

Amendment Tool

v1.4 30 Nov 2020

For office use

QC: No

Section 1: Project information

| | | | | |
|---|--|-------------------------------------|-------------------------------------|---|
| Short project title*: | The RECOVERY Trial | | | |
| IRAS project ID* (or REC reference if no IRAS project ID is available): | 281712 | | | |
| Sponsor amendment reference number*: | Non-Substantial Amendment 3 | | | |
| Sponsor amendment date* (enter as DD/MM/YY): | 02 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)*: | We wish to submit an update to the REGN-COV2 Investigators Brochure. The Reference Safety Information remains unchanged and there is no change to the risk:benefit analysis for the trial. | | | |
| 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 <input checked="" type="radio"/> | Wales <input type="radio"/> | Scotland <input type="radio"/> | Northern Ireland <input type="radio"/> |
| Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?: | <input checked="" type="radio"/> Yes | | <input type="radio"/> No | |
| Was this clinical trial of an investigational medicinal product (CTIMP) processed under the Combined Ways of Working (CWoW) pilot?: | <input type="radio"/> Yes | | <input checked="" type="radio"/> No | |
| Did the study receive Pharmacy Assurance?: | <input checked="" type="radio"/> Yes | | <input 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 <input checked="" type="radio"/> | Wales <input type="radio"/> | Scotland <input type="radio"/> | Northern Ireland <input type="radio"/> |
| Which nations had participating NHS/HSC organisations prior to this amendment? | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Which nations will have participating NHS/HSC organisations after this amendment? | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |

Section 2: Summary of change(s)

| | |
|------------------------------|--|
| What do you want to update?: | <input checked="" type="radio"/> Project information <input type="radio"/> New site/PI only |
|------------------------------|--|

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)*: | IB, SmPC - Non-substantial changes (e.g. that do not affect risk/benefit assessment) | | | |
| Further information (free text - note that this field will adapt to the amount of text entered): | | | | |
| 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 checked="" 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 checked="" type="radio"/> All | | <input type="radio"/> Some | |
| Add another change: <input type="checkbox"/> | | | | |

Section 3: Declaration(s) and lock for submission

| | |
|---|----------------------|
| Declaration by the Sponsor or authorised delegate | |
| <ul style="list-style-type: none">I confirm that the Sponsor takes responsibility for the completed amendment toolI confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf | |
| Name [first name and surname]*: | Joseph Butchinsky |
| Email address*: | ctrng@admin.ox.ac.uk |

| |
|---|
| Lock for submission |
| <p>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.</p> |
| <div>Lock for submission</div> |
| 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) | | | | (Y) | C |
| Overall reviews for the amendment: | | | | | | | | | | | | | | | | | | | |
| Full review: | | | | | | N | | | | N | | | | N | | | | N | |
| Notification only: | | | | | | Y | | | | Y | | | | Y | | | | Y | |
| Overall amendment type: | Non-substantial, no study-wide review required | | | | | | | | | | | | | | | | | | |
| Overall Category: | C | | | | | | | | | | | | | | | | | | |