**Appendix 1   
Data Verification Exercise Report**

EDGE ID: Date Verification Exercise:

|  |  |  |  |
| --- | --- | --- | --- |
| Attribute Name | Incorrect / Missing data | Action plan to address | Actions completed |
| 1. **MANDATORY CATEGORY 1** |  |  |  |
| PID Clinical Trial |  |  |  |
| Portfolio Studies |  |  |  |
| IRAS Reference No. |  |  |  |
| Study Category |  |  |  |
| Education |  |  |  |
| Multi Centre |  |  |  |
| Is UHL Lead Centre? |  |  |  |
| Lead Centre Name if not UHL |  |  |  |
| Sites Identified |  |  |  |
| Type of Research |  |  |  |
| Regulatory Approvals |  |  |  |
| Methodology |  |  |  |
| Primary Clinical Management Areas |  |  |  |
| Secondary Clinical Management Area |  |  |  |
| Type of Sponsor |  |  |  |
| Location of Sponsor |  |  |  |
| Support Department |  |  |  |
| Type of Funding |  |  |  |
| Definition of End of Trial |  |  |  |
| Patient Population |  |  |  |
| Primary Research Question |  |  |  |
| Secondary Research Question |  |  |  |
| In patient / Outpatient Study |  |  |  |
| LRI Clinics Supporting Study |  |  |  |
| LGH Clinics Supporting Study |  |  |  |
| GH Clinics Supporting Study |  |  |  |
| Outcome Measure |  |  |  |
| Device Study |  |  |  |
| NIGB Approval (CAG Approval) |  |  |  |
| Antimicrobial Agent or Process used |  |  |  |
| Monitoring Arranged (Monitoring Arranged) |  |  |  |
| Name of CRO/CRA Company used |  |  |  |
| CRO/CRA (CRO/CRA used) |  |  |  |
| PPI (Patient Public Involved in Study) |  |  |  |
| Translation Services ( Using Translation Service) |  |  |  |
| Accessible to BME |  |  |  |
| Lack of Capacity (Lack of Capacity to Consent) |  |  |  |
| PLR Used (A PLR has been identified) |  |  |  |
| Insurance (Type of Insurance) |  |  |  |
| ARSAC Certificate Required |  |  |  |
| Information Governance |  |  |  |
| NIPAG approval required |  |  |  |
| Ionising Radiation ticked in IRAS |  |  |  |
| Have you involved UHL Libraries |  |  |  |
| Study uses APPS/AI/Data Driven Technologies |  |  |  |
| All Mandatory Workflows Added |  |  |  |
| SAE Line Listings |  |  |  |
| 1. **LABORATORY INVOLVEMENT (CTIMPS ONLY)** |  |  |  |
| Added Samples / Tissue Workflow |  |  |  |
| Sample Collected from |  |  |  |
| Tissue Consent obtained for |  |  |  |
| Samples Storage Status |  |  |  |
| Type of Samples to be stored |  |  |  |
| New Sample |  |  |  |
| Surplus Sample |  |  |  |
| Archived Sample |  |  |  |
| Cells for Human Application |  |  |  |
| Analysis of DNA |  |  |  |
| Central Lab Used |  |  |  |
| Name & Address of Central Lab if used |  |  |  |
| Which samples will go to Central Labs |  |  |  |
| Accredited Lab Required |  |  |  |
| Name of accreditation scheme |  |  |  |
| Licensed Tissue Bank |  |  |  |
| Licensed Tissue Bank (Details) |  |  |  |
| Samples imported from outside UK |  |  |  |
| Originating Country of Samples |  |  |  |
| Type of Samples collected |  |  |  |
| Sample Processing |  |  |  |
| Name of UHL holder of samples during study |  |  |  |
| Location of ALL samples during study activity |  |  |  |
| Type of Sample tracking adopted |  |  |  |
| Name of Sample tracking adopted |  |  |  |
| Where will samples be processed for shipping |  |  |  |
| Final Destination of Samples outside of UHL |  |  |  |
| Final Destination of Samples within UHL |  |  |  |
| Will samples be exported from UHL to outside UK |  |  |  |
| Type of Test / Analysis to be carried out |  |  |  |
| Which analysis provided through UHL Lab Services |  |  |  |
| Activity at UHL Labs - tick all that apply |  |  |  |
| Tissue Disposal Arrangement |  |  |  |
| Archived UHL Labs |  |  |  |
| Archived External to UHL |  |  |  |
| Sample Freezers / Fridges on temp control system |  |  |  |
| Name of Temp Control system used (Int. Only) |  |  |  |
| SOP for reporting Temp deviations (Int. Only) |  |  |  |
| Are Freezers / Fridges linked to Emergency backup |  |  |  |
| Is this a dose escalation study |  |  |  |
| Analysis carried out by Sub-Contractor to UHL |  |  |  |
| List Sub-Contracting Tests & Organisation/s |  |  |  |
| Blood Transfusion |  |  |  |
| **3. LABORATORY INVOLVEMENT (NON-CTIMP)** |  |  |  |
| Added Samples / Tissue Workflow |  |  |  |
| Sample Collected from |  |  |  |
| Tissue Consent obtained for |  |  |  |
| Samples Storage Status |  |  |  |
| New Sample |  |  |  |
| Surplus Sample |  |  |  |
| Archived Sample |  |  |  |
| Cells for Human Application |  |  |  |
| Analysis of DNA |  |  |  |
| Type of Samples collected |  |  |  |
| Type of Samples to be stored |  |  |  |
| Sample Processing |  |  |  |
| Samples imported from outside UK |  |  |  |
| Originating Country of Samples |  |  |  |
| Location of ALL samples during study activity |  |  |  |
| Will samples be exported from UHL to outside UK |  |  |  |
| Name of UHL holder of samples during study |  |  |  |
| Type of analysis conducted - list all detailed |  |  |  |
| Which analysis provided through UHL Lab Services |  |  |  |
| Central Lab Used |  |  |  |
| Name & Address of Central Lab if used |  |  |  |
| Licensed Tissue Bank Used |  |  |  |
| Licensed Tissue Bank (Details) |  |  |  |
| Accredited Lab Required |  |  |  |
| Name of accreditation scheme |  |  |  |
| Name of Sample tracking adopted |  |  |  |
| Type of Sample tracking adopted |  |  |  |
| Tissue Disposal Arrangement |  |  |  |
| Archived External to UHL |  |  |  |
| Archived UHL Labs |  |  |  |
| Final Destination of Samples outside of UHL |  |  |  |
| Final Destination of Samples within UHL |  |  |  |
| Sample Freezers / Fridges on temp control system |  |  |  |
| Name of Temp Control system used (Int. Only) |  |  |  |
| SOP for reporting Temp deviations (Int. Only) |  |  |  |
| Are Freezers / Fridges linked to Emergency backup |  |  |  |
| Blood Transfusion |  |  |  |
| **4. Data Flows / GDPR v2 WEF 01/10/2020** |  |  |  |
| Legal Basis for Collection of Data |  |  |  |
| Is the Data Special Category |  |  |  |
| What Data will the Data Collection Tool(s) Hold |  |  |  |
| What is the Data |  |  |  |
| Is it Bulk Data |  |  |  |
| Name of Data Capture Tool(s) |  |  |  |
| Type of Data Collection Tool(s) |  |  |  |
| Description of Data Capture Tool(s) |  |  |  |
| Is data already collected for clinical purposes |  |  |  |
| Is relevant access authorised |  |  |  |
| Data Flow Mapping |  |  |  |
| Data Leaving UHL |  |  |  |
| Purpose of Transfer |  |  |  |
| Does data leave the originating department |  |  |  |
| Specific Address of Originating Data |  |  |  |
| Specific Address of Destination for Data |  |  |  |
| Additional details of all data flows |  |  |  |
| Legal Cover for Flow of Data |  |  |  |
| How is Data Sent |  |  |  |
| Is information provided via other teams |  |  |  |
| Are you collecting Children's PCD |  |  |  |
| Staff roles defined for Data Collection |  |  |  |
| Staff roles defined for CRF Completion |  |  |  |
| How are access controls managed |  |  |  |
| Staff added to Delegation Log |  |  |  |
| Are staff trained on the system and how |  |  |  |
| Electronic CRF - access arranged |  |  |  |
| Frequency of collection agreed |  |  |  |
| Mobile equipment used |  |  |  |
| Point of contact for data queries confirmed |  |  |  |
| Is 3rd party access allowed |  |  |  |
| Does a Confidentiality Agreement exist |  |  |  |
| Are there defined access controls |  |  |  |
| Does Data Collection Tool(s) Remote Access exist |  |  |  |
| Other HCP Social Care access - name protocol |  |  |  |
| Registration / Deregistration process |  |  |  |
| Password Strength - Define |  |  |  |
| Who will the data be shared with |  |  |  |
| In what Media is Data Set Stored |  |  |  |
| Data stored electronically - where? |  |  |  |
| Information Asset Owner |  |  |  |
| IAO Administrator |  |  |  |
| Name of Data Controller/s & Organisation |  |  |  |
| Name of Data Processor / s & Organisation |  |  |  |
| Business continuity plans in place |  |  |  |
| Data capture tools recorded on UHL Asset Register |  |  |  |
| Could the data re-identify with the right access |  |  |  |
| How long will the data set be stored |  |  |  |
| Specific location of originating data? |  |  |  |
| Where will the data tool be held? |  |  |  |
| How will information be disposed of |  |  |  |
| Date data to be destroyed |  |  |  |
| CAG Studies ONLY - Opt Outs considered |  |  |  |
| IG USE ONLY - Audited |  |  |  |
| IG Additional comments |  |  |  |
| **5. Ext / 3rd Party Data W.E.F 01-10-20** |  |  |  |
| Ext. Trans - Docs sent to Privacy |  |  |  |
| Where Sent to 3rd parties Only |  |  |  |
| Data leaving UK - Destination in EU |  |  |  |
| Registration no. for 3rd party where appropriate |  |  |  |
| Is there a Data Sharing Agreement in place |  |  |  |
| If data stored outside of UHL, explicit consent? |  |  |  |
| Name of Data Processor / s & Organisation |  |  |  |
| IG USE ONLY - Audited |  |  |  |
| IG Additional comments |  |  |  |
| Is data anonymised before transfer |  |  |  |
| How frequently will transfer take place |  |  |  |
| How & where will data be stored |  |  |  |
| Does 3rd party have Data Protection Officer (DPO) |  |  |  |
| IG Additional comments Name and contact details of DPO (3rd party) |  |  |  |
| If ICO Registered - enter ICO number |  |  |  |
| Additional IT Software / Hardware required |  |  |  |
| External access required to UHL systems |  |  |  |
| **6. MEDICAL DEVICES / EQUIPMENT** |  |  |  |
| What is / are the status of the equipment/device |  |  |  |
| What is the purpose of the study |  |  |  |
| MHRA Approval |  |  |  |
| Type of equipment used in study |  |  |  |
| Is equipment required specifically for the study |  |  |  |
| Is equipment provided by the sponsor |  |  |  |
| Equipment already delivered |  |  |  |
| Estimated date of delivery - if not already at UHL |  |  |  |
| Indemnity Arrangements |  |  |  |
| Space for equipment |  |  |  |
| Equipment used at home |  |  |  |
| Loss or Damage cover |  |  |  |
| Equipment Training |  |  |  |
| Calibration / Maintenance records |  |  |  |
| Named person/dept responsible for calibration |  |  |  |
| Equipment based at other site |  |  |  |
| What happens to equipment at end of study |  |  |  |
| **7. PHARMACY INVOLVEMENT** |  |  |  |
| Primary IMP (Name of IMP used in study) |  |  |  |
| Secondary IMP |  |  |  |
| Third IMP |  |  |  |
| Fourth IMP |  |  |  |
| Fifth IMP |  |  |  |
| IMP Status (Is the IMP licensed or not?) |  |  |  |
| Type of IMP (Type of IMP in use) |  |  |  |
| IMP Risk Rating (Risk Based assessment criterion) |  |  |  |
| IMP off Label (Use of IMP off label) |  |  |  |
| Bioequivalence or Bioavailability Study |  |  |  |
| ATIMP / GMO Study |  |  |  |
| **8. OBSOLETE W.E.F. 01/10/20 Data Flows / GDPR** |  |  |  |
| Legal Basis for Collection of Data |  |  |  |
| Is the Data Special Category |  |  |  |
| What Data will the Data Collection Tool(s) Hold |  |  |  |
| What is the Data |  |  |  |
| Is it Bulk Data |  |  |  |
| Name of Data Capture Tool(s) |  |  |  |
| Type of Data Collection Tool(s) |  |  |  |
| Description of Data Capture Tool(s) |  |  |  |
| Is data already collected for clinical purposes |  |  |  |
| Is relevant access authorised |  |  |  |
| Data Flow Mapping |  |  |  |
| Data Leaving UHL |  |  |  |
| Ext. Trans - Docs sent to Privacy |  |  |  |
| Ext. Transfer - DPIA required |  |  |  |
| Purpose of Transfer |  |  |  |
| Does data leave the originating department |  |  |  |
| Specific Address of Originating Data |  |  |  |
| Specific Address of Destination for Data |  |  |  |
| Additional details of all data flows |  |  |  |
| Legal Cover for Flow of Data |  |  |  |
| How is Data Sent |  |  |  |
| Is information provided via other teams |  |  |  |
| Are you collecting Children's PCD |  |  |  |
| Staff roles defined for Data Collection |  |  |  |
| Staff roles defined for CRF Completion |  |  |  |
| How are access controls managed |  |  |  |
| Staff added to Delegation Log |  |  |  |
| Are staff trained on the system and how |  |  |  |
| Electronic CRF - access arranged |  |  |  |
| Frequency of collection agreed |  |  |  |
| Mobile equipment used |  |  |  |
| Point of contact for data queries confirmed |  |  |  |
| Is 3rd party access allowed |  |  |  |
| Where Sent to 3rd parties Only |  |  |  |
| Data leaving UK - Destination in EU |  |  |  |
| Registration number for 3rd where appropriate |  |  |  |
| Does a Confidentiality Agreement exist |  |  |  |
| Is there a Data Sharing Agreement in place |  |  |  |
| Are there defined access controls |  |  |  |
| Does Data Collection Tool(s) Remote Access exist |  |  |  |
| Other HCP Social Care access - name protocol |  |  |  |
| Registration / Deregistration process |  |  |  |
| Password Strength - Define |  |  |  |
| Who will the data be shared with |  |  |  |
| In what Media is Data Set Stored |  |  |  |
| Data stored electronically - where? |  |  |  |
| Information Asset Owner |  |  |  |
| IAO Administrator |  |  |  |
| Name of Data Controller/s & Organisation |  |  |  |
| Name of Data Processor / s & Organisation |  |  |  |
| Business continuity plans in place |  |  |  |
| Data capture tools recorded on UHL Asset Register |  |  |  |
| Could the data re-identify with the right access |  |  |  |
| How long will the data set be stored |  |  |  |
| How will information be disposed of |  |  |  |
| Date data to be destroyed |  |  |  |
| CAG Studies ONLY - Opt Outs considered |  |  |  |
| IG USE ONLY - Audited |  |  |  |
| IG Additional comments |  |  |  |