# **Amendment Tool**

v1.6 06 December 2021

For office use QC: No

|  | EVIS   |   |  |  |   |  |  |
|--|--|---|--|--|---|--|--|
| IRAS project ID* (or REC reference if no IRAS project ID is available):  | 307862   |   |  |  |   |  |  |
| Sponsor amendment reference number*:   | Substantial Amendment 08   |   |  |  |   |  |  |
| Sponsor amendment date* (enter as DD/MM/YY):   | 14 February 2024   |   |  |  |   |  |  |
| 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)*:                                | 2). Removal of Sand 3). Removal of City H 4). Non-Substantial (A) Administrative upon B) Added Appendix Hevaluation. C) Updated the description of the consent forms. D) Updated the word consent forms. F) Updates to the das submitting the record G) Updates to the restudy documentation 5). Minor updates to Legal Rep (Scotland Legal Rep PIS/ICF's A) Update the wording participant information B) Updated the word consent forms.   | Iwell Hospital, West Edospital, Birmingham Changes to the Protodates: versioning. Hoto include further incription of the permitteription of the imbeddorovide further information to clarify who will tallinkage description of linkage applications cord retention and area, in relation to the leres the; Main PIS/ICF, Pagnand), Recoverto; and regarding how lorger, to ensure consistering to clarify who will | as a participating col:  formation regarded medications to ed process evaluation regarding to have access to a to clarify regard sits.  Its Summary, We red Capacity (Song the Sponsor appropriate of the state of the sponsor appropriate of | articipating site, PI g site, PI Dr Hema ling the imbedded o match the update uation to match the he imbedded proc the signed and up ling where the responents to ensure con study documents welfare Attorney/Gue cotland & England) and participating site y documentation.   | Dr Hema Patel.  Patel.  process  ed SpMC for  e addition of the cess evaluation su  loaded informed  ponsibility for  onsistency across will be retained.  ardian, Profession and Personal  tes will be retaining |  |  |
|  | collection.  6). Submission of a I in the context of the   | EVIS Consent Form,  | PIS and Intervie   | w Guide for the Qu   | ualitative Researc  |  |  |
|  | collection.  6). Submission of a I in the context of the   | EVIS Consent Form,  | PIS and Intervie   | w Guide for the Quarti   | ualitative Researc  |  |  |
|  | collection.  6). Submission of a I in the context of the   | EVIS Consent Form,  | PIS and Intervie   | w Guide for the Quarti   | ualitative Researc  |  |  |
| Project type (select):   | collection.  6). Submission of a I in the context of the   | EVIS Consent Form,  | PIS and Intervie   | w Guide for the Quarties Process Evaluation  | ualitative Researc  |  |  |
| Project type (select):   | collection.  6). Submission of a I in the context of the   | EVIS Consent Form,  | PIS and Intervie   | w Guide for the Quarties Process Evaluation  | ualitative Researd  |  |  |
|  | collection.  6). Submission of a lin the context of the Early Vasopressors in the Early Vasopres | EVIS Consent Form, in Sepsis (EVIS) Tria  | PIS and Intervie   | w Guide for the Quarties Process Evaluation  udy  issue bank  latabase   | ualitative Researd  |  |  |
| Has the study been reviewed by a UKECA-recognised Res Committee (REC) prior to this amendment?:  | collection.  6). Submission of a Bin the context of the Early Vasopressors is search Ethics  | EVIS Consent Form, in Sepsis (EVIS) Tria  | PIS and Intervie I imbedded EVIS Specific st Research t Research c   | w Guide for the Quarties Process Evaluation  udy  ssue bank  latabase  | ualitative Researd  |  |  |
| Has the study been reviewed by a UKECA-recognised Res Committee (REC) prior to this amendment?:  | collection.  6). Submission of a Bin the context of the Early Vasopressors is search Ethics  | EVIS Consent Form, in Sepsis (EVIS) Tria  | PIS and Intervie I imbedded EVIS Specific st Research t Research c   | w Guide for the Quarties Process Evaluation  udy  ssue bank  latabase  | rney/Guardian, Profession England) and Personal coating sites will be retaining that ion. If and uploaded informed of treatment and data cor the Qualitative Research Evaluation.                                 |  |  |
| Has the study been reviewed by a UKECA-recognised Res Committee (REC) prior to this amendment?:  What type of UKECA-recognised Research Ethics Committed is applicable? (select):  Is all or part of this amendment being resubmitted to the Recommittee (REC) as a modified amendment (i.e. a substate).  | collection.  6). Submission of a Bin the context of the Early Vasopressors is search Ethics  tee (REC) review  | EVIS Consent Form, in Sepsis (EVIS) Tria  | Specific st  Research t  Research t  Research t  Ministry of   | w Guide for the Quarties Process Evaluation  udy  ssue bank  latabase  REC  Defence (MoDREC  | ualitative Researd  |  |  |
| Has the study been reviewed by a UKECA-recognised Res Committee (REC) prior to this amendment?:  What type of UKECA-recognised Research Ethics Committee is applicable? (select):  Is all or part of this amendment being resubmitted to the Recommittee (REC) as a modified amendment (i.e. a substational previously given an unfavourable opinion)?   | collection.  6). Submission of a Bin the context of the Early Vasopressors is search Ethics  tee (REC) review  esearch Ethics antial amendment   | EVIS Consent Form, in Sepsis (EVIS) Tria  | Specific st  Research t  Research t  Research t  Ministry of   | ich as a participating site, PI Dr Hema Patel.  participating site, PI Dr Hema Patel.  tion regarding the imbedded process dications to match the updated SpMC for cess evaluation to match the addition of the regarding the imbedded process evaluation su access to the signed and uploaded informed urify regarding where the responsibility for g arrangements to ensure consistency across time that study documents will be retained.  Inmary, Welfare Attorney/Guardian, Profession apacity (Scotland & England) and Personal  Sponsor and participating sites will be retaining cross study documentation.  access to the signed and uploaded informed garding the duration of treatment and data  and Interview Guide for the Qualitative Research didded EVIS Process Evaluation.  Specific study  Research database  No  IHS/HSC REC  Ministry of Defence (MoDREC) |   |  |  |
| Has the study been reviewed by a UKECA-recognised Res Committee (REC) prior to this amendment?:  What type of UKECA-recognised Research Ethics Committee is applicable? (select):  Is all or part of this amendment being resubmitted to the Recommittee (REC) as a modified amendment (i.e. a substational previously given an unfavourable opinion)?   | Jeed ID* (or REC reference if no IRAS project ID between the project ID*) and the project ID* (substantial Amendment 08 substantial 08 substa | No No No Northern Irelar  |  |  |   |  |  |
| Has the study been reviewed by a UKECA-recognised Res Committee (REC) prior to this amendment?:  What type of UKECA-recognised Research Ethics Committee is applicable? (select):  Is all or part of this amendment being resubmitted to the Recommittee (REC) as a modified amendment (i.e. a substance previously given an unfavourable opinion)?  Where is the NHS/HSC Research Ethics Committee (REC) the study based?:  |  | No No No Northern Irelai  |  |  |   |  |  |
| Has the study been reviewed by a UKECA-recognised Res Committee (REC) prior to this amendment?:  What type of UKECA-recognised Research Ethics Committe is applicable? (select):  Is all or part of this amendment being resubmitted to the Recommittee (REC) as a modified amendment (i.e. a substate previously given an unfavourable opinion)?  Where is the NHS/HSC Research Ethics Committee (REC) the study based?:  Was the study a clinical trial of an investigational medicinal  | collection.  6). Submission of a Bin the context of the Early Vasopressors is search Ethics  tee (REC) review  esearch Ethics antial amendment  ) that reviewed  | EVIS Consent Form, in Sepsis (EVIS) Tria  Ye  England No  Ye  | Specific st Research t  | w Guide for the Quarties Process Evaluation  udy  ssue bank  latabase  REC  Defence (MoDREC  Scotland  Yes   | No No No Northern Irelai  |  |  |
| Has the study been reviewed by a UKECA-recognised Res Committee (REC) prior to this amendment?:  What type of UKECA-recognised Research Ethics Committe is applicable? (select):  Is all or part of this amendment being resubmitted to the Recommittee (REC) as a modified amendment (i.e. a substance previously given an unfavourable opinion)?  Where is the NHS/HSC Research Ethics Committee (REC) the study based?:  Was the study a clinical trial of an investigational medicinal OR does the amendment make it one?:  EudraCT number*: | collection.  6). Submission of a Bin the context of the Early Vasopressors is search Ethics  tee (REC) review  esearch Ethics antial amendment  ) that reviewed  product (CTIMP)   | EVIS Consent Form, in Sepsis (EVIS) Tria  Ye  England No  Ye  2021-006886-39  | Specific st Research t Research t Research t Ministry of I  S Wales No   | w Guide for the Quarties Process Evaluation  udy  ssue bank  latabase  REC  Defence (MoDREC  Scotland  Yes   | No No No No No No No No   |  |  |

| Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:   | Y       | es    |          | No               |
|---|---------|-------|----------|------------------|
| Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:                                  | Y       | es    |          | 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?: | Y       | es    |          | No               |
| Did the study involve adults lacking capacity OR does the amendment introduce this?:  | Y       | es    |          | No               |
| Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:                          | Y       | es    |          | No               |
| Did 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  |       |          |                  |
| Did the study involve children OR does the amendment introduce this?:   | Y       | es    |          | No               |
| Did the study involve NHS/HSC organisations prior to this amendment?:   | Y       | es    |          | No               |
| Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:  | Y       | es    |          | No               |
|   | England | Wales | Scotland | Northern Ireland |
| Lead nation for the study:  | No      | No    | Yes      | 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) Chief Investigator Sponsor Group 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 Organisa  | tions              |                       |                     |                  |
| Specific change (select - only available when area of change is selected first)*:   | Addition of sites under | taking the same a  | ctivities as existing | sites               |                  |
| Further information (free text - note that this field will adapt to the amount of text entered):                                      | 1). Addition of Aintree | University Hospita | l as a participating  | site, with PI Dr. B | en Morton        |
| Applicability:  |                         | England            | Wales                 | Scotland            | Northern Ireland |
| Where are the participating NHS/HSC organisations located by this change?*:   | d that will be affected | Yes                | No                    | No                  | No               |
| Will all participating NHS/HSC organisations be affected by some? ( <b>please note</b> that this answer may affect the categoriange): |                         | A                  | All                   | Se                  | ome              |
|   |                         |                    |                       | Remove all o        | changes below    |

|  | Change 2   |         |       |          |                  |  |  |  |
|--|--|---------|-------|----------|------------------|--|--|--|
| Area of change (select)*:  | Participating Organisat  | tions   |       |          |                  |  |  |  |
| Specific change (select - only available when area of change is selected first)*:                | area of Early closure or withdrawal of research sites  |         |       |          |                  |  |  |  |
| Further information (free text - note that this field will adapt to the amount of text entered): | t 2). Removal of Sandwell Hospital, West Bromwich as a participating site, PI Dr Hema Patel. |         |       |          |                  |  |  |  |
| 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? ( <b>please note</b> that this answer may affect the categorisation for the change): | ations be affected by this change, or only nay affect the categorisation for the | Sc | ome          |              |
|   |  |    | Remove all c | hanges below |

|   | Change 3                |                    |                      |                  |                  |  |
|---|-------------------------|--------------------|----------------------|------------------|------------------|--|
| Area of change (select)*:   | Participating Organisa  | tions              |                      |                  |                  |  |
| Specific change (select - only available when area of change is selected first)*:   | Early closure or withdr | awal of research s | ites                 |                  |                  |  |
| Further information (free text - note that this field will adapt to the amount of text entered):  | 3). Removal of City Ho  | spital, Birminghan | n as a participating | site, PI Dr Hema | Patel.           |  |
| Applicability:  |                         | England            | Wales                | Scotland         | Northern Ireland |  |
| Where are the participating NHS/HSC organisations located by this change?*:   | d that will be affected | 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): |                         | A                  | All                  | Some             |                  |  |
|   |                         |                    |                      | Remove all       | changes below    |  |

|   | Change 4  |  |  |   |   |
|---|---|--|--|---|---|
| Area of change (select)*:   | Study Documents   |  |  |   |   |
| Specific change (select - only available when area of change is selected first)*:   | Protocol - Non-substa   | ntial changes (e.g.  | not affecting safet  | ty or the scientific \  | value of the trial)   |
| Further information (free text - note that this field will adapt to the amount of text entered):                                      | 4). Non-Substantial Ch<br>A) Administrative upda<br>B) Added Appendix H<br>evaluation.<br>C) Updated the descri<br>noradrenaline.<br>D) Updated the descri<br>new appendix H, to prestudy.<br>E) Updated the wording<br>consent forms.<br>F) Updates to the data<br>submitting the record I<br>G) Updates to the record<br>study documentation, | ates: versioning. to include further in ption of the permitt ption of the imbede ovide further inform ag to clarify who will a linkage description inkage applications ord retention and a | nformation regardiced medications to ded process evalunation regarding the lawe access to the nation to clarify regardices sits. | match the update ation to match the le imbedded processes signed and uploing where the responsents to ensure constructions. | d SpMC for addition of the ess evaluation sub baded informed onsibility for |
| Applicability:  |   | England  | Wales  | Scotland  | Northern Ireland  |
| Where are the participating NHS/HSC organisations located by this change?*:   | d that will be affected   | Yes  | No   | Yes   | No  |
| Will all participating NHS/HSC organisations be affected by some? ( <b>please note</b> that this answer may affect the categoriange): | 9   | Д  | All  | Sc  | ome   |
|   |   |  |  | Remove all o  | hanges below  |

|   | Change 5   |
|---|--|
| 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 can be implemented within existing resource in place at participating organisations - Please specify in the free text below   |
| Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)* | <ul> <li>5). Minor updates to the; Main PIS/ICF, PIS Summary, Welfare Attorney/Guardian, Professional Legal Rep (Scotland &amp; England), Recovered Capacity (Scotland &amp; England) and Personal Legal Rep PIS/ICF's to;</li> <li>A) Update the wording regarding how long the Sponsor and participating sites will be retaining participant information, to ensure consistency across study documentation.</li> <li>B) Updated the wording to clarify who will have access to the signed and uploaded informed consent forms.</li> <li>C) Clarity added to the information provided regarding the duration of treatment and data</li> </ul> |

| collection.   |         |       |              |                  |
|---|---------|-------|--------------|------------------|
| Applicability:  | England | Wales | Scotland     | Northern Ireland |
| Where are the participating NHS/HSC organisations located that will be affect by this change?*:   | ted Yes | No    | Yes          | No               |
| Will all participating NHS/HSC organisations be affected by this change, or or some? ( <b>please note</b> that this answer may affect the categorisation for the change): | -       | All   | Sc           | ome              |
|   | ,       |       | Remove all o | hanges below     |

|   | Change 6  |                   |                    |                   |                  |
|---|---|-------------------|--------------------|-------------------|------------------|
| Area of change (select)*:   | Study Documents   |                   |                    |                   |                  |
| Specific change (select - only available when area of change is selected first)*:   | Other minor change to questionnaires, letters) participating organisati | that can be imple | emented within exi | sting resource in |                  |
| Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)* | 6). Submission of a EV in the context of the Early Vasopressors in      |                   |                    |                   |                  |
| Applicability:  |   | England           | Wales              | Scotland          | Northern Ireland |
| Where are the participating NHS/HSC organisations located by this change?*:   | d that will be affected   | Yes               | No                 | Yes               | No               |
| Will all participating NHS/HSC organisations be affected by some? ( <b>please note</b> that this answer may affect the catego change):  | •   | Δ                 | All                | S                 | Some             |
|   | •   |                   |                    | Add and           | ther 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]*: | Alison Hamilton                 |
|---------------------------------|---------------------------------|
| Email address*:                 | alison.hamilton@ggc.scot.nhs.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.

|           |     |   |                                       |       |                     |                 |           | F     | Review | bodie                 | es         |      |                   |                                |         |                    |         |                                |     |
|-----------|-----|---|---------------------------------------|-------|---------------------|-----------------|-----------|-------|--------|-----------------------|------------|------|-------------------|--------------------------------|---------|--------------------|---------|--------------------------------|-----|
|           |     | UK wide:                                |                                       |       | Eng                 | land a          | ınd Wa    | ales: |        | Scot                  | land:      |      | Northern Ireland: |                                |         |                    |         |                                |     |
|           | REC | Competent Authority<br>MHRA - Medicines | Competent Authority<br>MHRA - Devices | ARSAC | Radiation Assurance | UKSW Governance | REC (MCA) | CAG   | HMPPS  | HRA and HCRW Approval | REC (AWIA) | РВРР | SPS (RAEC)        | National coordinating function | HSC REC | HSC Data Guardians | Prisons | National coordinating function | Cat |
| Change 1: | N   |   |                                       | 1     |                     | (Y)             |           |       |        | (Y)                   | <u></u>    | 1    |                   | (Y)                            | 4       |                    |         |                                | Ne  |

| Change 2:                      | N     |                        |  |  |  | (Y) |  |  |  | (Y) |  |  |  | N   |  |  |  | В |
|--------------------------------|-------|------------------------|--|--|--|-----|--|--|--|-----|--|--|--|-----|--|--|--|---|
| Change 3:                      | N     |                        |  |  |  | (Y) |  |  |  | (Y) |  |  |  | N   |  |  |  | В |
| Change 4:                      | N     |                        |  |  |  | (Y) |  |  |  | (Y) |  |  |  | (Y) |  |  |  | Α |
| Change 5:                      | Y     |                        |  |  |  | Υ   |  |  |  | Υ   |  |  |  | Υ   |  |  |  | С |
| Change 6:                      | N     |                        |  |  |  | (Y) |  |  |  | (Y) |  |  |  | (Y) |  |  |  | С |
| Overall reviews for the amendr | nent: |                        |  |  |  |     |  |  |  |     |  |  |  |     |  |  |  |   |
| Full review:                   | Y     |                        |  |  |  | Υ   |  |  |  | Υ   |  |  |  | Υ   |  |  |  |   |
| Notification only:             | N     |                        |  |  |  | N   |  |  |  | N   |  |  |  | N   |  |  |  |   |
| Overall amendment type:        | Subs  | Substantial for review |  |  |  |     |  |  |  |     |  |  |  |     |  |  |  |   |
| Overall Category:              | А     | A                      |  |  |  |     |  |  |  |     |  |  |  |     |  |  |  |   |