Defence and Security
Accelerator

MODREC GUIDANCE FOR SUPPLIERS

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Introduction

This document seeks to address and assist in the decision making of whether or not to apply for a MOD Research Ethics Committee (MODREC) review.

Within The Ministry of Defence (MOD), scientific quality is reviewed by a Scientific Assessment Committee (SAC) and ethics review is provided by the MODREC.

MODREC is an independent body comprising of non-MOD (expert and lay) members supported by appropriate MOD advisers. MODREC is commissioned to review research projects involving human participants. It safeguards the rights, dignity and welfare of individuals volunteering to participate in research studies. They ensure that all research involving human participants either undertaken, funded or sponsored by MOD meets nationally and internationally accepted ethical standards.

Detailed information on the structure of MODREC and guidance documentation can be found on MODREC's Official Website.

This document has been designed to act as a straightforward guide to determine whether a MODREC Review will need to be obtained before research can commence. If more detailed information is required, all researchers should familiarise themselves with the Joint Service Publication 536 (JSP536), which details the policy, direction and guidance on the processes to follow.

A MODREC review is not required to submit a proposal to DASA. However, during the assessment stage, it is worth considering whether the work proposed meets the definition of research (see below). It is also worth checking whether it also meets the criteria for research involving human participants requiring ethical oversight as not all research will require a MODREC review. This document seeks to address and assist in the decision making of whether or not to apply for MODREC review.

If it is determined that a MODREC review will be required, please ensure that the review process has begun early enough so there is no delay in awarding contracts. This should then be allowed for in the project timeline. The combined SAC and MODREC processes **can take three months** and happen sequentially. The SAC cannot approve the application for submission to the MODREC until the contract has been awarded as both committees require assurance that the funding is available.

The templates referred to throughout the document need to be utilised in the event that a MODREC review is required. This is a scientific approach and marketing information will not have the desired level of complexity required for a MODREC review.

Roles and Responsibilities

There must be clear designation of responsibility and accountability, with clear lines of communication between all those involved in human research. The table below has been included to give an overview of each of the roles that will be involved. For more details on each, please refer to JSP 536, Governance of Research Involving Human Participants, Part 1: Directive.

Role	Responsibility
Chief Investigator (CI)	The CI is the overall lead researcher for a research project and normally the lead author of the research protocol. The CI is responsible for the overall conduct of a research project. **The CI and Research Sponsor have joint responsibility for deciding if a piece of work requires ethical oversight.**
The Research Team	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.
Funder	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.
Research Sponsor[1]	The Research Sponsor is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. **For MOD funded projects**, MOD is the Research Sponsor and the relevant Programme Manager will take on the role of Research Sponsor on behalf of MOD. The Research Sponsor and CI have joint responsibility for deciding if a piece of work requires ethical oversight.
Research Sites	Research sites are the organisations with day-to-day responsibility for the locations where a research project is carried out.
Regulators of Professions	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
Other Regulators	Regulators are statutory bodies that oversee particular activities according to their functions, which are set out in legislation
Employers	Employers are the organisations employing the CI and members of the research team.
Health and Social Care Providers	Providers are organisations that provide health or social care. This includes organisations providing services under contract with NHS or local authority providers or commissioners
Scientific Assessment Committee (SAC)	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. Dstl has its own SAC and further information is available on Dstl's Intranet regarding Research Involving Human Participants (RHIP).
MODREC	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

[1] 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

Guidelines for ascertaining whether a MODREC Review is required

There are three basic questions that should be addressed when deciding whether a MODREC review is required.

1. Are human participants involved?
2. Is your project research?
3. Is your project funded by the MOD[2], or does it involve MOD-employed staff or participants?

If the answer to **ALL** of the above questions is yes, then a MODREC review will need to be considered. Please note that each of the above has qualification criteria, explained in the following pages, with summarised guidance, to assist in determining whether a proposal will require a MODREC review. If further guidance is required, JSP536 Part 2 provides guidance and best practice advice.

Note: The decision not to submit a proposal for review is as important as the decision to do so, and, in some cases, holds more risk. Both the Chief Investigator and Research Sponsor need to take responsibility for the final decision on whether to submit a proposal for scientific and ethical review.

[2] DASA contracts arranged through Dstl are classed as funded by MOD

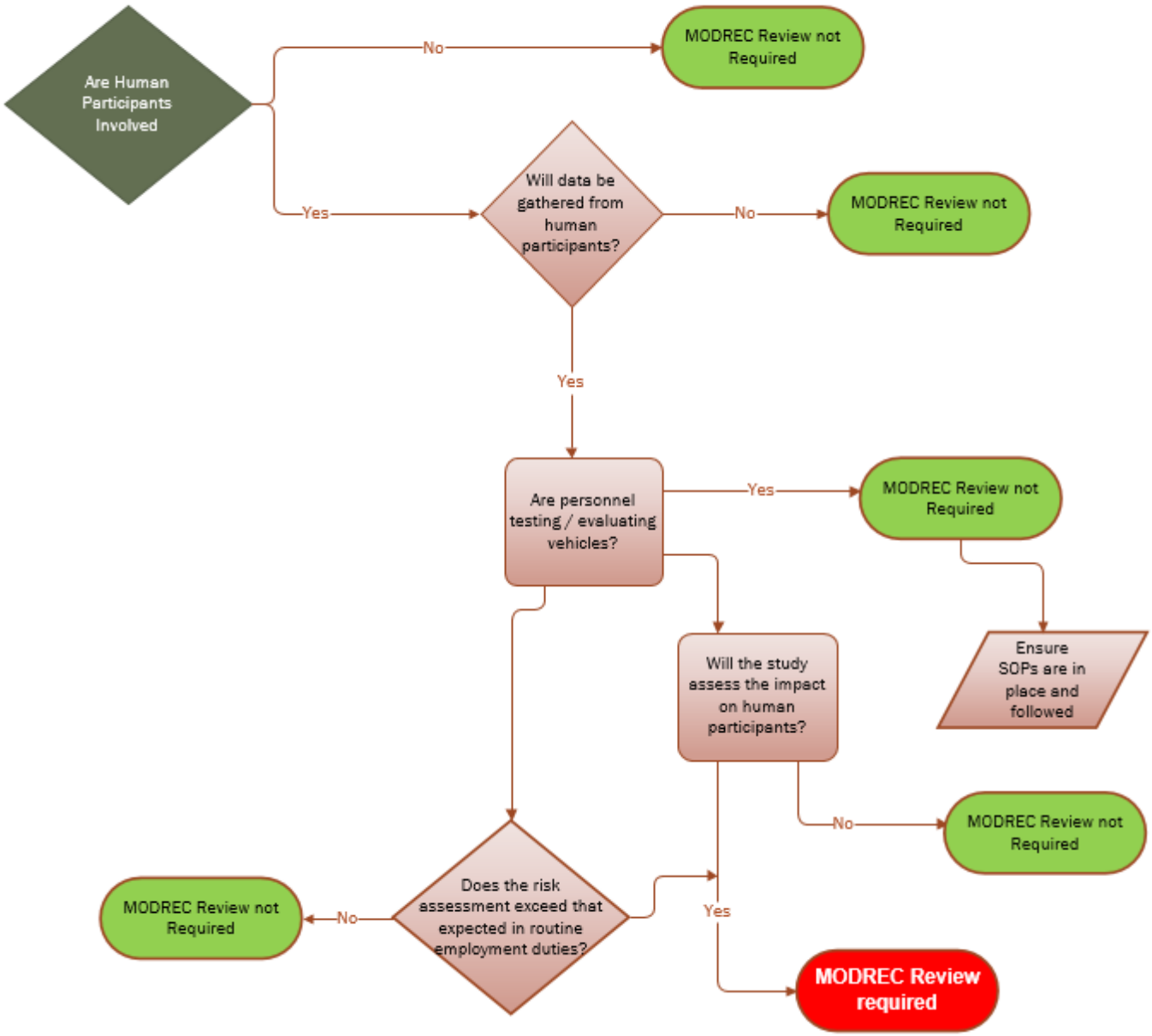
Considerations for MODREC Review

Are human participants involved?

Human participants include any persons of any age regardless of status (military, Civil Service, UK civilian or foreign national). Captured persons must never be used as research participants.

Human participants **do not** include:

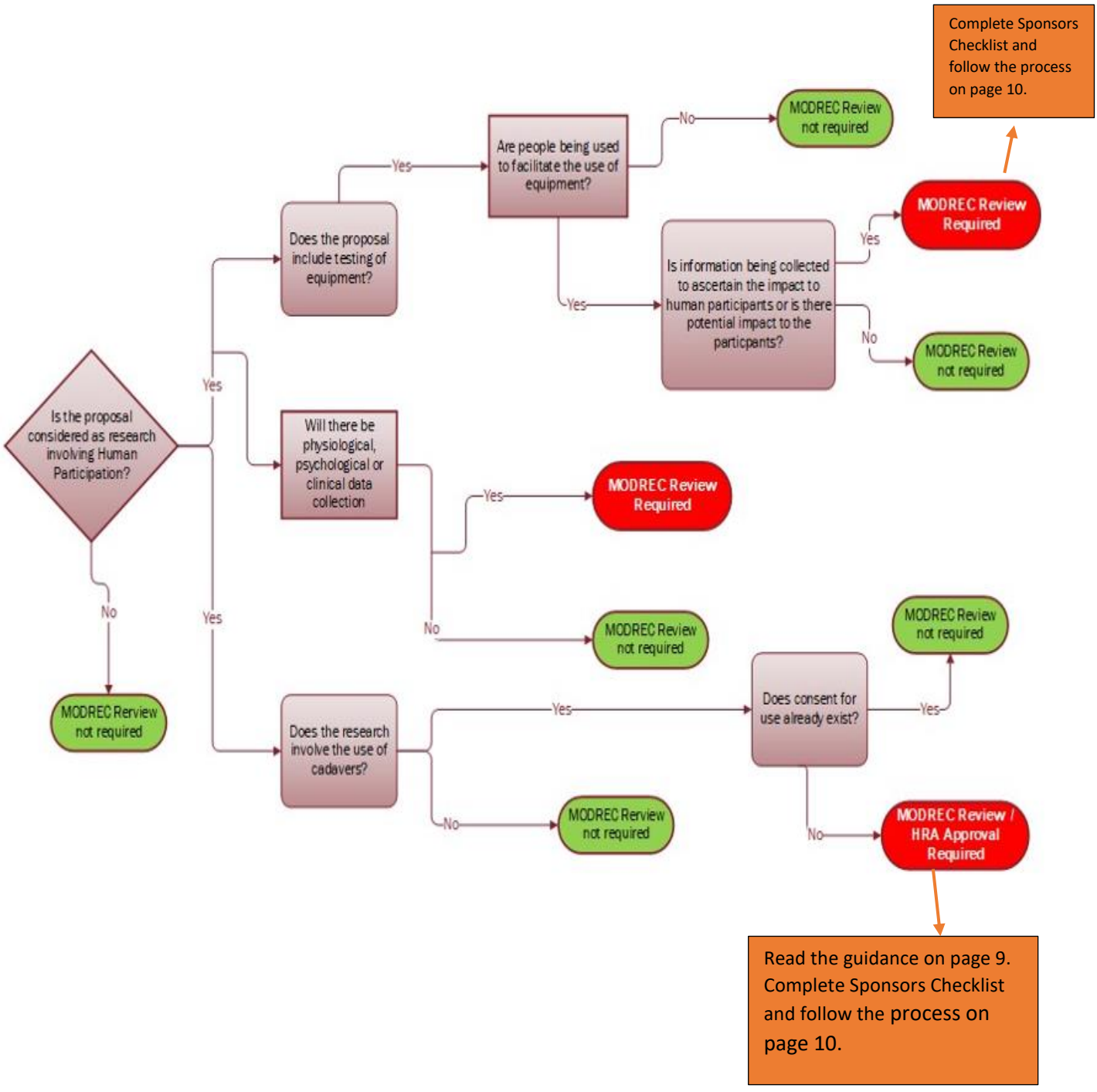
- Personnel that are testing or evaluating vehicles, equipment or materials, including assessment of the operability of commercially manufactured equipment that meets approved formal safety standards (and it is being used for the purpose for which it was designed and approved) unless:
    - A key output 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.);
    - the equipment being evaluated is also being used for safety critical life support during the test (e.g. a diving regulator)
- 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.
- Personnel carrying out SOPs or undergoing routine operational training techniques. This typically **does not** include personnel testing/evaluating vehicles and equipment, studies into new features or techniques/procedures on exercises/operations where SOPs are being followed (unless the purpose of the study is to assess the impact on human participants and human data will be gathered).
- To be excluded, the activity risk assessment must document that the risk of physical or psychological stress should not exceed that expected in the routine employment of that individual.
- Simple assessments such as comfort of wear, ability to move or conduct tasks in the equipment.



Refer to JSP 536, Governance of Research Involving Human Participants, Part 2: Guidance for further information.

Is your project research?

Research is defined as "the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods". **All DASA contracts approved by Dstl are considered research and therefore the following process flow should be considered.**
Some work could meet the definition of research without necessarily requiring MODREC Review. Administering a new drug to a human participant to assess its safety is clearly research and clearly needs MODREC review, whereas gathering anonymous feedback following a training session does not.



Research includes:

- All activities that are carried out in preparation for, or as a consequence of, the interventional part of the research such as screening potential participants for eligibility, obtaining participants' consent and publishing results.
- 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.
- Projects where the primary purpose of the research is educational to the researcher, either in obtaining an educational qualification or in otherwise acquiring research skills
- 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.

Research does **not include**:

- Audits of practice i.e. the comparison of a current or previously conducted non-research process with a "gold-standard".
- Service evaluation i.e. evaluating the effectiveness of a current or previously conducted non-research process. This includes evaluation of training.
- Low risk service improvement.
- Undergraduate student dissertations, or taught masters dissertations, are generally not considered research in this sense because they are not published and therefore not generalisable or transferable.

Testing of new equipment may or may not require MODREC approval depending on what the role of the human participant is and what data is being collected. If the human participant is simply there as a vehicle for the equipment and no human data is being collected, then MODREC approval is not required, even if the findings will be generalised. However, if data on how the new equipment is impacting the human participant is being collected and this will be generalised or published, then this would be considered research requiring MODREC approval. Generally anything that involves physiological, psychological or clinical data collection for research purposes will require MODREC approval.

> Note that there are ethical and data protection issues in using personal data without consent for research purposes. Research using the secondary analysis of datasets that include personal data (medical, employment related, behavioural, psychometric etc.) collected for non-research purposes without original consent for research, must be submitted for MODREC review.

You can also refer to JSP 536, Governance of Research Involving Human Participants, Part 2: Guidance

Annex 1B: Defining MOD Research Projects, give a comprehensive guide as to whether a MODREC review would be required for aspects of a research project.

Working with Cadavers

Research involving adults unable to consent for themselves are subject to various regulations and statutory guidance, as outlined in the HRA standard operating 3-4 JSP 536 Pt 2 (V3.2 May 21) procedures. MODREC will adopt the HRA standard operating procedures for this type of application.

Research involving human tissue is subject to the Human Tissue Act 2004 (England, Wales & Northern Ireland) and Human Tissue (Scotland) Act 2006. Guidance for the review of this type of research is contained within the HRA standard operating procedures. MODREC will adopt the HRA standard operating procedures for this type of application.

Where research is being undertaken that would routinely seek consent of the participants, but this cannot be achieved then an application should be made to the NHS Confidentiality Advisory Group4 to seek a 'Section 251 approval' 5 to conduct research work without consent.

The below has been taken from the Health research Authority Website:

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-tissue-banks-and-research-databases/

If your research project is:

- a Clinical Trial of an Investigational Medicinal Product (CTIMP) (with the exception of Phase 1 trials in healthy volunteers taking place outside the NHS)
- a Clinical Investigation or other study of a Medical Device
- a combined trial of an Investigational Medicinal Product and an Investigational Medical Device
- a Clinical Trial to study a novel intervention or randomised Clinical Trial to compare interventions in clinical practice
- a basic science study involving procedures with human participants
- a study administering questionnaires/interviews for quantitative analysis, or using mixed qualitative/quantitative methodology
- a study involving qualitative methods only
- **a study limited to working with human tissue samples (or other human biological samples) and data (specific project only)**
- a study limited to working with data (specific project only).

Then you will need to apply for HRA Approval

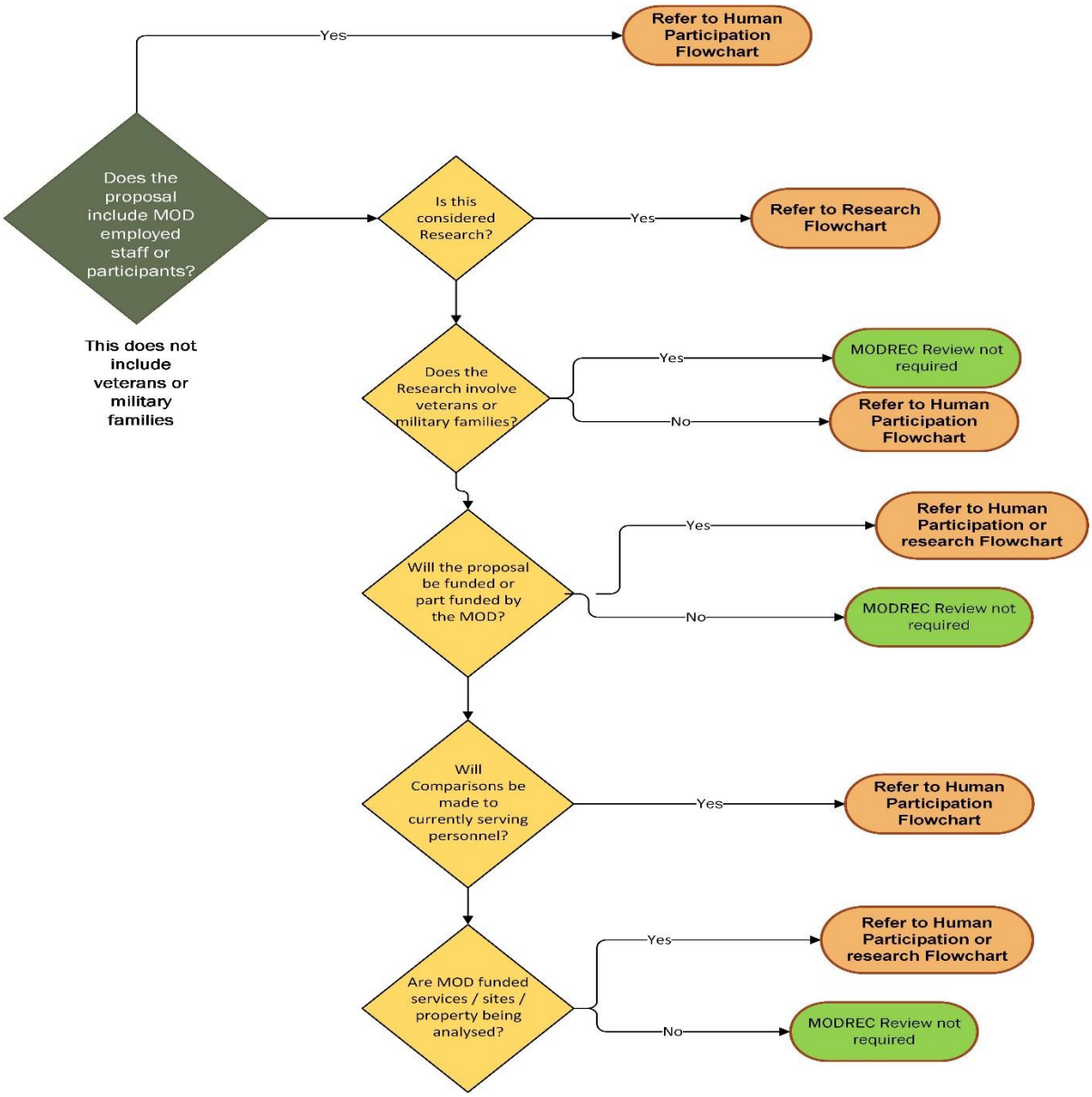
Is your project funded by the MOD, or does it involve MOD-employed staff or participants?

The answer to this question is "yes" if any researchers or participants are funded wholly or in part through a Dstl / MOD contract. This includes personnel conducting research as part of a degree or course of study funded by MOD or taking place during MOD-funded work time. A MODREC Review is required if any MOD participants could be emotionally or physically affected.

Research involving veterans or military families are generally **not included** unless:

- It is funded by MOD or conducted by MOD funded staff.
- Comparisons are to be made to currently serving personnel.
- MOD funded services/sites/property are being analysed, assessed or used.

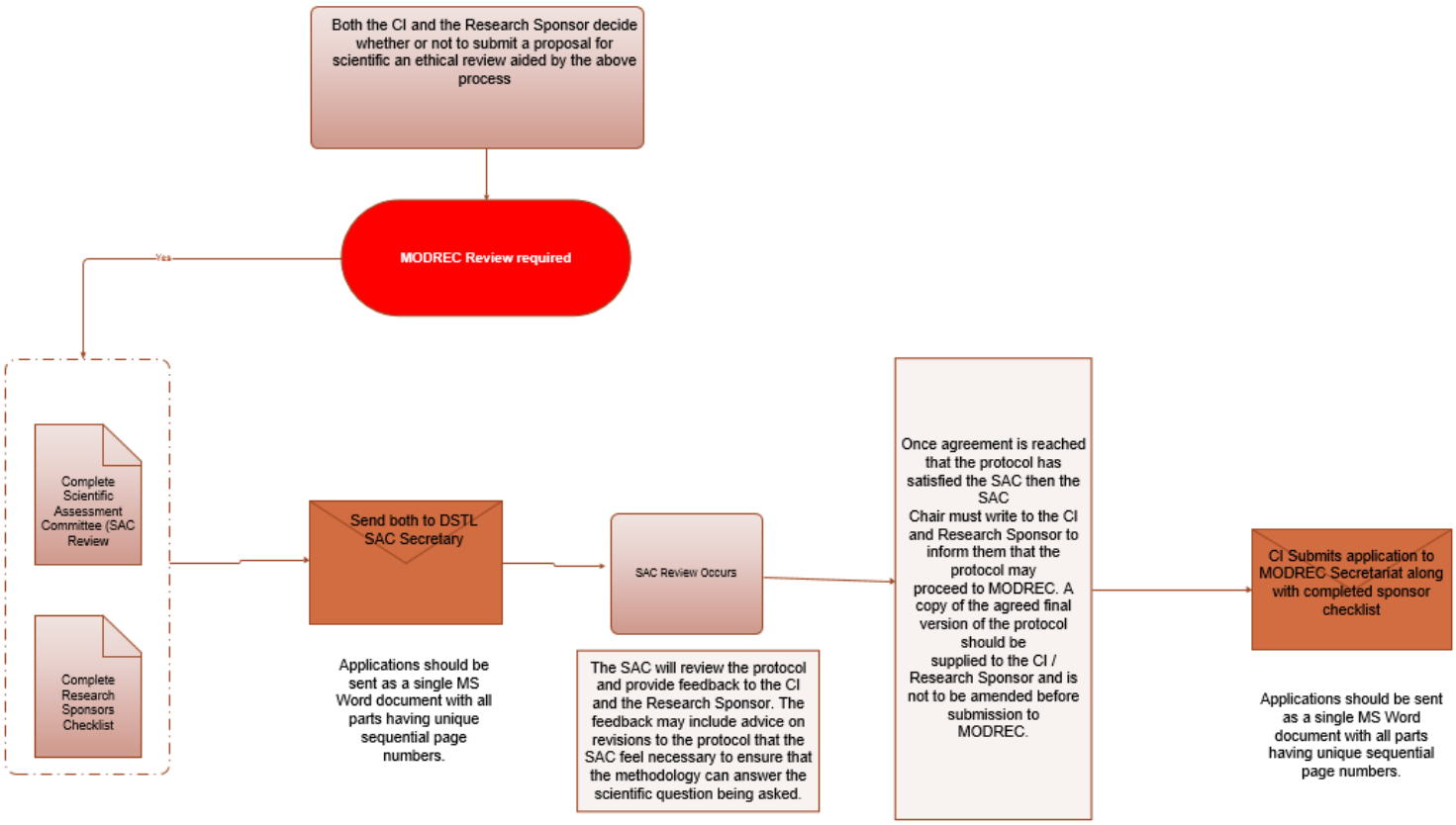
If Dstl staff are actively involved as human subjects in research and testing, regardless of funding origin, a MODREC Review will need to be considered.



Process for MODREC Submission

As this document outlines the process for obtaining MODREC Review, the below process is for information purposes only, for full information and guidance, please refer to the full Guidance on Applying for approval for MOD research involving humans.

The Sponsors Checklist must be completed before a study is submitted to MODREC for ethics review. A SAC review is a separate process that occurs prior to MODREC review. SAC approval is required to complete the Sponsors checklist. Please identify a relevant SAC and contact them for details of their review process. Dstl has its own SAC – Email DstlSACSecretary@dstl.gov.uk.



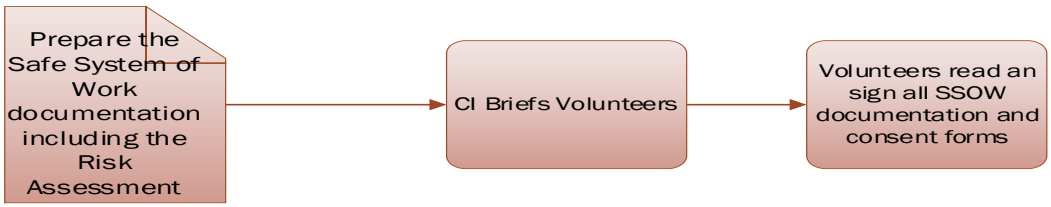
If a proposal is suitable for a proportionate review by MODREC, researchers will receive a decision within 20 working days of a validated application. Researchers will not be required to attend a MODREC meeting, all correspondence will be via email from the secretariat. If a full MODREC review is required, MODREC aims to meet on a monthly basis, usually on the first Tuesday of each month. The Chief Investigator will be invited to attend the review to address any queries and/or concerns raised by MODREC.

MODREC will provide a formal decision on the application as soon as practicable, and will provide formal feedback within 10 working days of it being considered at the meeting.

You can also refer to JSP 536, Governance of Research Involving Human Participants, Part 2:

Annex 1C: The process for scientific and ethics review, is a good guide to the process.

If MODREC approval is not necessary but volunteers are involved, e.g. to facilitate the use of equipment, then the following process should be followed.



If it is still unclear as to whether MODREC approval is needed, please contact your Innovation Partner at Accelerator@dstl.gov.uk.

Guidance documents

MODREC Official Site, that includes all the guidance documentation mentioned in this document and explanations of the full application process:

https://www.gov.uk/government/groups/ministry-of-defence-research-ethics-committees

MODREC and SACs operate according to Joint Service Publication 536 (JSP536) which is harmonised with guidelines set out by the UK's Health Research Authority. The links to this guidance can be found here:

https://www.gov.uk/guidance/apply-for-ethical-approval-for-mod-research-involving-humans

Full Guidance that includes links to the MODREC application form

https://www.gov.uk/guidance/apply-for-ethical-approval-for-mod-research-involving-humans

JSP 536, Governance of Research Involving Human Participants, Part 1: Directive
https://www.gov.uk/government/publications/defence-research-involving-human-participants-jsp-536

JSP 536 Governance of Research Involving Human Participants Part 2: Guidance
https://www.gov.uk/government/publications/defence-research-involving-human-participants-jsp-536