**CLINICAL STUDY REGISTRATION FORM (CSRF)**

**Purpose and scope of the CSRF**

This form serves as a FIRST NOTIFICATION by a clinical investigator to the RCSI Sponsorship Office and Beaumont Hospital (where applicable) of the plan to undertake a clinical research project.

The completion of this form is required for any interventional or observational or epidemiological or physiological research study which involve humans, human tissue and/or data, regardless of the source of funding, use of IMP or device.

**Process and procedure for the completion and review of the CSRF**

This form is to be completed by the study lead investigator as early as possible in the study planning process.

The Investigator must ensure that the responses and information provided in the form are comprehensive, clear and understandable by non-scientific of 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

When the study involves Patients of Beaumont Hospital, the form is shared with Beaumont Hospitals for review, feedback and confirmation of agreement with the RCSI sponsorship office and legal team requirements

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 the comments and requirements, sign the declaration and undertakings section of the form and return the signed form to the sponsorship office (sponsorship@rcsi.ie)

|  |  |
| --- | --- |
| **CLINICAL STUDY REGISTRATION FOR**M | Sponsor Office Ref: |
| **Note:** If the following applies1. The study is observational (i.e. does not involve any intervention and patient are treated in accordance with standard of care), RCSI does not play a sponsorship role in the study and the study PI/CI performs the study in his/her capacity as clinical investigator of Beaumont Hospital,
2. the study funding is not administered by RCSI (see section 8)
3. RCSI does not play any role in the processing/analysis of personal data and/or biological material (see sections 5, 10. 11)
4. No RCSI employees are involved in the support of the Study (see section 5)

Investigators should engage with the Sponsorship Office (sponsorship@rcsi.ie) before completing this form |
| **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): Dept:Email:  | **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 :**  **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: end date:**  **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[x]  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 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 text |  |
| **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 in place, the Investigator should liaise with Mandy Jackson at mandyjackson@rcsi.ie to ensure that there is sufficient funding to cover sponsorship costs (where applicable).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 Mandy Jackson at mandyjackson@rcsi.ie (Sponsorship Office) who will provide 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:**  |
| **10 Personal data** | Institutional comments and/or requirements |
| **10.1 Please clarify whether the study will require the processing of Personal or Pseudonomymised Data:** Yes [ ]  No [ ] **10.2 If Yes, please clarify if it requires pre-existing Personal or Pseudonomymised Data (e.g. data from Medical Records or data that was collected for another purpose)**Yes [ ]  No [ ]  **If yes,** p**lease name the hospital(s)/organization(s) where the pre-existing data was generated:** - Click here to enter text**10.3** **If the Study requires pre-existing Personal or Pseudonomymised Data, please clarify whether this pre-existing data was generated and is being processed:** **- for delivering healthcare** Yes [ ]  No [ ] **- for another purpose** Yes [ ]  No [ ]  **if Yes, please clarify other purpose (s)** Click here to enter text.**10.4 Please clarify if the Study requires newly generated Personal or Pseudonymised Data** Yes [ ]  No [ ] **If yes, please name the hospital(s)/organization(s) where this data is generated:**- Click here to enter text**10.5 If the Study requires newly generated Personal or Pseudonymised Data, please clarify whether the data is/will also be processed:**  **- for delivering healthcare** Yes [ ]  No [ ]  **- for other purposes** Yes [ ]  No [ ]  **if Yes, please clarify other purpose (s)** - Click here to enter text**10.6 If the study requires pseudonymised data, please clarify whether the original Personal Data:****- was pseudonymised for a purpose unrelated to the study**  Yes [ ]  No [ ] **- is pseudonymised for the purpose of the study**  Yes [ ]  No [ ] **. If Yes, please clarify which institution is  responsible for the pseudonymisation of Personal Data** **(a) Hospital/organisation where the data is/was originated** Yes [ ]  No [ ]  **(b) RCSI** Yes [ ]  No [ ]  **(c) another Institution** Yes [ ]  No [ ]  **If yes please name institution(s) below:** - Click here to enter text**10.7 Please name the organisations which are going to process Personal or Pseudonymised for the purpose of the Study**  **- Hospital staff (where the data is originated)** Yes [ ]  No [ ]  **- RCSI staff**  Yes [ ]  No [ ]  **- Staff from other Organisations** Yes [ ]  No [ ]  **If yes please name institutions below:**- Click here to enter text**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Note**: If the study requires the processing of Personal/Pseudonymised Data, the completion of a DPIA, PIL and Patient consent are requiredIf RCSI is the Data Controller of the Data processed for the purpose of the Study the RCSI DPIA template should be completed and reviewed by RCSI DPO together with PIL and Patient consent formIf the Study requires **pre-existing Data**, data subject’s consent to use his/her personal data for the study is required. Alternatively HRCDC Consent is requiredIf the study requires sharing of personal data (e.g. by the Hospital with RCSI) and the data provider processes the same data for a separate purpose (other than the study), data sharing provisions are required in the Clinical Trial Agreement. If a Clinical Trial Agreement is not required a data sharing agreement is requiredIf the study requires pre-existing pseudonymised data, a contract between the data provider and RCSI is required to govern the processing of pseudonymised data by RCSI If the study requires pseudonymisation of Personal Data prior to its sharing, a contract should govern the role of RCSI and the Hospital in the processing of personal data for the purpose of the study up to the pseudonymisation process Processing of Psuedonymised data by the data recipient who does not hold the identification key should be made subject to some contractual conditions to ensure that the identity of the data subjects is not revealed | **Data Protection roles of the Parties:** **DPIA**:  |
| **11 Biological samples** | Institutional comments and/or requirements |
| **11.1 Will the study require the analysis of biological samples?**Yes [ ]  No [ ] **If yes, please clarify:** 1. **The name of the organisation where the samples are/were originated:**

click here to enter text1. **The type(s) of biological sample to be analysed:**

[ ]  Blood[ ]  Urine[ ]  Tissue[ ]  other – **please clarify** **:** click here to enter text 1. **(c) where the biological samples are/were originated :**
2. click here to enter text
3. **(d) whether the biological samples are/were generated for a purpose unrelated to the study**

 Yes [ ]  No [ ]  **If Yes, please clarify other purposes by choosing 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 text **(e) 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** - Click here to enter text**(f) Please clarify if data generated from the analysis of the samples includes genetic data or another type of data which can be regarded as personal data**  Yes [ ]  No [ ]  If Yes, please name the Organisations involved in such analysis - Click here to enter text**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Note:** If the Study requires processing of biological samples, Patient consent is required.If the biological data is shared with RCSI by another organisation, Material sharing provisions within the Clinical Trial Agreement or in another agreement (E.g. Material Transfer Agreement) are requiredIf the analysis of biological material for the purpose of the study generates personal data, and RCSI is the Sponsor/and/or sole data controller for the purpose of the study, RCSI shall assume data controller responsibilities for the Personal Data generated from the analysis of the Biological Material and Data Protection provisions will be included in the agreement with governs the sharing of Material |  |
| 1. **Additional Details**
 | Institutional comments and/or requirements |
| Are there any other factors that should be highlighted at this point so that they can be brought to the Insurer’s attention and can be used in consideration for the Sponsorship Officer Risk assessment of the proposal? If so, please specify.\Click here to enter text. |  |

|  |
| --- |
| **Sponsor Officer’s and RCSI research contract team’s summary comments and conclusion** |
| **Conclusions on classification and study risk*** Benefit risk is positive (IMP administered in accordance with clinical care) so relatively low risk for study subjects.

• Interventional with invasive testing **Sponsorship office** oversight requirements:1. Sponsor confirmation of insurance
2. Green light
3. Sponsor Office review of protocol, PIL, IC

**Other requirements**1. RCSI and Beaumont DPO review of DPIA
2. Ethics approval
3. CTAs with sites
4. MTAs with UK universities
 |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_** **PRINT NAME SIGN DATE** |

|  |
| --- |
| **Investigator declaration** (to be completed after having reviewed the Sponsorship Officer comments and requirements) |
| **I hereby declare that**1. **I will ensure 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**  |