York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
SOP
R&D/S30

Access to Clinical Trials Protocols and RSI (Reference Safety Information)

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

SOP Reference:	R&D/S30
Version Number:	2.0
Author:	Mags Szewczyk
Implementation date of current version:	27th August 2020

Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Signature:	
	Date:	30th July 2020
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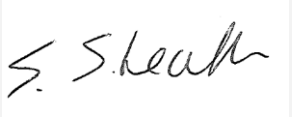
	Signature:	
	Date:	30th July 2020

This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	21st August 2017	
2.0	27th August 2020	Contact details updated/ procedure remains the same. Change of link to R&D website.

Contents

1 Introduction, Background and Purpose

When undertaking a research study it is important that:

- other health professionals are aware of a patient's involvement in a research study via the case notes or CPD;
- other health professionals have access to study information that might be relevant to a patient's medical care;
- research teams are notified of hospital admissions or adverse events in study patients if required by the trial protocol;
- the case notes for research participants are retained for a specified period following the end of the study.

This SOP describes access to research Protocols and Reference Safety Information (RSI) for CTIMP trials during and outside of normal working hours.

Research Teams are responsible for identifying (either in the patient case notes and/or on Core Patient Database (known as a CPD Flagging or Alert system), and /or via use of research wallet cards) that a patient is participating in a research study. This process is covered in R&D/S24.

When a research participant is admitted to a hospital, access to the study protocol or trial protocol and the applicable RSI (for CTIMP studies) may be required by health professionals as it might contain information relevant to the patient's medical care.

The Reference Safety Information (RSI) in a clinical trial is a list of medical events that defines which reactions are expected for the Investigational Medicinal Product (IMP). It is one single definitive list or document that determines which Serious Adverse Reactions (SARs) require expedited reporting to the Competent Authority (MHRA) and which are exempt.

The RSI should be clearly identified in the Protocol, and is usually located within the version of IB (Investigator Brochure) or SmPC (Summary of Product Characteristic) that has been approved and provided for the trial.

2 Who Should Use This SOP

This SOP is aimed at investigator teams and all health professionals who come into contact with research participants within the Trust.

3 When this SOP Should be Used

This SOP applies when access to research protocols and/or RSI may be required by clinical staff.

4 Procedure(s)

To access Information about a research study conducted within the Trust or to request copy of the current Clinical Trial Protocol & RSI, the relevant **Research Team can be contacted directly** (please refer to Staff Room: 'Research and Development' for contact details).

For general information about research studies taking place within the Trust the R&D Unit can be contacted: research.governance@york.nhs.uk or 01904 72 6996.

In the event of a **hospital admission/medical emergency** in a Trial participant, the physician responsible for the patient/or the Chief Investigator (CI)/Principal Investigator (PI) for the Trial may request access to the current trial Protocol or Reference Safety Information (usually held within the IB (Investigator Brochure)/SmPC (Summary of Product Characteristics) approved and provided for the trial).

During the normal working hours (9:00am -17:00pm) this request will be dealt with by a member of the Pharmacy Clinical Trials Team (01904 72 1684) or it can be directed to the relevant Research Team of the speciality with responsibility for the trial within the Trust (please refer to Staff Room: 'Research and Development' for contact details)

Out of normal working hours this request will be dealt with by the on-call Pharmacist and they must be contacted via the hospital switchboard.

5 Related SOPs and Documents

R&D/S24 Identifying Research participants in the Medical Records and on CPD

Appendix 1 Research & Development Contact Details

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Access to Clinical Trials of Investigational Medicinal Product (CTIMP trials) Protocols & Reference Safety Information (RSI*) for health professionals that care for trial participants, and might require information about the trial with regards to patients' medical care.

For **general information** about research studies taking place within the Trust the **R&D Unit can be contacted (01904 72 6996).**

In the event of a **hospital admission/medical emergency** in a Trial participant, the physician responsible for the patient/or the Chief Investigator (CI)/Principal Investigator (PI) for the Trial may request access to the current trial **Protocol and Reference Safety Information** (RSI* - usually held within the IB (Investigator Brochure)/SmPC (Summary of Product Characteristics) approved and provided for the trial).

➔ **During the normal working hours (9:00am -17:00pm)** this request will be dealt with by a member of the Pharmacy Clinical Trials Team (01904 72 1684) or it can be directed to the relevant Research Team of the speciality with responsibility for the trial within the Trust (please refer to contact details listed below).

➔ **Out of normal working hours this request will be dealt with by the on-call Pharmacist and they must be contacted via the hospital switchboard.**

Individual Research Teams can be contacted via the telephone numbers Listed below:

Clinical Research Care Groups	**Clinical Research Specialities**	**Telephone:**
Care Group 1	*Cardiology - Renal - Stroke - Gastroenterology - Hepatology - Respiratory - Cystic Fibrosis*	**5917 or 5878**
Care Group 2	*Scarborough Hospital Research/various specialities*	**01723 342024 or 01723 236194**
Care Group 3 & 5	*Perioperative - ICU Maternity - Obstetrics - Gynaecology – Paediatrics*	**4508**
Care Group 4	*Oncology – Haematology*	**6488 or 1278**
Care Group 6	*Ophthalmology - Rheumatology - Diabetes - Dermatology*	**5206 or 4933**

*The Reference Safety Information (RSI) in a clinical trial is a list of medical events that defines which reactions are expected for the Investigational Medicinal Product (IMP). It is one single definitive list or document that determines which Serious Adverse Reactions (SARs) require expedited reporting to the Competent Authority (MHRA) and which are exempt. The RSI should be clearly identified in the Protocol, and is usually located within the version of IB (Investigator Brochure) or SmPC (Summary of Product Characteristic) that has been approved and provided for the trial.