**Investigational Medicinal Product (IMP) Release Form**

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| **Sponsor:** Imperial College London | **ICTU Project No:** | | | **Protocol No:** 22SM8039 | | |
| **Study Title:** SepTiC | **Chief Investigator:** Prof Anthony Gordon | | | | | |
| **Principal Investigator:** | **Site name/ number:** | | | | | |
|  | **YES** | **N/A◊** | **Comments / Version date of document approved\*** | | **Location** | |
| **TMF** | **ISF** |
| Regulatory approval/notification i.e. MHRA | 🗸 |  |  | | 🗸 | 🗸 |
| Regulatory approval of amendment | 🗸 |  |  | | 🗸 | 🗸 |
| IMP Import Licence (if applicable) | 🗸 |  |  | | 🗸 |  |
| Approval of protocol by relevant Research Ethics Committee (REC) or Institutional Review Board (IRB) (add version and date of the current study protocol) | 🗸 |  |  | | 🗸 | 🗸 |
| Approval of protocol amendment(s) by the relevant Ethics Committee | 🗸 |  |  | | 🗸 | 🗸 |
| Approval of Participant Information Sheet and Consent Form by the relevant Ethics Committee (list all documents) | 🗸 |  |  | | 🗸 | 🗸 |
| Approval of any other participant facing documents (i.e. diaries), and recruitment/advertising material, by the relevant Ethics Committee |  | 🗸 | None approved to date | |  |  |
| Approval of participant compensation (if applicable) by relevant REC/IRB |  | 🗸 | None to date | |  |  |
| Main REC/IRB membership list§ | 🗸 |  | A copy the Governance arrangements for research ethics committees which contains REC/IRB constitution is filed in the TMF. | | 🗸 |  |
| REC/IRB GCP compliance statement§ | 🗸 |  | 🗸 |  |
| Approval of protocol by the HRA or equivalent | 🗸 |  |  | | 🗸 | 🗸 |
| Approval of protocol amendment(s) by the HRA or equivalent |  | 🗸 | None to date | |  |  |
| Approval of protocol/confirmation of capability and capacity by the relevant site specific R&D, as applicable | 🗸 |  |  | | 🗸 | 🗸 |
| Approval of protocol amendment(s)/ confirmation of capability and capacity by the relevant site specific R&D, as applicable |  | 🗸 | None to date | |  |  |
| Localised, approved Participant Information Sheet and Consent Form | 🗸 |  |  | | 🗸 | 🗸 |
| Localised, approved other participant facing documents(i.e. diaries), and recruitment/advertising material. |  | 🗸 | None submitted to date | |  |  |
| Approval of participant compensation (if applicable) by the HRA or equivalent |  | 🗸 | None to date | |  |  |
| Investigator Brochure | 🗸 |  |  | | 🗸 | 🗸 |
| Fully executed Clinical Trial Site Agreement(s) | 🗸 |  |  | | 🗸 | 🗸 |
| Signed protocol signature page by PI | 🗸 |  |  | | 🗸 | 🗸 |
| Signed protocol signature page by PI for any amendment(s) |  | 🗸 | None to date | |  |  |
| Completion of Site Signature and Delegation of Duties Log by relevant site staff, and signed off by PI | 🗸 |  |  | | 🗸 | 🗸 |
| Signed/dated CVs/GCP certificates for PI, co-investigators and nurses | 🗸 |  |  | | 🗸 | 🗸 |
| Completed training logs for staff on delegation log that had not attended the SIV. Evidence of OpenClinica Training and MOCA-Blind where relevant. | 🗸 |  |  | | 🗸 | 🗸 |
| Insurance certificate/letter of indemnity | 🗸 |  |  | | 🗸 | 🗸 |
| Laboratory accreditation certificates | 🗸 |  |  | | 🗸 | 🗸 |
| Laboratory normal/reference ranges | 🗸 |  |  | | 🗸 | 🗸 |
| IMP Certificate(s) of Analysis | 🗸 |  |  | | 🗸 | 🗸 |
| QP release certificate | 🗸 |  |  | | 🗸 | 🗸 |
| Instructions for handling the IMP and associated templates i.e. accountability logs, prescriptions, return/destruction logs etc. | 🗸 |  |  | | 🗸 | 🗸 |
| Sample IMP label(s) (please give details) | 🗸 |  | Box and vial labels | | 🗸 | 🗸 |
| Randomisation procedures | 🗸 |  |  | | 🗸 | 🗸 |
| Emergency code-break / unblinding procedures | 🗸 |  |  | | 🗸 | 🗸 |
| Sample CRFs / eCRFs and guidelines for completion | 🗸 |  |  | | 🗸 | 🗸 |
| IMP Management Plan | 🗸 |  |  | | 🗸 |  |
| Site Initiation Visit Report | 🗸 |  |  | | 🗸 | 🗸 |

**Note:**

Where documents are N/A please provide comment.

Where a membership list and GCP compliance statement are not available, a copy of the REC/IRB constitution should be obtained and reviewed for compliance.

**Collated by (Study Manager / Monitor / Co-ordinator):**

|  |  |
| --- | --- |
| Signature: |  |
| Print name: |  |
| Title: |  |
| Date: |  |

**Reviewed and Approved by (Study Manager / Co-ordinator / Operations Manager):**

|  |  |
| --- | --- |
| Signature: |  |
| Print name: |  |
| Title: |  |
| Date: |  |