

# Amendment Tool

v1.6 06 December 2021

For office use

QC: No

## Section 1: Project information

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |       |          |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|----------|
| Short project title*:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Spinal Immobilisation Study SIS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |       |          |
| IRAS project ID* (or REC reference if no IRAS project ID is available):                                                                                                                                                                                                                                                                                                                                                                                                                                           | 316755                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |       |          |
| Sponsor amendment reference number*:                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | NSA08                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |       |          |
| Sponsor amendment date* (enter as DD/MM/YY):                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 27 October 2023                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |       |          |
| Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*: | <p>Non-Substantial amendment to the Protocol version 5.0, 25Oct2023 for the following;</p> <ul style="list-style-type: none"> <li>•Added wording to clarify when the DMC meetings will occur</li> <li>•Added the use of the EQ-5D-Y (child friendly version of the form)</li> <li>•Added 'following blunt trauma' to the 2nd inclusion and 1st exclusion criteria.</li> <li>•Updated AE/SAE reporting period as per section 4, it states up until discharge, therefore the trial assessment table (Section 3.1, Table 1) and the follow up section have been updated to clarify AEs are only needed to be reviewed up until discharge.</li> <li>•Removed the wording to say 'c -spine not cleared stickers' are needed.</li> <li>•Minor grammatical/formatting changes.</li> </ul> <p>Non-substantial changes to the PIS'</p> <p>Adult PIS 2.0, 25Oct2023</p> <ul style="list-style-type: none"> <li>•Removal of the wording related to Qualtrics as this will not be used</li> <li>•Added REC name, approval date and updated CTU contact tel no.</li> <li>•Minor format/grammar updates</li> </ul> <p>Parent/Guardian PIS 2.0, 25Oct2023</p> <ul style="list-style-type: none"> <li>•Removal of the wording Where appropriate, your contact information may be shared with a third party in order to record your consent digitally. changed General Data Protection Regulation to UK General Data Protection Regulation and removed the Data Protection Act 2018</li> <li>•Added REC name and approval date</li> <li>•Removal of duplication text (what if there is a problem).</li> <li>•Minor format/grammar updates</li> </ul> |       |          |
| Project type (select):                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Specific study                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |       |          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Research tissue bank<br>Research database                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |       |          |
| Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:                                                                                                                                                                                                                                                                                                                                                                                                       | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | No    |          |
| What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):                                                                                                                                                                                                                                                                                                                                                                                                                     | NHS/HSC REC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |       |          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Ministry of Defence (MoDREC)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |       |          |
| Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a <b>modified amendment</b> (i.e. a substantial amendment previously given an unfavourable opinion)?                                                                                                                                                                                                                                                                                                                 | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | No    |          |
| Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:                                                                                                                                                                                                                                                                                                                                                                                                                              | England                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Wales | Scotland |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | No    | No       |
| Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:                                                                                                                                                                                                                                                                                                                                                                                                | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | No    |          |
| Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:                                                                                                                                                                                                                                                                                                                                                                                                     | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | No    |          |
| Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:                                                                                                                                                                                                                                                                                                                                                                      | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | No    |          |
| Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:                                                                                                                                                                                                                                                                                                                                     | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | No    |          |
| Did the study involve adults lacking capacity OR does the amendment introduce this?:                                                                                                                                                                                                                                                                                                                                                                                                                              | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | No    |          |
| Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:                                                                                                                                                                                                                                                                                                                                                              | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | No    |          |

|                                                                                                                                                     |         |       |          |                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|---------|-------|----------|------------------|
| Did the study involve prisoners or young offenders who are in custody or supervised by the probation service OR does the amendment introduce this?: | Yes     |       | No       |                  |
| Did the study involve children OR does the amendment introduce this?:                                                                               | Yes     |       | No       |                  |
| Did the study involve NHS/HSC organisations prior to this amendment?:                                                                               | Yes     |       | No       |                  |
| Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:                                                              | Yes     |       | No       |                  |
|                                                                                                                                                     | England | Wales | Scotland | Northern Ireland |
| Lead nation for the study:                                                                                                                          | Yes     | No    | No       | No               |
| Which nations had participating NHS/HSC organisations prior to this amendment?                                                                      | Yes     | No    | No       | No               |
| Which nations will have participating NHS/HSC organisations after this amendment?                                                                   | Yes     | No    | No       | No               |
| Was this a "single site, self sponsored" study in England or Wales prior to this amendment?                                                         | Yes     |       | No       |                  |

## Section 2: Summary of change(s)

**Please note:** Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the Amendment Tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, click the "Add another change" box.

| Change 1                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |       |          |                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|----------|------------------|
| Area of change (select)*:                                                                                                                                                   | Study Documents                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |       |          |                  |
| Specific change (select - only available when area of change is selected first)*:                                                                                           | Protocol - Non-substantial changes (e.g. not affecting safety or the scientific value of the trial)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |       |          |                  |
| Further information (free text - note that this field will adapt to the amount of text entered):                                                                            | <p>Non-Substantial amendment to the Protocol version 5.0, 25Oct2023 for the following;</p> <ul style="list-style-type: none"> <li>•Added wording to clarify when the DMC meetings will occur</li> <li>•Added the use of the EQ-5D-Y (child friendly version of the form)</li> <li>•Added 'following blunt trauma' to the 2nd inclusion and 1st exclusion criteria.</li> <li>•Updated AE/SAE reporting period as per section 4, it states up until discharge, therefore the trial assessment table (Section 3.1, Table 1) and the follow up section have been updated to clarify AEs are only needed to be reviewed up until discharge.</li> <li>•Removed the wording to say 'c-spine not cleared stickers' are needed.</li> <li>•Minor grammatical/formatting changes.</li> </ul> |       |          |                  |
| Applicability:                                                                                                                                                              | England                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Wales | Scotland | Northern Ireland |
| Where are the participating NHS/HSC organisations located that will be affected by this change?*                                                                            | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | No    | No       | No               |
| Will all participating NHS/HSC organisations be affected by this change, or only some? ( <b>please note</b> that this answer may affect the categorisation for the change): | All                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |       | Some     |                  |
| Remove all changes below                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |       |          |                  |

| Change 2                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Area of change (select)*:                                                                                                                                                                                                                   | Study Documents                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Specific change (select - only available when area of change is selected first)*:                                                                                                                                                           | Other minor change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that can be implemented within existing resource in place at participating organisations - Please specify in the free text below                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)* | <p>Non-substantial changes to the PIS'</p> <p>Adult PIS 2.0, 25Oct2023</p> <ul style="list-style-type: none"> <li>•Removal of the wording related to Qualtrics as this will not be used</li> <li>•Added REC name, approval date and updated CTU contact tel no.</li> <li>•Minor format/grammar updates</li> </ul> <p>Parent/Guardian PIS 2.0, 25Oct2023</p> <ul style="list-style-type: none"> <li>•Removal of the wording Where appropriate, your contact information may be shared with a third party in order to record your consent digitally. changed General Data Protection Regulation to UK General Data Protection Regulation and removed the Data Protection Act 2018</li> <li>•Added REC name and approval date</li> <li>•Removal of duplication text (what if there is a problem).</li> <li>•Minor format/grammar updates</li> </ul> |

|                                                                                                                                                                             |         |       |          |                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|-------|----------|------------------|
|                                                                                                                                                                             |         |       |          |                  |
| Applicability:                                                                                                                                                              | England | Wales | Scotland | Northern Ireland |
| Where are the participating NHS/HSC organisations located that will be affected by this change?*                                                                            | Yes     | No    | No       | No               |
| Will all participating NHS/HSC organisations be affected by this change, or only some? ( <b>please note</b> that this answer may affect the categorisation for the change): | All     |       | Some     |                  |
| Add another change                                                                                                                                                          |         |       |          |                  |

### Section 3: Declaration(s) and lock for submission

#### Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

|                                 |                              |
|---------------------------------|------------------------------|
| Name [first name and surname]*: | Susana Murphy                |
| Email address*:                 | susana.murphy@imperial.ac.uk |

#### Lock for submission

**Please note:** This button will only become available when all mandatory (\*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, [proceed to submit the amendment online](#). The "Submission Guidance" tab provides further information about the next steps for the amendment.

### Section 4: Review bodies for the amendment

**Please note:** This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

|                                    | Review bodies                                  |                                         |                                       |       |                     |                 |                    |     |       |                       |            |      |            |                                |                   |                    | Category: |         |                                |
|------------------------------------|------------------------------------------------|-----------------------------------------|---------------------------------------|-------|---------------------|-----------------|--------------------|-----|-------|-----------------------|------------|------|------------|--------------------------------|-------------------|--------------------|-----------|---------|--------------------------------|
|                                    | UK wide:                                       |                                         |                                       |       |                     |                 | England and Wales: |     |       |                       | Scotland:  |      |            |                                | Northern Ireland: |                    |           |         |                                |
|                                    | REC                                            | Competent Authority<br>MHRA - Medicines | Competent Authority<br>MHRA - Devices | ARSAC | Radiation Assurance | UKSW Governance | REC (MCA)          | CAG | HMPPS | HRA and HCRW Approval | REC (AWIA) | PBPP | SPS (RAEC) | National coordinating function | HSC REC           | HSC Data Guardians |           | Prisons | National coordinating function |
| Change 1:                          |                                                |                                         |                                       |       |                     | (Y)             |                    |     |       | (Y)                   |            |      |            |                                |                   |                    |           |         | A                              |
| Change 2:                          |                                                |                                         |                                       |       |                     | (Y)             |                    |     |       | (Y)                   |            |      |            |                                |                   |                    |           |         | C                              |
| Overall reviews for the amendment: |                                                |                                         |                                       |       |                     |                 |                    |     |       |                       |            |      |            |                                |                   |                    |           |         |                                |
| Full review:                       |                                                |                                         |                                       |       |                     | N               |                    |     |       | N                     |            |      |            |                                |                   |                    |           |         |                                |
| Notification only:                 |                                                |                                         |                                       |       |                     | Y               |                    |     |       | Y                     |            |      |            |                                |                   |                    |           |         |                                |
| Overall amendment type:            | Non-substantial, no study-wide review required |                                         |                                       |       |                     |                 |                    |     |       |                       |            |      |            |                                |                   |                    |           |         |                                |
| Overall Category:                  | A                                              |                                         |                                       |       |                     |                 |                    |     |       |                       |            |      |            |                                |                   |                    |           |         |                                |