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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**  **The study is covered by RCSI clinical trial policy  Protocol insurance requires the payment of an additional premium**  **Med mal is covered by CIS and current RCSI policy  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** |
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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](mailto: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):  Dept:  Email:  **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 text  If 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  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 text  If the study requires support from the Beaumont CRC the PI should engage with CRC team by emailing [crcapplications@rcsi.com](mailto: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 text   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 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 interviews   1. **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](mailto:researchgrantapplicationsupport@rcsi.ie)) to identify funding opportunities . When applying for funding please engage with the Sponosorship Office ([sponsorship@rcsi.ie](mailto: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:** |