# Amendment Tool

v1.6 06 December 2021

For office use

QC: No

**Section 1: Project information**

| | |
|---|---|
| Short project title*: | TICH-3 |
| IRAS project ID* (or REC reference if no IRAS project ID is available): | IRAS Project ID: 297457 |
| Sponsor amendment reference number*: | MA_18_23 |
| Sponsor amendment date* (enter as DD/MM/YY): | 20 July 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)*: | This amendment comprises change of PI x 2. |

| | | | | |
|---|---|---|---|---|
| Project type (select): | **Specific study** | | | |
| | Research tissue bank | | | |
| | 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 **modified amendment** (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 | Northern Ireland |
| | **Yes** | No | No | No |
| Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?: | **Yes** | | No | |
| EudraCT number*: | 2021-001050-62 | | | |
| Was this clinical trial of an investigational medicinal product (CTIMP) processed under the CTIMP combined review service (formerly known as the Combined Ways of Working (CWoW) pilot)?: | Yes | | **No** | |
| Did the study receive Pharmacy Assurance?: | 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 have Radiation Assurance OR is Radiation Assurance being sought for the first time because of this amendment?: | 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** | **Yes** | **Yes** | **Yes** |
| Which nations will have participating NHS/HSC organisations after this amendment? | **Yes** | **Yes** | **Yes** | **Yes** |

**Section 2: Summary of change(s)**

| What do you want to update?: | Project information |
|---|---|
| | **New site/PI only** |

**Please note:** Only use this option when adding a new site or Principal Investigator (PI) to a clinical trial of an investigational medicinal product (CTIMP). You will not be able to make any other changes at the same time.

**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)*: | Researchers |
| Specific change (select - only available when area of change is selected first)*: | PI - New PI, or temporary arrangements to cover the absence of a PI |
| Further information (free text - note that this field will adapt to the amount of text entered): | Dr Appukuttan Suman (E: Appukuttan.Suman@stockport.nhs.uk) will replace Dr Joseph Vassallo and become the new PI at Stepping Hill Hospital (Stockport NHS Foundation Trust).<br><br>Dr Cathy Patterson (E: cathy.patterson@belfasttrust.hscni.net) will replace Dr Patricia Fearon and become the new PI at Royal Victoria Hospital (Belfast Health and Social Care Trust). |

| Applicability: | England | Wales | Scotland | Northern Ireland |
|---|---|---|---|---|
| Where are the participating NHS/HSC organisations located that will be affected by this change?*: | **Yes** | No | **Yes** | No |
| Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** 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]*:* | Angela Shone |
| *Email address*:* | sponsor@nottingham.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 | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | UK wide: | | | | | | England and Wales: | | | | Scotland: | | | | Northern Ireland: | | | |
| | REC | Competent Authority MHRA - Medicines | Competent Authority 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 | Category: |
| Change 1: | | | | | | (Y) | | | | (Y) | | | | (Y) | | | | | B |
| Overall reviews for the amendment: | | | | | | | | | | | | | | | | | | | |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Full review: | | | | | | N | | | | N | | | | N | | | | | |
| Notification only: | | | | | | Y | | | | Y | | | | Y | | | | | |
| Overall amendment type: | Non-substantial, no study-wide review required | | | | | | | | | | | | | | | | | | |
| Overall Category: | B | | | | | | | | | | | | | | | | | | |