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| King’s Health Partners Clinical Trials OfficeAuthorised Site Signature and Delegation Log |

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| **Trial Title / IRAS Number:** | Beta-blockers Or Placebo for Primary Prophylaxis of oesophageal varices (BOPPP Trial) / 255446 |
| **Site Name / Number:** |  | **Chief Investigator:** | Dr Vishal Patel |
| **Principal Investigator:** |  | **Sponsor:**  | King’s College Hospital NHS Foundation Trust |

**General Guidance:**

* All personnel involved in the above trial must have read the protocol, received sufficient documented protocol and trial-specific training relevant to their role and delegated tasks.
* All personnel involved in the above trial must complete this log before they perform any trial-related procedures (including the Principal Investigator).
* The Principal Investigator must countersign as authorisation for an individual’s participation and delegated tasks.
* A start date and end date must be completed for all individuals and an up-to-date CV and GCP certificate should be filed for the duration of time staff are listed on the delegation log.
* Upon the closure of the trial at this site, all remaining end dates should be completed, and the Principal Investigator must sign where designated to verify all entries are correct to their knowledge.

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|  **Key for “Trial Role”:**Chief Investigator (CI)Principal Investigator (PI)Sub-Investigator (SI) | Research Nurse (RN)Research Assistant (RA) | Clinical Trials Pharmacist (CTP)Pharmacy Technician (PT) | Trial Manager (TM)Trial Coordinator (TC)Data Manager (DM) |

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| Key for “Delegated Duties”:1. Obtaining informed consent
2. Screening trial subjects
3. Confirm eligibility (inclusion / exclusion criteria review) \* trial medic only
4. Physical exam / clinical evaluations
5. Conducting study visits / assessments
6. Randomisation
7. (e)CRF completion and query resolution
8. Laboratory result review and sign off \* trial medic only
 | 1. Reporting SAEs
2. AE / SAE review and causality assessment \*trial medic only
3. IMP prescribing
4. Administering trial drug
5. IMP accountability
6. IMP dispensing
7. Maintaining Trial Master File/ Investigator Site File
8. Ethics Committee / HRA Interactions
9. Archiving
 | 1. Collection / processing / shipping of lab samples
2. Final (e)CRF sign off \*\*PI only

*Please specify below any other duties specific to above trial:*1. …………………………………………….
2. …………………………………………….
3. ..............................................................
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| **Name** **(Print)** | **Trial Role****(Select from key)** | **Delegated Duties (Select from key)** | **Staff’s initials** | **Staff’s signature** | **Principal Investigator’s Signature** | **Start Date****(DD / MMM / YYYY)** | **End Date****(DD / MMM / YYYY)** |
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| **Name** **(Print)** | **Trial Role****(Select from key)** | **Delegated Duties (Select from key)** | **Staff’s initials** | **Staff’s signature** | **Principal Investigator’s Signature** | **Start Date****(DD / MMM / YYYY)** | **End Date****(DD / MMM / YYYY)** |
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**Sign off by Principal Investigator at the closure of trial site:**

Print name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date (DD MMM YY): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Data Privacy Statement**

The above named Study Sponsor, being a public institution concerned with sponsoring health care research for the public good, will process the Personal Data that you provide in this staff signature and delegation log (together with associated personal data that you may provide as deemed necessary by the Study Sponsor, including CVs, training certificates and so forth, as well as other data about you obtainable from public sources or present in Source Data relating to the conduct of this Study) as necessary to fulfil its purposes in relation to this study and future studies, on the basis of the public interest in so doing (i.e. the legal basis for the processing of your personal data by and on behalf of the Study Sponsor as data Controller is that it is a task in the public interest).Your Personal Data processed for the purpose of this Study (or for future studies, as below) will not include Sensitive Personal Data, as defined in the Data Protection Legislation.

The overarching purpose of the Study Sponsor in processing your Personal Data in relation to this study is the exercise of its oversight responsibilities as Sponsor, as defined in The UK Policy Framework for Health and Social Care (and in clinical trial and/or clinical investigation legislation, as and where applicable). Copies of the documents containing your Personal Data may be taken by agents of the Study Sponsor to be provided to the Study Sponsor and / or sent to the Study Sponsor by the participating organisation, as required by the Study Sponsor and as appropriate for the maintenance of its oversight of study activities, including oversight of the appropriateness of persons delegated to undertake such activities.

The Study Sponsor will only process your Personal Data as required to fulfil its purposes in relation to this study and future studies (as described above), including processing only that data which is necessary for its purpose/s and retaining your personal data only for as long as required for its purposes (including, but not limited to, adhering to any legal or best practice requirements on the duration of retention of source data and other data relating to the conduct of health care research). Your Personal Data will be securely transferred to the Study Sponsor, and held there, in accordance with the data security policies of the Study Sponsor, access to, or copies of which, will be provided upon request.

In undertaking its obligations as a Sponsor of research, the Study Sponsor may make available your Personal Data to regulatory bodies or other parties with a legal duty, public duty or other legitimate interest in the oversight of healthcare research and the licensing, commissioning, etc. of healthcare interventions.

You have the following rights regarding your personal data:

* To be informed – you can ask the Study Sponsor what Personal Data they are processing about you and why.
* To access – you can ask the Study Sponsor to see the Personal Data that they hold about you and obtain a copy.
* Rectification – you can ask the Study Sponsor to correct any inaccurate information that they hold about you.
* Restriction – you can ask the Study Sponsor not to process information about you if the information is inaccurate, processed unlawfully, or no longer needed for the stated purpose.
* To object – you can ask that the Study Sponsor ceases its processing of your Personal Data, which it must do unless it is able to demonstrate compelling legitimate grounds for the processing which overrides your interests, rights and freedoms or that its processing is necessary for the establishment, exercise or defence of legal claims

Please note that if in exercising these rights you compromise the ability of the Study Sponsor to fulfil its stated purposes, you may be removed from your role in this study. If you want to ask about your rights, or have any other questions or complaints about how the Study Sponsor has handled your Personal Data, you can contact the Study Sponsor at any time via khpcto.crateam@kcl.ac.uk .Should you wish to contact the Data Protection Officer of the Study Sponsor you may do so via: kch-tr.dpo@nhs.net

If you are not satisfied with the response you receive to any questions in relation to your Personal Data or any requests that you make in order to exercise your rights in relation to your Personal Data, or if you believe that your Personal Data is being processed in a way that is not lawful, you can complain to the Information Commissioner’s Office (ICO).