**Please read the accompanying “Guidance for using the UHBW Protocol Template for Sponsored Studies (Non-CTIMP)” whilst writing your protocol, and check the “UHBW standard wording for non-IMP protocols” is included, and then delete this text**

****

# TITLE PAGE

|  |  |
| --- | --- |
| **Full/long title of study** |  |
| **Short title/study acronym** |  |
| **Protocol version number /date** |  |
| **IRAS Number** |  |
| **ISRCTN/Clinicaltrials.gov number** |  |
| **Sponsor** | University Hospitals Bristol and Weston NHS Foundation Trust (UHBW). |
| **Sponsor reference number** |  |
| **Funder name and reference number (if applicable)** |  |
| **Chief Investigator** |  |
| **Sponsor Representative** | Research and DevelopmentUniversity Hospitals Bristol and Weston NHS Foundation TrustEducation Centre, Level 3, Upper Maudlin StreetBristol, BS2 8AETel: 0117 342 0233.R&DSponsorship@uhbw.nhs.uk |

# PROTOCOL VERSION HISTORY

|  |  |  |  |
| --- | --- | --- | --- |
| **Amendment No.** State whether Substantial Amendment (SA) or Non-substantial amendment (NSA) | **Version No.** | **Version Date** | **Brief summary of change(s) and reason for update.** |
| Initial Application | 1.0 |  | Not applicable |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

# SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor’s SOPs, and other regulatory requirements.

I agree:

* to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor
* that no activity will commence at participating sites until Sponsor green light is confirmed
* that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

|  |  |
| --- | --- |
| **Chief Investigator:** |  |
| Signature:  | Date: |
| ...................................................................................................... | ....../....../..... |
|  |  |
| Name (please print): |  |
| ..................................................................................................... |  |
|  |  |
|  |  |
| **Interventional studies only****Research and Development representative as Study Sponsor:** |  |
| Signature: | Date: |
| ...................................................................................................... | ....../....../..... |
|  |  |
| Name (please print): |  |
| ..................................................................................................... |  |
|  |  |
| Position |  |
| ..................................................................................................... |

# KEY CONTACTS

|  |  |
| --- | --- |
| **Chief Investigator** |  |
| **Study Co-ordinator/Clinical Trials Unit** |  |
| **Sponsor** |  |
| **Joint-sponsor(s)/co-sponsor(s)**  |  |
| **Funder(s)** |  |
| **Key Protocol Contributors** |  |
| **Study Management and Oversight Committees** |  |
| **Statistician** |  |

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# LAY SUMMARY

# SYNOPSIS

|  |  |
| --- | --- |
| **KEY STUDY INFORMATION** |  |
| **Study Title** |  |
| **IRAS Number** |  |
| **Study Design/Type** |  |
| **Study Participants** |  |
| **Planned Sample size** |  |
| **Planned Study Period** |  |
| **End of study definition** |  |
| **Single site or multi-site** |  |
| **Research Aim(s)** |  |
| **Research objectives** |  |
| **Intervention(s) (if applicable)** |  |
| **Archiving period**  |  |
| **SAMPLES (If applicable)** |  |
| **DATA**  |  |

# LIST OF ABBREVIATIONS

|  |  |
| --- | --- |
| **Abbreviation** |  **Full text** |
| **CI** | Chief Investigator |
| **CRF** | Case Report Form |
| **GCP** | Good Clinical Practice |
| **GP** | General Practitioner |
| **HRA** | Health Research Authority |
| **ICF** | Informed Consent Form |
| **ISF** | Investigator Site File (This forms part of the TMF) |
| **NHS** | National Health Service |
| **PI** | Principal Investigator |
| **PPI** | Patient and Public Involvement |
| **PIS/PIL** | Participant Information Sheet/Leaflet |
| **RCT** | Randomised Control Trial |
| **REC** | Research Ethics Committee |
| **R&D** | Research and Development |
| **SMG** | Study Management Group |
| **SSC** | Study Steering Committee |
| **SOP** | Standard Operating Procedure |
| **TMF** | Trial Master File |
| **TMG** | Trial Management Group |
| **TSC** | Trial Steering Committee |
| **UHBW** | University Hospitals Bristol and Weston NHS Foundation Trust |

# FUNDING

|  |  |
| --- | --- |
| **Funders** | **Financial and Non-Financial support given** |
|  |  |
|  |  |

# ROLES AND RESPONSIBILITIES

## Role of sponsor and funder

## Study team

## Trial/study management committees/groups and individuals

## Protocol Contributors

# KEY WORDS

# BACKGROUND

# RATIONALE

# OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

## Primary objective

## Secondary objective(s)

### Outcome measures/endpoints

### Primary outcomes

### Secondary outcomes

# STUDY DESIGN AND SETTING

## Study design

## Study setting

# PARTICIPANT ELIGIBILITY CRITERIA

## Inclusion criteria

## Exclusion criteria

## Equality, diversity and inclusion considerations

# STUDY PROCEDURES

## Recruitment

### Participant identification

### Screening

## Payment

## Informed consent

## Randomisation scheme

### Method of implementing the randomisation/allocation sequence

### Blinding and Emergency unblinding

## Trial assessments

### Baseline data

### Follow-up assessments

### Qualitative assessments

## Withdrawal criteria

## Clinical samples: collection, storage and analysis

# ETHICAL AND REGULATORY CONSIDERATIONS

## Research Governance Statement

This study will be conducted in accordance with:

* The principles of Good Clinical Practice, as set out in the International Conference for Harmonisation of Good Clinical Practice (ICH GCP) guidelines
* The UK Policy Framework for Health and Social Care Research.

## Assessment and management of risk

## Research Ethics Committee (REC) and other Regulatory review & reports

## Regulatory Review & Compliance

The study will be performed subject to favourable opinion/ authorisation/permission or equivalent from all necessary regulatory and other bodies. This includes but is not limited to REC, HRA, NHS Trusts.

## Amendments

## End of study

# Patient & Public Involvement

# PROTOCOL COMPLIANCE

## Protocol Deviations

## Notification of Serious Breaches to GCP and/or the protocol

# DATA PROTECTION AND PATIENT CONFIDENTIALITY

# DATA MANAGEMENT

## Data collection tools and source document identification

### Source Data

### Source Documents

Where applicable a random sample of x% (at least 10%) of CRFs will be checked, by the study Research Team, against entries within the database and with the source data for quality purposes. The percentage checked will be increased if a significant error rate is found. In addition, the first set of recruitment data collected from a new site will be scrutinized.

### Case report forms

### CRFs as Source Documents

## Data handling and record keeping

The database and randomisation system will be designed so as to protect patient information in line with the General Data Protection Regulation. Study staff will ensure that the participants’ anonymity is maintained through protective and secure handling and storage of patient information at the study centres (as relevant) in line with the Ethics approval. All documents will be stored securely and only accessible by study staff and authorised personnel. Data will be collected and retained in accordance with the General Data Protection Regulation.

## Access to Data

## Access to the final study dataset

# STATISTICS AND DATA ANALYSIS

## Sample size calculation

## Planned recruitment rate

## Statistical analysis plan

### Summary of baseline data and flow of patients

### Primary outcome analysis

### Secondary outcome analysis

### Subgroup analyses

### Adjusted analysis

### Interim analysis and criteria for the premature termination of the trial

### Participant population

### Procedure(s) to account for missing or spurious data

## Other statistical considerations

## Economic evaluation

# SAFETY REPORTING

Adverse events will be recorded and reported in accordance with UHBW’s Research Safety Reporting SOP.

# QUALITY ASSURANCE, RISK ASSESSMENT AND MONITORING

## Risk Assessment

## Monitoring, audit and inspection

The study will be monitored in accordance with UHBW’s Monitoring SOP. All study related documents will be made available on request for monitoring and audit by UHBW, the relevant Research Ethics Committee and for any other regulatory authorities.

## Peer review

# INSURANCE AND INDEMNITY

This is an NHS-sponsored research study. If there is negligent harm during the clinical trial when the NHS body owes a duty of care to the person harmed, NHS Indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the trial. NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. Ex-gratia payments may be considered in the case of a claim.

# Financial and other competing interests

# FINANCE AND CONTRACTUAL ARRANGEMENTS INCLUDING EQUIPMENT SUPPLY AND INTELLECTUAL PROPERTY

# PUBLICATION AND DISSEMINATION

## Dissemination policy

## Authorship eligibility guidelines and any intended use of professional writers

# DOCUMENT STORAGE AND ARCHIVING

Study documents (paper and electronic) will be retained in a secure location during and after the study has finished. All essential documents, including patient records and other source documents will be retained for a period of 5 years following the end of the study. Where study related information is documented in the hard copy medical records – those records will be identified by a ‘Do not destroy before dd/mm/yyyy’ label where date is 5 years after the last patient last visit. Where electronic records are in use, trust policy will be followed

# REFERENCES

# APPENDICES

## APPENDIX 1 Study Flow Chart

## APPENDIX 2 Schedule of Procedures

## APPENDIX 3 -Data Flow diagram