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1. **Introduction**

The Medical Device Regulations 2002 (MDR 2002) and Good Clinical Practice (GCP) require the recording and reporting of adverse events that occur during clinical investigations of medical devices. Safety reporting for clinical trials falling under the scope of these regulations must be reported in accordance with this legislation, GCP, and in compliance with any other conditions stipulated in the trial protocol.

The following events are considered events which are reportable (to the MHRA Devices Adverse Incident Centre) ‘without delay’:

* Any SAE;
* Any device deficiency that might have led to an SAE if suitable action had not been taken, intervention had not been made or circumstances had been less fortunate;
* New findings/updates in relation to already reported events.

‘Without delay’ means:

* Immediately, but not later than 2 calendar days after awareness by sponsor of a new reportable event or of new information in relation to an already reported event where imminent risk of death, serious injury, or serious illness that requires prompt remedial action for other patients/subjects, users or other persons was identified.
* Immediately, but not later than 7 calendar days following awareness by sponsor of a new reportable event or of new information in relation to an already reported event which does not fall into the above category.

Events occurring outside the UK in a clinical investigation which is performed under the same clinical investigation plan (i.e. protocol) must also be reported.

Where necessary, an initial report that is incomplete can be submitted and followed up by a complete report. The Trust, as sponsor, may also request information in addition to that provided by the research team on the Trust’s Clinical Investigation of a Medical Device SAE form, such as the number of devices currently in use, used to date, and the number of participants enrolled to date.

The sponsor must fully record any adverse event of a type identified in the clinical investigation plan as being critical to the evaluation of the results of that clinical investigation.

Events and effects should be recorded from the time the participant signs the informed consent form, unless otherwise specified in the approved protocol.

1. **Purpose**

This SOP’s purpose is to describe the responsibilities and processes related to the identification, assessment, recording and reporting of adverse events occurring in Trust-sponsored Clinical Investigations of Medical Devices falling under the MDR 2002. This SOP applies to non-CE marked devices and CE marked devices used outside the intended use covered by the CE marking. Events occurring in device trials which use devices within their intended use should be reported as per the R&I SOP ‘Safety Reporting for Studies Other than CTIMPs’.

1. **Roles and Responsibilities**

**3.1 Duties Within the Organisation**

It is the responsibility of the Research Office to make Trustwide research policies (policies bearing the acronym “RI” in the reference number) and Trustwide research SOPs (SOPs bearing the acronym ‘RI SOP’ in the SOP reference number) available to all research active staff working on Trust premises.

It is the responsibility of the study’s Chief Investigator (for studies sponsored by the Trust) or Principal Investigator (for all other studies) to ensure that current copies of Trustwide research SOPs and policies relevant to delegated roles in the study are available to research staff.

It is the personal responsibility of all staff to follow Trustwide research SOPs, policies and other procedural documents. The Trust expects all research active staff to be able to demonstrate that they have read and adhere to those Trustwide research SOPs which are relevant to their practice.

All staff are expected to maintain a training record to demonstrate that they have read and understood all SOPs and policies relevant to their role. This record is expected to be kept up to date, with revised SOPs and policies being read and acknowledged in a timely manner. The record should be made available for review by monitors, auditors and the regulatory authorities. The Trust is not prescriptive about the form a training record should take, however evidence of adherence to Trustwide research SOPs and policies will be confirmed by research monitoring and audit. A template ‘Standard Operating Procedures (SOPs) Declaration Form’ is available from Research Managers and the Research Office.

**3.2 Specific to this SOP**

It is the responsibility of the Trust as sponsor to ensure that safety reporting responsibilities for device trials falling under the MDR 2002 are met in full. For the purposes of this SOP, the Research Office represents the Trust as sponsor.

The Trust, as sponsor, will submit all reportable events and any required summary reports to the MHRA unless this is formally delegated to the CI or a third party.

The sponsor or CI may take appropriate urgent safety measures in order to protect research participants against immediate hazard to their health or safety, without prior authorisation from the REC or MHRA. It is the CI’s responsibility to ensure that any urgent safety measures required to prevent harm to participants are effectively implemented at all research sites.

It is the responsibility of the Investigator to conduct safety reporting responsibilities as defined in the MDR 2002, this SOP and the approved protocol. The CI or a suitable delegate (or, for multi-site trials, the PI at site or suitable delegate) is responsible for eliciting details of any adverse events or device effects at each study visit by the participant, or as otherwise specified in the protocol, and ensuring that these are reported, recorded and evaluated appropriately.

The CI or suitable delegate (or the site PI or suitable delegate) is responsible for providing the Investigator assessment of **‘**relatedness’ of an event to the investigational medical device. This means assessing whether or not the event is an effect of the device. The CI or PI is also responsible for assessing the ‘expectedness’ of events which are determined to be related to the device. This means assessing whether or not the adverse effect is an expected effect of the device.

Where a PI has assessed an event at a participating site, the CI must then perform the sponsor’s assessment of ‘relatedness’ and ‘expectedness’ of the event using the relevant section of the Trust Device SAE form. This duty may only be delegated to another Investigator with the sponsor’s permission. The Trust may ask a senior clinician who is independent of the research team to provide either the sponsor’s opinion or a second opinion under certain circumstances (principally where the CI is the Investigator providing the initial assessment). This assessment must be documented using the relevant section of the Trust’s Clinical Investigation of a Medical Device SAE form.

Where the sponsor’s or CI’s opinion differs from that of a site PI, neither can downgrade the PI’s opinion without formal written evidence from that PI of their agreement to such a change.

Where the Trust sponsors a multi-site Clinical Investigation of a Medical Device, the sponsor ‘safety desk’ responsibility is delegated to the CI. This ‘safety desk’ responsibility may not routinely be delegated to another member of the CI’s team except with the sponsor’s permission and in exceptional circumstances.

The CI is also responsible for performing the sponsor’s assessment of trend analysis for non-serious events and effects.

If a trial subject or their partner becomes pregnant during a clinical trial or after participation (if the foetus could still be exposed to the investigational device), the pregnancy must be reported to sponsor, as should any adverse outcomes.

The Trust may delegate additional responsibilities of the sponsor to the CI, on a trial-by-trial basis. Such responsibilities must be explicitly stated in a delegation of responsibilities agreement. See R&I SOPs on ‘Delegating Responsibilities for Clinical Trials of Investigational Medicinal Products and Clinical Investigations of Medical Devices Sponsored by the Trust’ and ‘Trust Sponsorship of Clinical Investigations of Medical Devices (MHRA Regulated)’.

The Investigator is expected to maintain a log or spreadsheet of all adverse events and effects (including those reported as serious), which may be reviewed by oversight committees such as the Trial Steering Committee (TSC). Any trends must be reported by the Investigator to oversight committees in a timely manner.

**4 Definitions and Classification of Adverse Events and Device Effects**

Researchers should be aware that different definitions relate to adverse events in medical device trials from other research. These are set out in the guidance document MEDDEV 2.7/3 (May 2015).

**4.1 Adverse Event (AE)**

An AE is defined as:

Any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device.

This includes events related to the investigational device or the comparator and events related to the procedures involved. For users or other persons, the definition is restricted to events related to investigational medicinal devices.

**4.2 Adverse Device Effect (ADE)**

Any untoward and unintended effect in a subject related to the use of an investigational medical device. All adverse events judged by either the reporting investigator or the CI (on behalf of the sponsor) as having a reasonable causal relationship (e.g. definitely, probably or possibly related) to an investigational device qualify as Adverse Device Effects (ADEs).

This includes any AE resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the implantation, the installation, the operation, or any malfunction of the investigational medical device, or that is the result of erroneous or intentional misuse of the medical device. (MEDDEV 2.7/3 p. 5)

**4.3 Unanticipated Adverse Device Effect (UADE)**

An adverse device effect, the nature or severity of which is not consistent with the protocol, IB or risk assessment (i.e. is previously undocumented), but which does not meet the criteria for ‘Serious’ given in 4.4.

**4.4 Serious Adverse Event (SAE) and Serious Adverse Device Effect (SADE)**

The MDR 2002 do not define SAEs or SADEs, but require that serious adverse events are recorded and reported in line with Annex X of 93/42/EEC: ‘All serious adverse events must be fully recorded and immediately notified to all competent authorities of the Member states in which the clinical investigation is being performed’.

MEDDEV 2.7/3 defines an SAE as an:

‘Adverse event that:

1. Led to death, injury or permanent impairment to a body structure or a body function.
2. Led to a serious deterioration in health of the subject, that either resulted in:
* A life threatening illness or injury, or
* A permanent impairment of a body structure or a body function, or
* In-patient hospitalisation or prolongation of existing hospitalisation, or
* In medical or surgical intervention to prevent life threatening illness
1. Led to foetal distress, foetal death or a congenital abnormality or birth defect

NOTE 1: Planned hospitalisation for pre-existing condition, or a procedure required by the Clinical Investigation Plan, without a serious deterioration in health, is not considered a serious adverse event.’ (MEDDEV 2.7/3 p. 4)

A SADE is an SAE which is considered to be *related* to the investigational device.

Medical judgement should be exercised in deciding whether an adverse event/device effect is serious in other situations. Important adverse events/device effects that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require medical or surgical intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

**4.5 Unanticipated Serious Adverse Device Effect (USADE)**

A serious adverse effect, the nature and severity of which is not consistent with the protocol, IB, risk analysis report or risk assessment (i.e. is previously undocumented). The effect is considered to be serious, related to the device and unanticipated.

MEDDEV 2.7/3 p. 5 also defines an Anticipated SADE (ASADE) as ‘an effect which by its nature, incidence, severity or outcome has been previously identified in the risk analysis report.’

**4.6 Device Deficiency**

‘Device deficiency’ is described as ‘Inadequacy of an investigational medical device related to its identity, quality, durability, reliability, safety or performance. This may include malfunctions, use error or inadequacy in the information supplied by the manufacturer.’ (MEDDEV 2.7/3)

**4.7 Severity**

The term “severe” is often used to describe the intensity (clinical severity) of a specific event or effect. This is not the same as “serious”, as defined in 4.4. Criteria for grading severity should be included in the protocol.

* **Mild:** an event that is easily tolerated by the participant, causing minimal discomfort and not interfering with every day activities.
* **Moderate:** an event that is sufficiently discomforting to interfere with normal everyday activities.
* **Severe:** an event that prevents normal everyday activities

**4.8 Causality Assessment Activities**

During the causality assessment, clinical judgement shall be used and the relevant documents, such as the Investigator’s Brochure (IB), the Clinical Protocol or the Risk Analysis Report shall be consulted, as all the foreseeable serious adverse events and the potential risks are listed and assessed there. (MEDDEV 2.7.1, Revision 4 (June 2016). To be categorised as ‘expected’, the effect must be clearly listed in these documents.

Expected does not mean:

* An event commonly seen in this patient population or in patients with this particular disease
* A common side effect of surgery or of non-investigational devices or medications
* An effect which causes no concern for the investigator

The CI provides the sponsor’s assessment of the relatedness of adverse events and the expectedness of adverse device effects occurring in Trust sponsored Clinical Investigations of Medical Devices as described in 3.2.

**4.9 Classification of Adverse Events and Device Effects**

With reference to the below diagram, the definitions given in section 4 of this SOP, and the protocol, determine the nature of the adverse event.



**5 Recording and Reporting Adverse Events and Device Effects**

**5.1 Adverse Events (AE), Adverse Device Effects (ADE) and Unanticipated Adverse Device Effects (UADE)**

**5.1.1** Check whether the AE/ADE is classified in the protocol as being exempt from reporting. For exempted events, take action as specified in the protocol. If not exempt, or if a UADE, proceed as follows:

**5.1.2** Clearly document the following in the patient’s medical record:

* The date (and if possible the time) of the onset of the event,
* if completely resolved, the duration of the event,
* the severity of the event – mild, moderate, severe,
* whether the event is considered related to the study device or not,
* if considered related, record as an Adverse Device Effect,
* any treatment/medication given for the event, including dates, and
* the outcome of the event.

**5.1.3** Complete the Adverse Event page in the Case Report Form (CRF). A standard Trust Device AE reporting form is provided and should be used to record events. Completing this form includes the requirement to assess the relatedness and expectedness of the event.

**5.1.4** Enter the AE/ADE/UADE into the trial adverse event spreadsheet or adverse event log. This should be made available for the Data Monitoring Committee (DMC) where in place, Trial Steering Committee (TSC) and Sponsorship and Governance Oversight Committee (SAGO) review. A device-specific AE log is available from the Research Office.

**5.1.6** Take any other action as specified by the protocol. For example, some AEs/ADEs may be identified in the protocol as being of special interest - critical to evaluating the safety of the investigational device - and will have specific reporting requirements. For UADEs, consider whether the effect merits a change to the trial protocol, treatment regimen or risk-benefit analysis.

**5.1.7** If a trend appears to be developing for ADEs/UADEs, inform the DMC, TSC and SAGO.

**5.1.8** Follow up any ongoing AEs/ADEs/UADEs, documenting as in 5.1.2 at each study visit until resolved, returned to baseline, or other outcomes as otherwise specified in the protocol. AEs/ADEs/UADEs that are ongoing on completion of the trial should be followed up as required by the protocol and as clinically indicated.

**5.1.9**  AEs/ADEs or UADEs that result in the subject withdrawing - or being withdrawn - from the study must be recorded for inclusion in the annual progress report submitted to the REC.

**5.2 Serious Adverse Event (SAE) and Serious Adverse Device Effect (SADE)**

**5.2.1** Check whether the SAE/SADE is classified in the protocol as being exempt from reporting. For exempted events, take action as specified in the protocol. If not exempt, proceed as follows:

**5.2.2** Clearly document the following in the patient’s medical record:

* The date (and if possible the time) of the onset of the event,
* if completely resolved, the duration of the event/effect,
* the severity of the event/effect as per section 4.7 of this SOP,
* whether the event is considered related to the study device or not. If considered related, record as a Serious Adverse Device Effect (or Unanticipated Serious Adverse Device Effect, depending on the expectedness assessment),
* whether the event is considered expected or not,
* any treatment/medication given for the event/effect, including dates;
* the outcome of the event/effect.
	+ 1. Complete the Device SAE form as soon as possible after becoming aware of the event and send a scanned copy to the Trust’s sponsor office using the email address adverse.events@mft.nhs.uk. SAEs/SADEs **must** be reported to the sponsor office within 24 hours of the research team becoming aware of the event. The Trust’s Device SAE report form is provided at the start of your trial. This must be used to record and report events to the sponsor. Completing this form includes the requirement to assess the relatedness and expectedness of the event.
		2. The Trust as sponsor will report the SAE/SADE to the MHRA within 2 calendar days after receiving a Device SAE report from the research team (where there was risk of death, serious injury or serious illness that required prompt remedial action for other patients/subjects, users or other persons) or 7 days where there was no such risk identified.

**5.2.5** For multi-centre clinical investigations, 5.2.3-4 must be completed for SAEs/SADEs occurring at all sites.

**5.2.6** Complete the Adverse Event page in the CRF. A standard Trust Device AE reporting form is provided and should be used to record events.

**5.2.7** Enter the SAE/SADE into the trial adverse event spreadsheet or adverse event log. This should be made available for DMC, TSC and SAGO review.

**5.2.8** Take any other action as specified by the protocol. For example, some SAEs/SADEs may be identified in the protocol as being of special interest - critical to evaluating the safety of the investigational device - and will have specific reporting requirements.

**5.2.9** If a trend appears to be developing for SADEs, inform the DMC, TSC and SAGO.

**5.2.10** If the SAE/SADE is ongoing at the time of completing the initial report, it should be followed up and documented in the patient medical records at subsequent study visits until resolved, returned to baseline, or stabilised. Follow up reports should be sent periodically or at the sponsor’s request until the event is resolved. The Trust will report new information to the MHRA within 2 calendar days of being informed (where there was risk of death, serious injury or serious illness that required prompt remedial action for other patients/subjects, users or other persons) or 7 days where there was no such risk identified.

**5.2.11** SAEs/SADEs that are ongoing at the end of a participant’s involvement in the trial should be followed up as detailed in the protocol, or for 30 days if this is not specified.

**5.2.12** All SAEs/SADEs must be recorded in a line listing format for inclusion in the annual progress report and any summary reports required by the MHRA.

**5.2.13** SAEs/SADEs that result in the subject withdrawing - or being withdrawn - from the study must be recorded for inclusion in the annual progress report submitted to the REC.

**5.3 Unanticipated Serious Adverse Device Effect (USADE)**

**5.3.1** Clearly document the following in the patient’s medical record:

* The date *and the time* of the onset of the effect
* If completely resolved, the duration of the effect
* The fact that the event is considered to be an effect (i.e. is related to the investigational device)
* The fact that the event is considered unanticipated (i.e. that this is an Unanticipated Serious Adverse Device Effect)
* The severity of the effect - mild, moderate, severe
* Any action taken regarding the investigational device
* Any treatment/medication given for the effect, including dates
* The outcome of the episode

**5.3.2** Complete the Device SAE form as soon as possible after becoming aware of the event and send a scanned copy to the Trust’s sponsor office using the email address adverse.events@mft.nhs.uk. USADEs **must** be reported to the sponsor office within 24 hours of the research team becoming aware of the event. You must also follow up the report with a telephone call or email marked ‘urgent’ to the sponsor. The Trust’s Device SAE report form is provided at the start of your trial. This must be used to record and report events to the sponsor.

* + 1. The Trust as sponsor will report the USADE to the MHRA within 2 calendar days after receiving a Device SAE report from the research team (where there was risk of death, serious injury or serious illness that required prompt remedial action for other patients/subjects, users or other persons) or 7 days where there was no such risk identified.

**5.3.4** USADEs must be emailed to the relevant Research Ethics Committee (REC) within 15 days of the CI becoming aware of the event. This is delegated to the CI by MFT, unless otherwise stated.

**5.3.5** For multi-site trials, 5.3.1-5.3.3 must be followed for USADEs occurring at any site.

**5.3.6** Complete the Adverse Event page in the CRF. A standard Trust Device AE reporting form is provided and should be used to record events.

**5.3.7** Enter the USADE into the trial adverse event spreadsheet or adverse event log. This should be made available for DMC, TSC and SAGO review.

**5.3.8** If the USADE is ongoing at the time of completing the initial report, it should be followed up and documented in the patient medical records at subsequent study visits until resolved, returned to baseline, or stabilised. Follow up reports should be sent periodically or at the sponsor’s request until the event is resolved. The Trust will report new information to the MHRA within 2 calendar days of being informed (where there was risk of death, serious injury or serious illness that required prompt remedial action for other patients/subjects, users or other persons) or 7 days where there was no such risk identified.

**5.3.9** USADEs that are ongoing at the end of a participant’s involvement in the trial should be followed up as detailed in the protocol, or for 30 days if this is not specified.

**5.3.10** USADEs that are identified after a patient has completed a trial should be reported as outlined above.

**5.3.11** All USADEs must be recorded in a line listing format for inclusion in the annual progress report and any summary reports required by the MHRA.

**5.3.12** USADEs that result in the subject withdrawing - or being withdrawn - from the study must be recorded for inclusion in the annual progress report submitted to the REC.

**5.3.13** In multi-centre trials, all participating sites must be informed of USADEs and any associated urgent safety measures required (see section 5.5) without delay. This will usually be conducted by the Research office, but may be delegated to a member of the team or a third party vendor such as a Clinical Trials Unit (CTU).

**5.4 Device Deficiency**

In addition to events and effects as described in 5.1 to 5.3, device deficiencies are also reportable to the MHRA, where they may have led to an SAE in other circumstances (see section 4.4 for definition).

**5.4.1** Clearly document the following in the patient’s medical record:

* The date and time of the onset of the device deficiency
* The nature of the deficiency and any impact on the participant or action required as a result of the deficiency
* Any treatment/medication given to the participant, including dates
* The outcome of the episode

**5.4.2** Complete the Device Deficiency Form as soon as possible after becoming aware of the event and send a scanned copy to the Trust’s sponsor office using the email address adverse.events@mft.nhs.uk. Device deficiencies **must** be reported to the sponsor office within 24 hours of the research team becoming aware of the issue. A Device Deficiency Form is provided by the Research Office at the start of the trial.

* + 1. The Trust as sponsor will report the device deficiency to the MHRA within 7 calendar days after receiving a Device Deficiency Form from the research team.

**5.4.4** For multi-site trials, 5.4.1–5.4.3 must be followed for device deficiencies occurring at any site.

**5.4.5**  Enter the device deficiency into a line listing maintained for the trial. This should be made available for DMC, TSC and SAGO review.

**5.4.6** Follow-up of the long-term outcome of the device deficiency must be performed. In such cases, full details should be recorded on a follow-up Device Deficiency Form, the patient medical records and CRF. The Trust will report new information to the MHRA within 7 calendar days of being informed.

**5.4.7** Device deficiencies that result in the subject withdrawing - or being withdrawn - from the study must be recorded for inclusion in the annual progress report submitted to the REC.

**5.4.8** In multi-centre trials, all participating sites must be informed of device deficiencies and any associated urgent safety measures required (see section 5.5) without delay. This will usually be conducted by the Research office, but may be delegated to a member of the team or a third party vendor such as a Clinical Trials Unit (CTU).

**5.5 Urgent Safety Measures**

If necessary, the sponsor and CI must take appropriate measures to protect clinical trial subjects from any immediate hazard to their health and safety, such as any identified following a USADE or report of a device deficiency.

The sponsor must establish a procedure for emergency situations which enables the immediate identification and, where necessary, an immediate recall of the devices used in the investigation.

Such urgent safety measures are implemented quickly, without waiting for formal MHRA and REC approval, although MHRA advice is sought.

Where urgent safety measures are deemed to be required, the sponsor must immediately:

* Telephone the MHRA to discuss (the CI should also be asked to dial into the call to the MHRA), and
* Telephone the REC to report the situation.

Once the appropriate course of action has been determined, the CI must take the agreed action to ensure trial subjects are made safe.

Immediately, or no later than 3 days after action is taken, the sponsor must notify the MHRA and REC in writing of the measures being taken and the reasons for the measures. This must be done by submitting a completed substantial amendment form. The substantial amendment should be submitted as advised by the MHRA. This will usually be by email, marked ‘Urgent Safety Measure’.

If the trial is closed prematurely as a result of a safety signal, the End of Trial Form must be submitted to the MHRA and REC within 15 days. See the R&I SOP ‘End of Study Notification.’

Oversight Committees active for the trial should be notified in the event of an Urgent Safety Measure.

**5.6 Reporting a Pregnancy in a Trial Subject or Partner**

If a participant - or the partner of a participant - becomes pregnant while taking part in a device trial or during a stage where the foetus could have been exposed to the investigational device, the pregnancy must be reported to the sponsor and followed up until delivery, or as specified in the protocol. A ‘device trials pregnancy notification form’ is available for Trust sponsored Clinical Investigations of Medical Devices. Adverse pregnancy outcomes, such as a birth defect or congenital abnormality, constitute a Serious Adverse Event and must be reported to the sponsor as described in section 5.2.

**5.7 Breaking the Blind**

For blinded/masked trials where there are grounds to believe that a serious adverse event may be a USADE, or otherwise subject to expedited reporting, treatment allocations may need to be un-blinded for specific subjects. It is important the check the requirements of the trial protocol. If the event is found to have occurred in the control or comparator device arm, it will generally only satisfy the criteria for an SAE (unless thought to be due to any control device) and as such should not be subject to expedited reporting.

A system for breaking the blind should be detailed in the protocol and, as far as possible, should maintain blinding of individual clinicians and of trials staff involved in the day-to-day running of the trial. For example, limited representatives of the sponsor, or staff working on a separate trial might undertake the unblinding. However, the safety of patients in the trial always takes priority and unblinding clinicians may be unavoidable if the information is necessary for clinical management purposes.

**6** **Equality Impact Assessment**

The Trust is committed to promoting Equality, Diversity and Human Rights in all areas of its activities.

The Trust undertakes Equality Impact Assessments to ensure that its activities do not discriminate on the grounds of:

|  |  |
| --- | --- |
| Religion or belief | Age |
| Disability | Race or ethnicity |
| Sex or gender | Sexual orientation |
| Human Rights | Socio economic |

This SOP has been equality impact assessed by the author using the Trust’s Equality Impact Assessment (EqIA), and has been registered with the Service Equality Team.

The EqIA score falls under low priority; no significant issues in relation to age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sexual orientation are identified as raising a concern.

**7** **Consultation, Approval and Ratification Process**

Trustwide research SOPs are written by a member of the Research Office staff with relevant expertise and experience. Additional advice may be sought from members of the research community both within and external to the Trust.

Trustwide research SOPs are reviewed by a sub-group of the Sponsorship and Governance Oversight Committee (SAGO). They are ratified by SAGO, which is a sub-committee of the Group Research Governance Committee (GRGC). SAGO’s Terms of Reference are available on request from the Research Office.

Trustwide research SOPs will be reviewed at least every three years, with interim revisions made as required.

**8** **Dissemination and Implementation**

Dissemination

When approved, this SOP will be posted on the Trust Intranet sites. Only the current version will be available. Researchers who do not have access to the intranet can obtain copies of the master SOP list and all Trustwide research SOPs from the Research Office.

Notification of updates to SOPs will be made available via the Research Office Bulletin. The updated SOP list will also be disseminated to Research Managers who will update the Standard Operating Procedures (SOPs) Declaration Form, which forms part of the competency framework for both clinical and non-clinical research staff.

The master copies of all Trustwide research SOPs are stored in a document management system in the Research Office.

Implementation of Procedural Documents

Support and advice on the implementation of this SOP can be obtained from the Research Office or local Research Manager.

**9** **Monitoring Compliance to RI SOP 08D Safety Reporting in Clinical Investigations of Medical Devices (MHRA Regulated)**

Compliance to Trustwide research SOPs by researchers will be monitored via the Trust’s Research Governance Monitoring and Audit programmes.

Process for Monitoring Compliance and Effectiveness

The Quality Assurance Manager is responsible for monitoring compliance with Trustwide research SOPs.

Instances of non-compliance rated as critical will be escalated to the Senior Governance team and may be reported to the Sponsorship and Governance Oversight Committee.

**10 Standards and Key Performance Indicators ‘KPIs’**

Trustwide research SOPs will be available on the Trust intranet and from the Trust Research Office.

Trustwide research SOPs must be reviewed at least every three years or when significant changes to the document are required.

Awareness of Trustwide research SOPs will be delivered via R&I Staff Induction, the Research Office’s training programmes and at individuals’ annual appraisals.

**11 References and Bibliography**

Medical Device Directive 93/42/EEC

Guidelines on Medical Devices: Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC, MEDDEV 2.7/1 revision 4 (June 2016)

Guidelines on Medical Devices: Clinical Investigations Serious Adverse Event Reporting under Directives 90/385/EEC and 93/42/EEC, MEDDEV 2.7/3 (May 2015)

1. **Associated Trust Documents**

R&I SOPs:

* Protocol and GCP Deviations/Violation and Serious Breaches in Clinical Trials of Investigational Medicinal Products and Clinical Investigations of Medical Devices
* Trust Sponsorship of CTIMPs and Clinical Investigations of Medical Devices (MHRA Regulated)
* Delegating Responsibilities for Clinical Trials of Investigational Medicinal Products and Clinical Investigations of Medical Devices (MHRA Regulated) Sponsored by the Trust
* Safety Reporting for Studies Other than CTIMPs

Templates:

* SAE Form (Clinical Investigation of a Medical Device)
* Device Deficiency Form
* AE Form (Clinical Investigation of a Medical Device)
* AE Log (Clinical Investigation of a Medical Device)
* Clinical Trial Pregnancy Form