# Amendment Tool

v1.8 30 April 2025

For office use

QC: No

**Section 1: Project information**

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|---|---|
| Short project title*: | PROTECT-AEGIS |
| IRAS project ID* (or REC reference if no IRAS project ID is available): | 1011239 |
| Sponsor amendment reference number*: | Non-substantial amendment 2 |
| Sponsor amendment date* (enter as DD/MM/YY): | 10 April 2026 |
| 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)*: | The following will be changed for the PROTECT-AEGIS trial:<br>1) Addition of one new NHS site<br>2) Change of PI for two participating organisations |

| | | | | |
|---|---|---|---|---|
| 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* (if the study has a EudraCT number enter it here. If the study does not have a EudraCT number enter "N/A"): | N/A | | | |
| 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** | | |
| Was the study a performance evaluation study of an In Vitro Diagnostic (IVD) medical device^ (including as a companion diagnostic in a clinical trial of an investigational medicinal product)?: | Yes | **No** | | |
| Does the amendment make the study a performance evaluation study of an In Vitro Diagnostic (IVD) medical device^ (including as a companion diagnostic in a clinical trial of an investigational medicinal product)?: | Yes | **No** | | |
| ^ IVD medical devices are tests used on biological samples, such as tissues, blood or urine, to determine the status of a person's health. This may be a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination | | | | |
| 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** | | |
| Does the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?: (e.g. the study relies upon section 251 support in England and Wales, or equivalent in Scotland to set aside the common law duty of confidentiality) | Yes | **No** | | |
| Does 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** | | |
| Does 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 | **Yes** | No |
| Which nations will have participating NHS/HSC organisations after this amendment? | **Yes** | No | **Yes** | No |

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

| What do you want to update?: | Chief Investigator<br>Sponsor Group<br>Administrative |
|---|---|
| | **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, click the "Add another change" box.

| Change 1 | | | | |
|---|---|---|---|---|
| Area of change (select)*: | Participating Organisations | | | |
| Specific change (select - only available when area of change is selected first)*: | Addition of sites undertaking the same activities as existing sites | | | |
| Further information: explain what the change is, why the change is being made and any possible impact on study participants/carers (free text - note that this field will adapt to the amount of text entered): | 1. Addition of one new NHS site:<br>NHS Lanarkshire PI: Miriam Stephens: Miriam.Stephens@lanarkshire.scot.nhs.uk | | | |
| Applicability: | England | Wales | Scotland | Northern Ireland |
| Where are the participating NHS/HSC organisations located that will be affected by this change?*: | No | 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** | |
| | | | Remove all changes below | |

| Change 2 | | | | |
|---|---|---|---|---|
| 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: explain what the change is, why the change is being made and any possible impact on study participants/carers (free text - note that this field will adapt to the amount of text entered): | 1. Change of PI for two participating organisations:<br>a) The Royal Marsden NHS Foundation Trust new PI: Ravishankar Raobaikady: ravishankar.raobaikady@rmh.nhs.uk<br>b) Newcastle upon Tyne Hospitals NHS Foundation Trust new PI: Alison Blackburn: alison.blackburn1@nhs.net | | | |
| 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? (**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]*:* | Mays Jawad |
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| *Email address*:* | research.amendments@qmul.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, amendments to trials processed under the combined review service should be made using the new part of IRAS. Further information can be found on the "Submission Guidance" tab.**

**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) | | | | | New site |
| Change 2: | | | | | | (Y) | | | | (Y) | | | | N | | | | | B |
| Overall reviews for the amendment: | | | | | | | | | | | | | | | | | | | |
| Full review: | | | | | | N | | | | N | | | | N | | | | | |
| Notification only: | | | | | | Y | | | | Y | | | | Y | | | | | |
| Overall amendment type: | Non-substantial, no study-wide review required | | | | | | | | | | | | | | | | | | |
| Overall Category: | B | | | | | | | | | | | | | | | | | | |