter its CE marking.
5. Research involving incapacity to consent – for Clinical Trials of Investigational Medicinal Products (CTIMPs), the Mental Capacity Act does not apply since the Clinical Trials Regulations already deal with CTIMPs involving people who lack the capacity to consent to their participation.
6. The MODRECs are recognized under the Mental Capacity Act to review research within the scope of the Act. This Act extends only to England and Wales, similar legislation having already been passed in Scotland in the form of the Adults with Incapacity (Scotland) Act 2000. This means that if, for example, a participant who lacked capacity

was followed up in Scotland, then ethical approval would have to be sought from the Scotland A Research Ethics Committee in Edinburgh.

7. When does ethical approval need to be sought from another REC?

If you are a student then your university may require you to submit your protocol to its own REC. If so, there is no need to obtain this before applying to MODREC. Research within the NHS, involving NHS staff or premises, will normally require NHS REC approval unless the patients have been recruited to the study while under the care of MOD. For example, if a military casualty is enrolled in a clinical trial in Afghanistan and then transferred to Selly Oak hospital where further assessment takes part in accordance with the research protocol, MODREC approval on its own is sufficient.

A useful link is: <http://www.nres.npsa.nhs.uk/>

8. Can I appeal against the decision made by MODREC?

Yes. We are always happy to reconsider any decision especially if there is new information that can be taken into account. In the first instance it is best to contact the MODREC chairman (see Contacts). If the problem is still not resolved then appeal can be made via the Secretariat to the other MODREC (in the case of an application to MODREC (Gen) the appeal would be determined by MODREC (PPE) and vice versa).

9. Do I need to submit progress reports?

A progress should be sent to the MODREC Secretariat (ethics.sec@dstl.gov.uk) annually. This can be brief – half a page may well be sufficient. A copy of your final report needs to be submitted on completion of the project.

10. How do I get help?

The Scientific Advisory Committees (SACs) and MODREC are here to help you to achieve ethical approval. You may need some informal advice before submitting your protocol, help with responding to points raised by the SACs or MODREC etc. We are here to assist so please get in touch – see contacts.

11. What is the ‘fast track procedure’?

If there is a protocol that would normally be considered at a MODREC meeting but needs to be processed more quickly than that would allow then the fast track procedure may be used. A one star letter needs to be submitted explaining the request, for example operational urgency. The protocol will then be sent to the appropriate Scientific Advisory Committee (SAC) for urgent review. Once SAC approval has been obtained ethical review will be provided by three

members of MODREC.

12. What do I do if the protocol is ‘restricted’?

In this case it will need to be posted to the Secretary, but in case it gets lost please make sure that any protocols posted are sent by registered post.

13. How do I track progress?

Even e-mails can go astray so you must make sure that you receive acknowledgement of all your communications. If the delay is more than you are expecting please contact the Secretary (see Contacts).

14. Do I need MOD authorisation?

Yes. For example if you are carrying out research on MOD personnel you must have permission from MOD. For many protocols the funding is coming from MOD so it is aware of the study, but you may need further authorisation, for example from the commanding officer of military personnel whom you are hoping to recruit. If you are not employed by MOD and MOD is not funding your research you need to be especially careful about having the required permissions.

15. Are there Terms of Reference for MODREC?

They can be found at MODREC TORs.

16. Where can I find further information about the ethics of human research?

The National Research Ethics Service (NRES) provides extensive guidance including links to other sites - www.nres.npsa.nhs.uk

17. Are there any exceptions for operations?

No, there are no exceptions for operations

18. Do External MSCs require ethical approval?

External MSCs only require approval if they use MOD personnel or research is specific to operations

19. What are the Data Protection Act implications for research?

This answer is in preparation, email ethics@mod.uk in the interim

20. Is MOD approval required for publication of research?

Yes, existing MOD publication rules apply

21. When should I advise MODREC of any adverse effects that occur?

You are required to notify MODREC via the secretariat of any adverse events that occur during the research at the earliest possible opportunity - ethics.sec@dstl.gov.uk.

22. What do I do when I've completed the research?

Once the research is complete, you must provide MODREC, via the secretariat (ethics.sec@dstl.gov.uk), with a closure report.

23. Who do I contact about formal amendments to extant approved protocols?

You must contact the secretariat if these are required (see – Contacts)