# SOP03 Sponsor Review and Risk Assessment

1. **Introduction**

This Standard Operating Procedure (SOP) describes the process that De Montfort University will follow when conducting an initial review of an application in preparation for subsequent sponsor review and risk assessment (where required).

The initial document review will ensure:

* DMU is able to deliver the study with or without external support.
* That an appropriate Peer /Scientific Review has been conducted
* That a study has adequate funding

The outcome is that DMU as a Sponsor has ensured that there is robust study documentation and management process in place, and has completed a comprehensive review of a research application to identify appropriate actions to mitigate any identified risk(s). This enables DMU to provide an “in principle” decision to sponsor a study.

1. **Scope**

This SOP applies to all research governance staff, Faculty RIO staff, staff and students who request that DMU act as Sponsor for research activity under 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/).

1. **Sponsor Review**

On receipt of a complete application, the Research Governance Office will commence a sponsor documentation review. A Sponsor Review Form (Annex B) will be completed by the Research Governance Office for all studies. The Initial Sponsor documentation review may take up to 14 calendar days. Where required in accordance with Figure 1 the sponsor review will also include a sponsor risk assessment (See **Sponsor Risk Assessment**).

Where appropriate, a meeting to discuss the initial documentation review will be arranged with the Research Governance Office, Chief Investigator and relevant members of the study team.

Comments on the documentation and any additional questions generated by the Sponsor Risk Assessment Form will be sent to the CI, and where relevant the study team, for comment and document revision as appropriate.

A response to each question, revised documentation and any points of clarification will be required before a further review is conducted by the Research Governance Office.

1. **Sponsor Risk Assessment**

The Risk Assessment Form, (REf) which includes the Risk Analysis Matrix Tool helps to assess the potential risk(s) associated with a specific study. It is expected that the Risk Assessment Form be completed by the Research Governance Office in communication with the Chief Investigator, research team members and service managers as appropriate.

The risk assessment is dependent on an understanding of risks associated with the study and the capabilities of DMU (e.g. a high risk study by an experienced research team may be addressed by routine management processes, whereas a low risk study by an inexperienced research team may require additional management actions to mitigate risk, etc.).

The risk assessment also depends on current circumstances in DMU at that particular time, for example, if key resources or staff are available or unavailable, when the study is expected to be delivered.

The risk assessment is intended to ensure that risks are identified and addressed in a proportionate way. It is not intended to be overly intrusive and is designed to identify quickly and at an early stage any additional safeguards required for the management of a study. The key output is a list of actions required to manage any identified risks, and ensure the efficient delivery of the study to time and target.

In cases of research requiring a Risk Assessment the process will be started by the Research Governance Office. In order to progress the Sponsor decision, a meeting between the Chief Investigator, members of the study team, and service managers as appropriate will be a mandatory requirement. The purpose of this face-to-face meeting will be to discuss the Risk Assessment in detail, and to talk through any mitigation plans. The meeting will be followed-up by email, and further discussions may be conducted via email or telephone.

* 1. **Risk Assessment Form (Annex C**)

Each area has a set of specific questions. The answers will be subject to a likelihood, impact and residual risk score (Annex C). Mitigation strategies should be documented to address all concerns identified.

The Risk Assessment Form will be repeated as risk mitigation is completed, and will be revisited during the life cycle of the study if any material changes are made to the study documentation, staffing or operational circumstances. The Risk Assessment Form completion, review and revision record should be completed and the form should be saved using the format Year/Month/Day i.e. 2013/11/19. There may be multiple revisions to the form during the life cycle.

1. **Indemnity**

As part of the sponsor review, an assessment of indemnity insurance cover will take place.

On receipt of an application for sponsorship the Research Governance Office will forward this to the Insurance Office. Once the information has been received, the Insurance Office shall be responsible for assessment of the insurance requirements and where required, referral of the research activity to insurers.

Sponsor applications will be reviewed by the Insurance Office on a case by case basis. In a majority of cases, the cost of insurance for the trial will be met centrally by the University’s existing policies. In certain circumstances proposals may attract an additional insurance premium. There is no central fund for payment of additional insurance costs and therefore the investigator must meet the cost of any additional premium.

The Insurance Office will issue confirmation to the Research Governance Office who will, in turn, forward it to the Investigators when confirming sponsorship ‘in principle’.

Amendments that increase the number of sites, or have a significant impact on the protocol inclusion/exclusion criteria will be communicated by the Research Governance Office to the Insurance Office. A communication confirming that the insurance remains valid will be required as part of the amendment sponsor green light process.

In the event that the Insurers are not able to provide cover, the University will be unable to sponsor the study.

1. **Recommendation to Sponsorship Sub Group.**

Only when all queries, required amendments, and points of clarification have been satisfied, the Research Governance Office will make a recommendation to the Sponsor Sub-Group for their approval of ‘sponsorship in principle’. The sponsor sub-group will normally be consulted by email for low-risk applications being given up to 14 days to review, or by exceptional meeting for higher risk studies at the discretion of the Research Governance Office. The Sub-Group should normally be presented with a copy of the IRAS form, Peer Reviews, Sponsor Review form and Risk Assessment (where relevant). The sub-group may request to see full study documentation.

It should be noted that 8.1.9 Scheme of Delegation requires sponsorship to be approved by the Pro Vice Chancellor for Research.

The sponsor sub group should normally comprise the Director of Research Services, Research Governance Manager, and the relevant Faculty Head of Research Ethics. Sub-group approval may also constitute DMU ethics approval as peer review and Chair’s review has taken place and the RGO should update WorkTribe to ‘approved’.

1. **Sponsorship ‘in principle’**

Once Sponsor Sub-Group approval has been obtained, DMU confirm Sponsorship “in Principle” thereby giving authorisation to the Chief Investigator to progress applications to IRAS and the relevant Trusts/NHS organisations.

Sponsorship will remain ‘in principle’ only until all relevant external permissions have been received. The Sponsorship will be confirmed when the study team receive confirmation of the Sponsor approval.

Once sponsorship in principle has been issued, the Research Governance Office should update the ‘Sponsored Research Master List’. The Master List should be updated at all key stages.

1. **Sponsor Green Light Process**

Once the necessary regaultroy authoriy and NHS partner approvals have been sought, the Research Governance Office will complete the Green Light form (Annex D). DMU will issue a ‘green light’. 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:

* Sponsor Risk Assessment
* Sponsor Indemnity confirmation
* Regulatory Authority approvals
* Confirmation of capacity and capability from participating NHS organisation(s)
* REC Favourable opinion
* HRA approval
* Finance approval
* Third party agreements

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.**

1. **Monitoring by the Faculty of Health and Life Sciences Research Ethics Committee.**

All sponsored studies will be reported at and monitored by the HLS FREC.

The SOPs that govern this process will be reviewed at an annual meeting of the Sponsor Sub Committee.

1. **Document 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)** | | |
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Is the study a CTIMP or a Device Study (or both?)

Does the study involve participants?

Is it a non –intervention study (i.e. questionnaire, interview or sample collection study?)

Will participants receive an intervention or treatment that is not considered routine or standard care?

Is it a multicentre study?

Perform Risk Assessment and sponsor review.

Risk Assessment not required. Perform sponsor review.

Yes

Yes

Yes

Yes

No

No

No

Yes

No

No

Are participants ‘high risk’ (lacking capacity to consent, <18 years old, pregnant or breast feeding etc.,)

Yes

No

Figure Risk Assessment Requirements Flow Chart.