The **SUNRRISE** Trial (**S**ingle-**U**se **N**egative p**R**essure dressing for **R**eduction **I**n **S**urgical site infection following **E**mergency laparotomy) has been developed by West Midlands Research Collaborative and the North West Research Collaborative, and is managed by Birmingham Clinical Trials Unit (BCTU) and the North West Surgical Trials Centre (NWSTC).

The trial is funded by the Research for Patient Benefit (RfPB) programme of the National Institute for Health Research (NIHR) and is led by co-lead applicants Mr Richard Wilkin and Mr Hamish Clouston. It will be conducted at approximately 25 UK sites and this feasibility assessment is intended to ensure that your site has the necessary workload and infrastructure to run the trial effectively.

**Things that will be considered in selecting sites for the SUNRRISE Trial include:**

* Sites regularly performing emergency (non-elective) laparotomies.
* Research nursing support to assist with running the trial.
* The lead local researcher for a multi-centre study is the local Principal Investigator (PI); they must have experience of undertaking trials and GCP training completion certificate dated within 2 years.
* The site must be able to adhere to the requirements of the trial and its protocol and have adequate facilities, capacity and qualified staff, including enthusiastic surgical trainees, for the period the trial will run.
* Lack of conflict of existing trials run by the site that might either compete with SUNRRISE for participants or introduce recruitment bias.

**The following points outline what will be expected of a site if they take part in the trial so please think about whether your site can meet them.**

* All staff involved with the trial must be informed about the protocol, the investigational procedures and their authorised trial related duties. As a minimum the PI and a Research Nurse must attend initiation visit training.
* The site will maintain Investigator Site Files (ISF) that will contain all documents essential for the trials conduct.
* All trial data will be submitted in a timely manner using relevant Case Report Forms (CRFs).
* All SAEs will be reported to BCTU within 24 hours of the research staff becoming aware of the event.
* All trial related documents will be retained by site for at least 25 years after the trial is closed and will not be destroyed without permission from the Sponsor or their delegates, the BCTU.
* Monitoring will mainly be performed centrally but if onsite monitoring is required, a working space must be provided.
* In the **SUNRRISE** trial the role of PI carries certain responsibilities:
  + Ensuring that site adheres to the principles outlined in the UK Policy Framework for Health and Social Care Research, GCP guidelines, the Sponsor’s SOPs and other regulatory requirements as amended.
  + Ensuring the agreed protocol is followed, day-to-day conduct of the research, recruitment into the study at site, reporting adverse events, integrity of records and ensuring they are kept confidential.
  + Ensuring the Research Governance requirements for the centre and the study are met.
  + Helping healthcare professionals ensure participants receive appropriate care while involved in the trial.

**All sites require confirmation of capacity and capability from their Trust before the trial can commence at site.**

* No patients can be approached for consent or enrolled to join the study until this is in place.
* The **SUNRRISE** Trial Office can assist in the approval process when a completed form is returned to the **SUNRRISE** Trial Office (contact details on back page).
* The single-use negative pressure dressings (SUNPD) are provided for use in the trial by Smith and Nephew at no cost to the site. There are no excess treatment costs.

**Please Note:**

* BCTU strongly encourages that all people working on trials should be GCP trained.
* The local PI and anyone assessing eligibility and taking informed consent should be GCP trained; a copy of the certificate should be held at site and will be requested by R&D and the **SUNRRISE** Trail Office.
  + Doctors and research nurses can take consent for entry into the **SUNRRISE** Trial.

**PRINCIPAL INVESTIGATOR**

**Details of local Principal Investigator**

|  |  |  |  |
| --- | --- | --- | --- |
| Name |  | | |
| Position |  | | |
| Qualification |  | | |
| Department |  | | |
| Site name & Trust |  | | |
| Hospital |  | | |
| Address |  | | |
| Telephone |  | Fax |  |
| Email |  | | |
| Main employer  (if not Site) |  | | |
| State details of any honorary contacts: |  | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **1.** | **Is the PI part of the General Surgical on-call and involved in the care of emergency patients?** | Yes 🞏 | No 🞏 |

**Experience of the local Principal Investigator**

|  |  |  |  |
| --- | --- | --- | --- |
| **2.** | **Has the proposed PI been a PI, or is a PI for any other trials?** | Yes 🞏 | No 🞏 |

If answered YES, please provide the following details:

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Study: |  | | |
| Type of Study: |  | Recruitment Target: |  |

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| --- | --- | --- | --- |
| Name of Study: |  | | |
| Type of Study: |  | Recruitment Target: |  |

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| **3.** | **Has the proposed PI been a co-investigator, or is a co-investigator for any other trials?** If answered YES, please provide the following details: | Yes 🞏 | No 🞏 |

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| --- | --- | --- | --- |
| Name of Study: |  | | |
| Type of Study: |  | Recruitment Target: |  |

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| Name of Study: |  | | |
| Type of Study: |  | Recruitment Target: |  |

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| **4.** | **Does the PI have current (within 2 years) GCP training?** | Yes 🞏 | No 🞏 |
|  | If answered ‘No’, the PI needs to undertake GCP training prior to the participation in SUNRRISE. | | |

**Role as Principal Investigator**

|  |  |  |  |
| --- | --- | --- | --- |
| **5.** | **Has the PI agreed to take clinical responsibility for the trial at the site, and so confirming the interest of the site participating in the SUNRRISE Trial?** | Yes 🞏 | No 🞏 |
| **6.** | **Does the PI agree to being listed on the ethics/HRA application as PI for this site?** | Yes 🞏 | No 🞏 |
| **7.** | **Are there any conflicts of interest for this trial for the PI and/or site?** | Yes 🞏 | No 🞏 |

***Declaration of Principal Investigator (confirming accuracy of data recorded on this form)***

Name (print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_ \_\_ / \_\_ \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

**Site information**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **8.** | **Are topical negative pressure dressings available at your site?** | Yes - easily | | 🞏 | | Yes - on a named patient basis | | | 🞏 | No | 🞏 |
|  | **If yes, in what setting(s) are they used?**  (tick all that apply) | |  | | Emergency (non-elective) | | 🞏 | Elective | | | 🞏 |

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| **9.** | **How many General Surgical Consultants are there on the on-call rota?** | \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **10.** | **How many will allow their patients to participate in SUNRRISE?** | \_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Recruitment**

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| --- | --- | --- |
| **11.** | **How many emergency laparotomies were seen at your site last calendar year?**  Please estimate if information is not readily available | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **12.** | **How many of those patients would have been eligible for participation in SUNRRISE based on the inclusion and exclusion criteria?**  Please estimate if information is not readily available | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **13.** | **Please state the number of patients expected to be recruited:** | |
|  | **i. In the first year?** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
|  | **ii. For the duration of the study?** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

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| **14.** | **The wound review at 30 days (follow-up) is integral to the trial and must take place 30-37 days post-operation – this may not be in line with the standard practice of all Trust.**  **Please indicate where/how this research activity will take place/ be achieved.**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **15.** | **Are there any trials currently recruiting at your centre, which may conflict / compete for patients within this trial?** | Yes 🞏 | No 🞏 |
|  | If yes, please provide details: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **16.** | **Do you have the staff capacity to undertake this trial?** (e.g. research nurses, data managers) | Yes 🞏 | No 🞏 |
|  | If no, please comment: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

**Local Research Team**

**Lead trainee**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Full Name (incl. title) |  |  | Department |  |
| Position |  |  | Telephone |  |
| Qualification |  |  | Email |  |

**Other trainees in the local team**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Full Name (incl. title) |  |  | Full Name (incl. title) |  |
| Position |  |  | Position |  |
| Qualification |  |  | Qualification |  |
| Department |  |  | Department |  |
| Telephone |  |  | Telephone |  |
| Email |  |  | Email |  |

**Research nurse**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Full Name (incl. title) |  |  | Full Name (incl. title) |  |
| Position |  |  | Position |  |
| Qualification |  |  | Qualification |  |
| Department |  |  | Department |  |
| Telephone |  |  | Telephone |  |
| Email |  |  | Email |  |

**Other trial administration staff (trial co-ordinator, data manager)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Full Name (incl. title) |  |  | Full Name (incl. title) |  |
| Position |  |  | Position |  |
| Qualification |  |  | Qualification |  |
| Department |  |  | Department |  |
| Telephone |  |  | Telephone |  |
| Email |  |  | Email |  |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Is there a clinical trials office or department that BCTU should correspond with to help in the set-up of your site?** | | | | | | Yes 🞏 | No 🞏 |
|  | If answered ‘Yes’, please supply a contact name and contact details below: | | | | | | |
| Full Name (incl. title) | |  |  | Department |  | | |
| Position | |  |  | Telephone |  | | |
| Qualification | |  |  | Email |  | | |

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| --- | --- | --- | --- | --- |
| **Who in your Local R&D Office should the SUNRRISE Trial Office liaise with regarding the set-up of the trial?** | | | | |
| Full Name (incl. title) |  |  | Department |  |
| Position |  |  | Telephone |  |
| Qualification |  |  | Email |  |

|  |
| --- |
| **Please provide any other pertinent information regarding the local team who will deliver the trial at site that you wish to make us aware of below:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Thank you for the completing the Site Feasibility Assessment & Registration Form.**

Please return to the **SUNRRISE** Trial Office by post, email or fax:

|  |  |
| --- | --- |
| **SUNRRISE** Trial Office  Birmingham Clinical Trials Unit (BCTU)  Public Health Building  University of Birmingham  Edgbaston  Birmingham  B15 2TT | E-mail: SUNRRISE@trials.bham.ac.uk  Fax: 0121 415 8871  **If available, the following documents can also be sent with the completed assessment form:**   * **Signed and dated CVs for researchers** * **Latest GCP certificates when available (should be within 2 years when site opens)** * **Local Trust headed paper (electronic version)** |