SUNRRISE

Single Use Negative pRessure dressing for Reduction In Surgical site infection following Emergency laparotomy

Site-specific Training Presentation

PART 5

- Delegation of duties and training
- Associate PI scheme and authorship policy
- PI oversight
- Compliance, monitoring and audits
- Confidentiality
- Investigator site file
- Archiving

UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit | WM Research Collaborative | NWRC North West Research Collaborative

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Delegation Log

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- A delegation log is provided in the ISF along with guidance on its completion
- **All staff undertaking research activity should sign delegation log and the duties be authorised by the PI prior to performing any study activities**
- PI to complete delegation log too
- CVs (signed & dated) and evidence of GCP training for all staff on delegation log must be present in ISF and provided to the **SUNRRISE** Trial Office
  - These should be updated every three years, ideally two, but Trust requirements may differ
  - **GCP for staff taking consent and confirming eligibility is required, but GCP recommended for all staff**
- Change of staff – the **SUNRRISE** Trial Office must be notified of all staff changes
  - Copies of delegation log to be sent to **SUNRRISE** Trial Office when it is updated; **don't forget to add end ("To") dates**
- Completed delegation logs to be filed in ISF

Delegation Log

- By signing an entry on the delegation log, the PI is confirming that:
  1) The person is authorised to perform the study procedures that the person has detailed in the task section
  2) The person is qualified to undertake these tasks
  3) The person is appropriately informed about the study protocol and relevant study procedures
- No person listed on the delegation log should carry out any study related activity until they have been delegated the duty from the PI
- A persons start date on the study cannot and should not pre-date the date the PI signs their entry on the delegation log

The delegation log may sometimes seem a paper exercise but it is essential - it is documented evidence of the appropriate delegation of the investigator's responsibilities by the PI as part of the their oversight of the trial

Training

General SUNRRISE training (study-specific)

- All staff working on the trial must be trained in the protocol & study procedures before undertaking ANY trial activities and addition to the delegation log
- Provided by **SUNRRISE** team during the SIV and then subsequently disseminated by PI
  - Training videos available online or can be delivered by teleconference/video conference by **SUNRRISE** team upon request)
- Use SIV slides as training material in conjunction with protocol and guidelines covering:
  - Trial overview (background, rationale, trial design)
  - Objectives and outcome
  - Patient eligibility
  - Participant identification and consent
  - Randomisation procedures
  - Trial activities, paperwork, CRFs (and completion of), DCFs
  - Safety reporting
  - Trial supplies

Ensure all staff involved in the trial (directly and indirectly) are aware that before a patient can be randomised, a SUNRRISE-specific consent form must be completed by the patient (or a declaration form by the personal consultee), **especially if they are new to research and/or the trial**

Training

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SUNPD application training

- To be completed before applying a SUNPD (PICO 7) to the emergency laparotomy wound of a SUNRRISE participant
- Training in the application of SUNPD will be provided by a Smith & Nephew representative prior to sites opening recruitment
- Subsequent training on the application of SUNPD (e.g. of new staff) will be disseminated by the PI
  - Only staff trained in the application of SUNPD should place the dressings

Wound assessment training

- To be completed before reviewing/assessing the emergency laparotomy wound of a SUNRRISE participant and completing the associate CRF
- Wound assessment training will be provided by an online module accessed via the "Training" section of the trial website; www.birmingham.ac.uk/SUNRRISE
  - Only staff that have completed the training module should assess wounds

Training

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Documenting training

- Evidence of training must be in ISF (section 3)
- Template training log is provided in ISF (it is acceptable to use your own)
  - Online system now available that can be used in concert with paper log; https://bctu-redcap.bham.ac.uk/surveys/?s=9CXYNHDKCD
- Other evidence to document training:
  - Minutes from meetings
  - Confirmations provides by online systems associated with SUNRRISE

Authorship

- Published under a corporate authorship policy
  - E.g. 'The SUNRRISE Trial Collaborators, the North West Research Collaborative and the West Midlands Research Collaborative'
- There will be no named authors in the main authorship line but individuals will be named within the paper and roles will be defined
  - All collaborators will be named and will be PubMed citable
- Authors will be listed as per their involvement within each part of the study/manuscript
  - Writing group and list of local collaborators
- To be included in the list of local collaborators, the collaborator needs to have been involved in the pathway of at least 6 participants
  - Local collaborators will be listed according to hospital and then alphabetically; local consultant and trainee leads will be identified

Associate PI Scheme

- Aims to engage, recognise and promote junior doctor engagement in NIHR portfolio research to develop them to be PIs of the future
- Supported by NIHR
- Open to any junior doctor, nurse or allied healthcare professional willing to make a significant contribution to the conduct and delivery of a trial at a local level
- One associate PI per site, per study, at any given time with a minimum commitment term of 6 months
- Full details of the scheme and the associated checklist are available on the NIHR website; https://www.nihr.ac.uk/documents/associate-principal-investigator-pi-scheme/25040
- Please contact the **SUNRRISE** Trial Office with any queries

PI oversight

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The PI is ultimately responsible for the conduct of the SUNRRISE Trial at the site

- Article 73 of the Clinical Trial Regulation:
  PI must ensure compliance
- Shall assign tasks among members in a way in which safety of subject is not compromised
- Not compromising reliability and robustness of data generated in trial

PI oversight

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Oversight includes, but is not limited to:

- Ensuring the **decision to include a participant** in a trial is documented in the medical notes:
  - confirmation of eligibility
  - when/who approached the patient and gave them the PIS
  - when/who took consent for entry into trial
- Being able to provide evidence that all team members have received **appropriate training** prior to duties being delegated to them – e.g. training log/records, GCP
- Ensuring the **integrity of the data** being submitted for use in the trial – e.g. sign-off of CRFs

Protocol Compliance

Each Principal Investigator must:

- Read the approved protocol and sign protocol signature page
- Adhere to the approved protocol
- Ensure current protocol is in ISF
- Be responsible for enrolling only those patients who meet eligibility criteria

PROTOCOL SUNRRISE

PI SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Principal Investigator agrees to conduct the trial in compliance with the approved protocol.
I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

This protocol has been approved by:

Trial Name:	The SUNRRISE Trial
Protocol Version Number:	Version: 3.0
Protocol Version Date:	05 - Aug - 2020
PI Name:	
Name of Site:	
Signature and date:	_____ __/__/____

PI declaration for CRF Data

- PI is required to compete "Declaration Form for CRF Data" for <u>each</u> participant
  - Once all required CRFs have been completed and provided to the SUNRRISE Trial Office, and any data queries resolved
  - Review CRFs and confirm all data featured are accurate
  - Due approximately 3 weeks after the Day 30 assessment is completed BUT it may be preferred to wait until it is requested by the **SUNRRISE** Trial Office, who will only do so after all (if any) query are resolved
- CRFs may include a "PI declaration" section BUT following the implementation of the "Declaration Form for CRF Data", this <u>does not need to be completed on the individual CRFs</u> before sending to the **SUNRRISE** Trial Office
  - This was originally used to document the local PI confirmation that all the data featured on the form are accurate and demonstrate oversight
  - This section has been retain to allow this mode of data sign-off to continue if preferred

Audit and Inspection

- Your sites is subject to audit/inspection by Sponsor
  - Can occur at any time during recruitment and follow-up
  - Investigators are obliged to cooperate in any audits/inspections
- Investigators must tell the Trial Manager immediately if they are being inspected/audited
  - E.g. local audits by R&D

Monitoring

Aspects of the trial that are monitored include:

- Review of site file
  - Fully regulatory documentation present
  - Current protocol, PIS, ICF present
- Consents
  - Copies sent to BCTU for this purpose
  - Sending asap increase the chances of resolving any issues whist the patient is still in hopsital
- AEs/SAEs
- Enrolment and screening logs
- Delegation Logs, CVs & GCP training, trial training
- Source data verification - may involve direct access to patient notes

Types of Monitoring

Central Monitoring

- SUNRRISE Trial Office will:
  - Be in regular contact with the site research team to check on progress and address any queries that they may have
  - Check incoming CRFs for compliance with the protocol, data consistency, missing data and timing
  - Ask sites for missing data or clarification of inconsistencies or discrepancies
  - Protocol compliance via checks on data
  - Ask sites to complete document checklists (e.g. Investigator Site File Checklist)

Monitoring Visits

- On-site monitoring visits may occur if triggered - requires access to medical notes
- Triggers for onsite monitoring visits include but are not limited to:
  - Poor CRF return
  - Poor data quality
  - Low SAE reporting rates
  - Excessive number of participant withdrawals or deviations
- If a monitoring visit is required, the trial office will contact the site to arrange a date for the proposed visit and will provide the site with written confirmation

Deviations and Breaches

Deviations (non-compliances)

- Protocol deviations (including missed or delayed tests or visits) must be reported to the **SUNRRISE** Trial Office as soon as possible
- Note to File to be completed – see CRF completion guidance in ISF
  - Some CRFs allow for non-compliances ice to be documented
    e.g. Randomisation (QoL completion), Wound Assessment (method and timing of assessor)

Serious breaches in GCP or trial protocol

- A serious breach is a breach which is likely to effect to a significant degree:
  - Safety or physical or mental integrity of trial subjects
  - Scientific value of trial
- All trial investigators must promptly notify CI or Sponsor of a serious breach
- Serious breaches reported to REC
- Corrective and preventative action plan (CAPA) prepared and implemented
- Lead to possible suspension from further recruitment

Confidentiality

- **All information collected during course of trial will be kept strictly confidential**
- Trial numbers will be allocated and all data received by co-ordinating centre will be pseudo-anonymised (unless otherwise stated)
- Sites will comply with all aspects of General Data Protection Act 2018 (and subsequence regulations) and operationally this will include:
  - Consent from patients or consultee/representative to record personal details including name, date of birth, address, telephone number, NHS number and hospital number
  - Appropriate storage, restricted access and disposal arrangements for patients personal and clinical details
  - Consent from patients for access to their medical records by responsible individuals from research staff or from regulatory authorities, where it is relevant to trial participation
  - Consent from patients for data collected for trial to be used to evaluate safety and develop new research

Investigator site file (ISF)

- **The Investigator Site File contains the essential documents necessary for the PI and the research team to conduct a trial**
- All centres will be provided with a site file, which is to be stored securely
- Sites are expected to keep the site file up to date e.g. following amendments to the trial or changes to the processes within the study
- Version control document for key documents (protocol, PIS, ICF, CRF etc.) can be found at the front of the site file - **must be kept up to date** and current approved documents used
- The site file will be monitored by site staff and by a representative of Sponsor
  - ISF checklists (see monitoring)
- Records should be handled in accordance with instructions from Sponsor
- If any documents that should be stored in the site file are kept elsewhere, a Note to File should be filed in the relevant section referencing the true location

Investigator site file (ISF)

NO.	SECTION
	Front of File
1	List of Contacts
2	Current and Superseded Trial Protocols
3	Site Initiation and Trial Training Documents
4	Study Personnel
5	Sponsorship, Insurance and Indemnity
6	Ethics Committee and Regulatory Affairs (REC and HRA)
7	R & D
8	Patient Information Sheet and Consent Forms Supply of current PIS, ICF and GCP letter are stored in section 18 (Study-related supplies)
9	Patient Identification Logs and Completed Consent Forms

NO.	SECTION
10	Randomisation Procedure & Eligibility
11	SUNPD & Smith and Nephew
12	Data Collection (Management and Guidelines)
13	Safety / SAE Reporting
14	Monitoring and Audit
15	Interim and Final Reports
16	Correspondence
17	Ad-doc documents
18	Study-Related Supplies
19	CRFs N.B. Version control document is kept at the front of the site file. Please ensure this is up to date.
20	Completed CRFs

Record Retention & Archiving

At end of trial:

- It is the responsibility of the PI to ensure all essential trial documentation and source documents (e.g. signed ICFs, ISF, participants' hospital notes, copies of CRFs etc.) at their site are securely retained for at least 10 years

No documents will be destroyed without prior approval from the SUNRRISE Trial Office on behalf of the Sponsor

- Once permission is given by the Sponsor, documents can be archived in accordance with the sites processes and procedures in an appropriate archive facility
- If the PI leaves after the end of the study, all responsibility for archiving should be transferred to a designated person acceptable to the Sponsor
- Following written authorisation from Sponsor, arrangements for confidential destruction will then be made

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Thank you

Please remember to document your training:

- Online - using electronic SUNRRISE Training Record; https://bctu-redcap.bham.ac.uk/surveys/?s=9CXYNHDKCD
- Hardcopy – using the paper Training Log for your site, which should be located in section 3 of the Investigator Site File

Please contact us if you have any questions…

sunrrise@trials.bham.ac.uk