**Application No :** XXXX/MODREC/XX

**Ministry of Defence Research Ethics Committee (MODREC)**

**MODREC Application Form**

Sixth Issue - V3.1

 **Application No :** XXXX/MODREC/XX

**MODREC Application Form**

Sixth Issue - V3.1

**Follow the guidance below on how to complete and submit the application form:**

**APPLICATION COMPLETION:**

1. Populate **ALL** sections (unless you are certain it is not relevant), in which case state why.
2. Delete all blue guidance text.
3. Complete the Research Sponsors checklist at Appendix 1.
4. Append **ALL** supporting documentation **within** the application (see Section 23).
5. Create a **separate document** that contains the CVs (ideally 2-page short-form) of all investigators listed in Section 4. Include the Independent Medical Officer’s CV (if relevant), and ideally the CV of the Volunteer Advocate (if relevant).
6. Guidance for researchers can be found within JSP 536, Part 2, here [Defence research involving human participants (JSP 536) - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/defence-research-involving-human-participants-jsp-536)

**APPLICATION SUBMISSION:**

1. Once the application is completed in full, email this along with the CVs to the relevant Scientific Assessment Committee (SAC), for scientific review. SAC contact details can be found here - [Ministry of Defence Research Ethics Committee - GOV.UK (www.gov.uk)](https://www.gov.uk/government/groups/ministry-of-defence-research-ethics-committees#contacts).
2. Once approved, the SAC will forward the application to the MODREC Secretariat (DST-MODRECTeam@mod.gov.uk), to undergo an ethics review.
3. Study Title (including any abbreviated titles)

*Please insert the title of study along with any additional abbreviated / simplified titles if necessary*

1. Version History

*Insert further rows for additional amendments*

| **Version** | **Number** | **Date** |
| --- | --- | --- |
| SAC Approved  |  | *Add SAC name* |  |
| MODREC Favourable Opinion |  |  |
| Amendment 1 etc |  |  |

1. Summary of Project

*Please include no more than one page, summarising the rationale, aims and methods*

1. Investigators

*In a separate document, please provide a short-form professional CV(no more than two page) for the Chief Investigator, each named Investigator and the Independent Medical Officer (if applicable), or the Volunteer Advocate (ideally, if applicable)*

|  |
| --- |
| **4a. Chief Investigator****Name and Title:**      **Grade/Rank:**      **Post Title:**      **Department:**           **Address:**      **Telephone:**      **Email:**      **4b. Does this project contribute towards a qualification?** Yes/No.**Type of qualification:**      **Research Supervisor:**      **Post Title:**      **Department:**      **Address:**      **Telephone:**      **Email:**      **4c. Other Investigators/Collaborators/External Consultants**     **4d. Name of the Volunteer Advocate or Independent Medical Officer** *An individual must be listed for this role as they are an independent point of contact for research participants. It is essential that a CV is provided for Independent Medical Officers. Ideally a CV would be provided for the Volunteer Advocate. However, as a very minimum, describe the Volunteers Advocate’s normal role and their relationship to the participants*     **Address:****Telephone:**      **Email:**     |

1. Research Sponsor

*Please ensure the Research Sponsor checklist has been completed at Appendix 1.**Your Sponsor should be Cc’d into the email that is submitted to the SAC. As per JSP 536, please ensure you have your Sponsor’s approval before the MODREC application is submitted, as they are ultimately responsible for the work. If your Sponsor is non-MOD, then your MOD authoriser (see Appendix 1, row 4g) should also be Cc’d into email to the SACs*

|  |
| --- |
| **Research Sponsor (the organisation):****Research Sponsors Representative (named individual):**       **Title / Rank / Grade:**      **Position:**   **Address:**      **Phone Number:**      **Email:**       |

1. Preferred Timetable

|  |
| --- |
| **6a. Preferred Start Date:** *The ethics review process via MODREC will typically take around 2 months. However, in addition to this, you also should factor in the time it takes to undergo Scientific Assessment Committee (SAC) review, prior to MODREC, as well as the time it takes to respond to revisions that are required throughout the entire review process* **6b. Expected Date of Completion:**      |

1. Other Organisation(s) Involved and Funding

|  |
| --- |
| **7a. Department / Organisation Requesting the Research (if applicable):****7b. Department / Organisation Undertaking the Research:**     **7c.If you are receiving funding please provide details here:** *All research is funded either externally, through internal funds, or in kind. Please describe the source of funding and any contractual obligations. Where relevant, say what measures you will take to avoid any undue influence from funders or sponsors over the independence and integrity of data analysis, reporting or presentation of the research results. Please also ensure that all participants or external organisations involved in the research / work are aware of the source of funding e.g. in the Participant Information Sheet. If the funder has specifically requested evidence of ethics review please also describe their requirements here and attach any relevant guidance as an appendix if applicable. This is to help MODREC ensure they provide the review with the evidence you need.*      **7d. Please declare any potential conflicts of interests:**      **7e. Type of research:** *Please select one and delete the rest*1. Student (psychological/social survey)
2. Student (physiological/medical/clinical)
3. Student (other)
4. Psychological/social survey
5. Physiological/medical/clinical
6. Equipment
7. Other, please describe:
 |

1. Scientific Assessment Committee (SAC) Approval

|  |
| --- |
| **8a. Name of SAC that has reviewed / approved this application:** *All research must have undergone scientific review and approval by a SAC prior to MODREC submission.*      **8b. Date of SAC approval:**      **8c. SAC reference number:**      |

1. Purpose of the Study and Defence Benefit

*Please provide no more than two pages outlining the purpose of the study, referencing any previous work in this area to justify the study aims, describing how the results of the study will be used, and how this work will benefit the Ministry of Defence.*

1. Study Design, Method and Data Analysis

*Please include the overall method / design and analysis; any pre-study and post-study procedures; provide a brief summary of the nature of the participants’ involvement; describe the statistical methods and / or any other relevant techniques (e.g. for qualitative research) to be used in the analysis of the results and state from whom data analysis advice has been sought; any study restrictions; withdrawal procedures and codes of conduct for undertaking this study; if the study is collaborative or incorporates the involvement of another organisation the responsibilities of each party should be explained.* ***Please keep this section concise and certainly no more than six pages.***

1. Safety

| **11a. Explain the safety of the research be managed?**     **11b. Who is the named person taking responsibility for the overall safety of the research? In addition, who is the named person that will be responsible for day-to-day safety of the research?**     **11c. Explain the researchers conducting this study be made aware of:*** + 1. **Their responsibilities for reporting any new safety issues which arise after the start of the project, and**

**ii. Their responsibilities for reporting adverse events in the conduct of the project?** |
| --- |

1. Ethical Considerations and Research Integrity

| **12a. Ethical Considerations:***Please list any anticipated ethical issues and describe how you will address them.**All projects will have ethical issues such as requirement for informed consent, potential conflicts of interest, handling confidential data etc.*    **12b. Confirm that you have read the MOD the policy on Research Integrity (JSP 732 – see here,** [Research integrity (JSP 732) - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/research-integrity-jsp-732)**), and you agree to abide by this directive.** Yes/No.    |
| --- |

1. Participants

| **13a. Number of Participants:**      **13b. Lower Age Limit:** *Please note, in the UK, the legal age of consent is 16 years of age, meaning that if 16 and 17 year-olds are represented within the target participant population, MODREC would expect this group to be included in the study*      **13c. Upper Age Limit:**      **13d. Sex *or* Gender ratio (please state which):***Please note, MODREC would expect to see study samples that represent the target population, which has implications for the recruitment of women / females. For some studies biological sex is the relevant parameter, and others it is gender.***13e. Please provide a brief justification for the choice of sample** *Provide details of the power calculation where appropriate* |
| --- |

1. Selection Criteria

| **14a. List your participant inclusion criteria:***It is suggested that the study inclusion criteria is also detailed in the Participant Information Sheet***14b. List your participant exclusion criteria:***Please note this is not the opposite of your inclusion criteria, rather these should be additional exclusions that may apply once the inclusion criteria have been applied* |
| --- |

1. Recruitment

| **15a. Describe how potential participants will be identified:**     **15b. Describe how potential participants will be approached:**     **15c. Describe how potential participants will be recruited:** |
| --- |

1. Consent

| **16a. Describe the process you will use when seeking and obtaining consent:**     **16b. Do you plan to include participants who are children (under 16 yrs)?** Yes/No. *If yes, please give details of how you will gain relevant consent and/or assent.*          **16c. Do you plan to include participants who lack capacity to consent?** Yes/No.*If yes, please give details of how you will gain relevant consent or consultee advice.*     **16d. Do you plan to include any prisoners?** Yes/No. **16e. Are there special pressures that might make it difficult for people to refuse to take part in the study (e.g. subordinates)?** *Please explain how you will address these issues* |
| --- |

1. Participant Involvement: Risks, Requirements and Benefits

| **17a. Describe potential hazards, risks or adverse effects that may be associated with the study?**      **17b. Will pregnant or nursing mothers be included?** Yes/Yes - Possibly/No.*If no, please describe your pregnancy screening process. If not screening for pregnancy but women are included in the study then state ‘Yes, possibly’. Please note the method used to screen for pregnancy depends on the risks to a pregnant/nursing mother inadvertently being involved. For a drug study this may require repeated blood tests, whereas for a questionnaire study self-declaration may be appropriate.*    **17c. Does your study involve invasive procedures such as blood taking, muscle biopsy or the administration of a medicinal product?** Yes/No.*If yes, please provide details and indicate the experience of the investigators in the use of these invasive procedures*     17d. If medical devices are to be used on any participant, do they comply with the requirements of the Medical Devices Directives?**17e. Does your study involve the exposure of participants to ionising radiation (e.g. Dual-Energy X-ray Absorptiometry measurements (DEXA), Peripheral Quantitative Computed Tomography scans (pQCT), administration of radiopharmaceuticals etc.)?** Yes/No.* + 1. ***If yes, please add details below, and provide confirmation that a review has been undertaken and approved from a Medical Physics Expert (MPE) and Clinical Radiation Expert (CRE). Note, that the Defence Consultant Advisor in Radiology may provide a CRE review. It is recommended that the MPE and CRE are involved at the earliest stages to ensure any exposures are Justified.***

     **17f. List the locations or sites where the work will be undertaken:**     17g. Are there any other research studies being performed at the locations / sites listed at para. 17f at the same time as this study? Yes/No/Unknown* + 1. If yes (to the above), is the Unit Chain of Command aware of and approved these potentially concurrent research activities? Yes/No/Unknown.
		2. If yes (to the above (17g / 17g.i)), what mitigations have been put in place to ensure research participants are not overburdened, and that the studies do not interfere with each other?

17h. Will group or individual interviews / questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting? Yes/No.*If so, please list these topics and explain how you will prevent, or respond to potential participant distress*     **17i. Is it possible that criminal or other disclosures requiring action (e.g. evidence of professional misconduct), could be made during the study?** Yes/No.*If yes, give details of what procedures will be put in place to deal with these issues*     **17j. Describe any expected benefits to the research participant:** *If none, state none.*     17k. Under what circumstances might a participant not continue with the study, or the study be terminated in part or as a whole? |
| --- |

1. Financial Incentives, Expenses and Compensation

| **18a. Will travel expenses be given?** Yes/No.*If yes, please give details*     **18b. Is any financial payment or other reward, apart from travel expenses, being offered to participants?** Yes/No.*If yes, please give details and justification*      **18c. Has payment of the Experimental Test Allowance (ETA) been considered for UK Service Personnel (see - JSP 752, chap 10 section 3, here** [JSP 752 -Tri-Service regulations for expenses and allowances - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/jsp-752-tri-service-regulations-for-expenses-and-allowances)**) ?** Yes/No.*Please note, ETA is only applicable to UK Service Personnel. If you answered ‘Yes’, please provide a summary of the ETA amount. If you answered ‘No’, please provide justification for this decision*18d. Is this a study in collaboration with a commercial organisation? *For example, pharmaceutical company or an equipment or device manufacturer. Please give the name of the company and describe any real or potential conflicts of interest.* |
| --- |

1. Confidentiality, Anonymity and Data Storage

| **19a. What steps will be taken to ensure participant confidentiality?** *Please note that ‘confidentiality’ refers to how personal data will be handled, shared and stored. Personal data is defined by UK GDPR and includes link-anonymised data. Additional safeguards also need to be in place if special category data (e.g. medical records) are to be used. You should discuss these issues with your Data Protection Officer before filling in this section*      19b. Give details of any anonymisation procedures (if applicable)*Anonymous data refers to data that cannot be linked to any individual (living or dead) and thus falls outside of UK GDPR legislation. However, please note that anonymisation goes beyond simply removing names or using an identifier or code (link anonymisation).* **19c. Who will have access to the records and resulting data?**     **19d. Where, and for how long, do you intend to store the Consent Forms and other**  **records?** *Please describe how this will be undertaken in accordance with the Organisation’s Data Protection Policy.***19e: Have the Participant Information Sheet(s) and Consent Form(s) been reviewed and confirmed to be Data Protection Act 2018/UK GDPR compliant in accordance with your organisational arrangements?** Yes/No. |
| --- |

1. Participant Information Sheet

***Please write the Participant Information Sheet (PIS) in lay language and avoid the use of technical terminology***

***Please use this template, or alternatively ensure that all the headings below are included in your version of the PIS***

| **Study title:**   **MODREC Application No:** XXXX/MODREC/XX  **Invitation to take part:** *Explain briefly what this form is about why the potential participant has received it*     **What is the purpose of the research?***Please include a simple overview of the research, no more than a couple of paragraphs*     **Who is doing this research?** *MOD involvement and any funding should be mentioned.*     **Why have I been invited to take part?** *List the inclusion criteria (if relevant)*      **Do I have to take part?**No, participation is entirely voluntary. **What will I be asked to do?***Explain clearly and simply, exactly what participants will be asked to do, and the time commitment involved. A table can be helpful if the study is long or complex*     **What is the device or procedure that is being tested?** *Delete if not applicable*     **Are there any direct benefits to me of taking part?** *Often there are not any direct benefits to the participants. If this is the case, say so. Benefits do not include those experienced by the research(er), or the organisation.*      **What are the possible disadvantages (or risks) of taking part?** *Explain any known or anticipated risks or disadvantages to taking part, which could relate to the participants health (physical / psychological), and / or career. If there are none, say so.*     **Can I withdraw from the research and what will happen if I withdraw?** *Confirm that participants can withdraw at any time without giving a reason. Explain whether or not the data provided up to the point of withdrawal can also be withdrawn, and if it cannot (for instance if data analysis has already begun) ensure there is a consent item that states this.*     **Will I receive any expenses or payments?** *Advise if any payments / reasonable expenses will be paid; explain the payment scale if the participant withdraws before completing the study. If the Experimental Test Allowance is being paid, explain what constitutes a test; advise that payment will be made in their pay and is subject to tax and NI contributions. Explain the maximum and minimum amounts to be paid*     **Will my taking part or not taking part affect my career?** *In particular, consider the potential career effects to uniformed participants (military / police), should the previously detailed risks emerge*      **Who do I contact if I have any questions?** *Typically, this should be the Chief Investigator – see section 4a*Name: *Ensure any reference to military rank is removed*      Address:      Tel No:      Email:      **Who do I contact if I have a complaint?***Typically, this should either be the Volunteer Advocate, or Independent Medical Officer who are independent of the study – see section 4d*Name: *Ensure any reference to military rank is removed*      Address:      Tel No:      Email:      **What happens if I suffer any harm?**If you suffer any harm as a direct result of taking part in this study, you can apply for compensation under the MOD’s No-Fault Compensation Scheme.**What will happen to any samples I give?** *Delete if not applicable*     **Will my records be kept confidential?** *This should comply with your organisational data protection policy. This is the best place for any required GDPR text*     **Who has reviewed the study?**This study has been reviewed and given favourable opinion by the Ministry of Defence Research Ethics Committee (MODREC).**Further Information and Contact Details***Typically, this might be the Chief Investigator*Name : *Ensure any reference to military rank is removed*    Address :      Tel No :      Email :      **Compliance with the Declaration of Helsinki**This study will be conducted in accordance with the principles defined in the Declaration of Helsinki [[1]](#footnote-2) as adopted at the 64th WMA General Assembly at Fortaleza, Brazil in October 2013. |
| --- |

1. Consent Form for Participants in Research Studies

***Please use this Consent Form template and tailor the consent items specifically to your study. It is fine to delete, add to, or edit the statements below. Alternatively, if you plan to use a different consent form template, please ensure that you have considered each of the below items for possible inclusion in your form.***

|  |
| --- |
|  |
| Title of Study:       **MODREC Reference:** XXXX/MODREC/XX |
|  | Please Initial or Tick Boxes |
| * + - 1. The nature, aims and risks of the research have been explained to me. I have read and understood the Participant Information Sheet and understand what is expected of me. All my questions have been answered fully to my satisfaction.
 |  |  |  |
| * + - 1. I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and be withdrawn from it immediately without having to give a reason. I also understand that I may be withdrawn from the study at any time by the research team. In neither case will this be held against me in subsequent dealings with the Ministry of Defence.
 |  |  |  |
| * + - 1. I understand that the screening process to decide if I am suitable to be selected as a participant may include completing a medical screening questionnaire and/or a physical examination by a Medical Officer and I consent to this*.*
 |  |  |  |
| * + - 1. I consent to the processing of my personal information for the purposes of this research study. I understand that such information will be treated as confidential and handled in accordance with the provisions of the Data Protection Act 2018 and UK GDPR.
 |  |  |  |
| * + - 1. This consent is specific to the particular study described in the Participant Information Sheet and shall not be taken to imply my consent to participate in any subsequent or future study / data analysis or deviation from that detailed here.
 |  |  |  |
| * + - 1. I understand that in the event of my sustaining injury or illness as a direct result of participating as a volunteer in this research, I or my dependants may enter a claim with the Ministry of Defence for compensation under the provisions of the No-Fault Compensation Scheme, details of which are attached.
 |  |  |  |
| * + - 1. **I agree to participate in this study.**
 |  |  |  |
| Participant’s Statement:I **……………………………………………………**agree that the research project named above has been explained to me to my satisfaction, and I agree to take part in the study. Signed : Date:           |
| Investigator’s Statement:I **……………………………………………………**confirm that I have carefully explained the nature, demands and any foreseeable risks of the proposed research to the Participant.Signed : Date: |
| **Contact Details of Chief Investigator:** Name: *Ensure any reference to military rank is removed*      Address:      Tel No:      Email:  |
| **Contact Details of Independent Medical Officer or Volunteer Advocate:** *if appropriate* Name: *Ensure any reference to military rank is removed*      Address:      Tel No:      Email:       |
|       |

1. Arrangements for the Payment of No-Fault Compensation to Participants in Studies That Received a MODREC Favourable Opinion[[2]](#footnote-3)

|  |
| --- |
| 1. The MoD maintains the 'No Fault Compensation Scheme' specifically for the payment of no-fault compensation to, or in respect of, a volunteer who suffers illness and/or personal injury as a direct result of participating in research conducted on behalf of the MoD. The no-fault compensation arrangements apply to research participants (Military, Civilian, or non-MoD) who take part in a trial that has been approved by the MoD Research Ethics Committee.
2. A research participant wishing to seek no-fault compensation under these arrangements should contact the Directorate of Judicial Engagement Policy, Common Law Claims 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 (eg. 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 approved 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 King’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**1. **Compensation for Service Personnel.** Service personnel who took part in studies before 06 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,[[3]](#footnote-4) as are details of the claim’s process.
2. In the event of service personnel suffering injury or disability as a result of their participation in MoDREC approved MoD research on or after 06 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,[[4]](#footnote-5),[[5]](#footnote-6) and are also available on the DBS-Vets website.[[6]](#footnote-7) Claims should be made to DBS-Vets following the instructions available on the MoD Intranet and DBS-Vets website.
3. In the event of service personnel suffering injury or disability as a result of their participation in MoDREC approved MoD research which is sufficiently serious for subsequent medical discharge from the services, their medical records will automatically be forwarded to DBS-Vets for consideration of compensation and pension enhancements [[7]](#footnote-8) 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.
4. However, if either a Service person or their dependants receive payment under the MoD 'no fault compensation' arrangements (or as the result of a common law compensation claim) for the same condition as that for which a pension is received, any pension entitlement may be reduced since compensation should not be paid twice for the same injury, disability or death.
5. **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 approved MoD research, their dependants may be entitled to receive benefits.
6. **Common Law Compensation.** If a research participant or their representative believes that injury, disability or death was caused by the negligence of the MoD or its staff, and do not wish to pursue the possibility of a 'no-fault' compensation payment, a common law claim for compensation should be submitted to Directorate of Judicial Engagement Policy, Common Law Claims & Policy (DJEP-CLCP) (at the address in Para 2 above) detailing the full facts of the claim and stating that common law compensation is being sought.

**Multinational/Multicentre Research and Research Involving Other Government Departments**15. When MoDREC is involved in studies which involve Departments other than the MoD there may be a requirement for specific Compensation Arrangements on a study by study basis. |

1. Supporting Documentation

|  |
| --- |
| List and provide the titles of all appendices: *Note appendices 1 to 3 are common to all applications** Appendix 1 – Research Sponsors checklist.

*If the Research Sponsor is not from the MOD, provide additional, explicit, written approval from an individual within the MOD at a minimum rank / grade of OF5 / B2 level** Appendix 2 – List of acronyms.
* Appendix 3 – List of references.

**Please add the applicable appendices from the list below within this application. Delete accordingly:*** Appendix X – Explicit, written approval from an individual within MOD at a minimum of OF5 / B2 level.

*This is not applicable if there is a MOD Sponsor. See Appendix 1** Appendix X – Inclusion of introductory letters / recruitment emails / posters / press advertisements.

*It is likely that most studies will require these** Appendix X - Letter to general practitioners.

*This might be required if, unexpected, incidental medical findings of concern emerge** Appendix X - Letter to parents / guardians.
* Appendix X - Letter of other research ethics committee opinion or other approvals.

*It is not necessary to add any ethics approvals gained Universities, as MODREC is the authoritative Research Ethics Committee. You may wish to add SAC approval here** Appendix X - Details of MHRA approval and/or correspondence.
* Appendix X - Inclusion of questionnaires / topic guides / interview questions / subjective rating scales.

*If you are using an electronic questionnaire you may have to convert the questions and ratings scales into a MS Word format** Appendix X - Evidence of permission from organisation where research is to be conducted.

*This could be a military unit, hospital, or university** Appendix X - Clinical Radiation Expert (CRE) assessment of the justification of the participants’ radiation exposure.

*This must be included when a study involves the use of radiological procedures (including DEXA Scanning), or radioactive materials – see Section 17e** Appendix X - Medical Physics Expert (MPE) assessment of the risks to participants.

*This must be included when a study involves the use of radiological procedures (including DEXA Scanning), or radioactive materials – see Section 17e* Please list any separate documents that you are submitting to support this application: *Add accordingly** CVs of named investigators.
* CV(s) of supervisor(s).
* CV of Volunteer Advocate or Independent Medical Officer.
 |

**Appendix 1. Research Sponsors Checklist**

***Definition:***

The “Research Sponsor” is a distinct role from the “Research Funder” even if in many cases the two may be the same organisation. The Research Sponsor’s role is to take legal responsibility for the conduct of the research and acts as an additional point of contact should any concerns be raised by regulators, professional bodies or members of the public

**Additional Guidance for Research Sponsors**[[8]](#footnote-9)

1. MOD expects that an organisation that agrees to sponsor research (i.e. acts as Research Sponsor) at any level is confident in its ability to meet the responsibilities as laid down in JSP 536 (which is harmonised with the UK Policy Framework for Health and Social Care Research[[9]](#footnote-10)). Research Sponsors who are not confident in all aspects of the role may use a contract research organisation (CRO) to perform one or more of the Research Sponsor’s activities in order to achieve the requirement. Along with providing assurances as to the quality and feasibility of the research, meeting these standards will also ensure that any research falling under statutory regulations (e.g. Clinical Trial Regulations, Mental Capacity Act, Human Tissue Act etc.) comply with the relevant legislation.

2. Authority to represent the Research Sponsor is normally delegated to University or NHS Research and Development offices, or within the MOD, to administrative units overseen at the minimum of OF5 / B2 level. The individual representing the Research Sponsor and the Chief Investigator cannot be the same person. The following checklist may be helpful to individuals asked to sign-off on behalf of the Research Sponsor for a piece of research.

3. Single Services, MOD Organisations and TLBs have Scientific Assessment Committees (SACs) that support the Research Sponsor in ensuring the appropriateness and scientific quality of the research. Where an organisation does not have a SAC they are required to have arrangements in place with an established SAC to ensure scientific review.

4. The Research Sponsor is also responsible for ensuring that appropriate consideration has been given to issues such as the security classification of the research work, liaising with MOD security personnel as required. There must also be data handling procedures in place that comply with current UK legislation and guidance from the Information Commissioner’s Office. Advice can be sought from organisations data protection officers to ensure compliance.

|  |  |
| --- | --- |
| **Title of Research:** |  |
| **Name of Chief Investigator:** |  |
| **Research Sponsor (organisation):** |  |
| **Name and position of Research Sponsor’s representative:** |  |
| **Responsibility** | **Achieved? (Y/N)** |
| a. The research has been assessed by a SAC and is suitably designed, and the protocol/ethics application is of a suitable standard (as outlined in JSP536, Part 2, Chapter 2). This includes: |  |
| 1. The research takes into account the literature including systematic reviews of relevant existing research evidence and other relevant research in progress. |  |
| 2. Where appropriate, makes use of patient and public involvement. |  |
| 3. The methods are scientifically sound (e.g. demonstrated through independent expert review), safe, legal and feasible, and remain so for the duration of the research, taking account of developments while the research is ongoing. |  |
| 4. The research output is relevant to MOD, its partners or Other Government Departments. |  |
| b. The investigators, research team and research sites are suitable and appropriate contracts are in place for the duration of the research project. |  |
| c. The 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. Adequate provision has been made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project. |  |
| e. Appropriate arrangements for making data and tissue accessible (with adequate consent and privacy safeguards) are in place after the research has finished. |  |
| f. Arrangements are in place for review by MODREC (if required) and any other relevant approval bodies before the research begins.  |  |
| g. Where the Research Sponsor is not the MOD, the research has explicit written approval from an individual within MOD at the minimum of OF5 / B2 level. |  |
| h. Regulatory and practical arrangements (such as risk assessments, security assessment and data protection arrangements) will be in place before the research to begins. |  |
| i. Adequate finance and management arrangements for the research are in place including competent risk and data management.  |  |
| j. 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. Projects are registered, disseminated and reported appropriately. |  |

In addition to the above, Research Sponsors of clinical trials of investigational medicinal products have particular legal duties – see https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/. It is recommended that any research falling under the Clinical Trials Regulations are conducted in collaboration with an established Clinical Trials Research Unit.

**Note: regarding student research**

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

(JSP 536 Part 1 Chapter 3 paragraph 13)

Appendix 2: List of Acronyms

Appendix 3: List of References

***Other Appendices - delete / add accordingly. Each appendix should begin on a new page***

**Appendix X: Explicit, written approval from an individual within MOD at a minimum of OF5 / B2 level.**

**Appendix X: Inclusion of introductory letters / recruitment emails / posters / press advertisements.**

**Appendix X: Letter to general practitioners.**

**Appendix X: Letter to parents / guardians.**

**Appendix X: Letter of other research ethics committee opinion or other approvals.**

**Appendix X: Details of MHRA approval and/or correspondence.**

**Appendix X: Inclusion of questionnaire / topic guide / interview questions.**

Appendix X: Evidence of permission from organisation where research is to be conducted.

Appendix X - Clinical Radiation Expert (CRE) assessment of the Justification of the Participants’ radiation exposure.

Appendix X - Medical Physics Expert (MPE) assessment of the risks to participants.

1. World Medical Association Declaration of Helsinki [revised October 2013]. Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects. 64th WMA General Assembly, Fortaleza (Brazil). [↑](#footnote-ref-2)
2. Section agreed with DJEP-CLCP Dep Hd 28/10/13. [↑](#footnote-ref-3)
3. <http://www.veterans-uk.info/pensions/wdp_new_index.html> [↑](#footnote-ref-4)
4. DIN <http://defenceintranet.diif.r.mil.uk/libraries/corporate/DINS%20Archive/2008/01102RestrictDINs.pdf> [↑](#footnote-ref-5)
5. Armed Forces Compensation Scheme - Statement of Policy. <http://defenceintranet.diif.r.mil.uk/libraries/library1/DINSJSPS/20110714.1/974_AFCS_Statement%20of%20policy4.pdf> [↑](#footnote-ref-6)
6. <http://www.veterans-uk.info/pensions/afcs_new.html> [↑](#footnote-ref-7)
7. <http://www.veterans-uk.info/pensions/med_discharge.html> [↑](#footnote-ref-8)
8. Adapted from “HRA Expectations of Sponsors” <https://www.hra.nhs.uk/documents/794/sponsors-expectations.docx> (accessed 5 Dec 19). [↑](#footnote-ref-9)
9. <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/> (Accessed Nov 2019). [↑](#footnote-ref-10)