

Amendment Tool

v1.4 30 Nov 2020

For office use

QC: No

Section 1: Project information

| | | | | |
|---|--|-------------------------------------|-------------------------------------|-------------------------------------|
| Short project title*: | UK-ROX | | | |
| IRAS project ID* (or REC reference if no IRAS project ID is available): | 288506 | | | |
| Sponsor amendment reference number*: | NSA03 | | | |
| Sponsor amendment date* (enter as DD/MM/YY): | 20 May 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)*: | Change 1, 2 and 4: Adding new research sites Change 3: Change of PI at existing sites | | | |
| Project type (select): | <input checked="" type="radio"/> Specific study <input type="radio"/> Research tissue bank <input type="radio"/> Research database | | | |
| Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?: | <input checked="" type="radio"/> Yes | | <input type="radio"/> No | |
| What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select): | <input checked="" type="radio"/> NHS/HSC REC <input type="radio"/> 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)? | <input type="radio"/> Yes | | <input checked="" type="radio"/> No | |
| Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?: | England | Wales | Scotland | Northern Ireland |
| | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?: | <input type="radio"/> Yes | | <input checked="" type="radio"/> No | |
| Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?: | <input type="radio"/> Yes | | <input checked="" type="radio"/> No | |
| Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?: | <input type="radio"/> Yes | | <input checked="" type="radio"/> 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?: | <input type="radio"/> Yes | | <input checked="" type="radio"/> No | |
| Did the study involve adults lacking capacity OR does the amendment introduce this?: | <input checked="" type="radio"/> Yes | | <input type="radio"/> No | |
| Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?: | <input type="radio"/> Yes | | <input checked="" type="radio"/> No | |
| Did the study involve prisoners OR does the amendment introduce this?: | <input type="radio"/> Yes | | <input checked="" type="radio"/> No | |
| Did the study involve NHS/HSC organisations prior to this amendment?: | <input checked="" type="radio"/> Yes | | <input type="radio"/> No | |
| Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?: | <input type="radio"/> Yes | | <input checked="" type="radio"/> No | |
| Lead nation for the study: | England | Wales | Scotland | Northern Ireland |
| | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Which nations had participating NHS/HSC organisations prior to this amendment? | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Which nations will have participating NHS/HSC organisations after this amendment? | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

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, tick 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 (free text - note that this field will adapt to the amount of text entered): | <p>Adding new research sites:</p> <p>St George's Hospital (St George's University Hospitals NHS Foundation Trust) Joint PI: Dr Dagan Lonsdale and Dr Deborah Dawson (dlonsdal@sgul.ac.uk; deborah.dawson@stgeorges.nhs.uk)</p> <p>Leeds General Infirmary (Leeds Teaching Hospitals NHS Foundation Trust) PI: Dr Richard Gould (richard.gould@nhs.net)</p> <p>Basingstoke and North Hampshire Hospital (Hampshire Hospitals NHS Foundation Trust) PI: Dr Anthony Ashton (antony.ashton@hhft.nhs.uk)</p> <p>Colchester General Hospital (East Suffolk and North Essex NHS Foundation Trust) PI: Dr Mohamed Ramali (mohamed.ramali@esneft.nhs.uk)</p> <p>Morrison Hospital (Swansea Bay University Health Board) PI: Dr Ceri Battle (ceri.battle@wales.nhs.uk)</p> <p>University Hospital Southampton (University Hospital Southampton NHS Foundation Trust) PI: Dr Ahilanandan Dushianthan (a.dushianthan@soton.ac.uk)</p> <p>University Hospital Lewisham (Lewisham and Greenwich NHS Trust) PI: Dr Mick Jennings (mick.jennings@nhs.net)</p> <p>Northampton General Hospital (Northampton General Hospital NHS Trust) PI: Dr Nazrudeen Ali (nazrudeen.ali@ngh.nhs.uk)</p> | | | |
| Applicability: | England | Wales | Scotland | Northern Ireland |
| Where are the participating NHS/HSC organisations located that will be affected by this change?* | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 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): | <input type="radio"/> All | | <input checked="" type="radio"/> Some | |
| Add another change: <input checked="" type="checkbox"/> | | | | |

| Change 2 | |
|---|--|
| 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 |
| | <p>Alexandra Hospital (Worcestershire Acute Hospitals NHS Trust) PI: Dr Olivia Kelsall (olivia.kelsall@nhs.net)</p> |

Further information (free text - note that this field will adapt to the amount of text entered):

Worcestershire Royal Hospital (Worcestershire Acute Hospitals NHS Trust)
PI: Dr Olivia Kelsall (olivia.kelsall@nhs.net)

Stepping Hill Hospital (Stockport NHS Foundation Trust)
PI: Dr Ahmed Zaki (ahmed.zaki@stockport.nhs.uk)

Royal United Hospital, Bath (Royal United Hospitals Bath NHS Foundation Trust)
PI: Professor Jerry Nolan (jerry.nolan@nhs.net)

Norfolk and Norwich University Hospital (Norfolk and Norwich University Hospitals NHS Foundation Trust)
PI: Dr Stephen Hutchinson (stephen.hutchinson@nnuh.nhs.uk)

Southmead Hospital (North Bristol NHS Trust)
PI: Dr Matt Thomas (matt.thomas@nbt.nhs.uk)

Royal Sussex County Hospital (University Hospitals Sussex NHS Foundation Trust)
PI: Dr Barbara Phillips (Barbara.Phillips@nhs.net)

Princess Royal Hospital (University Hospitals Sussex NHS Foundation Trust)
PI: Dr Barbara Phillips (Barbara.Phillips@nhs.net)

Countess of Chester Hospital (Countess Of Chester Hospital NHS Foundation Trust)
PI: Dr Peter Bamford (peter.bamford3@nhs.net)

Wrexham Maelor Hospital (Betsi Cadwaladr University Health Board)
PI: Dr John Harris (john.harris2@wales.nhs.uk)

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|--|-------------------------------------|-------------------------------------|---------------------------------------|--------------------------|
| Applicability: | England | Wales | Scotland | Northern Ireland |
| Where are the participating NHS/HSC organisations located that will be affected by this change?* | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 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): | <input type="radio"/> All | | <input checked="" type="radio"/> Some | |

Add another change:

| Change 3 | | | | |
|--|---|--------------------------|---------------------------------------|--------------------------|
| 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): | <p>New PI at sites: Northern General Hospital (Sheffield Teaching Hospitals NHS Foundation Trust) Former PI: Professor Gary Mills (g.h.mills@sheffield.ac.uk) New PI: Dr Max Richardson (max.richardson@nhs.net)</p> <p>Warwick Hospital (South Warwickshire NHS Foundation Trust) Former PI: Dr Ben Attwood (ben.attwood@swft.nhs.uk) New PI: Dr Tahir Saeed (Tahir.Saeed@swft.nhs.uk)</p> | | | |
| Applicability: | England | Wales | Scotland | Northern Ireland |
| Where are the participating NHS/HSC organisations located that will be affected by this change?* | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 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): | <input type="radio"/> All | | <input checked="" type="radio"/> Some | |

Add another change:

| Change 4 | |
|---------------------------|-----------------------------|
| 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 (free text - note that this field will adapt to the amount of text entered): | <p>Craigavon Area Hospital (Southern Health & Social Care Trust) PI: Dr Rob Charnock (rob.charnock@southerntrust.hscni.net)</p> <p>West Middlesex University Hospital (Chelsea and Westminster Hospital NHS Foundation Trust) PI: Dr Monica Popescu (monica.popescu@nhs.net)</p> <p>The Walton Centre (The Walton Centre NHS Foundation Trust) PI: Dr Chris Whitehead (chris.whitehead@thewaltoncentre.nhs.uk)</p> <p>Yeovil District Hospital (Yeovil District Hospital NHS Foundation Trust) PI: Dr Agnieszka Kubisz-Pudelko (agnieszka.kubisz-pudelko@ydh.nhs.uk)</p> | | | |
| Applicability: | England | Wales | Scotland | Northern Ireland |
| Where are the participating NHS/HSC organisations located that will be affected by this change?* | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 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): | <input type="radio"/> All | | <input checked="" type="radio"/> Some | |
| Add another change: <input type="checkbox"/> | | | | |

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]*: | Keji Dalemo |
| Email address*: | keji.dalemo@icnarc.org |

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) | | | | | | | | N | New site |
| Change 2: | | | | | | (Y) | | | | | (Y) | | | | | | | | N | New site |
| Change 3: | | | | | | (Y) | | | | | (Y) | | | | | | | | N | B |
| Change 4: | | | | | | (Y) | | | | | (Y) | | | | | | | | (Y) | New site |
| 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 | | | | | | | | | | | | | | | | | | | |
| For office use: | | | | | | | | | | | | | | | | | | | | |
| New nation(s): | This amendment adds new participating nation(s) for the first time: Northern Ireland. Ensure that HARP is updated and the relevant national coordinating function(s) are notified. | | | | | | | | | | | | | | | | | | | |
| Adults lacking capacity in new nation(s): | This amendment includes adults who lose/lack capacity for the first time in: Northern Ireland. The original REC review was undertaken in: England. Consider whether a new REC review is required to cover the new nation(s) being added and advise the applicant. | | | | | | | | | | | | | | | | | | | |