| Standard Operating Procedures (SOP) for: | | | |
|---|---|---|---|
| **Risk Assessment** | | | |
| SOP Number: | **23** | Version Number: | **8.0** |
| Effective Date: | **15/05/2017** | Review Date: | **15/05/2019** |

| | |
|---|---|
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|---|---|
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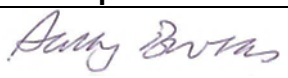
| Signature |  |
| Date | **28/04/2017** |

| Purpose and Objective: |
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| To standardise the process of carrying out risk assessments for research projects as part of the Joint Research Management Office (JRMO) decision to sponsor trials. |
| **Scope:** |
| This SOP applies to JRMO staff, especially the Governance section, and to Bart's Health NHS Trust (BH) and Queen Mary University of London (QMUL) sponsored studies only.<br><br>All CTIMPs, ATMPs and Clinical Investigations (MHRA governed device studies) which are sponsored by BH/QMUL (known as JRMO sponsored trials) will be risk assessed according to this SOP.<br><br>All other research projects will be risk assessed as per *SOPs 12a/b BH/QMUL Sponsorship of Non-CTIMPs*. These include **interventional trials**, **studies within vulnerable populations** and all other QMUL or BH sponsored studies. These will be risk assessed by the Governance Team using the risk assessment section of the governance feedback form (see *SOP 12b BH/QMUL Sponsorship of Non-CTIMPs [JRMO]*).<br><br>**Exceptions:**<br><br>**QM REC reviewed studies are not included in the JRMO risk assessment process.**<br><br>**Externally Sponsored Studies will not be risk assessed by the JRMO.**<br><br>The risk assessment is the responsibility of the sponsor. The local assessment of risks and feasibility will be the responsibility of the local Principal Investigator (PI) and Department Review Group (see *SOP 14*). Externally Sponsored studies will show within ReDA as risk "not set" to indicate this.<br><br>**NOTE:** The Governance Team should alert the CI and Department Review Groups to any studies that raise cause for concern, or have elements of high risk, if seen during the review process. |

| Abbreviations: | |
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| APR | Annual Progress Report |
| ATMP | Advanced Therapy Medicinal Product(s) |
| BH | Barts Health NHS Trust |
| CI | Chief Investigator |
| CRF | Case Report Form |

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| CTIMP | Clinical Trial of an Investigational Medicinal Product(s) |
| DSUR | Development Safety Update Report |
| EOT | End of Trial |
| GCP | Good Clinical Practice |
| IMP | Investigational Medicinal Product |
| IRAS | Integrated Research Application System |
| JRMO | Joint Research Management Office |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| PI | Principal Investigator |
| QMUL | Queen Mary University of London |
| RA | Risk Assessment |
| REC | Research Ethics Committee |
| ReDA | Research Database Application |
| SAE | Serious Adverse Event |
| SOP | Standard Operating Procedures |
| SUSAR | Suspected Unexpected Serious Adverse Reaction |

Definitions:

**Risk in Clinical Trials**

This can be defined as the likelihood of a potential hazard occurring and resulting in harm to the participant and/or an organisation, or to the reliability of the trial results.

For every trial there is a core set of risks inherent to the protocol that relate to the safety of the participants and the integrity/reliability of the results. All organisations involved need to understand these risks so that appropriate control measures, resources, procedures and processes are implemented during the trial to ensure the safety of the trial participants, and lead to high-quality results.

**Risk Assessment**

This is essentially a process of identifying the potential hazards associated with a trial, and assessing the likelihood of those hazards occurring and resulting in harm. This risk assessment will include:

- The risks to participants in relation to the IMP
- All other risks related to the design and methods of the trial (including risks to participant safety and rights, as well as to the reliability of results)

Relevant SOPs:

SOP 7: Costing and Contracting

SOP 11a: BH/QMUL Sponsorship of CTIMPs, ATMPs and Clinical Trials of Non-CE Marked Medicinal Devices – Process for Researchers

SOP 11b: BH/QMUL Sponsorship of CTIMPs, ATMPs and Clinical Trials of Non-CE Marked Medicinal Devices – Process for JRMO Staff

SOP 12a: BH/QMUL Sponsorship of Non-CTIMPs (Researchers)

SOP 12b: BH/QMUL Sponsorship of Non-CTIMPs (JRMO)

SOP 14: Review of Research Including Peer Review and Departmental Authorisation

| SOP Text | | |
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| | Responsibility | Activity |
| 1. | GCP Manager | **Trials under MHRA regulations (CTIMPs, ATMPs and Clinical Investigations) will be risk assessed by the GCP team using the *SOP 23: Associated Document 1 – JRMO Comprehensive Risk Assessment (RA) Tool*.**<br><br>Risk assessment (RA) should be undertaken as early as possible in the trial design stage to identify potential hazards. It is good practice to undertake RA as a team so everyone is aware of all the potential hazards at each stage of the trial and define actions which may be taken.<br><br>At provisional approval stage, a full assessment is performed and risk adaptions are incorporated into the protocol and study design using the JRMO Comprehensive RA Tool.<br><br>At the green-light to activate sites stage, the RA is verified prior to final declaration of sponsorship being issued.<br><br>A copy of the RA should be filed within the sponsor oversight files.<br><br>For each hazard, the following should be considered:<br><br>a) The associated risks to the particular trial<br>b) The potential consequences of each hazard occurring<br><br>Reasonable steps must be taken to reduce the risks by:<br><br>1) Reducing the probability of the hazard occurring, or<br>2) Minimising its adverse consequences. |
| 2. | GCP Manager | **GCP Manager conduct the IMP Risk Assessment and classify the RA outcome.**<br><br>Once the RA has been performed, a score will be allocated on the basis of the number of "High Risk" categories. Scores will be rated as:<br><br>• Low risk: 1 to 4<br>• Medium risk: 5 to 9<br>• High risk: 10 to 14<br>• Unacceptable risk: 15 or more.<br><br>QMUL and BH cannot agree to sponsor any study rated as an "unacceptable risk".<br><br>Action must be taken to lower the risk of these studies.<br><br>If a study is rated as an "unacceptable risk" this should be flagged immediately to the CI and the Costing and Contracts Team. Depending on the stage of the submission, the grant application or funding bid being submitted may have to be changed or an alternative sponsor found.<br><br>If a study risk score changes post initial classification to become "unacceptable" (see Section 5) the Sponsor Oversight Group (SOG) should be immediately informed and kept up-to-date with the actions and adaptions taken to lower the risk. |

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| | | The GCP Manager will work with the CI to lower the risks and hazards to an acceptable level. |
| 3. | GCP Manager | **Feedback and discuss RA with CI.**<br>**During the Kick-off meeting the RA will be discussed and classification agreed.**<br>**Once documentation is finalised - Email to the assigned Governance Officer.** |
| | Governance Officer | **Log and file completed RA.**<br>On receipt of competed RA documentation, log result within ReDA and file document electronically and in paper format, as per *SOP 10: JRMO Filing*. |
| 4. | Sponsors Oversight Group (SOG) | **The SOG should be kept up-to-date with adaptations / mitigations agreed and should be alerted if the risk level cannot be lowered.**<br>If the risk remains unacceptably high, the SOG will formally meet with the CI and decide on a course of action, |
| 5. | GCP Manager | **The RA form should be reviewed and amended if necessary.**<br>The GCP Manager should consider whether the RA is affected when substantial amendments are made to the protocol or other key trial documents. If reassessment is needed it will be documented within the GCP Manager's review email.<br>If a study risk score changes post initial classification to become "unacceptable" (see Section 5) the SOG should be immediately informed and kept up-to-date with the actions and adaptions taken to lower the risk.<br>The RA should also be considered annually within the JRMO and, for studies where held, the CI meeting. Any change in status will be recorded in the meeting notes. |
| **All other types trial, study or project (BH/QMUL Sponsored Studies only):** | | |
| 6. | Assigned Governance Officer | **The following types of trials will be Risk Assessed by the Assigned Governance Officer using *Associated Document 2 - JRMO Non-CTIMP Risk Assessment Tool*:**<br>• **CE-marked device trials**<br>• **Surgical intervention**<br>• **Removal of tissue for use in research**<br>• **Qualitative research involving a vulnerable participant population**<br>All other projects will be deemed a "low risk" and assessed via the normal NHS site confirmation route (e.g. peer, ethical and departmental review).<br>Once all documents have been reviewed within the submission, the Assigned Governance Officer should complete the Non-CTIMP RA Tool. |

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| | | For each risk description, consider what would happen if there was a problem in this area and how likely that is to happen. Enter "Consequence" and "Likelihood" scores.<br><br>For areas where a risk description is not applicable, enter "1" for Consequence and "1" for Impact, giving an overall risk score of "1" ("low" class) for that risk area.<br><br>For each risk description area, calculate the risk score by multiply the Consequence score by the Likelihood score.<br><br>The Final Risk Score is then calculated by adding all the risk scores together and dividing by "9" to create an average.<br><br>It is the risk assessor's discretion to increase the risk rating if it is felt that certain risk areas are heavily weighted and of concern.<br><br>This form is a tool to guide and alert the assessor of problematic areas and how to manage these.<br><br>All "Moderate" and "High" risk studies should be discussed with the Team Leader.<br><br>"High" risk studies should be also discussed with the GCP Manager.<br><br>Any anomalies or questions will be discussed with the Governance Team Leader and escalated to the Operations manager if needed<br><br>Once completed, sign the RA form, scan it (if applicable) and save it in JRMO electronic file(s). A hard copy should be put in the relevant section of the JRMO (paper) files.<br><br>Update ReDA with the score. |

## List of Appendices

There are no appendices associated with this SOP.

## List of Associated Documents

| Document | Document Name |
|---|---|
| Associated Document 1 | JRMO Comprehensive Risk Assessment Tool |
| Associated Document 2 | JRMO Non-CTIMP Risk Assessment Tool |

## Change Control

This section outlines changes from version 7.0 to version 8.0 of this SOP.

| Section Changed | Summary and description of change |
|---|---|
| Whole document | Re-allocation of risk assessments to GCP and Governance team. |
| Associated Documents | Risk Assessment Tools have been re-written, and now include CI signature:<br>*Withdrawn: AD 1 – Risk Assessment Tool v2*<br>*Added: AD 1 – JRMO Comprehensive Risk Assessment Form v1.0*<br>*Added: AD 2 – JRMO Non-CTIMP Risk Assessment Tool v1.0* |