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| **CLINICAL STUDY REGISTRATION FORM (CSRF)** | **Ref. n.** |

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| **Study title:** |
| **RCSI Investigator Name:**  |

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| **OUTCOME OF THE STUDY ASSESSMENT**  (To be completed by Sponsorship Officer and the Research Contract Officer)**Note for the Investigator**: please ensure that the information included in this table is accurately reflected in the ethics application, DPIA, PIL and Consent form. This form must be included in the documentation submitted to the ethics committee, the DPO(s), and the Hospital for final approval |
| **STUDY TYPE:** [ ]  **Observational involving clinical procedure** [ ]  **Interventional non regulated** [ ]  **Interventional regulated IMP**[ ]  **Interventional regulated device**  |
| **INSURANCE - protocol**[ ]  **The study is covered by RCSI clinical trial policy** [ ]  **Protocol insurance requires the payment of an additional premium****INSURANCE - medical malpractice**[ ]  **Med mal is covered by CIS** [ ]  **Med mal is covered by RCSI**[ ]  **Med mal cover for** (insert name) **needs to be added to RCSI policy**[ ]  **Med mal cover for private hospital** (insert site name) |
| **SPONSORSHIP OVERSIGHT**[ ]  **Not applicable**[ ]  **Protocol review** (and amendments, when applicable)[ ]  **Application for HPRA & NREC approval** (and amendments, when applicable)[ ]  **Site Initiation Visit**[ ]  **Green light**[ ]  **Monitoring**[ ]  **Pharmacovigilance** [ ]  **Audit of service provider(s)** [ ]  **Other:** (pls clarify) |
| **SPONSORSHIP COST** [ ]  **Not applicable** [ ]  **The costs associated with sponsorship oversight are available below**(include screen shot of pdf) |
| **CONTRACTUAL REQUIREMENTS** [ ]  **Clinical Trial agreement** between:[ ]  **Clinical study agreement (for observational studies)** between:[ ]  **Material transfer agreement** between:[ ]  **Material and Data Sharing agreement** between:[ ]  **Data sharing/processing agreement**  between:[ ]  **Letter of Agreement** between: |
| **DATA PROTECTION ROLES OF THE ORGANISATIONS IN RELATION TO THE PROCESSING OF PERSONAL DATA FOR THE PURPOSE IN THE STUDY** **RCSI OTHER: (include name)**[ ]  **Data Controller** [ ]  **Data Controller** [ ]  **Joint Data controller** [ ]  **Joint Data controller** [ ]  **Data Processor** [ ]  **Data Processor** **Chief Investigator SITE: (include name) OTHER SITE(s): (include name(s))**[ ]  **Data Controller** [ ]  **Data Controller** [ ]  **Joint Data controller** [ ]  **Joint Data controller** [ ]  **Data Processor** [ ]  **Data Processor** **OTHER PARTY: (include name) OTHER PARTY: (include name)**[ ]  **Data Controller** [ ]  **Data Controller** [ ]  **Joint Data controller** [ ]  **Joint Data controller** [ ]  **Data Processor** [ ]  **Data Processor** |
| **DATA PROTECTION REQUIREMENTS** [ ]  **Patient information leaflet**[ ]  **Consent form**[ ]  **DPIA**[ ]  **Pre-screening agreement**[ ]  **Consent declaration**[ ]  **Transfer impact assessment** [ ]  **Standard contractual clauses** |
| **SPONSOR OFFICER’S SUMMARY COMMENTS AND CONCLUSION** |
| (please complete) |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_** **PRINT NAME SIGN DATE** |

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| **INVESTIGATOR DECLARATION** (to be completed after having reviewed the comments in the form included in the next section of this document as well as the summary comments, conclusions and requirements outlined above)  |
| **I hereby declare that**1. **I confirm that the resources (i.e. funding and support staff) required for delivery of the study are in place**
2. **I will make sure that any requirement identified by RCSI sponsorship Office and legal team are in place as it will be specified in the comment section of this form**
3. **I am committed to oversee and bring the study to its completion**
 |
| \_\_\_\_\_**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **PRINT NAME SIGN DATE**  |

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| **HOW TO COMPLETE THE CLINICAL STUDY REGISTRATION FORM (CSRF)** |
| **When to complete this form**This form must be completed by an RCSI clinical Investigator who is planning to lead a clinical study. **Note well:** form should only be completed after having engaged with RCSI Sponsorship Office and been asked to complete it. **How to complete this form**The Investigator must ensure that the responses and information provided in the form are comprehensive, clear and understandable by non-scientific or clinical personnel.The Investigator shall submit the completed form by email to RCSI Sponsorship Office (sponsorship@rcsi.ie) together with any other documentation available at that time (Study Protocol, Patient information leaflet, Investigators Brochure, the Risk/Benefit Analysis document etc.). The Sponsorship Officer will review the form (and any documents provided with it) to classify the study, make a risk assessment, clarify RCSI role in the study as sponsor (where applicable), and determine/clarify in the form institutional and regulatory requirements (e.g. ethics approval, HPRA approval, insurance Consent declaration, etc, as applicable). The Sponsorship Officer may share the form (and any documentation associated with it) with the University’s underwriters if confirmation of insurance is required. RCSI legal team will also review the form to identify any legal/contractual requirements. The requirements identified by the Sponsorship Office and legal team are documented in the comment section of the form.Upon completion of the institutional review process the form is returned to the study lead Investigator to confirm sponsorship and clarify applicable requirements before the study can commence.The Lead Investigator is required to review all the comments and requirements included in the form and in the “outcome of the assessment” section in the first page of this document, sign the declaration and undertakings section included in the second page of this document and return the signed document to the sponsorship office (sponsorship@rcsi.ie)When the study involves Patients of Beaumont Hospital, the form is shared with Beaumont Hospital as part of the ethics, data protection and legal review process. |

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| **Section to be completed by the Study Lead Investigator or nominee** | **(Section to be completed by Sponsorship Office and legal team)**  |
| 1. **Investigator(s)**
 | Institutional comments and/or requirements |
| **1.1 Your contact details** Your Name: Your employer(s): Email: Telephone:**1.2 Your affiliation with RCSI**[ ]  contract of employment with RCSI [ ]  joint contract of employment with RCSI and hospital  [ ]  RCSI tutor [ ]  RCSI postgraduate student [ ]  honorary affiliation [ ]  none**Note:** If RCSI is required to play the sponsor role in the study affiliation to RCSI is required. If you have no affiliation with RCSI, you can apply for honorary research fellow appointment. Please email sponsorship@rcsi.ie**1.3 Your role : please clarify whether you are the study’s Chief Investigator, i.e. whether  you have conceived and lead the study**  [ ]  Yes [ ] no**1.4 If you are not the study Chief Investigator**  **(a**) **Please clarify whether you played any role in the design of the study** [ ]  Yes [ ] No **(b) please name the Chief Investigator and his/her contact details**Name: Employer(s): Click here to enter textDept: Click here to enter textEmail: Click here to enter text**1.5 Does the subject matter of the research study form the basis of a thesis of an RCSI PhD/MD/MSc student?** [ ]    Yes [ ] No | **RCSI CI/PI affiliation and role in the study**:  |
| 1. **Study team (Hospital)**
 | Institutional comments and/or requirements |
|  **2.1 Please clarify if your study Team will involve other employees of your hospital** [ ]  Yes [ ] no**2.2 If yes, please specify their role** (select from one or more from the following options)[ ]  Sub-investigator [ ]  Registrar/MD[ ]  Research nurse or assistant[ ]  Lab technician[ ]  Pharmacist[ ]  Other If you selected other, please clarify**:** Click here to enter textIf you have selected any of the above **please clarify the study team member’s role** in the study: Click here to enter text | **Hospital team involved in the study**:  |
| 1. **Project Details**
 | Institutional comments and/or requirements |
| **3.1 Clinical Study Title :**  Click here to enter text**3.2 Brief Summary of the Proposed Study – attach separate sheet if necessary*** Include details of Study Methodology
* Include details of any clinical procedures human subjects will undergo including any diagnostics interventions other than bloods (e.g. imaging).

**3.3 Anticipated recruitment start date:**  Click here to enter text  **end date:**  Click here to enter text **3.4 Type of study:*** Investigational Medicinal Product study [ ]
* Medical device study [ ]
* Other [ ]  Please specify: Interventional (non-regulated)

 **3.5 Study category:** Regulated  [ ]  Interventional\*  [ ]  Non-interventional [ ]  **Note:** if the Study is interventional it requires a Clinical Trial Agreement (to be prepared by the Research Contracts team)**3.6 Study registration:**Please name the study register that you plan to register the study with (e.g. clinicaltrials.gov, ISRCTN etc.)Click here to enter text  | **Study classification and risk level**: **Procedure risk (where applicable):** **Risk benefit:** **Approval requirements** **Contractual requirement**: **Sponsorship oversight requirements**: |
| **4. RCSI role in the study** | Institutional comments and/or requirements |
| **4.1 Please clarify RCSI role in the study:**[ ]  Sponsor[ ]  Local sponsor for an international study.  If applicable please name international Sponsor Click here to enter text[ ]  RCSI assumes certain sponsor responsibilities on behalf of the Sponsor  If this applies, please name the Sponsor of the Study Click here to enter text[ ]  RCSI administers the funding supporting the Study.  If this applies, please clarify Click here to enter text[ ]  None of the above.  | **RCSI**:  |
| **5 Involvement of RCSI employees or students in the study** | Institutional comments and/or requirements |
| **5.1 Will the study involve other RCSI employees or students:** Yes [ ]  No [ ] **If yes, please clarify:**  Click here to enter text**5.2** **If yes, please specify role of RCSI employees/students** (select from one or more from the following options)[ ]  Sub-investigator[ ]  Clinical research support[ ]  Other research support **Please clarify:** Click here to enter text[ ]  Project management/coordination [ ]  Collection / processing of phenotypic data [ ]  Patient consent [ ]  Statistical analysis [ ]  Data Management [ ]  Collection of biological samples [ ]  Analysis of biological samples [ ]  Other **Please clarify:** Click here to enter text**5.3 Will you require support from the RCSI (Beaumont or Rotunda) CLINICAL RESEARCH CENTRE ?**  Yes [ ]  No [ ] If yes, please clarify support type:[ ]  Clinical research nursing support [ ]  Co-ordination/management [ ]  Other **Please clarify:** Click here to enter textIf the study requires support from the Beaumont CRC the PI should engage with CRC team by emailing crcapplications@rcsi.com and completing the Beaumont CRC Study registration process.  An overview of supports and services available in the CRC can be found at the following link: <https://www.rcsi.com/dublin/research-and-innovation/research/resources-and-facilities/clinical-research-centre/work-with-us>  |  |
| **6. Clinical sites and/or university/ies involved in the study**  | Institutional comments and/or requirements |
| **6.1 CLINICAL SITES****Please name any clinical sites (e.g. Hospitals, GPs, other private practices) who will be involved in the Study**1. **Organisation Name:**  Click here to enter text

**Clinical Investigator name** (other than yourself, if applicable)**:** Click here to enter text **Involvement in study design:** Yes [ ]  No [ ]  **Role in the study**: Recruiting site [ ]  Other [ ]   **if you selected Other, please clarify:** Click here to enter text 1. **Organisation Name:**  Click here to enter text

**Clinical Investigator name** (other than yourself, if applicable)**:** Click here to enter text **Involvement in study design:** Yes [ ]  No [ ]  **Role in the study**: Recruiting site [ ]  Other [ ]   **if you selected Other, please clarify:** Click here to enter text **6.2 UNIVERSITIES OR OTHER RESEARCH PERFORMING ORGANISATIONS****Please name any other University or Research Performing Organisation which will be involved in the Study**1. **Organisation Name:**  Click here to enter text

**Investigator name:** Click here to enter text **Involvement in study design:**  Yes [ ]  No [ ] Role in the study:[ ]  Clinical research support[ ]  Other research support **Please clarify:** Click here to enter text[ ]  Collection / processing of clinical data [ ]  Patient consent [ ]  Statistical analysis [ ]  Data Management [ ]  Collection of biological samples [ ]  Analysis of biological samples [ ]  Other **Please clarify:** Click here to enter text1. **Organisation Name:**  Click here to enter text

**Investigator name:** Click here to enter text **Involvement in study design:**  Yes [ ]  No [ ] Role in the study: [ ]  Clinical research support[ ]  Other research support **Please clarify:** Click here to enter text[ ]  Collection / processing of clinical data [ ]  Patient consent [ ]  Statistical analysis [ ]  Data Management [ ]  Collection of biological samples [ ]  Analysis of biological samples [ ]  Other **Please clarify:** Click here to enter text**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Note**: The sponsor of the study will have to enter into an agreement with the organisations listed above which sets out the responsibilities, obligations, terms and conditions of all the Parties involved in the Study in relation to the clinical trial and/or sharing and/or processing of personal data and/or biological material | **Sites:** **Other Universities:**  |
| **7. Other third party/ies involved in the study** | Institutional comments and/or requirements |
| **7.1 Please clarify if there is any other third party involved in the Study** Yes [ ]  No [ ]  **If Yes, please provide information below**1. **Third Party’s name:**

 **Third Party’s role:**  Collaborator [ ]  Service provider [ ]   **Involvement in study design:**  Yes [ ]  No [ ]  **Third Party’s responsibilities:**[ ]  provision of IMP[ ]  provision of device[ ]  provision of software[ ]  analysis of clinical data[ ]  analysis of biological material[ ]  other – Transcription of qualitative interviews1. **Third Party’s name:** Click here to enter text.

 **Third Party’s role:**  Collaborator [ ]  Service provider [ ]   **Involvement in study design:**  Yes [ ]  No [ ] **Third Party’s responsibilities:**[ ]  provision of IMP[ ]  provision of device[ ]  provision of software[ ]  analysis of clinical data[ ]  analysis of biological material[ ]  other - Click here to enter text**7.2 Please clarify if any of the parties named above have any commercialisation rights:** Click here to enter textClick here to enter text**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Note**: If other third Party/ie is/are involved in the study on a collaborative basis, depending on the third party’s role, it may be necessary to put in place a collaboration agreement, which governs the third party’s participation/role in the Study. If the study is interventional and therefore requires a Clinical Trial agreement, the third party could be added as a party in the Clinical Trial agreement.If a third Party is involved in the study on a service basis, procurement rules should be complied with and a contract should be put in place to govern the terms of the service  |  |
| 1. **Funding**
 | Institutional comments and/or requirements |
| **8.1 Please clarify if you have already secured funding to support the study**Yes [ ]  No [ ] **8.2 If you have already secured funding to support the study,** **(a) please clarify funding source**[ ]  Private funding[ ]  Industry funding[ ]  Peer reviewed funding (e.g. HRB, SFI, EI, European funding)[ ]  Other – please clarify: Click here to enter text **(b) please clarify if the funding has already been registered at RCSI and you have a**  **research account (if a grant/project code is available please advise)**Yes [ ]  No [ ]  **8.3 If you have not secured any funding to support the study, please clarify whether you are planning to apply for funding**Yes [ ]  No [ ]   **If Yes, please clarify funding source and deadline for funding application (if applicable):** Click here to enter text**If No, please clarify reason for not applying:** Click here to enter text**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Note**: If funding is not in place, the Investigator should engage with ORI pre-award team (researchgrantapplicationsupport@rcsi.ie) to identify funding opportunities . When applying for funding please engage with the Sponosorship Office (sponsorship@rcsi.ie ) for an estimate of sponsorship costs (where applicable).  |  **Funder** : |
| **9 Participant Information and other info which may have an impact on insurance premium** | Institutional comments and/or requirements |
| **9.1 Anticipated Number of Participants:**  Click here to enter text**9.2 Please explain why the anticipated number of participants is realistic :** Click here to enter text**9.3 Participant Type:** Click here to enter text.Patients [ ]  Healthy volunteers [ ]  Other [ ]  If you have selected other, please clarify  Click here to enter text.**9.4 Please clarify if your study will involve any of the following study participants:** *Please click the boxes as appropriate:*Pregnant women [ ]  Children under 16 [ ]  **9.5 Please clarify whether any of the study participants have one of the following conditions:***Please click the boxes as appropriate:*HIV [ ]  Hepatitis [ ]  CJD [ ] another critical condition [ ] **9.6 Please clarify if your study will involve** *Please click the boxes as appropriate:*Genetic engineering [ ]  Contraceptives [ ] Administration or use of medicinal substances, devices or equipment manufactured by the University [ ] **9.7 Please clarify if the study involves diagnostic interventions other than bloods:** Yes [ ]  No [ ]  If Yes, please specify the type of intervention, by whom the intervention is carried out and where it will occur: Click here to enter text**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Note:** Responses to 9.4, 9.5, 9.6 may have an impact on insurance (additional premium may be required) | **Patient Population**: **Insurance cover:**  |

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| **DATA PROTECTION** |  |
| **A.**  **Retrospective chart review and consent** | Institutional comments and/or requirements |
| **Please clarify whether the study requires retrospective chart review for the identification of Study****Participants:**Yes [ ]  No [ ]  **If Yes, pls clarify who is going to conduct the retrospective chart review**  Click here to enter text **Please clarify your plan for consenting study participants:**[ ]  Specific consent (in accordance with Health Research Regulations)[ ]  Parent/Guardian Consent[ ]  Parent/Guardian Consent + Child Assent [ ]  Deferred consent [ ]  Consent exemption based on HRR 2021 Amendments which apply to Retrospective Chart Review[ ]  Consent exemption based on HRR 2021 Amendments which apply to (Pre‐screening) action to determine eligibility or suitability for inclusion in the research[ ]  HRCDC consent declaration |  |
| **B. Pre-existing Personal Data** | Institutional comments and/or requirements |
| **Does the research study require access to/the use of pre-existing personal or pseudonymised data, which was generated for a purpose unrelated to the study?** Yes [ ]  No [ ]  If you selected YES, please complete section 1-7 of this table B for each dataset undergoing the same processing activities (copy and paste content below if necessary)**1. Please clarify the Data type:** [ ]  Non-sensitive personal data [ ]  Date of Birth[ ]  Address [ ]  Sex[ ]  Ethnicity [ ]  Health data[ ]  Genetic data[ ]  Biometric data[ ]  Other - Pls clarify Click here to enter text  **2. Please clarify whether this pre-existing data was generated and is being processed:** **- for delivering healthcare** Yes [ ]  No [ ] **- for another purpose (unrelated to your study)** Yes [ ]  No [ ]   **If Yes, pls clarify**  Click here to enter text  **3. Please name the organisation(s) where the pre-existing data was generated, the individual  representing that Institution and his/her role in the study (if any):****Organisation’s name:**  Click here to enter text**Representative name:**  Click here to enter text**Representative Involvement in the study design** Yes [ ]  No [ ]  **Organisation’s name:**  Click here to enter text**Representative name:**  Click here to enter text**Representative Involvement in the study design** Yes [ ]  No [ ] **Organisation’s name:**  Click here to enter text**Representative name:**  Click here to enter text**Representative Involvement in the study design** Yes [ ]  No [ ]  **4**. **Please select the data processing activities of the data identified above which will be performed  for the purpose of the study**

|  |  |  |
| --- | --- | --- |
| [ ]  Screening[ ]  Collection[ ]  Consultation[ ]  Copy[ ]  Retrieval[ ]  Organisation[ ]  Recording[ ]  Transfer | [ ]  Alignment or combination[ ]  Aggregation[ ]  Structuring[ ]  Pseudonymisation[ ]  Anonymisation[ ]  Adaptation or Alteration[ ]  Disclosure by transmission | [x]  Analysis[ ]  Erasure/destruction[ ]  Archive[ ]  Storage[ ]  Transcription |

**5. Please name any other organisation not named above which is going to process the pre-existing  data identified above for the purpose of the study:**  **Organisation’s name:**  Click here to enter text**Representative name:** Click here to enter text**Representative Involvement in the study design** Yes [ ]  No [ ]  **Organisation’s name:**  Click here to enter text**Representative name:**  Click here to enter text**Representative Involvement in the study design** Yes [ ]  No [ ] **6. Please select the data processing activities which the organisations named above will perform for  the purpose of the study:**

|  |  |  |
| --- | --- | --- |
| [ ]  Screening[ ]  Collection[ ]  Consultation[ ]  Copy[ ]  Retrieval[ ]  Organisation[ ]  Recording[ ]  Transfer | [ ]  Alignment or combination[ ]  Aggregation[ ]  Structuring[ ]  Pseudonymisation[ ]  Anonymisation[ ]  Adaptation or Alteration[ ]  Disclosure by transmission | [x]  Analysis[ ]  Erasure/destruction[ ]  Archive[ ]  Storage[ ]  Transcription |

**7. If applicable, please clarify how data is going to be transferred to other organisations:** Click here to enter text  |  |
| **C. Newly Generated Personal Data**  | Institutional comments and/or requirements |
| **Does the research study require access to/use of newly generated/prospective personal data or pseudonymised data?**Yes [ ]  No [ ] If you selected YES, please complete section 1-7 of this table B for each dataset undergoing the same processing activities (copy and paste content below if necessary). Information about prospective data generated from the analysis of biological samples should be included in table D 1. **Please clarify the data type that is going to be processed for the purpose of the study:**

[ ]  Non-sensitive personal data [ ]  Date of Birth[ ]  Address [ ]  Sex[ ]  Ethnicity [ ]  Health data[ ]  Genetic data[ ]  Biometric data[ ]  Other - Pls clarify Click here to enter text**2. Please clarify if the data selected above will also be processed:**  **- for delivering healthcare** Yes [ ]  No [ ]  **- for other purposes unrelated to your research project** Yes [ ]  No [ ]  **if YES, please clarify other purpose (s):**  Click or tap here to enter text.**3. Please name the institution(s)/organisation(s) where this data is generated:** **Organisation’s name:**  Click here to enter text**Representative name:**  Click here to enter text**Representative Involvement in the study design** Yes [ ]  No [ ]  **Organisation’s name:**  Click here to enter text**Representative name:**  Click here to enter text**Representative Involvement in the study design** Yes [ ]  No [ ] **4**. **Please select the data processing activities of the data identified above which will be performed  for the purpose of the study**

|  |  |  |
| --- | --- | --- |
| [ ]  Screening[ ]  Collection[ ]  Consultation[ ]  Copy[ ]  Retrieval[ ]  Organisation[ ]  Recording[ ]  Transfer | [ ]  Alignment or combination[ ]  Aggregation[ ]  Structuring[ ]  Pseudonymisation[ ]  Anonymisation[ ]  Adaptation or Alteration[ ]  Disclosure by transmission | [x]  Analysis[ ]  Erasure/destruction[ ]  Archive[ ]  Storage[ ]  Transcription |

**6 .Please name any other organisation not named above which is going to process the newly generated personal data identified above for the purpose of the study:**  **Organisation’s name:**  Click here to enter text**Representative name:** Click here to enter text**Representative Involvement in the study design** Yes [ ]  No [ ]  **Organisation’s name:**  Click here to enter text**Representative name:** Click here to enter text**Representative Involvement in the study design** Yes [ ]  No [ ] **7. Please select the data processing activities which they will perform for the purpose of the study:**

|  |  |  |
| --- | --- | --- |
| [ ]  Screening[ ]  Collection[ ]  Consultation[ ]  Copy[ ]  Retrieval[ ]  Organisation[ ]  Recording[ ]  Transfer | [ ]  Alignment or combination[ ]  Aggregation[ ]  Structuring[ ]  Pseudonymisation[ ]  Anonymisation[ ]  Adaptation or Alteration[ ]  Disclosure by transmission | [x]  Analysis[ ]  Erasure/destruction[ ]  Archive[ ]  Storage[ ]  Transcription |

**(h) If applicable, please clarify how data is going to be transferred to other organisations:**Click or tap here to enter text. |  |
| **D. Biological Samples** | Institutional comments and/or requirements |
| **Will the study require the analysis of biological material?**Yes [ ]  No [ ] If YES, for each type of biological material being used for the purpose of the study, please provide the information in each section (1-7) of this table 1. **Sample type** (e.g. blood, saliva,urine etc.): Click here to enter text
2. **Please name the organisations where the biological samples are/were originated**
* **Organisation name:**

 Click here to enter text  **Scientists/clinician representing the Organisation:**  Click here to enter text  **Representative Involvement in the study design** Yes [ ]  No [ ] * **Organisation name:**

Click here to enter text **Scientists/clinician representing the Organisation:** Click here to enter text **Representative Involvement in the study design** Yes [ ]  No [ ] * **Organisation name:**

Click here to enter text **Scientists/clinician representing the Organisation:** Click here to enter text1. **Please clarify whether the biological samples are/were generated for a purpose unrelated to the study**  Yes [ ]  No [ ]

 **If YES, please clarify other purpose(s) from the following:**[ ]  previous study/ies[ ]  biobanking[ ]  future study/ies (for small collection of samples which are not regarded as a biobank)[ ]  delivery of healthcare[ ]  other **please clarify:**  Click here to enter text1. **Please clarify whether the biological samples will be processed (for the purpose of the study) where they are/were originated**

 Yes [ ]  No [ ]  **if NO, please name the organisation(s) where the samples are going to be processed for the purpose of the study and clarify what analysis each organisation is going to perform:** * **Organisation name:**  Click here to enter text

**Name of the scientists/clinician representing the Organisation:**  Click here to enter text**Analysis being conducted on the samples:**  **:**  Click here to enter text**Representative Involvement in the study design** Yes [ ]  No [x] * **Organisation name:**  **:**  Click here to enter text

**Name of the scientists/clinician representing the Organisation:**  Click here to enter text**Analysis being conducted on the samples:**  Click here to enter text**Representative Involvement in the study design** Yes [ ]  No [ ] 1. **If the biological samples are not generated by the organisation who is going to analyse them, please clarify which of the following apply:**

[ ]  **the samples will be pseudonymised prior to sharing**  [ ]  **the samples will be anonymised prior to sharing**  [ ]  **The samples have already been pseudonymisation for a purpose unrelated to the study prior  to sharing**[ ]  **The samples have already been anonymised for a purpose unrelated to the study prior  to sharing**[ ]  **The samples will be shared with health data (including personal data)**1. **Please clarify if the analysis of the biological samples is going to generate genetic data or other data that can be regarded as personal data:** Yes [ ]  No [ ]
2. **Upon completion of the analysis, pls clarify what is going to happen with any remaining biological samples**:
* **They will be returned to the organisation owning the samples** Yes [ ]  No [ ]
* **They will be destroyed** Yes [ ]  No [ ]
* **They will be biobanked** Yes [ ]  No [ ]
* **They will be shared with another Organisation for further analysis** Yes [ ]  No [ ]
* **The samples derivatives will be shared with another Organisation for further analysis**

 Yes [ ]  No [ ]  |  |
| **Artificial Intelligence** |  |
| 1. **Does your study involve artificial intelligence (AI)?**

         Yes **☐** No **☐****If yes, please complete the rest of this section of the form**1. Please describe planned use AI in your study**:**   **:**

Click here to enter text1. Please clarify if the use of artificial intelligence in your study have an impact on the treatment of one specific patient or more broadly on treatment strategy: if yes, please clarify

Click here to enter text1. please clarify if AI will be used to process personal data

         Yes **☐** No **☐**1. If yes, please clarify if consent has been or will be obtained for the processing of data by artificial intelligence:

         Yes **☐** No **☐**1. Please clarify if the use of AI is specified in the consent form and PIL

         Yes **☐** No **☐**1. Please clarify if study participants been informed of their right to object to their data being processed by artificial intelligence;

         Yes **☐** No **☐** |  |
| **Medical malpractice Insurance**  |  |
| Will any member of the study team perform an intervention, clinical procedure or assessment as an RCSI employee, self-employee or RCSI student, who is not an employee of the hospital where the study is conducted  Yes [ ]  No [ ] if you have selected yes above, please complete the next section of this form for the relevant study team member as applicable Name of the team member: **:**  Click here to enter text1. Team member role/employment status:

[ ]  RCSI PhD Student not employed by the hospital/site where he/she performs the intervention[ ]  RCSI PhD Student performing an intervention in RCSI[ ]  RCSI MD Student not employed by the Hospital/site where he/she performs the intervention [ ]  RCSI MD Student performing an intervention in RCSI[ ]  Nurse employed by RCSI[ ]  Physiotherapist employed by RCSI[ ]  Physiotherapist (self-employed)[ ]  Other, pls clarify: Click here to enter text1. intervention performed by the team member named above:

[ ]  drug / medication administration; [ ]  therapy; [ ]  non-invasive treatment [ ]  clinical assessment or procedure (including blood draw) [ ]  invasive treatment [ ]  surgical procedure1. Is the intervention is conducted on children or pregnant participants Yes [ ]  No [ ]
2. Does the intervention involve the delivery of gene therapy Yes [ ]  No [ ]
3. Study area of research:

[ ]  Bariatrics / [ ]  Weight loss, [ ]  Neurology, [ ]  Cardiology, [ ]  Maternity [ ]  Antenatal [ ] None of the aboveName of the team member: Click or tap here to enter text.1. Team member role/employment status:

[ ]  RCSI PhD Student not employed by the hospital/site where he/she performs the intervention[ ]  RCSI PhD Student performing an intervention in RCSI[ ]  RCSI MD Student not employed by the Hospital/site where he/she performs the intervention [ ]  RCSI MD Student performing an intervention in RCSI[ ]  Nurse employed by RCSI[ ]  Physiotherapist employed by RCSI[ ]  Physiotherapist (self-employed)[ ]  Other, pls clarify: Click here to enter text1. intervention performed by the team member named above:

[ ]  drug / medication administration; [ ]  therapy; [ ]  non-invasive treatment (including blood draw) [ ]  clinical assessment or procedure (including blood draw)[ ]  invasive treatment [ ]  surgical procedure1. Is the intervention is conducted on children or pregnant participants Yes [ ]  No [ ]
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[ ]  Bariatrics / [ ]  Weight loss, [ ]  Neurology, [ ]  Cardiology, [ ]  Maternity [ ]  Antenatal [ ] None of the above |  |
| **Additional Details** |  |
|  Are there any other factors in the research study that should be brought to the attention of the Research Contracts office (eg collection of biological material which could cause potential harm to the patient requiring additional insurance)? If so, please specify.Click or tap here to enter text. | **I**nstitutional comments and/or requirements |
|  |  |