Safety Reporting to the Western Sydney Local Health District (WSLHD) Research Office
(WSLHD Human Research Ethics Committee & WSLHD Research Governance Office)

REVISION HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Rev No</th>
<th>Author</th>
</tr>
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<tbody>
<tr>
<td>26 October 2018</td>
<td>1</td>
<td>Lani Attwood, Research Governance Manager</td>
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Purpose and Scope
This document is designed to provide guidance for researchers performing clinical trials and other clinical research within WSLHD, of the requirements of safety reporting to the WSLHD Human Research Ethics Committee (HREC) and/or the WSLHD Research Governance Office (RGO.)

A clinical trial is a study which involves the use of an investigational medicinal product, biological or investigational medical device (not included in the Australian Register of Therapeutic Goods). Or a study which uses a medicine or medical device outside of its approved indications as outlined in the Australian Register of Therapeutic Goods (ARTG). Safety reporting for research designed using a non-therapeutic intervention (clinical research) should align, as far as possible, with the requirements outlined in this document.

The information contained in this guide is based on the NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods (2016) and the NSW Health Policy Directive Safety Monitoring and Reporting for Clinical Trials Conducted in NSW Public Health Organisations.
**WSLHD HREC Responsibilities**

Human Research Ethics Committees are required to perform oversight of the risk benefit ratio for clinical trials being performed under their approval. This oversight is provided by ensuring that safety monitoring plans are appropriate, that participants are informed about the risks and benefits of participation, monitor the risk benefit ratio throughout the life of the trial and acknowledge receipt of any safety-related communication.

**WSLHD HREC Safety Reporting Requirements**

The following table is designed to assist you with identifying the safety reporting requirements for WSLHD HREC and the party responsible for this reporting.

<table>
<thead>
<tr>
<th>Safety Report</th>
<th>Responsible Party</th>
<th>Timeframe</th>
<th>Documentation*</th>
</tr>
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<tbody>
<tr>
<td>Significant Safety Issue (SSI) implemented as an Urgent Safety Measure (USM)</td>
<td>Sponsor through the coordinating Principal Investigator</td>
<td>No later than 72 hours after the sponsor becoming aware of the safety event</td>
<td>OHMR SSI Notification Form or Sponsors template</td>
</tr>
<tr>
<td>Significant Safety Issue (SSI) NOT implemented as an Urgent Safety Measure (USM)</td>
<td>Sponsor through the coordinating Principal Investigator</td>
<td>Within 15 days of the sponsor becoming aware of the safety event</td>
<td>OHMR SSI Notification Form or Sponsors template</td>
</tr>
<tr>
<td>Investigator’s Brochure Updates/Addenda</td>
<td>Sponsor through the coordinating Principal Investigator</td>
<td>As and when updates are generated</td>
<td>New edition of Investigators Brochure, Summary of Changes Document &amp; Signed CPI Declaration.</td>
</tr>
<tr>
<td>Annual Safety Report</td>
<td>Sponsor through the coordinating Principal Investigator</td>
<td>Accompanying the annual progress report or when provided by the sponsor annually.</td>
<td>Sponsors Annual Safety Report template accompanying WSLHD HREC Annual Report Template.</td>
</tr>
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*Note all safety reporting to WSLHD HREC must be emailed to WSLHD-ResearchOffice@health.nsw.gov.au*
WSLHD RGO Responsibilities
Research Governance Officers are required to monitor the safety of a clinical trial at a site under their jurisdiction and act upon information which may impact on the institutions duty of care to patients and clinical trial participants at that site. This monitoring is achieved by assessing whether safety events that occur at a site impact on the medico-legal risk, responsible conduct of research or contractual obligations. Research Governance Officers must acknowledge the receipt of this communication, and where appropriate, act on this information to facilitate corrective and preventative action.

WSLHD RGO Safety Reporting Requirements

<table>
<thead>
<tr>
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<th>Documentation*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significant Safety Issue (SSI) that may lead to implementation of an Urgent Safety Measure (USM), amendment or halt/termination of the trial (this SSI may have occurred at any site the trial is being conducted in)</td>
<td>Site Principal Investigator (PI)</td>
<td>No later than 72 hours after the site PI becoming aware of the safety event.</td>
<td>OHMR SSI Notification Form or sponsors template accompanied by the WSLHD RGO Ongoing Site Authorisation Form</td>
</tr>
<tr>
<td>Suspected Unexpected Serious Adverse Events (SUSARs) that occur at WSLHD site/s.</td>
<td>Sponsor through the site Principal Investigator</td>
<td>No later than 72 hours after the site PI becoming aware of the safety event.</td>
<td>OHMR Local SUSAR/USADE/URSAE Notification Form or sponsors template accompanied by the WSLHD RGO Ongoing Site Authorisation Form</td>
</tr>
</tbody>
</table>

*Note all safety reporting documentation must be accompanied by the WSLHD Research Governance Ongoing Site Authorisation Form and submitted to WSLHD-RGO@health.nsw.gov.au

*Any safety reporting outside of the above safety reporting requirements for commercially sponsored clinical trials, will be subject to the WSLHD Research Governance Ongoing Site Authorisation Fee as of January 2019.*
Clinical Trials – WSLHD Study Sponsor

If you are a Principal Investigator conducting a clinical trial within WSLHD where you require WSLHD to act as the study sponsor, you are advised to engage with the WSLHD Research Office when preparing your study protocol to discuss these requirements. When acting as a study sponsor in a Clinical Trial, WSLHD as an organisation hold the following responsibilities in relation to patient safety and reporting;

- Ensuring that the study protocol has clear safety reporting processes and procedures in line with the NHMRC Safety Reporting Requirements.
- Notification to the Australian Therapeutic Goods Administration (TGA) of the clinical trial through the Clinical Trial Notification Scheme.
- Reporting of Suspected Unexpected Serious Adverse Reactions to the TGA and any reporting requirements to the manufacturer of the investigational product/device.

Some of the above responsibilities may be delegated to the Co-ordinating Principal Investigator on behalf of WSLHD. To avoid delays in the approval process to conduct your research please arrange to meet with WSLHD Research Office staff in the early planning stages of your project.

Clinical Trials – Study Sponsor outside of WSLHD (Commercial Companies or Collaborative Group)

The WSLHD HREC and/or WSLHD Research Governance Office will review the study protocol to ensure that there is a clearly defined process in place for the collection, verification, classification, reporting and management of adverse events prior to ethical approval and/or site authorisation. Clarification may be sought on these processes and supporting documents such as sponsor safety notification templates and clinical trial notification repository records may be requested during the review process.
### Definitions

| **Investigational Medicinal Product (IMP)** | A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, a new patient group or when used to gain further information about an approved use.  

**Note:** This definition includes biologicals used as investigational medicinal products. |
| **Investigational Medical Device** | Medical device being assessed for safety or performance in a clinical investigation  

**Note:** This includes medical devices already on the market that are being evaluated for new intended uses, new populations, new materials or design changes. |
| **Significant Safety Issue (SSI)** | Safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial. |
| **Urgent Safety Measure (USM)** | A measure required to be taken in order to eliminate an immediate hazard to a participant’s health or safety.  

**Note:** This type of significant safety issue can be instigated by either the investigator or sponsor and can be implemented before seeking approval from HRECs or institutions. |
| **Serious Adverse Event (SAE)** | A Serious Adverse Event is defined as any untoward medical occurrence in a clinical trial or other clinical research project that:  

- results in death;  
- is life-threatening;  
- requires in-patient hospitalisation or prolongation of existing hospitalisation;  
- results in a persistent or significant disability/incapacity;  
- is a congenital anomaly/birth defect; or  
- is a medically important event or reaction. |
| **Suspected Unexpected Serious Adverse Event (SUSAE)** | An SAE that is defined above which should be considered unexpected if the nature, severity or frequency of that event is not consistent with the information in the Investigator’s Brochure if the product or device is unapproved or if it is not documented in the current Australian Product Information if the product is approved and registered on the Australian Register for Therapeutic Goods (ARTG) |
| **Urgent Safety Measure (USM)** | A measure required to be taken in order to eliminate an immediate hazard to a participant’s health or safety.  

**Note:** This type of urgent safety measure can be instigated by either the investigator or sponsor and can be implemented before seeking approval from HRECs or institutions. |