

Amendment Tool

v1.2 11 Jun 2020

For office use

QC: No

Section 1: Project information

| | | | | |
|---|--|-------------------------------------|-------------------------------------|-------------------------------------|
| Short project title*: | RECOVERY Trial | | | |
| IRAS project ID* (or REC reference if no IRAS project ID is available): | 281712 | | | |
| Sponsor amendment reference number*: | Substantial Amendment 11 | | | |
| Sponsor amendment date* (enter as DD/MM/YY): | 19 November 2020 | | | |
| Summary of amendment including justification*: | We wish to add colchicine to the trial to determine if it improves outcomes in people hospitalised with COVID-19. | | | |
| Project type: | <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?: | <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? | <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 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 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 | |
| | England | Wales | Scotland | Northern Ireland |
| Lead nation for the study: | <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 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 Changes" tab. To add another change, tick the "Add another change" box.

| Change 1 | | | | |
|--|---|-------------------------------------|-------------------------------------|-------------------------------------|
| Area of change (select)*: | Study Design | | | |
| Specific change (select - only available when area of change is selected first)*: | New arm - Addition of a study arm or placebo/control group | | | |
| Further information (free text): | We wish to add colchicine to the main randomisation (part A) where it will be compared with usual care alone among people for whom it is both suitable and available at their site. We also wish to remove azithromycin from the protocol as we have recruited a sufficient number of participants to answer this question. | | | |
| 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?: | <input checked="" type="radio"/> All | | <input type="radio"/> 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 minor document change that can be implemented within existing resource in place at participating organisations - Please specify in the free text below | | | |
| Further information (free text): | We have amended the PIS/ICF for the addition of colchicine and removal of azithromycin. We have also clarified that the serum sample is required for people entering part B of the main randomisation (not just those who might receive convalescent plasma). This has always been the case in the protocol, but we are clarifying the PIS/ICF. | | | |
| 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?: | <input checked="" type="radio"/> All | | <input type="radio"/> Some | |

Add another change: ☒

| Change 3 | | | | |
|--|--|-------------------------------------|-------------------------------------|-------------------------------------|
| Area of change (select)*: | Study Documents | | | |
| Specific change (select - only available when area of change is selected first)*: | Other minor document change that can be implemented within existing resource in place at participating organisations - Please specify in the free text below | | | |
| Further information (free text): | We wish to submit a revised poster that can be used to advertise the trial locally. This takes account of the fact that there are now treatments available for COVID-19. | | | |
| 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?: | <input checked="" type="radio"/> All | | <input type="radio"/> Some | |

Add another change: ☒

| Change 4 | |
|---------------------------|-----------------|
| Area of change (select)*: | Study Documents |

| | | | | |
|--|--|-------------------------------------|-------------------------------------|-------------------------------------|
| Specific change (select - only available when area of change is selected first)*: | Other minor document change that can be implemented within existing resource in place at participating organisations - Please specify in the free text below | | | |
| Further information (free text): | We are submitting the updated Investigators Brochure for REGN-COV2 and will use this as the Reference Safety Information once approved. | | | |
| 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?: | <input checked="" type="radio"/> All | | <input type="radio"/> Some | |

Add another change: ☒

| Change 5 | | | | |
|--|--|-------------------------------------|-------------------------------------|-------------------------------------|
| Area of change (select)*: | Study Documents | | | |
| Specific change (select - only available when area of change is selected first)*: | Other minor document change that can be implemented within existing resource in place at participating organisations - Please specify in the free text below | | | |
| Further information (free text): | Change in randomisation ratio for main randomisation part A from 2:1 to 1:1. 2:1 was used when there were multiple arms, but now not necessary. | | | |
| 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?: | <input checked="" type="radio"/> All | | <input type="radio"/> Some | |

Add another change: ☒

| Change 6 | | | | |
|--|--------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| 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): | | | | |
| 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?: | <input checked="" type="radio"/> All | | <input type="radio"/> Some | |

Add another change: ☐

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 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]*: | Heather House |
| Email address*: | heather.house@admin.ox.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 PDF copy of the completed amendment tool that can 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, refer to the "Submission Guidance" tab for 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 | | | | | | | | | | | | | | | | | Category: | |
|------------------------------------|------------------------|---|---------------------------------------|-------|---------------------|-----------------|--------------------|-----|-------|-----------------------|------------|------|------------|--------------------------------|-------------------|--------------------|---------|-----------|--------------------------------|
| | 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 |
| Change 1: | Y | Y | | | | (Y) | | | | (Y) | | | | (Y) | | | | (Y) | A |
| Change 2: | N | N | | | | (Y) | | | | (Y) | | | | (Y) | | | | (Y) | C |
| Change 3: | N | N | | | | (Y) | | | | (Y) | | | | (Y) | | | | (Y) | C |
| Change 4: | N | N | | | | (Y) | | | | (Y) | | | | (Y) | | | | (Y) | C |
| Change 5: | N | N | | | | (Y) | | | | (Y) | | | | (Y) | | | | (Y) | C |
| Change 6: | N | N | | | | N | | | | N | | | | N | | | | N | N/A |
| Overall reviews for the amendment: | | | | | | | | | | | | | | | | | | | |
| Full review: | Y | Y | | | | N | | | | N | | | | N | | | | N | |
| Notification only: | N | N | | | | Y | | | | Y | | | | Y | | | | Y | |
| Overall amendment type: | Substantial for review | | | | | | | | | | | | | | | | | | |
| Overall Category: | A | | | | | | | | | | | | | | | | | | |