|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Source Data Verification – Consent and Eligibility** | | | | | | | |
| **Patient Information** | | | | | | | |
| Trial Number: |  | | |  | Correct PIS/consent versions signed? |  | |
| Initials: |  | | |  | Pt initialled all boxes? |  | |
| Date of Birth: |  | | |  | Pt signed and personally dated? |  | |
| Sex: |  | | |  | Person taking consent signed and dated? |  | |
| Date Randomised: |  | | |  | Name of person taking consent: |  | |
| PIS version: |  | | |  | Person taking consent on delegation log? |  | |
| Consent version: |  | | |  | Date consent signed by both parties: |  | |
|  | | |  |  |  |  | |
| **Eligibility – Inclusion Criteria check** | | | |  | **Eligibility – Exclusion Criteria check** | | |
| 50 years or over | |  | |  | Inability or refusal to provide informed consent | |  |
| Elective Major Intra-peritoneal Surgery using an open technique | |  | |  | Anticipated requirement for invasive or non-invasive mechanical ventilation for at least four hours after surgery as part of routine care | |  |
|  | |  | |  | Pregnancy or obstetric surgery | |  |
|  | |  | |  | Previous enrollment in PRISM trial | |  |
|  | |  | |  | Participation in a clinical trial of a treatment with a similar biological mechanism or related primary outcome measure | |  |
|  | |  | |  | Clinician refusal | |  |
|  | | | | | | | Confirm patient eligible: |
| Yes / No |
| Comments: | | | | | | | |

Monitor name Signature