# SOP 01 Approval Process for NHS Research Sponsored

# by De Montfort University

1. **Background**

This Standard Operating Procedure (SOP) sets out a process within De Montfort for researchers to apply for sponsorhip by the University, and for the University to review and approve such application. The Health Research Authority (HRA) oversee research ethics and governance for research with NHS patietns and staff.

Researchers consdidering research with the NHS should familiarise themselves with the HRA decision tools that will help establish if the study requires NHS Reasrch Ethics Committee (REC) approval: <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/>. Note that all studies recruiting staff and/or patients via the NHS will require HRA approval. If the study recruits patients, NHS REC approval will be required and this is managed via the HRA approval process. Applications for HRA approval are made via the [IRAS system](https://www.myresearchproject.org.uk/). Both IRAS and HRA website contain a wealth of useful guidance.

1. **Scope**

This SOP applies to all staff, and students where relevant, who request DMU act as Sponsor for research in accordance with the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/) , and to research ethics and governance staff invovled in the review and approval of such applications.

The Sponsor Approval Process includes but is not limited to:

* Ensuring DMU can meet the requirements of the Policy to act as ‘sponsor’ (Appendix 1: Requirement of Sponsors).
* Identifying appropriate actions required to mitigate any identified risks
* Receiving confirmation that all necessary approvals and permissions from relevant authorities are in place for each site
* Has received satisfactory confirmation that the research can be delivered in accordance with the approved protocol / contracts and study documentation

**Important:** Studies that fall under the following categories are subject to further legal requirements for which DMU **CAN NOT** act as sponsor:

* Clinical trial of an investigational medicinal product
* Clinical investigation or other study of a medical device
* Combined trial of an investigational medicinal product and an investigational medical device

Anyone wishing to undertake any of the above studies will need to source sponsorhip from a commercial provider.

1. **Applicaton Process**

A summary of the process can be found in Appendix 2: Pre-Submission Phase and Appendix 3: Post-Submission Phase. Researchers should discuss potential projects involveing NHS patients or staff at the earliest possible time with their Faculty Head of Research Ethics / Research Governance Office.

Where a project falls outside of the portfolio of research that DMU is able to sponsor (for example Clinical Trials of Investigational Medicianl Products, CTIMPs), researchers may need to find altnerative arrangements for sponsorhip which may incur additional costs to the research project.

***It is imperative that all staff invovled in research with the NHS have read the UK Policy Framework for Health and Social Care Research and are familiar with their respective roles and responsbilities.*** It is noteworth that Chief Investigators are responsible for ‘satisfying themselves that everyone involved in the conduct of the research is qualified by education, training and experience, or otherwise competent, to discharge their roles in the project’. DMU expects all Chief Investigators to satisfy themselves that the research team (including themselves) have completed training via the Health Reasrch Authority [website](https://www.hra.nhs.uk/planning-and-improving-research/learning/) before submitting an application, inlcuding guidance for [student research](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/).DMU also expects where research invovles patients, the Chief Investigator will have completed trainig in Good Clinical Practice: <https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm>.

The process works on the principal that DMU ethics approval is not required where the research porject is wholy covered by the NHS ethics review. If a study ahs multiple components that invovle activities both within and outside of the NHS, such as DMU students acting as control groups, the research team should discuss their application with the Research Governance Office as both NHS and DMU ethics approval may be required. Although DMU ethics approval will not normally be sought, we still utilise DMU’s WorkTribe ethics module to process applications and the necessary peer reviews required before submitting to HRA.

**DMU WILL NEVER SPONOSOR RESEARCH STARTED BEFORE ALL NECESSAY APPROVALS HAVE BEEN GRANTED (‘RETROSPECTIVLY’).**

* 1. **WorkTribe Application**

Sponsorship approval will be managed through the WorkTribe ethics application module. An ‘applicaton’ refers to the WorkTribe submission and all supporting doccumentation.

Researchers should complete a new WorkTribe ethics application for their research project, identifying the need for external review in the Scope tab. The required minimal information should then be completed and the following supported doccumentation uploaded into the Doccuments tab.

* 1. **Supporting Doccumentation Requirements – Minimum Requirements**

The following supporting doccuments should alos be uploaded to the application by the applicant:

* Protocol
* Chief Investigator form (SOP01 Annex A)
* Site Feasibility form (SOP01 Annex B)
* Completed draft Integrated Research Application System (IRAS) form
* Draft local information pack (see [IRAS help pages](https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack))
* Participant documentation which may include Consent Forms, Participant Information Sheets/Leaflets (PIS), Letters of Invitation, Letter to GP etc
* Study recruitment aids i.e. Posters, Advertisement text etc
* Evidence of Peer Review as relevant to nature of study if this has already been completed as part of funding applications etc.,
* Evidence of costing and confirmation of adequate funding available
* CVs of research team (including CI)
  1. **Supporting Doccumentation Requirements – Further Guidance**

It is expected that as a minimum, study documentation will be submitted by the researchers. All documentation associated with the project should be uploaded to the studies’ WorkTribe ethics application.

* + 1. Completed Sponsor Application Supporting Forms

The following supporting forms must be completed and submitted as part of the required documents when requesting that DMU act as Sponsor for a research study. The forms ask for information that will be used to inform the Sponsor Risk Assessment.

* Chief Investigator Responsibility Form (Annex A)
* Study Feasibility Assessment Form (Annex B)
  + 1. Protocol

A research study protocol must detail clearly all aspects of the study design and methodology. It must detail procedures associated with the entire study and be compliant with all relevant regulatory, ethical and legal requirements. These requirements will vary depending on the nature of the research activity and must be discussed in detail during the development of a research protocol.

A research protocol must be written following the HRA protocol template: <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/>. Where an existing protocol is available that contains the same information requirements as the HRA template, this may be used. For example this could be a protocol developed as part of a funding application.

You should pay particular attention to HRA’s strategy to involve public and patients in the design of research projects: <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/>. RECs can place a lot of weight on such involvement and may help in gaining a favourable opinion.

The study protocol must contain appropriate consideration of statistical analysis. Ideally, advice should be sought at an early stage, and consideration must be given to the data processing aspects of the proposed study and the format of the study report. This can be detailed in the protocol with all the necessary information on the analysis, including important details such as adjusting for multiple testing and handling missing data, as required. Alternatively, for clinical trials (non-CTIMPs) or where a fuller consideration of statistical analysis is required, this can documented in a separate Statistical Analysis Plan.

Once the final Protocol has been approved it must not be informally altered. Any amendments must be made following the correct procedure (SOP06).

* + 1. Full Data Set IRAS

The Integrated Research Application System requires information about the study and should be completed once a final protocol has been agreed by the Chief Investigator (CI) and study collaborators as appropriate. The information in the IRAS forms must be consistent with the Protocol and all other study documentation. The Full Data Set must be submitted for the Sponsor review, as this includes all parts of the form printed as a PDF and uploaded to WorkTribe.

Please note that every question must be answered as appropriate to the study, and references such as ‘see above’ must be avoided as when the form splits for submission to the various regulatory agencies some information may be lost.

Please be aware that some questions ask for information about the study in language which can be understood by a ‘lay’ person. In addition, it is recommended that you do not simply copy and paste the protocol into the IRAS form.

Guidance on specific questions can be found within the IRAS form and it is recommended that researchers take the time to read the FAQs and Question Specific Advice available within IRAS.

* + 1. Participant Information Documentation

It is imperative that participants are fully informed about their involvement within the study.

*‘Proportionality should be applied to the provision of information to potential research participants54. The more research deviates from established practice or otherwise detrimentally affects the balance between the anticipated risks and benefits, the greater the amount of information that needs to be provided to potential participants. By the same token, the closer the research is to standard practice, the less need there is to provide patients and service users with detailed and lengthy information.’ (UK Policy Framework for Health and Social Care Research).*

Templates and guidance for patient information and consent forms are available via the Faculty/Research Governance webpages, alongside templates on the [HRA web pages](http://www.hra-decisiontools.org.uk/consent/examples.html) that are particularly useful for special circumstances. Where DMU templates are used, these must be reviewed against HRA’s requirements particularly in relation to GDPR: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/>.

It is important that participants give express permission for each aspect of the research. This may include storage of their data or tissues outside of the NHS organisation that provides their care. Permission must also be sought to allow the Sponsor to access their medical notes and research data as part of the monitoring and audit process. Wording for these aspects is suggested on the templates.

All Participant documentation must be reviewed by the Sponsor as part of the Sponsor Risk Assessment and Approval Process.

* + 1. Study recruitment aids

Any literature, or scripts that are proposed to increase awareness of a research study must be reviewed as part of the Sponsor review process. This will also be required for submission to the NHS Research Ethics Committee (REC). Generic posters and general awareness, informing that specific departments conduct research, do not necessarily require individual approval, but when referring to a specific study or a number of studies formal approval is required. This includes adding information on websites and utilizing social media as a method of recruitment.

* + 1. Peer Review

It is DMU’s responsibility to ensure that projects are ‘scientifically sound (through independent expert review)’, (UK Policy Framework). At least two separate independent reviews are required from relevant experts in the subject area using the peer review form template (Annex C). The Peer Review process ensures the methodology employed in a research study will produce robust and credible results. It is expected that the reviewer is independent from the research team and that they should not have had any input into the design, supervision, collaboration, recruitment, conduct and subsequent analysis of the research study.

Where the project has undergone thorough, independent peer review as part of a funding application (or similar), this may be used. Appropriate evidence must be uploaded into the project’s WorkTribe application. The Research Governance Office will assess the review to ensure it meets the requirements and retain the right to request further reviews if considered necessary to fulfil their duty as Sponsor.

Where peer review is not available, the Research Governance Office will arrange for it to be done via the Faculty Research Ethics peer review process. Once accepted, the peer reviews will be uploaded to the project WorkTribe application by the Faculty Research Office, and the application transferred back to the Research Governance Office. A copy of the Peer Review form is attached as Appendix B. Peer review must be undertaken before confirmation of Sponsorship is agreed and before IRAS submission.

* + 1. Evidence of costing & funding

Evidence of adequate funding provision for the duration of the study must be provided.

Where a study is long term, an undertaking to ensure adequate funds will be identified during the course of the research is expected. In cases where adequate funding is not forthcoming for future years, it will be expected that the University/School will underwrite the study to ensure completion. In these cases a discussion to agree provision of funding in subsequent years will form part of the Sponsor Risk Assessment and Approval Process. Where the project is unfunded, a supporting statement will be required from the appropriate Head of School/Research Institute Director or PVC Dean confirming their support for the study, taking into consideration time commitments required for staff to complete the research. For studies completed as part of a post-graduate qualification, the supervisor should provide details of funding arrangements.

* + 1. CVs of research team

It is the responsibility of DMU as sponsor to ensure that the research team are suitable. CVs should be submitted for all key members of the research team including the Chief Investigator.

1. **Sponsor Doccumentation Review**

Once a valid application has been confirmed, the Research Governance Office will commence the Sponsor Review Process following SOP03 resulting in DMU’s agreement to act as sponsor ‘in principle’. **An IRAS application for HRA approval must not be submitted until confrimation of ‘sponsorship in principle’ has been provided by the Research Goverenance Office.**

1. **NHS Research Ethics Committee Review**

The CI must keep the RGO informed throughout the course of NHS REC review. Every effort must be taken by the CI to attend the REC meeting as many concerns can be addressed during that discussion. The CI must inform the RGO if they are unable to attend. Where the CI is a PhD student, the student’s supervisor must also attend the meeting. The RGO must be copied into, and forwarded a copy of all communication between the CI and HRA/REC.

1. **Sponsor Green Light Process**

Once the necessary regaultroy authoriy and NHS partner approvals have been sought, DMU will issue a ‘green light’ (SOP05). Completion of this process provides assurance that all the relevant documentation has been received to confirm appropriate approvals and permissions, including but not limited to:

* Regulatory Authority approvals
* Confirmation of capacity and capability from participating NHS organisation(s)
* REC Favourable opinion
* HRA approval

The Chief Investigator should ensure that HRA/REC approval letters, and confirmation of capacity and capability are forwarded to the Research Governance Office.

An email/ letter confirming Sponsor Green Light and therefore giving permission to commence the research will be generated. Recruitment activity must NOT commence prior to receipt of the Sponsor Green Light Confirmation email/ letter.

**RECRUITMENT TO RESEARCH MUST NOT START UNTIL YOU HAVE RECEVIED CONFIRMATION OF ‘GREEN LIGHT’ FOR THE SITE.**

1. **Non- Compliance**

Where it is identified that the processes detailed above have not been followed a Non-Compliance will be implemented at a minimum of a Major finding.

1. **Doccument Control**

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| **DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT** | | | | | | |
| **Author:** Douglas Gray | | | | | **Job Title:** Faculty Head of Research Ethics (HLS) | |
| **Approved by:** University Research Ethics Committee | | | | | **Date Approved:** 14/04/2021 | |
| **REVIEW RECORD** | | | | | | |
| **Date** | **Issue**  **Number** | | **Reviewed By** | **Description of Changes (If Any)** | | |
| 16/12/21 | 2 | | Research Governance Manager | Inclusion of further detail relating to study protocol leading to the removal of a separate study protocol SOP. | | |
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|  |  | |  |  | | |
| **DISTRIBUTION RECORD:** | | | | | | |
| **Date** | | **Name** | | **Dept** | | **Received** |
| 01/12/21 | | DG | | HLS | |  |
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### Appendix 1: Requirement of Sponsors

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| A | Identifying and addressing poorly designed or planned research and poor quality research proposals, protocols or applications and ensuring that research proposals and protocols:  • take into account systematic reviews of relevant existing research evidence and other relevant research in progress,  • make appropriate use of patient, service user and public involvement and  • are scientifically sound (e.g. through independent expert review60), safe, ethical, legal and feasible and remain so for the duration of the research, taking account of developments while the research is ongoing; |
| B | Satisfying itself that the investigators, research team and research sites are suitable; |
| C | Ensuring that roles and responsibilities of the parties involved in the research and any delegation by the sponsor of its tasks are agreed and documented; |
| D | Ensuring adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project; and |
| E | Ensuring appropriate arrangements are made for making information about the research publicly available before it starts (unless a deferral is agreed by or on behalf of the research ethics committee); agreeing appropriate arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after it has finished; and ensuring arrangements for information about the findings of the research to be made available, including, where appropriate, to participants |
| F | Ensuring that, where expected or required, the research has approval from a research ethics committee and any other relevant approval bodies before it begins; |
| G | Verifying that regulatory and practical arrangements are in place, before permitting the research to begin in a safe and timely manner; |
| H | Putting and keeping in place arrangements for adequate finance and management of the research project, including its competent risk management and data management; |
| I | Ensuring that 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. |

### Appendix 2: Pre-Submission Phase

Appendix 3: Post-Submission Phase

**RECRUITMENT TO RESEARCH MUST NOT START UNTIL YOU HAVE RECEVIED CONFIRMATION OF ‘GREEN LIGHT’ FOR THE SITE.**