Ministry of Defence

JSP 536
Governance of Research Involving Human Participants

Part 2: Guidance

Foreword

This Part 2 JSP provides guidance in accordance with the policy set out in Part 1 of this JSP; the guidance is sponsored by the Defence Authority for Governance of Research Involving Human Participants. It provides policy-compliant business practices which should be considered best practice in the absence of any contradicting instruction. However, nothing in this document should discourage the application of sheer common sense.

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 staff 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:

   a. 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.

   b. 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
JSP 200	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:

Job title/e-mail	Email	Telephone
Deputy Head Medical Policy, HQ JMG	SG-DMed-Med-Pol-GpMailbox@mod.gov.uk	94422 4657 01543 434657
SO2 Medical Policy, HQ JMG	SG-DMed-Med-Pol-GpMailbox@mod.gov.uk	94422 4669 01543 434557
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

Scope

5. **Guidance to potential research teams**. This JSP Part 2 provides guidance to potential research teams on the requirements and considerations prior to, during and after proceeding with a protocol for research involving human participants. This includes submission for scientific and ethics review of the protocol. This Part 2 also provides the standard operating procedures (SOPs) for MODREC.

MODREC Standard Operating Procedures (SOPs)

6. The SOPs in this document are modelled on those for Research Ethics Committees published by the Health Research Authority (HRA)[1]. The MODREC Secretariat will keep this document in review in light of changes made to the HRA SOPs.

7. MODREC is recognised by the United Kingdom Ethics Committee Authority (UKECA) for the review of clinical trials under the Clinical Trials Regulations. When a project falling under this (and any other) statutory tool is submitted to MODREC the latest version of the HRA's published 'Standard Operating Procedures for Research Ethics Committees' will be used alongside this document to ensure MODREC fulfils its statutory duties.

[1] https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-committee-standard-operating-procedures

Contents

1 Requirements and considerations prior to proceeding with a research protocol

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Introduction

1. Part 1 of this JSP directs the requirements and considerations that must be made prior to proceeding with a protocol for research involving human participants (see Part 1, Chapter 3 'Responsibilities'). This Part 2 provides further guidance.

2. If a potential Chief Investigator (CI) is unsure as to whether their protocol is research[2] involving human participants and must meet the requirements of this JSP, they should consider the questions and notes at Annexes A and B to this chapter, 'Does my protocol need to be submitted for scientific / ethics review?'and 'Defining Projects'. It may help to discuss the proposed work with their employer / supervisor or chain of command.

3. It is primarily the responsibility of the CI, working with the Research Sponsor representative, to ensure that these requirements are met, and where necessary, to ensure that issues are resolved and reflected within the final research protocol, prior to any recruitment of human participants.

4. An overall illustration of scientific and ethical review including the pre-MODREC and MODREC processes is provided at Annex C to this chapter.

Scientific Review

5. The CI, working with the Research Sponsor, must ensure that all MOD research falling under this JSP undergoes a scientific review. This must happen through a Scientific Assessment Committee (SAC). Further details can be found at Chapter 2.

Ethics Review

6. The CI, working with the Research Sponsor, must ensure that all MOD research falling under this JSP undergoes an ethics review. This must happen through the MOD Research Ethics Committee (MODREC). Guidance on submitting to MODREC can be found at Chapter 3.

7. Where the CI and Research Sponsor are unsure as to whether their work falls under this JSP, a non-binding opinion as to the interpretation of Annex A may be obtained from a MODREC sub-committee via the MODREC Secretariat.

Further Considerations

8. As part of the assessment of a research protocol consideration needs to be given by the CI and Research Sponsor, assisted by the SAC and to a lesser extent MODREC, to issues including:

[2] See JSP 536 Part 1 Chapter 1 paras 7 and 8.

a. **Security**. Has an appropriate security classification been applied to the protocol which will, where appropriate, carry over to the research report and the assessment for eventual release of the results? Security classification should reflect the research topic, the research subjects and locations involved and any other partner nations taking part in the research.

b. **Appropriateness**. All MOD sponsored research[3] must have an output that has utility to the MOD or other government departments (OGDs). CIs and Research Sponsors must ensure that research is appropriate to the Research Strategies and Priorities of the MOD or OGDs.

c. **Data Handling**. All research data must be handled with respect to current Data Protection Legislation (i.e. DPA 18) and the Caldicott Principles. Where research is being undertaken that would routinely seek consent of the participants, but this cannot be achieved (e.g. retrospective cohort studies) then it will be the responsibility of the CI and Research Sponsor to make an application to the NHS Confidentiality Advisory Group[4] to seek a 'Section 251 approval'[5] to conduct research work without consent.

Public Participation

9. Where appropriate, patients or research participants (especially members of the Armed Forces) may be included in the design or assessment of feasibility of the research. This may include, but is not restricted to:

a. Having participant information, questionnaires and study de-briefs assessed for readability and comprehension within the proposed research participant group or expert patient groups;

b. Assessing whether proposed testing can be conducted in the environment or at the frequency proposed without detriment to military training or operations;

c. Ensuring that the proposed research subjects are not already involved in multiple other research proposals (research overload).

10. Public participation in research design or conduct is often undertaken for NHS research. However, within the MOD the topics being researched, the security and personal safety of research participants, wider MOD security consideration[6] and the potential for adverse public comment on MOD research should be considered before undertaking public consultation for MOD or MOD-sponsored research. Where the research is being conducted with NHS or with other clinical partners then these factors need to be carefully considered before an automatic assumption is made in favour of undertaking public participation.

[3] Including sponsorship by release of personnel to conduct the research, payment of university fees or provision of access to specialist support or equipment.
[4] https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group (accessed Nov 19).
[5] Under Section 251 of the NHS Act 2006.
[6] Such as classification of a research or equipment programme, location of the research, identification of MOD specialist research sites and the needs for commercial security.

Research Sponsor's Check List

11. The Research Sponsor should complete the check-list at Annex D and provide confirmation to MODREC with the research protocol that the required review of scientific quality along with other responsibilities has been completed. Failure to provide this confirmation may delay processing of the application by MODREC.

Annex 1A: Does my protocol need to be submitted for Scientific and Ethics Review?

Checklist for protocols that require review in accordance with JSP 536	
The decision as to whether a protocol requires review lies with the Research Sponsor in collaboration with the Chief Investigator. This guide must be read in conjunction with Parts 1 and 2 of JSP 536 (refer to Part 1 Chapter 1 paras 6-14 for full direction on research that is within scope and needs review). Review is required if the answer to **ALL** three questions below is **YES**.	
Question 1	
Is your project funded by the MOD, or does it involve MOD-employed staff or participants?	**Yes / No**

• Review is required if any researchers or participants are funded (including paid) wholly or in part by the MOD, and the research is relevant to their MOD role or activities.
• 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.
• Research involving veterans or military families are generally not included unless:
  o It is funded by MOD or conducted by MOD funded staff.
  o Comparisons are to be made to serving personnel.
  o MOD funded services/sites/property are being analysed, assessed or used.
• Cadets, including under 18 cadets, are included if participating as cadets.	

Question 2	
Is your project research?	**Yes / No**
• Research is defined as “the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods”. • Audit and service evaluation (including evaluation of existing training) are not research, and do not require review, unless there are significant (i.e. ethical) issues. It is up to the Research Sponsor and Chief Investigator to determine what a significant ethical issue might be. Please refer to annex 1B for definitions of these other types of activities. • In order to be research there must be the intention to publish the results/outcomes (e.g. as a technical report, briefing note, peer reviewed article etc.) so as to add to knowledge or inform organisational policy/practice. 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. However, there is the expectation that undergraduate projects/dissertations will receive the appropriate ethics review from the awarding institution.	
Question 3	
Are human participants involved?	**Yes / No**
• Will data (quantitative, qualitative or observational) be gathered from human participants (inclusive of all ages, military / civilian status and nationality)? • You must still answer ‘yes’ to this question even if you will use anonymity. • 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 review. Note that there are ethical and data protection issues in using personal data without consent for research purposes.

- 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.
- Captured persons must never be used as research participants.

Answered 'no' but still concerned?

- Review can still be requested if there are any other significant issues identified by the Research Sponsor /CI , and a review would benefit the project (in terms of accountability).
- Such projects can be reviewed at the discretion of the SAC/ MODREC if accompanied by a letter stating the reason why a review is being requested.

Unsure or need further advice?

Advice and, if necessary, a non-binding opinion on whether your protocol requires review may be sought from the relevant SAC or MODREC (visit MODREC website for details).

Annex 1B: Defining MOD Research Projects

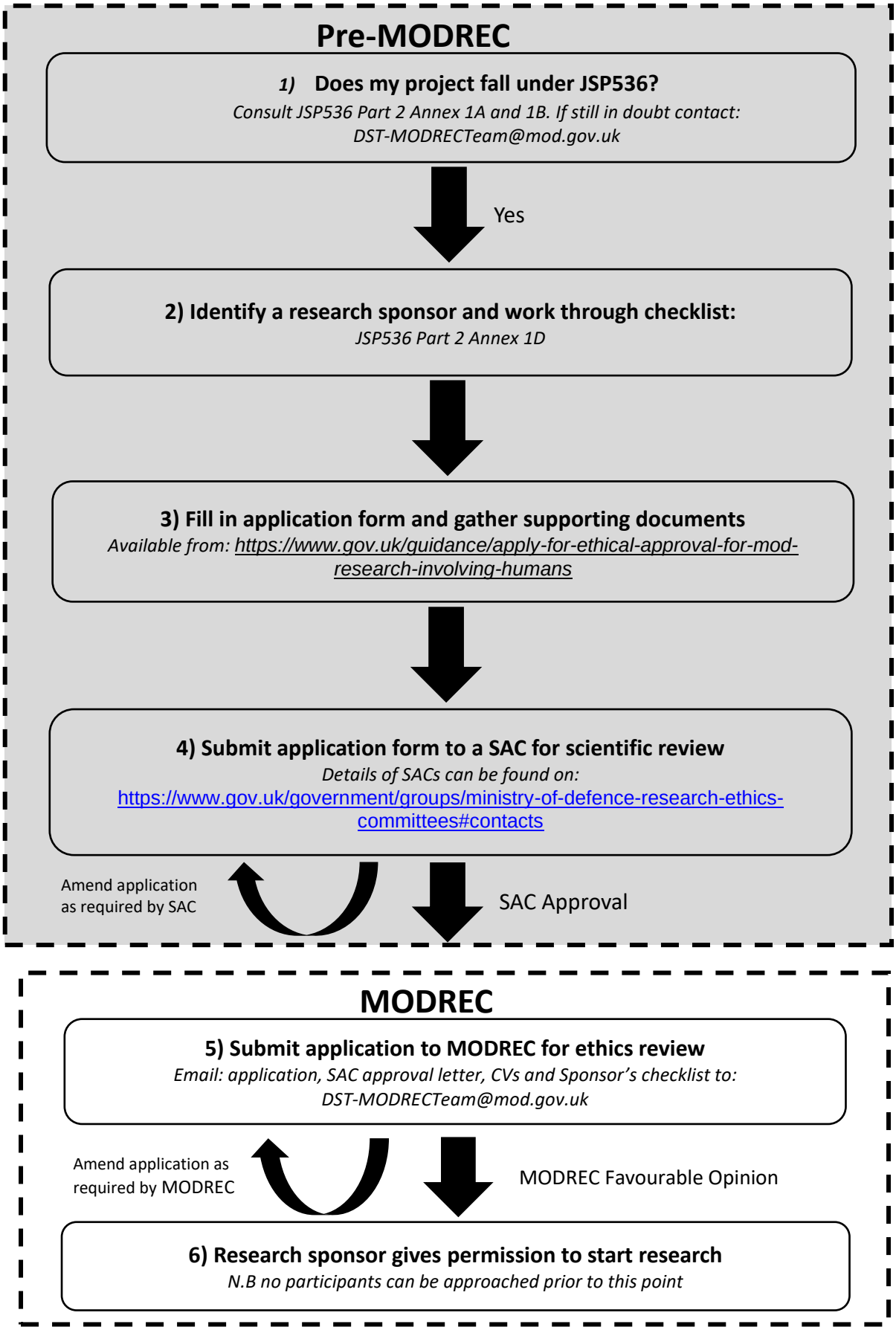
This table describes the key characteristics of research, service evaluation, audit and health surveillance projects in order to assist with deciding how a project should be managed. Each of these project types has their own separate governance requirements which you will need to arrange before starting the work. A programme of work may involve more than one project type, but each individual project within the programme should sit clearly under one column. If you find that your planned project spans more than one column, it is likely that its scope and purpose is not defined clearly enough. Consider making revisions to the project design to ensure that it clearly sets out what you want to achieve, and the methodology you will use.

	RESEARCH	(SERVICE) EVALUATION / IMPROVEMENT / DEVELOPMENT	EQUIPMENT EVALUATION	CLINICAL/ NON-FINANCIAL AUDIT	HEALTH SURVEILLANCE
PURPOSE	The attempt to derive generalisable or transferable new knowledge to answer questions with scientifically sound methods including studies that aim to generate hypotheses, studies that aim to test hypotheses, and observational studies.[1]	Designed and conducted solely to define or judge current care or service or process.	To evaluate equipment, vehicles and materials, including assessment of operability, maintainability, supportability and trainability.	Designed and conducted to produce information to inform delivery of best care or practice.	Designed and conducted to assess priorities, evaluate interventions, and detect and manage threats to health and adverse health status (including incidents, risk factors, hazards, outbreaks and epidemics, may also address health inequalities).
QUESTION/ HYPOTHESIS	***Quantitative research*** – can be designed to test a hypothesis as in a randomised controlled trial or can simply be descriptive as in a survey. ***Qualitative research*** – can be used to generate a hypothesis, usually identifies/explores themes.	Designed to answer the question: "What standard does this service or process achieve?" This is normally addressed by asking those in receipt of the service or process.	Designed to answer questions such as: "Can this equipment be operated/maintained by service personnel, as defined in a Target Audience Description, in a manner that is effective, efficient and safe?"	Designed to answer the question: "Does this service reach a predetermined or pre-established standard?"	Designed to answer the questions: "Is there a need to start, continue or stop defined public health interventions", or "Is there need for further investigations", or "What is the cause of this outbreak (often of a disease) or incident and how do we manage it?"
AIM	***Quantitative research*** - addresses clearly defined questions, aims and objectives. ***Qualitative research*** – sometimes has clear aims and objectives but may not establish the exact questions to be asked until research is underway.	Measures current service or process without reference to a standard (In the case of service improvement / development the current service may be compared to the previous service).	Measures against defined System Requirements using subjective and objective data recorded in a non-invasive manner.	Measures against a standard.	Measures against historical (or geographical) comparators and/or defined levels (triggers) for action. Systematic, quantitative or qualitative methods may be used.
INTERVENTIONS	***Quantitative research*** – may involve evaluating or comparing interventions, particularly new ones. However, some quantitative research such as descriptive surveys, do not involve interventions. ***Qualitative research*** – seeks to understand the perceptions and reasoning of people.	Evaluation involves an intervention, service or process already in use only. Service improvement or development involves a new intervention or service, or one that is new to that context. The choice of treatment, care or services is that of the care professional and patient/service user	May involve evaluating or comparing technologies, particularly new ones. For example, a novel display for a military platform.	Involves an intervention already in use only. The choice of treatment, care, service or practice is according to standard guidance.	Intervention (if relevant) in use only. Any choice of intervention, treatment, care or services is based on best public health evidence or professional consensus, but may also be used to assess the need for an intervention when/where none is being taken currently.

[1] JSP 536 Part 1 – Page 1-2 – para. 10c, Part 2 – Annex1A – Question 2 – 3rd bullet point

		according to guidance, professional standards and/or patient/service user preference.			
DATA	Usually involves collecting data that are additional to those for routine care or service (but not always). May involve comparing data on treatments, samples or investigations additional to routine care. May involve data collected from interviews, focus groups and/or observation.	Usually involves analysis of existing data but may also include administration of interview(s) or questionnaire(s).	May require non-invasive human performance data to be recorded – e.g., time to acquire target; perceived mental workload, aiming accuracy, procedural errors. Subjective perceptions are typically recorded.	Usually involves analysis of existing data but may include administration of simple interview(s) or questionnaire(s).	May involve analysis of existing routine data supplied under license/agreement or administration of interview or questionnaire to those in the population of interest. This includes collection of data on hazards, exposures and other data to enable interpretation of issues relevant to the population rather than the individual. May also require evidence review.
PARTICIPANT ALLOCATION	***Quantitative research*** – study design may involve allocating patients/service users/healthy volunteers to an intervention. ***Qualitative research*** – does not usually involve allocating participants to an intervention.	No allocation to intervention: the intervention is chosen before the evaluation.	Typically involves service personnel who have experience with the equipment under development or similar equipment. Allocation to specific groups is not typically required.	No allocation to intervention: the intervention is chosen before the audit.	Not applicable. Collects data on issue of concern *in situ*. May involve allocation to control group to assess risk and identify source of incident, but no allocation to intervention.
RANDOMISATION	May involve randomization.	May involve randomization for sampling, but not for treatment/ care/ intervention.	May involve randomisation but this is not typical.	May involve randomization for sampling, but not for treatment/ care/ intervention/ practice.	May involve randomization for sampling, but not for treatment/ care/ intervention.
DURATION	Time-limited collection and analysis of data, usually with defined end-point and outputs.	May be regularly repeated.	Time-limited collection and analysis of data, usually with defined end-point and outputs.	May be regularly repeated.	Ongoing, and usually open-ended, collection and analysis of data, with regular dissemination.
INFLUENCE	Findings may influence clinical or public health practice or policy.	Findings should influence practice.	Findings will influence design of equipment, vehicles or materials.	Findings should influence practice.	Findings should influence clinical or public health practice or policy.
RESPONSIBILITY	Responsibility to act on findings is not always clear. Responsibility to publish findings.	Responsibility to act should always be clear.	Responsibility to act may not always be clear and follow-on activities may be required.	Responsibility to act should always be clear.	Responsibility to act should always be clear.
IMPACT	Actions informed by findings often taken a considerable time after findings reported.	Actions informed by findings sometimes taken soon after findings reported.	Actions informed by findings usually taken soon after findings reported, although the ultimate consequence of findings may take years to be realised.	Actions informed by findings sometimes taken soon after findings reported.	Actions informed by findings usually taken soon after findings reported.
SAC and MODREC Review?	Yes	No	No	No	No

Annex 1C: The process for scientific and ethics review



Annex 1D: Additional Guidance for Research Sponsors[1]

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.

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[2]). 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.

[1] Adapted from "HRA Expectations of Sponsors" https://www.hra.nhs.uk/documents/794/sponsors-expectations.docx (accessed 5 Dec 19).
[2] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/ (accessed Nov 19).

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)

2 Scientific Review

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Aim of scientific review

1. The aim of the scientific review is to ensure that the research is 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 the MOD and its agencies.

2. Quality research will also be safe, ethical, legal and feasible, and remain so for the duration of the research, taking account of developments while the research is ongoing.

Requirement for scientific review

3. All applications are required to demonstrate that they are of a suitable design to answer the research question being posed. Achieving this is the responsibility of the Chief Investigator (CI) working with the Research Sponsor[1]. For research being conducted within, or funded by, the MOD (or otherwise subject to this JSP), scientific review is achieved by submission of the research proposal to a Scientific Assessment Committee (SAC)[2].

4. Where the research proposal has already been through a scientific review or peer review process out-with the MOD (e.g. through a University supervisor) this does not remove the requirement for review through a SAC. However, details of the external review and any changes made to the protocol following that review should be forwarded to the SAC and will form part of their consideration of the protocol.

Selecting a SAC

5. Most research submitted to a SAC will come from its own organisation. However, where research is tri-Service, crosses organisational boundaries, or comes from an organisation without its own SAC, the following need to be taken into consideration in selecting the relevant SAC:

a. The make-up of the study population (e.g. a primarily Army study population would normally be reviewed by the Army SAC);

b. The specific study topic; some SACs have greater expertise in certain study areas (such as aviation or diving and underwater medicine) and may be more suitable to review protocols in these areas;

c. The organisational affiliations of the research study team;

d. Which organisation is sponsoring the research and whether there is a specific link between that organisation and a nominated SAC.

[1] Refer to JSP 536 Part 1 Chapter 3 paras 10-13 and Annex 1B of this document.
[2] The responsibilities and principles by which SACs operate can be found in JSP 536 Part 1 Chapter 3.

Submission to a SAC

6. Once the CI and the Research Sponsor are content that the research protocol is ready for review, they should contact the appropriate SAC Chair and arrange for submission of the protocol. Applications can be made on a MODREC Application form (found on the MODREC Website), or if available, a SAC-specific application form (note that a MODREC application form will still be required when applying for ethics review by MODREC as described in Chapter 3).

SAC Review

7. A SAC review is an iterative process, involving discussion between the CI and the SAC. It is not the SACs role to re-write protocols, hypotheses or scientific questions; however, where there are issues with the quality of the science or a study's ability to answer the scientific question then the SAC should advise the CI and Research Sponsor that changes need to be made to the protocol to resolve the problems.

8. The SAC will review the protocol and provide feedback to the CI and the Research Sponsor. The feedback may include advice on revisions to the protocol that the SAC feel necessary to ensure that the methodology can answer the scientific question being asked.

Timelines of reviews

9. SACs review protocols to meet a 20-working day turnaround (10 days for proportionate review, see para 11). Where possible the report should reach the CI / Research Sponsor in time to meet the timeline for submission to the next MODREC meeting. 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 of a 1*rank or above.

Expedited Review

10. 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.

Proportionate Review

11. The proportionate review process allows for a rapid (10 working 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[3]. They are likely to include MSc protocols that have already been reviewed by a University Supervisory process. The SAC may use a sub-committee review process to speed the assessment.

Decisions

12. Once agreement is reached that the protocol has satisfied the SAC then the SAC Chair must write to the CI and Research Sponsor to inform them that the protocol may

[3] See also the criteria for proportionate ethics review as outlined in Chapter 4.

proceed to MODREC. A copy of the agreed final version of the protocol should be supplied to the CI / Research Sponsor and is not to be amended before submission to MODREC.

Appeals process

13. An appeal against the SAC decision must be submitted to the SAC Chair within 20 working days of receipt of the decision. The Chair of the original SAC is to seek the agreement of a second SAC to conduct a further review of the protocol.

14. The second review will be in accordance with the standard procedures for the review of any new application. The second SAC may consider the matters raised during the initial review but is not bound by them. It should consider carefully any representations made by the applicant.

16. If the second SAC review approves the application then the Chair of the original SAC, the Research Sponsor and CI will be notified, and the protocol can then be submitted to MODREC for ethics review in accordance with normal procedures.

16. If the second SAC produces an unfavourable opinion then no further appeal is possible for the same research proposal.

3 New Applications for Ethics Review

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Submission of new applications

1. An application for ethics review of a research study must be made by the Chief Investigator (CI) for that study. Applications may not be submitted by the Research Sponsor(s) or other members of the research team on behalf of the CI. The CI should normally be professionally based in the UK. For international studies with a co-ordinating investigator outside the UK, an individual based in the UK must be nominated as the CI responsible for the conduct of the research in the UK. MODREC may agree exceptionally to an application being submitted by a CI based outside the UK but will consider as part of the ethics review whether adequate arrangements are in place for supervision of the study in the UK.

2. Only one application for ethics review must be submitted in relation to any research protocol (except where two applications are required for non-CTIMPs[13] involving adults lacking capacity in both England/Wales and Scotland).

3. A full application must be submitted for each protocol in the case of research projects with separate protocols governing one or more sub-studies in addition to the main study.

4. All new applications for ethics review by MODREC will be submitted to the MODREC Secretariat on the standard application form available from the MODREC website. The standard application form may be revised from time to time by the MODREC Secretariat.

5. The point of contact for all pre-submission inquiries is the MODREC Secretariat.

Validation of Applications

6. An email acknowledgment will be sent within 2 working days of an application for ethics review arriving in the MODREC mailbox.

7. All applications will be reviewed for validation by the MODREC Secretariat within 10 working days of receipt, to ensure the following conditions are met:

   a. The application has been submitted using an application form template no more than six months old.

   b. If the application has been submitted by a student, their university supervisor has approved the submission (an email or statement of support will suffice).

   c. The start date of the study is at least six weeks (30 working days) in advance of the submission/current date (except for UOR/UBRs).

   d. All key documents have been included as annexes/appendices which may include:

[13] Clinical trials of investigational medicinal products.

(1) Participant Information Sheet (PIS).

(2) Informed Consent Form (ICF).

(3) Examples of introductory letters/recruitment emails/posters/press advertisements.

(4) Details of MOD No-Fault Compensation Scheme (refer to JSP 536 Part 1 Chapter 6).

(5) List of acronyms.

(6) List of references.

(7) Statement from Sponsor confirming that the application has undergone SAC review, is scientifically sound, and complies with all relevant legislation.

(8) Examples of letters to General Practitioners.

(9) Examples of letters to parents/guardians.

(10) Letter of other Research Ethics Committee favourable opinion or other approvals.

(11) Details of MHRA approval and/or correspondence.

(12) Examples of questionnaires/topic guide/interview questions.

(13) Evidence of permission from organisation (e.g. hospital/university) where research is to be conducted.

(14) Where a study involves the use of radiological procedures, radioactive materials or DEXA scanning then an assessment of the MOD Radiation Protection Advisor of the risks to participants must be included.

e. All the above documents have been included within a single Microsoft Word file, with unique sequential page numbers throughout, and annexes/appendices identified appropriately

f. Short CVs (maximum 2 pages) for all named investigators, supervisor(s), and Independent Medical Officer (IMO) or Volunteer Advocate (VA) have been submitted in a single separate document[14].

g. All acronyms have been written in full on first use in all standalone documents within the application

h. All parts of the application are legible when printed on A4 paper

i. The application has undergone a thorough spelling and grammar check

[14] CVs should use work addresses, phone numbers and e-mails wherever possible.

8. Validated applications will be assigned a MODREC reference number and allocated to the next available MODREC review slot. An invitation for the CI to attend and joining instructions will be sent to the CI (or their representative).

a. It is the responsibility of the CI to extend the invitation to additional members of the research team (Sponsor, Supervisor, Technical Partner, etc.) that may be required to attend.

b. The CI must confirm the names of all attendees at least 10 working days before the meeting date to allow sufficient time for them to be booked in to the venue.

9. Invalid applications will be returned to the CI (or their representative) for revision, with reasons given for invalidation. The MODREC Secretariat may also provide advice on common themes within the application that MODREC may typically require clarification on.

Retrospective applications

10. In some cases, applicants may disclose that the research has already started without first obtaining a favourable ethics opinion. This is a breach of research governance. In the case of a CTIMP, a criminal offence may also have been committed. All such cases must be reported to the relevant Chain of Command.

11. Such applications should be considered invalid, and MODREC is not obliged to proceed with any form of ethics review. An ethics opinion cannot be given retrospectively. However, MODREC has the discretion to consider the protocol and any other available documentation and to issue a letter to the applicant giving ethics advice regarding the project. The Chair may deal with the matter personally or the project may be considered at a full meeting of MODREC or in sub-committee. If MODREC considers the application is not research, the correspondence must make clear that the project must not be presented as research in the future.

12. If the applicant terminates the research and then submits a valid application to start a new project, this may be reviewed in the normal way, taking account of any concerns about the suitability of the investigator and Research Sponsor.

Applications for Research Databases, Research Involving Human Tissue, and Research Involving Adults Unable to Consent for Themselves

13. Guidance and standard operating procedures for applications that involve the establishment of research databases are provided in the HRA standard operating procedures. MODREC will adopt the HRA standard operating procedures for this type of application.

14. 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.

15. Research involving adults unable to consent for themselves are subject to various regulations and statutory guidance, again outlined in the HRA standard operating

procedures. MODREC will adopt the HRA standard operating procedures for this type of application.

Applications to other regulators and review bodies

16. As well as a favourable opinion from MODREC, some research projects require regulatory approvals under a range of legislation applicable to the UK as a whole or to particular countries. Applications for regulatory approval may proceed in parallel with the ethics review. Applicants are encouraged to submit applications at the same time but may apply in sequence if they prefer.

17. It is the responsibility of the Research Sponsor to ensure that a research study has appropriate regulatory approval as well as a favourable ethics opinion before it starts. It is not necessary for evidence of regulatory approval to be provided to MODREC before it confirms the final ethics opinion. The CI is requested to provide evidence of regulatory approval for MODREC's records as soon as this is available, but it is not the responsibility of MODREC to follow this up proactively.

18. It is the responsibility of the Research Sponsor to ensure that both MODREC and the relevant regulator are informed where necessary of significant developments during the initial application process or post-approval. This includes changes made as a result of review by one body that need to be notified to the other body to ensure it has all the relevant information required to give a final decision. Substantial amendments must be submitted during the review process where appropriate.

Review of applications by MODREC

19. All valid applications for an ethics opinion will be reviewed at a full meeting of MODREC (held in accordance with the following procedures) except where an application meets the criteria for proportionate review (see Chapter 4).

20. Procedures relating to the outcome of the ethics review, including the decisions available at meetings and the request for further information or clarification following the meeting, are set out in Chapter 7.

Expedited Review

21. 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 UOR/UBR.

22. Where a Research Sponsor or CI believes that such circumstances may apply, they must first gain written approval from Head, Research and Clinical Innovation and forward this to the MODREC Secretariat, who will seek the opinion of the MODREC Chair.

23. Options for a special sub-committee or exceptional meeting of the full MODREC committee will be considered by the Secretariat and MODREC Chair and the decision along with any operational arrangements communicated to the CI.

24. Adherence to timeframes set by Universities or other educational establishments, specific availability of research populations, or deployment / employment constraints will

not be considered for an expedited review unless the project also falls under the UOR/UBR definition.

4 Proportionate Review

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Introduction to Proportionate Review (PR)

1. PR is appropriate for research studies raising no material ethics issues. These are projects involving straightforward matters that can be identified and managed routinely in accordance with standard research practice and existing guidelines. **Studies that offer no material ethics issues have:**

a. minimal risk,

b. minimal burden, and

c. minimal intrusion for research participants.

There must also be **minimal risk to researchers**.

2. Applications suitable for PR are reviewed by a sub-committee rather than at a full meeting of MODREC. PR sub-committees will normally be conducted via correspondence, but in exceptional cases can meet face-to-face or via teleconference. The applicant will be notified of the final decision within 20 working days of receipt of a valid application.

3. Criteria for determining whether a study is suitable for review through MODREC's PR process are broadly consistent with those developed by the Health Research Authority (HRA). The criteria are kept under review in the light of: developments in policy and guidance; feedback from researchers and Research Sponsors, and opinion from the Research Ethics Service.

4. Applications that **are not** usually suitable for PR include:

a. Clinical Trials of Investigational Medicinal Products (CTIMPs).

b. Clinical investigations of medical devices prior to CE marking.

c. Research involving adults lacking capacity to consent or subject to the Mental Capacity Act (England/Wales) / Adults with Incapacity (AWI) (Scotland).

d. Research involving exposure to ionising radiation which is additional to that received during routine (or planned) clinical care for any participant.

e. Research involving exposure to environmental extremes (altitude, thermal stress etc.) or significant physiological strain (heavy exercise, protective clothing etc.) where physiological / medical safety limits or procedures are required.

f. Establishing a Research Tissue Bank.

g. Establishing a Research Database.

h. Applications requiring review by the HRA's Confidentiality Advisory Group (CAG).

i. Research involving prisoners.

j. Studies funded by US government departments (such as the Department for Health and Human Services).

k. Research involving residents, or information about residents, in Residential Care Homes in Northern Ireland.

l. Research involving patients, or information about patients, in Nursing Homes or Independent Health Care Clinics in Northern Ireland.

5. Applications that **are** usually suitable for PR include:

a. Research using existing data or tissue that is anonymous[15] to the researcher.

b. Research using existing data or tissue that was/were taken with consent for research.

c. Research using 'surplus or extra tissue' with consent (such as additional blood samples taken at the time of routine sampling; tissue taken during a clinically directed procedure that is not needed for diagnostic or confirmatory testing and would otherwise be disposed of or destroyed, or non-invasive or minimally invasive procedures in non-vulnerable groups).

d. Questionnaire research that does **not** include highly sensitive[16] areas or where accidental disclosure would **not** have serious consequence (sensitive questionnaires that are validated for use in the proposed population and used by experienced practitioners are acceptable for PR).

e. Research interview / focus group that does not include highly sensitive areas or where accidental disclosure would **not** have serious consequence (sensitive interviews/focus groups conducted by experienced practitioners may be acceptable for PR).

f. Research surveying the safety or efficacy of established non-drug treatments involving limited intervention and **no** randomisation to different treatments and **no** change or delay to the participant's standard care or treatment.

g. Minimally invasive basic science studies involving a small number of participants (for instance taking a small number of blood samples or other similar minimally invasive interventions).

[15] Anonymous: where the researcher (or anyone outside a direct care team) does not intend to access any identifiable data during any of the stages of research. *Link-anonymised (or pseudo-anonymised) data,* where the researcher can identify the participant, does not fit category a.

[16] Highly sensitive: This refers to questions which may cause anxiety because of the nature of the question or of the population being asked. Assessment of a question's sensitive nature might be influenced by whether the answers are to be anonymised. Examples of topics often considered highly sensitive include HIV status, sexual activity, recreational drug use and mental health.

h. Studies that do not fit categories a-g but do not have any ‘Material Ethics Issues’.

6. Research involving children can be considered for PR where it does not have any ‘material ethics issues’.

7. There are additional factors that are considered by the MODREC Secretariat and MODREC Committee when assessing whether an application is suitable for PR. This list provides indicative examples but is not exhaustive:

a. Invasiveness of the research procedures.

b. The possibility of research procedures producing incidental findings of clinical importance.

b. The possibility of research procedures, when considered together, being overly arduous and/or burdensome.

c. The vulnerability of the participant group at the time of approach to participate (for example recruitment taking place soon after diagnosis of a serious condition, or the recruitment of particularly young or junior military personnel).

d. The inclusion of genetic testing.

e. The overall sensitivity of the application and topics being covered combined with the potential for participant distress.

f. Where research is likely to collect enough anonymous data to potentially identify individuals.

g. The experience of the research team in both the proposed research field and methodological approach.

h. The possibility of causing reputational damage to the MOD.

Submission and validation of applications

8. Submissions for MODREC PR must be made to the MODREC Secretariat using the standard MODREC application process including the normal application form and providing the same information as required for a full committee review.

9. The criteria for suitability for PR will be based on the indicative lists above and the most recent ‘No Material Ethics Issues Tool’ (NMEIT) published on the HRA website[17].

10. On receipt of an application assigned for PR, the MODREC Secretariat will check the study’s suitability for PR against the current criteria as part of the validation process. Consideration will also be given to any significant ethics issues described by the applicant in the application form that might indicate a need for review at a full meeting. Advice can be sought from the Chair and/or a MODREC sub-committee where required.

[17] https://www.hra.nhs.uk/ (accessed Nov 19).

11. A decision on whether an application is suitable for PR will normally be made within five working days.

Sub-committee procedures

12. To be quorate a PR sub-committee will consist of at least three members and will include: an expert member; a lay member, and a MODREC officer acting as Chair (whose additional role as expert or lay member will also be taken into account). All members must have at least six months service each on MODREC. The sub-committee's opinion on any application submitted for PR will be issued on behalf of MODREC.

13. Sub-committees can also carry out other delegated MODREC business.

14. Sub-committees can seek the advice of MODREC's advisors as required.

15. Sub-committees will provide a written report summarising their activity and decisions to the next main MODREC meeting.

Decisions on applications

16. The decision for PR applications may either be final (either favourable or unfavourable) or provisional. In addition, PR sub-committees may issue **no opinion** where the sub-committee decides that the application must be referred for further review at a full MODREC meeting because:

(a) the study falls outside the indicative criteria for PR; or

(b) it raises significant ethics issues requiring wider discussion.

17. There is no option to issue a provisional opinion pending advice from a referee in PR applications. If the application needs referee advice it will be transferred for review at a full meeting.

18. An unfavourable opinion must only be issued for PR applications when the application is of such poor quality that it would not benefit from review at a full MODREC meeting.

No opinion and referral to full committee

19. Where a PR sub-Committee gives no opinion, the MODREC Secretariat must contact the applicant to explain that the application is being referred to a full meeting. The MODREC Secretariat will identify the next suitable meeting slot available and liaise with the applicant to confirm the date and time. If the applicant refuses the first available meeting, the review timeline will be paused until the validation date for submissions to the meeting that the applicant has accepted. Once the allocation is agreed the MODREC Secretariat will send a letter confirming the no opinion decision and the arrangements for further review. The reasons for referral to a full MODREC meeting will be explained in the letter, and a copy will also be included with the application when circulated for review by the full MODREC committee.

20. Review of the application at the full MODREC meeting will be in accordance with this JSP. The 60-day review timeline can subsequently be stopped in the usual way if the full committee gives a provisional opinion with a request for further information in writing.

Appeal process for PR studies

21. Where a request is made to appeal an unfavourable opinion given for a study reviewed by a PR sub-committee, the study will be reviewed by a full meeting of MODREC.

5 Full Meetings of MODREC

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Meeting schedules

1. MODREC will hold at least 10 scheduled full meetings in each year for the purposes of reviewing the ethics of applications. Additional meetings may be held where necessary to ensure that an ethics opinion on an application is given within the relevant time limit, to discuss matters relating to the establishment or operating procedures of MODREC, for training purposes, or to address projects relating to Urgent Operational Requirements (UOR/UBRs)[18].

2. Meetings to review applications should normally be held at intervals of one month. A longer interval is permissible when meetings span holiday periods but should not exceed two months where this can be avoided. Scheduled meetings may be cancelled with the agreement of the Chair.

3. The schedule of committee meetings for the year commencing on 1 January will be agreed between the Secretariat and MODREC chair by 30 September in the previous year. The schedule will set out the dates, times and venues of meetings and the closing date for validated applications to each meeting. All members of MODREC must be issued with details of the schedule and this should also be published on the MODREC website.

4. The closing dates for applications should normally be 14 working days prior to each MODREC meeting to allow distribution of applications to MODREC members.

Agenda

5. An agenda must be prepared for the meeting by the MODREC Secretariat. The agenda must include at least the following:

a. The date, time and venue of the meeting

b. Apologies for Absence

c. Minutes of the previous meeting and matters arising

d. Report from the MODREC Secretariat

e. Update from any Sub-Committee(s)

f. Any other business

g. Declaration of competing interests

h. Applications for ethics review to be considered at the meeting

[18] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/528625/DSPCR_Chapter_09_UOR_Procurement_Jun_16_Edn.pdf (accessed 5 Dec 19).

i. Date, time and location of subsequent MODREC meetings

6. It is important that MODREC meetings include sufficient applications to maintain the expertise of MODREC and justify the resources involved, but not so many as to undermine the rigour of the ethics review. MODREC must review three to six new applications per meeting on average, and no more than seven.

7. Section 7 describes arrangements for MODREC business that may be conducted by sub-committees. The agenda for MODREC meetings may include items that would normally be reviewed in sub-committee, in particular where the Chair considers it important that a wider discussion takes place. In allocating business between the Committee and sub-committee meetings, the MODREC Secretariat and the Chair must weigh carefully the requirement to give ethics opinions within time limits, the need to conduct MODREC business both efficiently and with due care, and the overall demands of the agenda on members.

Report from the MODREC Secretariat

8. Members will be notified in writing of business undertaken outside MODREC meetings, including at least the following:

a. Decisions or actions taken by Committee officers or members under delegated authority

b. Decisions taken by a sub-committee either at a meeting or in correspondence (the minutes of any PR sub-committee and sub-committee meetings may be appended to the MODREC Secretariat's report or copied to members separately)

c. Decisions taken by the Chair on modified amendments

d. Progress reports on research with a favourable opinion

e. Receipt of annual safety reports on CTIMPs, and reports of Data Monitoring Committees

f. Notification of the conclusion or early termination of research

g. Notice of non-substantial amendments

h. Receipt of final study reports

9. Where MODREC has previously delegated authority to the Chair, named members or a sub-committee to issue its opinion following receipt of further information or clarification from the applicant, it must be notified once the opinion has been issued. The following information must be provided in the report:

a. The ethics opinion given on the application

b. The members that were involved in considering the further information

10. Where an unfavourable opinion was given a brief summary of the applicant's response highlighting the points that failed to meet MODREC's requirements must be provided to the committee.

11. The MODREC Secretariat report should normally be distributed prior to the meeting. Once the report has been finalised any further business that takes place prior to the meeting may be deferred to the report for the following meeting. Where exceptionally the Chair or Secretariat considers it essential that a matter is reported to MODREC as soon as possible, a further written report may be prepared, or an oral report made to the meeting.

12. The Secretariat's report is mainly for the information of members and should not require detailed discussion. The decisions taken by Committee officers or members on behalf of MODREC, or by sub-committees, do not need to be ratified by MODREC. However, members must be allowed to raise any concern about the decisions taken on their behalf, or about information received on the progress or safety of research. Any such concerns must be considered by MODREC and recorded in the minutes.

Distribution of papers for meetings

13. The MODREC Secretariat will arrange for distribution of the documents (either in paper or electronic format) for the meeting as soon as possible after the agenda is finalised and applications have been validated, and in any case no later than 10 working days prior to the meeting (with the exception of Proportionate Review applications where there has been prior agreement). Documents for the information of members may be distributed nearer to the date of the meeting or, exceptionally, tabled at the meeting. Under no circumstances should full applications be tabled at the meeting unless by prior arrangement with the Chair based upon security classification. The local requirements for distribution of documents should be discussed with members and agreed by MODREC.

14. All members attending the meeting will receive and review the application form and all supporting documentation for each new application.

15. Members will return hard copies of documentation to the MODREC Secretariat for secure destruction at the end of each MODREC meeting. Members may retain documentation if they are included on a sub-committee providing further advice or review of an application. Once a final opinion has been agreed the application form and supporting documentation must be returned to the Secretariat at the next available opportunity or deleted if held electronically. The same process applies for any reviews by sub-committee.

Attendance of the Chief Investigator and Research Sponsor's representative

16. The Chief Investigator or delegated representative must be invited to attend the meeting at which his/her application is to be reviewed. The Research Sponsor's representative and other members of the research team are welcome to attend alongside the Chief Investigator. The purpose of this is to be available to respond directly to requests from MODREC for further information, clarification or reassurance. In this way, many issues of concern to MODREC may be resolved at the meeting. Even where further consideration needs to be given by the Chief Investigator and Research Sponsor after the meeting to matters raised by MODREC, their attendance to hear the points raised in person may well prove to have been helpful in formulating a satisfactory response.

17. It is not compulsory for the CI, Research Sponsor or members of the research team to attend, and consideration of the application must not be prejudiced if they are unable or unwilling to attend.

18. CI / Research Sponsors attendance at meetings must be confirmed by ten working days prior to the MODREC meeting.

19. In the case of applications submitted by students it is strongly recommended that the academic supervisor attends the MODREC meeting with the student. In addition, where the student is conducting the research under supervision within the NHS or social care services, the professional supervisor should also attend.

20. It is not the purpose of the CI's attendance to make a formal presentation of the study.

Quorum requirements and meeting attendance

21. The quorum for reviewing applications at meetings of MODREC is seven members, with the following members being required within that group of seven:

- the Chair or another officer;
- at least one expert member; and
- 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.

In addition, at least one special advisor should be present (in a non-voting capacity, so not counted as one of the seven members)

22. The following must not be counted for the purpose of quorum when reviewing applications:

- members of the MODREC Secretariat;
- additional advisors or referees;
- members who are yet to arrive at the meeting, or who have left prior to the study being reviewed;
- members who submit written comments but do not attend in person.

23. Where a quorum is not present, the Committee may not give an opinion on any new application for ethics review. The Committee may discuss the applications on the agenda and give preliminary advice to applicants, though it must not issue formal requests for information at this point. The applications will need to be re-booked for further review at a quorate meeting of MODREC. MODREC review time limits remain extant until the conclusion of a quorate meeting.

24. A Committee meeting, or part of the meeting, at which a quorum of members is not present, may proceed with any other business on the agenda as if it were a sub-committee meeting, provided that the Chair (or vice-Chair or alternate vice-Chair) and at least one other member is present.

25. The MODREC Secretariat must keep a record of attendance, indicating which members were present for the discussion of each application for ethics review.

26. Where the MODREC Secretariat is concerned that a forthcoming meeting may not be attended by a quorum of members due to foreseen absences, they must consider the following options in liaising with the MODREC Chair:

a. co-opting up to two additional members;

b. postponing and re-arranging the meeting;

c. cancelling the meeting.

27. If the meeting is postponed, cancelled or not quorate, the MODREC Secretariat must consider the need to ensure that the applications listed on the agenda are processed within the time limit.

28. Additional members may be co-opted to the Committee in liaison with the MODREC Chair using security cleared individuals currently on the Independent Scientific and Technical Advice (ISTA) Register.

29. A member who is unavailable to attend a meeting may submit comments in writing on any agenda item. These should normally be received by the MODREC Secretariat at least three working days prior to the meeting so that copies may be made available in advance to other members. Where later comments are received, they may be tabled at the meeting at the discretion of the Chair. The minutes must record that written comments were submitted from the member or deputy member concerned and reflect unattributably any specific points addressed by MODREC in the ethics review. A member who submits written comments but does not attend the meeting in person does not count towards the quorum.

Referees

30. MODREC may seek the advice of a referee on any aspects of an application that are relevant to the formation of an ethics opinion, and which lie beyond the expertise of the members or on which the Committee is unable to agree. These referees may be specialists in ethics, specific diseases or methodologies, or they may be representatives of communities, patients or special interest groups. Referees may be a member of another REC. However, when providing expert advice as a referee they are acting as an expert referee and not in their capacity as a REC member; the process for expert advice must therefore be followed.

31. Requests for expert referee advice from MODREC members must be agreed by the Chair (or Chair of a sub-committee) and addressed via the MODREC Secretariat.

32. Referees are not voting members of MODREC and must not be involved in the business of MODREC other than that related to the application on which their advice is sought.

32. The advice of a referee should be sought using one of the following procedures:

a. The MODREC Secretariat or Chair may write to the referee seeking written advice prior to the meeting. A copy of the advice received must be made available to members prior to the meeting or tabled at the meeting. The substance of the advice and identity of the referee must be recorded in the minutes.

b. The referee may be invited to attend the meeting in person for discussion of the application concerned. The attendance of the referee and the substance of his/her advice at the meeting must be recorded in the minutes. As the referee is present only to provide advice to the committee, they would not normally personally question the Research Team at the meeting and do not have a vote in the decision taken by MODREC.

c. The Committee may decide at the meeting to give a provisional opinion and seek written advice following the meeting. The MODREC Secretariat or Chair should normally write to the referee within 5 working days of the meeting. The written advice received must then be considered promptly in accordance with procedures agreed at the meeting.

33. The timescale for ethics review does not stop while the advice of a referee is sought, only once a written request for further information is made to the CI.

34. Referees will be required to treat in confidence all information provided about the application, except where already in the public domain, and to return or destroy any application documentation following provision of their opinion and any attendance at MODREC. When a referee is approached to provide specialist advice, the advice given must be recorded in the minutes as given by a referee but not attributed to the referee by name or designation. The MODREC Secretariat must also record what the Committee decided to do when taking the advice into consideration. When specialist advice is requested after the meeting, prior to a decision being given, the advice provided must be reviewed by a sub-committee of MODREC.

35. The opinion reached by MODREC on an application is MODREC's own. It may draw on the referee's advice in framing its opinion, including any request for further information, and may indicate to the applicant that it has sought advice from a referee. However, it must not cite the referee directly or otherwise disclose the referee's identity in the opinion correspondence except with his/her express permission. The original correspondence and any reports from a referee must be retained for subsequent reference where necessary.

Declarations of interest

36. Members (and advisors) must declare to the Committee any material interests they may have in relation to an application for ethics review or any other matter for consideration at that meeting. Such a declaration must be made orally at the meeting, prior to the matter being considered, or in writing to the Chair prior to the meeting. A material interest is any personal or business interest that may, or may be perceived to, unduly influence the member's or the Committee's judgement about the matter concerned.

37. Where the member declaring an interest is the CI, another key investigator / collaborator, or the Research Sponsor's representative named on the application form, the member must leave the room and take no part in the ethics review of the study.

38. In the case of any other declared interest the Committee must collectively consider whether it is a material interest and, if so, whether it is appropriate for the member concerned to take any part in the review of the application. Account must be taken of the closeness of the member's interest in the application and the potential for a conflict of interest. There is no need to record any declarations which the Committee decided was not material in the minutes of the meeting. In some cases, the declaration of the interest

may in itself be sufficient to ensure that the decision of the Committee is not unduly influenced. Otherwise, the Committee has the following options:

a. The member must leave the meeting room and take no part in the discussion or the vote on the application.

b. The member may remain in the meeting room in order to provide any relevant information requested by other members but must not vote.

c. The member may remain in the meeting room and take a full part in the review.

39. The minutes must record any declaration of interest the Committee considers to be material, and its decision on the procedure to be followed.

Confidentiality of proceedings

40. MODREC members do not sit on the Committee in any representative capacity and need to be able to discuss freely the applications submitted to them. For this reason, MODREC meetings must be held in private, and members must be encouraged to raise any matters of concern.

41. MODREC members must be provided with terms and conditions of appointment including the requirements to keep MODREC business confidential.

42. Arrangements must be in place for the destruction of confidential meeting papers after the meeting, including guidance for deleting electronic versions of documents.

Observers

43. External observers may be invited to attend MODREC meetings, subject to written invitation setting out the terms under which observer status is permitted, the signature of a confidentiality agreement, and the agreement of MODREC at the meeting to be attended.

44. External observers must have no vested interest in any applications being considered at the meeting. In particular, Research and Development (R&D) Directors and R&D managers must not be permitted to attend meetings of RECs at which applications for which they have research governance responsibilities, are to be reviewed.

45. Meetings, or parts of meetings, may also be attended from time to time by MOD staff, auditors, and other senior staff from the appointing authority in accordance with JSP 536. The Chair must be notified prior to the meeting.

46. Observers must take no part in MODREC's deliberations or decisions on particular applications. However, 'official observers' may provide operational advice.

47. If any observer is present, the Chair must verbally inform any investigator who attends the meeting. The investigator must be given the opportunity to object to the presence of an observer (other than an official observer). If there is an objection, the observer must be asked to leave the meeting room for that item. The attendance of observers must be recorded in the minutes.

Conduct of business and decision-making

48. The Chair is responsible for the conduct of the business and for ensuring that the Committee reaches clearly agreed decisions on all matters. Where the Chair is unavailable, the meeting must be chaired by the vice-Chair or another member appointed by the Chair for the purposes of chairing the meeting in question. Only the Chair or a nominated vice-Chair may chair the review of studies falling under the clinical trials regulations.

49. The Chair of the meeting must have regard to this guidance in this JSP on the conduct of meetings and be guided by the Secretariat.

50. The meeting should reach unanimous decisions by consensus wherever possible. Where a consensus is not achievable a formal vote must be taken by a counting of hands. The decision of the Committee must be determined by a simple majority of those members present and entitled to vote. A record must be kept of the number of votes, including abstentions, in the minutes. Where the vote is tied, the Chair may give a casting vote, but must first consider any other options to arrive at a more consensual decision.

51. Where any member wishes to record his/her formal dissent from the decision of the Committee, this must be recorded in the minutes but not included in the opinion letter.

Responsibilities of the MODREC Secretariat (during the MODREC meeting)

52. The secretary to the meeting will be a member of the MODREC Secretariat.

53. The responsibilities of the MODREC Secretariat in relation to meetings include (but are not limited) to:

a. Publishing the schedule of MODREC meetings.

b. Preparing the agenda.

c. Distributing/making available the agenda and papers as well as arranging the destruction of confidential waste after the meeting.

d. Inviting CIs to attend and making the necessary arrangements.

e. Preparing the venue.

f. Recording apologies for absence prior to the meeting.

g. Raising with the Chair any concern that a meeting may not be quorate.

h. Recording attendance by members, referees and observers for the discussion of each application for ethics review.

i. Advising the meeting as necessary on compliance with operating procedures and, where relevant, the need for MODREC to consider legal requirements applying to the ethics review (e.g. the criteria for approval under the Mental Capacity Act). If clarification on legal or policy matters is required, or the Secretariat have any

concerns about the meeting, the Secretariat must provide this to the Chair after the meeting, seeking further guidance if necessary, before any opinion is issued.

j. Providing guidance to members if inappropriate issues are raised during the meeting and advising members on the correct use of decisions.

k. Making a written record of the meeting.

l. Recording individual votes where a vote is taken on a decision (e.g. 12 for / 3 against).

m. Preparing the minutes of the meeting for review by the Chair, and subsequent approval at the following meeting.

n. Notifying applicants of decisions taken at the meeting and taking other follow-up action as necessary.

o. Recording any material declarations of interest and subsequent actions.

Minutes

54. The minutes of MODREC meeting must be prepared by the secretary to the meeting. The substantive content of letters must be approved by the Chair before letters are issued to applicants giving the Committee's decision.

55. In relation to applications for ethics review or notices of substantial amendment, the minutes must contain a record of the following for each study, whether in the main text of the minutes or in attachments:

a. The members, deputy members, co-opted members, referees and observers present for the review.

b. Any material interests declared, and the decision of the Committee on the participation of the member or deputy member concerned.

c. The submission of written comments by members, detailing the relevant MODREC reference number.

d. The substance of any advice given by a referee.

e. The decision of MODREC on the application.

f. A summary of the main ethics issues considered.

g. In the case of a favourable opinion, any conditions to be met prior to the start of the study or additional non-binding advice to be given to the applicant.

h. In the case of an unfavourable opinion, the predominant reasons for the decision are clearly stated and are distinguished from other comments or advice suggested by MODREC.

i. In the case of a provisional opinion, the further information requested by MODREC and the arrangements for considering the information and issuing the final opinion of MODREC.

j. Where an unfavourable opinion is given on a notice of substantial amendment, the reasons for the decision, clearly distinguished from other comments and advice given by MODREC, and any delegation of responsibility for giving the opinion of MODREC on a modified amendment.

k. The outcome of any vote taken.

l. Any formal dissent from the decision of MODREC by a named member, with reasons.

m. Whether an application was reviewed on a voluntary basis rather than as a requirement of policy or legislation.

56. Except for declarations of interest or an individual member's dissent from the final decision, the minutes must be presented as the outcome of collective discussion and must not attribute particular statements to individuals attending the meeting or providing written comments. The minutes of the meeting must be written in the third person and contain an accurate record of what was discussed during the meeting. Verbatim comments should not be included in the minutes unless specifically requested.

57. The minutes must be submitted to the following meeting of MODREC for ratification as a true record. Any necessary revisions must be incorporated in the final version of the minutes. Where revisions are made to the minutes, the Chair must consider the need to write to applicants correcting any inaccuracies or clarifying points made in the letter sent after the meeting. However, no substantially new request for information must be made at this point.

58. Subject to the provisions of the Freedom of Information Act, the minutes must be treated as official sensitive and not routinely disclosed to applicants or Research Sponsors. For the purposes of MODREC governance, copies of minutes must be made available on request to the appointing authority or auditors. Minutes will be made available routinely to the SAC Chairs.

59. The opinion of MODREC on each application for ethics review must be published in the MODREC annual report (see JSP 536 Part 1 Chapter 5 Para 71).

6 Sub-Committees

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General sub-committee guidance

1. Sub-committees may exercise the following functions on behalf of MODREC:

   a. Providing advice as to whether a study is suitable for PR or full MODREC review.

   b. Review of new applications submitted for PR.

   c. Review of Substantial Amendment and Modified Amendments (in exceptional circumstances when not delegated to the Chair) relating to an application to which MODREC has given a favourable opinion.

   d. Reviewing responses provided by the applicant following a provisional opinion.

   e. Reviewing specialist advice provided by a referee when a provisional opinion pending specialist advice has been issued.

   f. Providing advice/opinions on issues raised during the monitoring (by sponsors/CIs) of research studies to which MODREC has given a favourable opinion.

   g. Review of annual progress reports, notifications of the conclusion of the trial or reports of early termination, and final study reports.

   h. Review of urgent safety measures taken by the Research Sponsor.

   i. Review of annual safety reports together with lists of Suspected Serious Adverse Reactions (SSARs) in the case of CTIMPs.

   j. Review of serious adverse events (in the case of other research).

   k. Review of any other safety reports.

   l. Serious breach notifications.

   m. Referees' advice.

   n. Any other responsibilities delegated by full MODREC or requested by the Chair.

2. Sub-committee meetings may undertake a mix of the business listed above. It is not necessary to establish separate sub-committees, or arrange separate meetings, to undertake different types of business.

3. A sub-committee must not undertake the primary review of a new application except where it is accepted for proportionate review.

4. Sub-committee business may be conducted at face-to-face meetings, by telephone meetings or by correspondence between the members. When delegating a decision to a

sub-committee MODREC may require that a face-to-face or telephone meeting is arranged. Otherwise it is at the discretion of the sub-committee Chair how the sub-committee business is conducted. Consideration must be given to the significance of the matters to be discussed.

Authority of sub-committees

5. A sub-committee has delegated authority to take decisions on behalf of MODREC on the matters listed above. Decisions taken by the sub-committee should not require ratification at the Committee meeting unless the sub-committee specifically decides to refer a matter for further consideration and decision by the full Committee. Decisions made by a sub-committee on behalf of MODREC cannot be subsequently reversed by MODREC.

Establishment of sub-committees

6. MODREC may establish more than one sub-committee and may operate a mix of standing and ad hoc sub-committees.

7. The quorum for sub-committee business (excluding Proportionate Review) is the Chair of MODREC (or a vice-Chair) and at least one other member. It is desirable but not essential for both an expert and lay member to be involved.

8. The MODREC Secretariat is responsible for ensuring that appropriate expertise is available to any sub-committee, depending on the business to be undertaken. This may include a MODREC advisor if deemed necessary.

Distribution of papers

9. The agenda and papers for sub-committee meetings should normally be distributed no later than 3 working days prior to the meeting. The local requirements for distribution of papers should be discussed and agreed by members of the sub-committee.

10. In the case of standing sub-committees, papers may be submitted electronically when available, and a record of circulated papers/emails kept by the MODREC Secretariat.

Conduct of sub-committee business by correspondence

11. Sub-committee business may be conducted by correspondence. The MODREC Secretariat must list the business in an email to the members concerned with deadlines for receipt of comments. A separate agenda document is not required in this case.

12. Where business is conducted by correspondence, the sub-committee Chair is responsible for reviewing any comments made by other members and for making decisions on behalf of MODREC. Telephone discussions or a teleconference or videoconference may be held between the Chair and the members involved. Where there are differences of view among members, these may be discussed further at a meeting of the sub-committee or the full Committee, at the discretion of the MODREC Chair.

13. All decisions made in correspondence must be recorded in the next report to MODREC.

Referees

14. Specialist referees may be invited to submit written advice prior to a sub-committee meeting, or to attend the meeting in person, in the same way as for a MODREC meeting.

Responsibilities of the MODREC Secretariat

15. The responsibilities of the MODREC Secretariat in relation to sub-committee business conducted in correspondence are:

a. Distributing papers to members and specifying dates for written comments to be returned.

b. Co-ordinating correspondence and arranging for written comments to be reviewed by the MODREC Chair if required.

c. Co-ordinating requests for additional information from the Sub-Committee as appropriate.

d. Preparing draft letters for Sub-Committee Chair review.

e. Recording the final decision as appropriate.

f. Issuing the decision/opinion letter as appropriate.

7 Giving an Ethics Opinion

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Statutory and/or policy requirements

1. MODREC is recognised by UKECA and must follow guidance including timelines published in the HRA's standard operating procedures for RECs when conducting reviews under statutory authority.

2. All other research reviewed at a full meeting of MODREC will be reviewed within 60 working days from validation.

3. For all applications subject to a 60-working day time limit the aim is for a final opinion to be given within 40 working days, allowing for the review timeline to stop where a provisional opinion is given and a response from the research team is requested.

4. For applications accepted for proportionate review, the final opinion should be given within 20 working days, allowing for the review timeline to stop once where a provisional opinion is given and a response from the research team awaited.

Decisions available to MODREC

5. MODREC must reach one of the following decisions on any application reviewed at a full meeting or a proportionate review sub-committee meeting:

   a. **Final opinion**. The Committee may reach a final opinion on the application. This opinion may be either:

      1. favourable; or

      2. unfavourable.

   b. **Provisional opinion with request for further information**. The Committee may decide that a final opinion cannot be issued until further information or clarification has been received from the applicant. It must indicate a provisional opinion in the initial review.

   c. **Provisional opinion pending consultation with referee**. A full meeting may decide that a final opinion cannot be issued until further advice has been sought from a referee. It must indicate a provisional opinion but not make a formal request for further information from the applicant at this stage.

6. The MODREC Secretariat must ensure that the minutes clearly record the decisions taken by MODREC, any further information requested from applicants, and the agreed procedures for considering that information and issuing MODREC's opinion.

Notification of the decision to the Chief Investigator and Research Sponsor

7. The MODREC Secretariat must ensure that notification of the decision is sent to the Chief Investigator and Research Sponsor within 10 working days of a full meeting, or within 5 working days of proportionate review by sub-committee. All letters must be in the name of the Chair of MODREC, who has ultimate responsibility for, and should approve, the content. It is acceptable for the letter to be signed by a vice-Chair or member of the Secretariat acting under delegated authority from the Chair.

8. The letter to the Chief Investigator must include an appropriate heading, reference number, date on which the study was reviewed by MODREC and, in the case of a provisional opinion, a list of information requests or clarification that need addressing by the investigator. In the case of an unfavourable opinion a clear rationale must be given for the committee's decision. A point of further contact (agreed by the Committee) must also be provided should the research team require further information.

Suspension of the review timeline

9. The timeline must be suspended from the date on which the request for further information is sent to the Chief Investigator. It must be re-started on the date when a complete response is received ("the re-start date").

10. Where the response arrives in a piecemeal fashion, the re-start date is the date on which the final part of the response is received.

11. The re-start date is the date on which a complete response is received in the Secretariat office, not the date on which the information is considered by MODREC and judged to be acceptable or otherwise.

Requirement for a complete response

12. If the Chief Investigator's response is incomplete or does not appear to fully address the matters raised, MODREC is entitled to insist on a complete response before issuing its final opinion. The MODREC Secretariat must contact the applicant setting out the further information or clarification still required. The letter / email may be issued more than once if the response continues to be incomplete. It is recommended that the MODREC Secretariat contacts the applicant (or arranges for the Chair to do so) to discuss the outstanding points and clarify what is expected. MODREC is not entitled to raise any new issues or concerns at this stage of the process. The review timeline must remain suspended until a complete response is received.

13. The applicant should normally be allowed a period of no more than two months to respond to the request for further information. The provisional opinion letter will request a response within one month. If the applicant has not responded within one month, a reminder letter should be sent. If no response is received within one further month, the Secretariat should normally advise that MODREC considers the application to have been withdrawn. The applicant would then be required to submit a new application in order to obtain an ethics opinion. However, the MODREC Secretariat may extend the two-month period at the request of the applicant where there are reasonable grounds for requiring more time to respond.

14. The response to the Committee's request for further information must be provided personally by the Chief Investigator. It may include information supplied by a representative of the Sponsor, or by other key investigators or collaborators, but must always be assured by the CI.

Final opinion following consideration of the information

15. On receipt of a complete response from the Chief Investigator, MODREC must issue its final opinion on the application, which may be favourable or unfavourable.

Further advice from a referee

16. In some cases, MODREC may decide at the meeting it wishes to consult a referee. If so this decision, and the area of expertise required, must be recorded in the minutes.

17. Where a full meeting of MODREC decides that it cannot give a final opinion until it has obtained further advice from a referee, it must issue a provisional opinion but defer the final opinion until the further information has been received. The letter to the CI must explain that MODREC will be consulting a referee and will write again either to give a final opinion or to make a formal request for further information. The letter must summarise the discussion at the meeting and indicate the areas of concern to MODREC, but it must not request any response from the applicant at this point. The review timeline does not stop as a request for further information has not yet been issued.

18. The Chair or MODREC Secretariat should initially contact the prospective referee by phone or e-mail to establish whether he/she is willing and able to provide expert advice within the required timescale. It must be established that the prospective referee has no connection with the research that might give rise to a conflict of interest. Advice must also be given to the potential referee regarding the appropriate non-disclosure agreement.

19. Requests must be as specific as possible about the issues of concern to MODREC and the expert advice required. A copy of the application form must be provided, together with any supporting documentation required by the referee. Where possible, the letter should be sent within 5 working days of the meeting. The referee should be asked to respond in writing within a further 10 working days.

20. Once the referee's advice has been received it must be considered promptly by a sub-committee of specified members (as determined at the full meeting). If it is decided to make a request for further information or clarification at this point, a letter must be issued to the CI taking into account the advice of the referee. The review timeline stops at this point.

Regulatory approval

21. It is the responsibility of the Research Sponsor to ensure, where necessary, that a research study has appropriate regulatory approval from other bodies (Medicines and Healthcare Regulatory Authority, Human Tissue Authority etc) as well as a favourable ethics opinion before it starts.

Insurance, indemnity and compensation

22. Before confirming a favourable opinion on any research (including both CTIMPs and non-CTIMPs), MODREC must assure itself that the Research Sponsor and CIs will have appropriate insurance or indemnity cover for the potential legal liability arising from the research and consider provision in proportion to the risk for compensation or treatment in the event of injury, disability or death attributable to participation.

Notifying other bodies of the progress of applications

23. It is the responsibility of the CI to inform other interested bodies of the progress of the ethics review. MODREC is not accountable for ensuring that bodies such as the Research Sponsor, funder and relevant organisations, such as the SAC, are kept informed and provided with copies of any documentation required.

Variation of the opinion

24. Where MODREC has given an opinion and subsequently receives information suggesting that the opinion is based on a factual error or misunderstanding, it may vary its opinion. This could apply where there has been an error or misunderstanding in relation to:

a. The application or the further information provided by the applicant or advice from a referee.

b. Interpretation of relevant legal or regulatory requirements.

c. The application of other published guidance to the conduct or management of the study.

25. An unfavourable opinion may be varied to a favourable opinion where the reasons for the opinion no longer apply.

26. A favourable opinion may be varied by issuing a new favourable opinion letter clarifying the terms of the opinion. The need for this might arise where the study would otherwise be in breach of law, regulation or other recognised good practice, or it is not reasonably practicable to comply with the changes requested by MODREC as part of a provisional opinion or the conditions attached to the final opinion.

27. A provisional opinion may be varied to a favourable opinion by issuing a new letter clarifying the terms of the opinion. The need for this might arise where the study would otherwise be in breach of law, regulation or other recognised good practice, or it is not reasonably practicable to comply with the changes requested by the REC as part of a provisional opinion.

28. A variation of the opinion may be requested by the CI or Research Sponsor by writing to the Chair of MODREC through the Secretariat.

29. Requests to vary the opinion must be considered by the Chair and other members as appropriate and a decision communicated to the CI within 35 working days of receipt of the request. Where the opinion is varied, the MODREC Secretariat must issue a new version of the final opinion letter. The letter must state that the previous opinion is superseded by this opinion and explain how the opinion has been varied, for example by

confirming MODREC's agreement to relevant points, withdrawing previous requests or amending the conditions.

Approval to proceed with research

30. A favourable opinion from MODREC does not imply that research activity can begin. Confirmation of management permission or approval from relevant organisation(s) to proceed with the research also needs to be in place. The various responsibilities in relation to carrying out the research are described in JSP 536 Part 1 Chapter 3.

Duration of a favourable ethics opinion

31. MODRECs favourable ethics opinion for a specific research study applies for the duration of the study, except where action is taken to suspend or terminate the opinion. Extension of the study period represents a substantial amendment. If the research is open ended a review (initially by a MODREC sub-committee) must be conducted every five years.

32. It must be noted that continuation of the ethics opinion only applies to the study as described in the application, the protocol and any amendments made by the Research Sponsor. Further applications must be made for ethics review where required to undertake additional studies. In the case of studies involving human tissue which is 'relevant material' under the Human Tissue Act 2004, samples held in England, Wales and Northern Ireland, may be retained after the declaration of the end of the trial, for analysis or verification of research data for up to one year. After this period legal authority to hold any human tissue under the ethics review for this project will expire.

Review of a favourable ethics opinion

33. The CI or Research Sponsor may ask MODREC to review its favourable opinion or seek advice from MODREC on any ethics issue relating to the study at any time.

34. MODREC may review its favourable ethics opinion of a study at any time in the light of safety reports, progress reports, refusal to register the study (if applicable), issues raised by media reports or any other information received about the conduct of the study.

35. MODREC may also review its favourable ethics opinion of a study in the light of concerns raised by participants, patients, service users, carers, members of the public or patient organisations, researchers etc, where they present relevant new information not originally considered by MODREC, related to any of the following:

a. Social or scientific value; scientific design and conduct of the study.

b. Risks to the safety or physical or mental integrity of participants.

c. The competence or conduct of the Research Sponsor or investigator(s).

d. The feasibility of the study.

e. The adequacy of the site or facilities.

f. Suspension or termination of regulatory approval for the study.

g. Information provided to participants and documentation associated with the study.

36. Where it is decided that MODREC should review its opinion based on the new information presented, the study should normally be allocated to the next full meeting of MODREC.

37. Where MODREC is required to review its opinion the MODREC Secretariat will write to the person raising the concern giving a summary of actions being taken. If the individual continues to raise concerns the matter will be referred by the Chair and / or Secretariat to the JSP 536 owner.

38. If MODREC takes the decision to withdraw its favourable ethics opinion a letter must be sent to the Research Sponsor and CI notifying them of the decision. The letter must specify the following:

a. Whether the opinion is suspended or terminated.

b. The reasons for the suspension or termination.

c. The date from which the suspension or termination applies.

d. The Research Sponsor's options to discuss the issue further with MODREC.

e. Any advice or direction in relation to participants already recruited and, in the case of suspension.

f. The period of the suspension and arrangements for further review.

g. Any conditions which are to be satisfied before the favourable opinion may be re- confirmed, either generally or at a particular site.

39. MODREC's favourable ethics opinion should normally be suspended for no longer than 6 months. The suspension must be kept under regular review at each full meeting of MODREC, taking account of any further information received from the Research Sponsor or other bodies. Once the Research Sponsor has satisfied the conditions attached to the suspension, the favourable opinion must be re-instated. If the conditions have not been satisfied within 6 months, MODREC may consider terminating the opinion. However, exceptionally the suspension may be extended if the outcome of relevant investigations is still awaited. During a period of suspension, the Research Sponsor may make representations in writing to the MODREC Secretariat for consideration by a sub-committee and/or main MODREC meeting at any time if it considers that there are no reasonable grounds for the suspension.

Options available to the applicant upon receipt of an unfavourable opinion

40. Where MODREC has given an unfavourable opinion on an application for ethics review, the applicant has the following options:

a. They may submit another application, which must be reviewed as a new application.

b. A request may be made to vary the opinion where it appears to be based on error or misunderstanding. When the opinion is varied, the review timeline must remain stopped from when the original opinion was issued until the error or misunderstanding is resolved. The review timeline should then be corrected accordingly.

41. If the applicant decides to submit a new application on the same or a similar topic, the assumption must be that the applicant is attempting to address the concerns raised by MODREC when it rejected the previous application. The applicant should duplicate the original application form and amend to incorporate the relevant changes. It must be clearly indicated on the application form that it relates to a research proposal that has been previously reviewed and must cite the previous MODREC reference number. There is no need to highlight changes as the new application will enter the MODREC process from the beginning.

42. There is no appeals process following an unfavourable MODREC opinion unless the project falls under statutory legislation as outlined in the HRA's standard operating procedures[19]. In the latter case the HRA appeal process will be followed requiring liaison between the MODREC Secretariat and HRA.

[19] https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-committee-standard-operating-procedures/ (accessed 5 Dec 19).

8 Amendments to Research Given a Favourable Opinion

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General policy

1. Where an amendment is being made to a study requiring a statutory ethics review, definitions and processes will be taken from the HRA standard operating procedures.

2. For non-statutory review, a “substantial amendment” is defined as an amendment that is likely to affect to a significant degree any of the following:

   a. The safety or physical or mental integrity of the subjects of a study.

   b. The scientific value of the study.

   c. The conduct or management of the study.

   d. The quality or safety of any investigational medicinal product used in a trial.

3. It is the duty of the Chief Investigator (CI) and Research Sponsor to identify substantial amendments and notify the SAC, MODREC and any other relevant authorities. Research Sponsors and CIs may seek advice from the MODREC Secretariat who may seek further advice from the MODREC chair. The time taken to obtain this advice is not counted as part of any review period.

4. Unless otherwise stated by the HRA due to statutory requirements, a 35-working day timeline applies to the review of all substantial amendments.

5. Substantial amendments may be reviewed by a sub-committee of MODREC, or where time allows, at a full meeting of the Committee. They must not be reviewed by the Chair acting alone.

Procedures for notifying amendments

6. A study is generally considered to have commenced when any of the procedures set out in the protocol are initiated. Occasionally the Research Sponsor or CI may propose to revise the terms of the MODREC application, the protocol or other supporting documentation after a favourable opinion has been given but before the study commences. If this revision meets the criteria for a substantial amendment it must be notified and reviewed in the same way as would happen for a substantial amendment submitted after the study has started.

7. A Substantial Amendment form may exceptionally be submitted with or during the initial application for ethics review. This might be necessary where the research is being reviewed in parallel by another UK regulatory body (e.g. the MHRA) and significant changes need to be made as a result of that review. It could also be necessary in an international study where the trial has already started, and significant issues have arisen in the conduct of the trial, or where issues are raised in the course of regulatory applications in other countries. The Research Sponsor might then need to amend the protocol and

notify this as a substantial amendment to regulatory authorities and ethics committees in each country. In these circumstances it is acceptable for a Substantial Amendment form to be included as part of the initial application package or submitted during the review process. If MODREC's opinion of the overall study is favourable, the amendment may be listed with the documents approved in the favourable opinion letter for the study. There is no need to issue a separate opinion letter for the amendment. However, if the amendment is submitted during the ethics review and there is insufficient time to review it within the 60-day period, it may be reviewed separately, and an opinion given following the issue of the opinion on the main application, and within 35 working days of receiving the amendment.

8. A Substantial Amendment form is available in Annex A and may be submitted by either the Research Sponsor or the CI, but must always be authorised by both the CI and a representative of the Research Sponsor.

9. In all cases, the Substantial Amendment (or any modified amendment) must summarise the change(s) included in the amendment and briefly explain the reasons in each case or refer to supporting documentation explaining the changes. One notice of amendment may refer to a number of different changes. The form must be completed in language comprehensible to a lay person and submitted with any relevant supporting documentation, including the study protocol, which are clearly marked with the changes being made. If the changes listed are unclear, the amendment may be marked as invalid and further information requested by the MODREC Secretariat.

10. Amendment requests must be submitted to the MODREC Secretariat electronically together with the documents that have been modified, showing both the previous and the new wording. For CTIMPS, notices of amendment can be produced in IRAS or submitted on the EU Notification of Substantial Amendment form. It is acceptable for extracts to be provided or for the changes to be listed in a separate document, showing both the previous and the new wording.

11. The Research Sponsor or CI may also include other supporting information, such as a summary of trial data, an updated safety analysis or a report from a trial monitoring committee. Where the amendment could significantly affect the scientific value of the research, it may be helpful if further evidence of scientific review commensurate with the scale of the research is provided.

Validation of notice of amendments

12. The 35 working days within which an ethics opinion of an amendment must be given begins when a valid Amendment application form is received by the MODREC Secretariat.

13. The relevant date ("the validation date") is the working day (up to 1600 hours) on which the valid notice of amendment and all supporting documents are received by the MODREC Secretariat.

14. A Substantial Amendment is accepted as valid if all the following criteria are met:

a. The relevant Substantial Amendment form has been completed in full, including the Research Sponsor's amendment number

b. Relevant extracts or new versions of revised documents have been submitted, showing the new version number and date and giving both the previous and new wording which is clearly identifiable

c. The amendment has been authorised by the named applicant on behalf of the Research Sponsor, or by the CI and the Sponsor's authorised representative

d. The study is still in progress, i.e. the end of the study has not yet been declared.

15. It is the responsibility of the MODREC Secretariat to decide whether or not the Amendment application is valid and to notify the Research Sponsor and CI. Notification must be given within 5 working days of receipt, except if the sub-committee is able to review the amendment and reach an opinion within 5 working days.

16. Where a notice of substantial amendment is invalid, but the outstanding information or documentation appears relatively straightforward, the MODREC Secretariat may be able to follow this up with the applicant. Where this occurs, the validation date is the date on which the last part of the information required for a valid application is received by the Secretariat.

Notification of non-substantial amendments

17. Where changes are made to a research study that the Research Sponsor considers minor rather than substantial amendments, there is no requirement to obtain an ethics opinion. They may be notified to the MODREC for information, and this may be helpful where the change relates to the contact details for the study or involves minor clarifications or updates to the information sheet or consent form for participants. It is helpful if the correspondence states clearly that the amendment is not considered to be substantial and an ethics opinion is not required.

18. Non-substantial amendments do not need to be reported to the Committee. The MODREC Secretariat is not required to acknowledge receipt of any non-substantial amendment. If a non-substantial amendment is received, an e-mail response may be sent informing the applicant that non-substantial amendments do not need to be submitted to MODREC. Referral of non-substantial amendments to the Chair or other members for information is at the discretion of the MODREC Secretariat.

19. Where a Research Sponsor or CI notifies MODREC of a non-substantial amendment, but the MODREC Secretariat considers that it should have been regarded as substantial and requires ethics review, the matter must be brought to the attention of the Chair and, if the Chair agrees, must be discussed at a meeting of the sub-committee or Committee. MODREC may review its opinion of a study at any time. In the case of a CTIMP it is for the Research Sponsor to interpret the guidance on what is substantial. However, the MODREC may review any information it receives.

20. Where the study has been marked as finished, substantial amendments are usually not accepted. However, it can be helpful to MODREC to be made aware of changes affecting key individuals which occur during the follow up to the completion of a study. For example, CI, PI, trial manager or Research Sponsor contacts may change. The researchers or Research Sponsor may be encouraged to notify such changes to MODREC in a letter or e- mail. This will be treated as 'for information only' and should not be managed as an amendment.

Review of substantial amendments

21. Substantial amendments must be reviewed by a sub-committee of MODREC or by the Committee itself. They may not be reviewed by the Chair acting alone, except where the Chair has been given delegated authority at a meeting to review a modified amendment.

22. The CI and / or a representative of the Research Sponsor may be invited to attend a sub-committee or Committee meeting to respond to questions about the amendment.

23. MODREC may either reject or approve a substantial amendment (note this is different from an ethics opinion as the committee is either rejecting or approving the modification of a study with an ongoing favourable opinion). It is not permitted to approve part of the amendment only. However, when rejecting an amendment MODREC may indicate which parts of the amendment would have been acceptable and give guidance on the submission of a modified amendment taking account of its concerns. The MODREC secretariat must notify the Research Sponsor and CI of the decision. The decision letter must include the same information that would be included in an opinion letter on a new application, including a contact point for receipt of queries from the applicant.

24. Where MODREC has given a final decision on an amendment and subsequently receives information suggesting that the decision is based on a factual error or misunderstanding, it may vary its decision.

25. The 35-working day review timeline does not stop pending receipt of any further information or clarification requested by MODREC relating to a substantial amendment. If time allows MODREC may invite the Research Sponsor or CI to provide further information or clarification in writing by a specified date within the period of 35 working days allowed for the review. In cases where further information or clarification is provided, this should be recorded in the minutes. If the further information is not provided by this date, or is incomplete or unsatisfactory, the amendment may be rejected.

26. Where it appears that the amendment may significantly affect the scientific value of the study, for example because it modifies the recruitment targets, the selection criteria or the data analysis, MODREC may require that the applicant provides evidence of further scientific review in support of the amendment.

Modified amendments

27. Where MODREC rejects a substantial amendment, the Research Sponsor or CI may submit a modified amendment taking account of the Committee's concerns. The notice of amendment form must be re-submitted, amended as necessary, and be accompanied by any supporting documents that have been modified. The form must be clearly marked to indicate that it relates to a modified amendment.

28. The amendments may be divided into more than one modified amendment to allow for separate decisions to be given on each part of the package.

29. The MODREC Secretariat must make arrangements for a modified amendment to be reviewed as soon as possible by a sub-committee or, if authority has previously been delegated, by the Chair of a sub-committee. The MODREC Secretariat must notify the Research Sponsor and CI of the decision of MODREC within 14 working days of the

receipt of the modified amendment. If MODREC does not notify its decision within 14 working days, the researcher is permitted to make the proposed change forthwith.

30. Decisions on modified amendments taken by the Chair under delegated authority must be reported to the Committee in the MODREC Secretariats report.

Amendments requiring submission of a new application

31. MODREC must always adopt a proportionate approach in assessing whether a Substantial Amendment may be reviewed as submitted or whether a new application should be requested. A new application should only be required where a proposed amendment would fundamentally alter the nature of the research and the extent of the involvement of, or risk to, existing and/or potential participants. Examples might be where the proposed amendment involves:

a. A change in the primary purpose or objective of the research, such as introduction of additional genetic studies.

b. A substantial change in research methodology.

c. Introduction of new and substantially different classes of investigations or other interventions (rather than simply re-scheduling or modifying those already approved).

d. Recruitment of a new group or type of participant (especially if these would be regarded as being from vulnerable groups).

e. A proposed sub-study with a different CI.

f. Where an amendment involves the submission of a separate protocol.

32. Where a complex or extensive amendment is to be considered by MODREC it may be more appropriate to establish a sub-committee of more than the usual number of members if that would be helpful, or to allocate the Substantial Amendment to a slot at a meeting of the full committee. In either case the researcher may be invited to attend. Either option may compromise timelines and, if this does happen, the reasons must be noted and recorded.

33. All applications reviewed under PR (Proportionate Review) should match the ‘No Material Ethics Issues Tool’ (NMEIT). Any subsequent proposed Substantial Amendments to such studies may be reviewed by the PR Committee or any other sub-committee. Where the proposed changes are significant, the sub-committee may consider that:

a. The amendments are reasonable but raise significant or complex ethics issues which the sub-committee considers need wider discussion – it must refer the amendment to a full meeting of MODREC.

b. The amendments are unreasonable because they should be subject of a new application(s). It does not necessarily follow, where amendments to a PR application would make the application fall outside the NMEIT, that a new application is required. The relevant guidance listed above must be applied.

Appointment of a new CI or Research Sponsor

34. The appointment of a new CI is a substantial amendment, requiring a favourable opinion from MODREC. In addition to the notice of amendment, a statement signed by the outgoing CI where possible (although a signature from the Research Sponsors representative is acceptable where the signature of the outgoing CI is not possible) should also be provided. The applicant must also submit a copy of the new Chief Investigator's CV and the application form signed by the new CI.

35. The appointment of a new Research Sponsor is a substantial amendment requiring approval from MODREC. In addition to the notice of amendment (which must be signed by the outgoing Research Sponsor) the applicant must re-submit the application form signed by the new Research Sponsor.

36. CI or local Principal Investigators (PI) may be absent due to annual leave, sick leave, maternity leave, sabbatical or for other reasons. For short absences, the CI or PI is responsible for arranging adequate cover. Where this has not been possible, for example because the absence was unforeseen, the Research Sponsor will be responsible for ensuring that appropriate arrangements are made for the continued conduct of the study. The organisation hosting the research is responsible for monitoring the conduct of the study. For absences shorter than 4 weeks, it is not necessary to notify MODREC.

Urgent safety measures

37. The Research Sponsor, CI or any PI may make changes to the conduct of a study for urgent safety-related reasons without first giving notice to MODREC or obtaining approval of the amendment so long as MODREC is notified as soon as is practicable.

Annex 8A: Template for notice of substantial amendments

Please include all the following headings in your amendment request:

- Protocol / MODREC Number.
- Protocol Title.
- Chief Investigator / s.
- Organisation.
- Research Sponsor.
- Date of Favourable Ethics opinion.
- Date research started.
- No. of participants involved.
- No. of under 18s involved.
- Description of Amendment.
- Rationale for Amendment.
- Signature and date.

9 Conduct of Research

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Commencement of the research

1. Research should normally commence within 12 months of the date on which a favourable ethics opinion is given by MODREC. A study is generally considered to have commenced when any of the procedures set out in the protocol are initiated.

2. If the study not commence within 12 months the Chief Investigator (CI) must give MODREC a written explanation for the delay.

3. If the project not commence within 24 months a further explanation must be given and a decision will be taken by the MODREC chair as to whether the project must require re-review before commencing.

4. If a study is abandoned prior to commencement, the CI or Research Sponsor must notify MODREC by letter, giving reasons. It is not necessary to submit the form for declaring the conclusion or early termination of the study. If a study is abandoned and it is later proposed to start it afresh, a new application must be made.

Monitoring of research given a favourable opinion

5. Under the Clinical Trials Regulations, the Research Sponsor of a clinical trial of an investigational medicinal product has a variety of statutory responsibilities for notifying the relevant REC of developments in the research after it has started. These are outlined in the HRA SOPs, and must be adhered to if MODREC is the relevant REC.

6. For other types of studies MODREC must keep under review the favourable ethics opinion given to any research study in the light of progress reports and significant developments in the research.

7. Other than by means of the reports that the Research Sponsor and investigators are required to submit, MODREC has no responsibility for proactive monitoring of research studies. The accountability for this lies with the Research Sponsor and the employing organisation.

8. The Chief Investigator and representatives of the Research Sponsor may be requested to attend a meeting of MODREC or sub-committee at any time to discuss any ethics or safety concerns about the research.

Urgent safety measures and Serious Adverse Events (SAE)

9. MODREC must be notified immediately, and in any event within 3 working days, when urgent safety measures have been taken and the reasons why. The notice must set out the reasons for the urgent safety measures and the plan for further action.

10. Where an urgent safety measure requires an amendment to study documentation such as the participant information sheet or consent form, this must be submitted as a substantial amendment to MODREC as soon as it is possible to do so. The substantial

amendment must be marked as being in response to urgent safety measures and a copy of the urgent safety measure notification submitted with the amendment. MODREC will aim to give a formal decision on the substantial amendment within 28 working days.

11. MODREC is not required to approve urgent safety measures prior to implementation. However, notifications of urgent safety measures must be reviewed at a meeting of MODREC or MODREC sub-committee. MODREC must consider whether the measures taken are appropriate in relation to the apparent risk to participants, and what further action the Research Sponsor and investigator(s) propose to take. Where any concern arises about the safety or welfare of participants or the conduct of the research MODREC must address these with the Research Sponsor or CI in writing.

12. Further guidance for clinical trials reporting other types of event are available in the HRA SOPs[20].

13. An SAE is defined as an untoward occurrence that:

a. results in death;

b. is life-threatening;

c. requires hospitalisation or prolongation of existing hospitalisation;

d. results in persistent or significant disability or incapacity;

e. consists of a congenital anomaly or birth defect; or

f. is otherwise considered medically significant by the investigator.

14. An SAE occurring to a research participant must be reported to MODREC where in the opinion of the Chief Investigator the event was:

a. "Related" – that is, it resulted from administration of any of the research procedures, and

b. "Unexpected" – that is, the type of event is not listed in the protocol as an expected occurrence.

15. Reports of related and unexpected SAEs must be submitted within 15 working days of the CI becoming aware of the event, using the SAE report form for non- CTIMPs published on the HRA website[21]. For CTIMPs the mechanism laid out on the MHRA website[22] is to be used and the MODREC and SAC notified separately.

16. Individual reports of SAEs must be reviewed at a sub-committee or Committee meeting.

[20] https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-committee-standard-operating-procedures/ (accessed 5 Dec 19).
[21] https://www.hra.nhs.uk/ (accessed 5 Dec 19).
[22] https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency (accessed Nov 19).

Protocol Violations

17. Protocol violations are non-compliances in relation to the protocol resulting from error or fraud / misconduct and identified through the Research Sponsor's monitoring, or inspection by regulatory bodies.

18. The primary responsibility for investigating protocol violations and taking corrective action lies with the Research Sponsor. It is not necessary to notify MODREC of minor protocol violations unless they constitute a 'serious breach' (see below). Where a Research Sponsor voluntarily notifies MODREC of a minor protocol violation the MODREC Secretariat must acknowledge receipt and send the report to the Chair for information. There is no need for any further action unless the Chair considers that the violation, taken alone or in combination with other reports of minor violations, should be treated as a serious breach.

19. A 'serious breach' is defined as a breach of the protocol or of the conditions or principles of Good Clinical Practice (or equivalent standards for conduct of non- CTIMPs) which is likely to affect to a significant degree the safety or physical or mental integrity of the trial subjects, or the scientific value of the research.

20. The Research Sponsor must notify MODREC and relevant regulatory bodies of a serious breach in any study within 7 working days of the matter coming to their attention. The report may be provided by the Chief Investigator or other representative of the Research Sponsor, copied to the Research Sponsor.

21. Reports of serious breaches must give details of when the breach occurred, the location, who was involved, the outcome and any information given to participants. An explanation must be given and MODREC informed what further action the Sponsor plans to take. Any such report must be considered at a meeting of the Committee or by a sub-committee.

22. Where MODREC receives information other than from the Research Sponsor suggesting that a serious breach may have occurred in relation to an application for ethics review or the conduct of research, consideration must be given to notifying the following:

a. The Research Sponsor

b. The CI's employer

c. The Chief Executive and R&D Director for any relevant organisation(s)

d. Other regulatory bodies where applicable

23. Following notification of the Research Sponsor/relevant authority, MODREC must be kept fully informed of any action taken. It is up to MODREC to consider whether any action needs to be taken in relation to the ethics opinion for the research, in particular where there could be an immediate risk to the safety of participants. MODREC may review the favourable ethics opinion for the study or for a particular site. The opinion on a non-CTIMP may be suspended pending the outcome of further investigation by other bodies. Such a decision must only be taken after careful consideration of the implications for research participants already recruited.

24. A member of MODREC who becomes aware of a possible serious breach must report this to the Chair and MODREC Secretariat.

Final reports

25. A summary of the final report on the research must be submitted to MODREC within one year of the conclusion of the research. A template for final reports is included in Annex 9A. As a minimum, MODREC should receive information on whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research including any feedback to participants. Reports may be submitted electronically (using name and 'submitted electronically' in lieu of a signature).

26. All such reports must be acknowledged by the MODREC Secretariat and reviewed by the Chair or, at the Chair's discretion, by another member of the Committee or a sub-committee. The full Committee must be notified of the receipt of the report in the MODREC Secretariats report. At the discretion of the Chair, copies or summaries may be distributed to members. No further action is required unless the Chair considers that issues are raised requiring discussion at a meeting of MODREC or sub-committee.

27. If the final report is not received within one year of the conclusion of the research the MODREC Secretariat should send a reminder to the Research Sponsor.

Annex 9A: Template for final / update reports

Please include all the following headings in your final report. For update reports delete areas that are not required.

- Protocol / MODREC Number.
- Protocol Title.
- Chief Investigator / s.
- Organisation.
- Research Sponsor.
- Date of Favourable Ethics opinion.
- Date research started.
- Date research completed (if in year).
- Research Abstract.
- No. of participants involved;
    - planned;
    - currently recruited / consented.
- No. of under 18s involved.
- Amendments required and dates approved.
- All adverse events.
- Progress of research.
- List of publications resulting/including this research.
- Signature and date.

10 Storage and Retention of Documentation

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1. Statutory requirements on the storage of documentation for some types of research are described in the HRA standard operating procedures.

2. For other types of research there is no requirement to retain documentation relating to applications that are withdrawn prior to giving an ethics opinion.

3. Documentation is considered to be retained where it is held in electronic form and can be accessed where necessary. It is not necessary to retain original paper copies except in the case of consent forms (although even these can be scanned where practicable).

4. Final copies of the minutes of full MODREC meetings and sub-committee business must be retained indefinitely. Where electronic versions are available, paper copies may be destroyed.

5. Retention periods for study documentation (other than Consent Forms, see para 7) is dependent upon study outcome:

Study documentation retention dates by study outcome	
Scenario	**Retention date**
Study abandoned prior to commencement	10 years from date on which MODREC was notified
Study terminated early by the Research Sponsor	10 years from the date of early termination (as notified by the Research Sponsor)
Study halted following termination of favourable opinion by REC	10 years from the date of halt
Study halted following termination of regulatory approval by MHRA or other relevant body	10 years from the date of the termination of regulatory approval
Study completed	10 years from the date of the conclusion of the study (as notified by the Research Sponsor in the Final Study Report (Annex A to Chapter 9))

6. The following documents must be retained by the MODREC Secretariat at least until the retention date (normally 10 years):

a. MODREC application form and all accompanying documentation (including any revised versions provided during initial review, but not CVs)

b. Notices of substantial amendment and all accompanying documentation (including any revised versions provided during ethics review)

c. All reports of Serious Adverse Events

d. The latest version of the Protocol/Investigator's Brochure where applicable

e. Annual safety reports where applicable

f. Annual progress reports where applicable

g. Reports of actual or alleged serious breaches, and any related documentation or correspondence

h. Other reports submitted by the Research Sponsor, e.g. reports from Data Monitoring Committees

i. Declaration of the conclusion or early termination of the study

j. All correspondence with the Research Sponsor, Chief Investigator on the initial application, appeals, substantial amendments, progress/safety reports or other matters relating to the conduct or management of the study

k. Any correspondence about the study with study participants or individuals or groups representing participants, patients or service users

l. Any correspondence with other regulatory or governance bodies about the study

m. Any correspondence with referees including all reports and comments provided by referees.

7. Participant consent forms must be retained by the Research Sponsor in either hard or electronic copy in line with the Data Protection Act 2018 but for no longer than 7 years unless there is a legal basis to do so[1]. It is no longer necessary for copies to be sent to the MODREC Secretariat

[1] Advice from Dstl Data Protection Officer 18 Dec 18.