# Amendment Tool

v1.4 30 Nov 2020

For office use

QC: No

**Section 1: Project information**

| | | | | |
|---|---|---|---|---|
| Short project title*: | PACKMaN | | | |
| IRAS project ID* (or REC reference if no IRAS project ID is available): | 1003404 | | | |
| Sponsor amendment reference number*: | Substantial Amendment 2 | | | |
| Sponsor amendment date* (enter as DD/MM/YY): | 11 March 2021 | | | |
| 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)*: | See appended summary document for full details. Main changes include:<br>Trial team details amended<br>Typos and formatting corrected and minor amendments to text<br>Revision to consent process<br>Letters to participants and legal representatives and consent forms amended to reflect revised consent process<br>Revised ED leaflet<br>New hospital sites added for the purposes of secondary data collection | | | |
| Project type (select): | ◉ Specific study<br>○ 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<br>○ 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: ○ |
| Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?: | ◉ Yes | ○ No | | |
| Was this clinical trial of an investigational medicinal product (CTIMP) processed under 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 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 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: | ◉ | ○ | ○ | ○ |
| Which nations had participating NHS/HSC organisations prior to this amendment? | ☑ | ☐ | ☐ | ☐ |
| Which nations will have participating NHS/HSC organisations after this amendment? | ☑ | ☐ | ☐ | ☐ |

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

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|---|---|
| What do you want to update?: | ○ Chief Investigator<br>○ Sponsor<br>○ Administrative<br>◉ Project information |

**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, tick 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)*: | Correction of typographical errors | | | |
| Further information (free text - note that this field will adapt to the amount of text entered): | Updated typos and formatting throughout | | | |
| Applicability: | England | Wales | Scotland | Northern Ireland |
| Where are the participating NHS/HSC organisations located that will be affected by this change?*: | ☑ | ☐ | ☐ | ☐ |
| 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: ☑

| Change 2 | | | | |
|---|---|---|---|---|
| Area of change (select)*: | Study Documents | | | |
| Specific change (select - only available when area of change is selected first)*: | Other significant change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that will have additional resource implications for participating organisations - Please specify in the free text below | | | |
| Further information (free text - note that this field will adapt to the amount of text entered): | New and revised letters and consent forms for patients and legal representatives to detail revised consent process. Revised ED leaflet to include SAE reporting and emergency unblinding contact details | | | |
| Applicability: | England | Wales | Scotland | Northern Ireland |
| Where are the participating NHS/HSC organisations located that will be affected by this change?*: | ☑ | ☐ | ☐ | ☐ |
| 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: ☑

| Change 3 | | | | |
|---|---|---|---|---|
| Area of change (select)*: | Participating Organisations | | | |
| Specific change (select - only available when area of change is selected first)*: | Addition of new sites undertaking different activities, or a change to activities undertaken by existing sites | | | |
| Further information (free text - note that this field will adapt to the amount of text entered): | Addition of new sites (site type two: Hospital Trusts) - please see attached list of hospitals. Local Collaborators will be appointed at each hospital to provide oversight. | | | |
| Applicability: | England | Wales | Scotland | Northern Ireland |
| Where are the participating NHS/HSC organisations located that will be affected by this change?*: | ☑ | ☐ | ☐ | ☐ |
| 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: ☑

| Change 4 | |
|---|---|
| Area of change (select)*: | Participant Procedures |
| Specific change (select - only available when area of change is selected first)*: | Recruitment - Change in identification, approach, recruitment or consent of participants |
| | Consent procedure revised to remove full written informed consent being taken by attending paramedic (verbal assent will still be obtained prior to randomisation). The justification for this is that, for written informed consent to be taken in the ambulance it requires that the patient is deemed to have capacity, their pain is under control, there is no need for ongoing clinical care that would interrupt the consent process, and there is sufficient time for the |

| | |
|---|---|
| Further information (free text - note that this field will adapt to the amount of text entered): | clinical care that would interrupt the consent process, and there is sufficient time for the patient to consider their participation and sign the consent form before arriving at hospital. In reality, we believe this will be a very rare occurrence and that patients' capacity to provide written informed consent at this stage will be impaired due to ongoing pain and/or side effects of ketamine or morphine. Instead, full written informed consent will be taken by the Research Paramedic as soon as practically possible after the patient has arrived at hospital. This change has the support of our ambulance service partners.<br><br>The option for remote consent has been included and a new e-consent form has been designed to allow consent to take place more easily where a face-to-face visit is not possible |

| Applicability: | England | Wales | Scotland | Northern Ireland |
|---|---|---|---|---|
| Where are the participating NHS/HSC organisations located that will be affected by this change?*: | ☑ | ☐ | ☐ | ☐ |
| 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: ☑

| Change 5 | |
|---|---|
| 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): | Revised consent process and other minor revisions - see appended document for list of all minor changes |

| Applicability: | England | Wales | Scotland | Northern Ireland |
|---|---|---|---|---|
| Where are the participating NHS/HSC organisations located that will be affected by this change?*: | ☑ | ☐ | ☐ | ☐ |
| 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]*:* | Mathew Gane |
| *Email address*:* | sponsorship@warwick.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: | | | |
| | Competent Authority MHRA - Medicines | Competent Authority MHRA - Devices | EMAC | Confirmation Assurance | HRA and HCRW Governance | MHRA (MCA) | | NIHR CPMS | HRA and HCRW Approval | AWIA (AWIA) | | RAEC (RAEC) | National coordinating function | REC | Data Guardians | | National coordinating function |

| | REC | Com MHR | Com MHR | ARS | Radia | UKS | REC | CAG | HMP | HRA | REC | PBPI | SPS | Natio | HSC | HSC | Priso | Natio | Category: |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Change 1: | N | | | | | N | | | | N | | | | | | | | | N/A |
| Change 2: | Y | | | | | Y | | | | Y | | | | | | | | | A |
| Change 3: | Y | | | | | Y | | | | Y | | | | | | | | | B |
| Change 4: | Y | | | | | Y | | | | Y | | | | | | | | | A |
| Change 5: | N | | | | | (Y) | | | | (Y) | | | | | | | | | A |
| Overall reviews for the amendment: | | | | | | | | | | | | | | | | | | | |
| Full review: | Y | | | | | Y | | | | Y | | | | | | | | | |
| Notification only: | N | | | | | N | | | | N | | | | | | | | | |
| Overall amendment type: | Substantial for review | | | | | | | | | | | | | | | | | | |
| Overall Category: | A | | | | | | | | | | | | | | | | | | |

| This amendment relates to: | |
|---|---|
| Part 1: | No |
| Part 2: | Yes |
| Notification for authorisation to the competent authority (MHRA - Medicines): | |
| Notification for an opinion to the ethics committee (REC): | Yes |