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| **MATERIAL AND DATA INFORMATION FORM (MDIF)** | **Ref. no.** |

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| **Study Title:** |
| **RCSI Investigator Name:** |

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| **DATA PROTECTION ROLES FOR THE PURPOSE OF THE STUDY**  The table in this page is completed by 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 MDIF form must be included in the documentation submitted to the ethics committee, the DPO(s), and the Hospital for final approval. |
| **Data Controller(s):**  **Data Processor(s):** |
| **CONTRACTUAL REQUIREMENTS**  **Framework LOA (specify template type):**  **Material transfer agreement between:**  **Material transfer and data sharing/processing agreement between:**  **Data sharing/processing agreement between:**  **Joint Data Controllers agreement between:** |
| **DATA PROTECTION REQUIREMENTS**  **Patient information leaflet**  **Consent form**  **DPIA**  **Pre-screening agreement**  **Consent declaration**  **Transfer impact assessment**  **Standard contractual clauses** |
| **RESEARCH CONTRACT OFFICER’S COMMENTS AND CONCLUSION ON DATA PROTECTION ROLES** |
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| **Investigator declaration / commitment** (to be completed after having reviewed the Research Contracts Office comments and requirements) |
| I hereby declare that the information provided is accurate and commit to ensure that   1. any requirement set out in this form is in place in accordance with the instructions provided by RCSI Research Contract Office. 2. in the event of any change of plan in relation to the use of personal data and/or biological material for the purpose of the study which would have an impact on the information provided in this form, this form will be amended and shared with RCSI Research Contract Office in a timely manner. |
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| **HOW TO COMPLETE THE MATERIAL AND DATA INFORMATION FORM (MDIF)** |
| **When to complete this form**  This form must be completed by an RCSI affiliated clinical Investigator who is planning to lead a research study/project which requires the collection and/or transfer of biological material and/or personal data. The form should be completed as early as possible in the study planning process.  **Note well:** Form should only be completed after having engaged with RCSI Clinical Research Contracts 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 of clinical personnel.  The Investigator shall submit the completed form by email to RCSI Clinical Research Contracts team ([clinrescont@rcsi.ie](mailto:clinrescont@rcsi.ie)) together with any other documentation available at that time which is relevant to the research study.  RCSI Clinical Research Contracts will review this form (and any documents provided with it) to clarify RCSI data protection role in the study and identify any legal/contractual requirements.  The requirements identified by RCSI Clinical Research Contracts are documented in the comment section of the form above.  Upon completion of the institutional review process this form is returned to the study/project Investigator to clarify requirements before  the study can commence.  The study Investigator is required to review the comments and requirements, sign the declaration and undertakings section of this form and return the signed form to RCSI Clinical Research Contracts ([clinrescont@rcsi.ie](mailto:clinrescont@rcsi.ie)).  When the study involves patients of Beaumont Hospital, this form is shared with Beaumont Hospitals as part of the ethics, data protection and legal review process. |

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| **MATERIAL AND DATA INFORMATION FORM**  (sections to be completed by the RCSI Study Investigator or nominee) | (Sections to be completed by RCSI Research Contract Office) |
| 1. **Investigator(s) Details** | Institutional comments and/or requirements |
| **1.1 Contact details:**  Name: Click or tap here to enter text.  Employer(s): Click or tap here to enter text.  Dept.: Click or tap here to enter text.  Email: Click or tap here to enter text.  Telephone: Click or tap here to enter text.  **1.2 Affiliation with RCSI:**  contract of employment with RCSI  joint contract of employment with RCSI and hospital  RCSI tutor  RCSI postgraduate student  honorary affiliation  none  **1.3 Your role : please clarify whether you are the study Lead Investigator, i.e. whether   you have conceived and will lead the research study**  Yes No  **1.4 If you are not the Lead Investigator:**  **(a**) **Please clarify whether you played any role in the design of the study**  Yes No  **(b) Please provide the Lead Investigator contact details:**  Name: Click or tap here to enter text.  Employer(s): Click or tap here to enter text.  Dept.: Click or tap here to enter text.  Email: Click or tap here to enter text.  Telephone: Click or tap here to enter text.  Lead Investigator’s affiliation with a University (if any) Click or tap here to enter text.  University name: Click or tap 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 |  |
| **2. Study Details** | Institutional comments and/or requirements |
| **2.1 Study Title:**  Click or tap here to enter text.  **2.2 Brief Summary of the Proposed Research:**  Click or tap here to enter text.  **2.3 Study planned start date: end date:** |  |
| **3. Consent** |  |
| **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 or tap 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 |  |
| **4. 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 YES**   1. **Please clarify the Data type:**   Non-sensitive personal data  Health data  Genetic data  Biometric data  Other - Pls clarify Click or tap here to enter text.  **(b) Please clarify whether this pre-existing data was generated and is being processed:**  **- for delivering healthcare** Yes  No  **- for another purpose (unrelated to your research project)** Yes  No  **If Yes, pls clarify**  Click or tap here to enter text.  **(c) 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):**   1. **Organisation’s name:**  Click or tap here to enter text.   **Representative name:**  Click or tap here to enter text.  **Representative email**: Click or tap here to enter text.  **Representative’s role in the study:**  Click or tap here to enter text.  **Representative Involvement in the study design** Yes  No  **(d) Please select the data processing activities which will be performed for the purpose of the study by   the organisation named above:**   * **Pseudonymisation** Yes  No * **Data Recording**  Yes  No * **Data Analysis** Yes  No * **Data Storage** Yes  No * **Data Transfer** Yes  No * **Other: pls clarify**  Click or tap here to enter text.   **(e) 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 name:**  Click or tap here to enter text.   **Name of the scientists/clinician representing the Organisation:**  Click or tap here to enter text. **Representative role in the study (if any):** Click or tap here to enter text.  **Representative email**: Click or tap here to enter text.  **Representative Involvement in the study design** Yes  No  **(f) Please select the data processing activities which they will perform for the purpose of the study:**   * **Data Storage** Yes  No * **Data Analysis**  Yes  No * **Data Pseudonymisation**  Yes  No * **Data Transfer** Yes  No * **Other: pls clarify**  Click or tap here to enter text.   **(g) If data is being transferred under (f) above, please describe the method of transfer:**  Click or tap here to enter text. |  |
| **5. Newly Generated Personal Data** | Institutional comments and/or requirements |
| **Note:** This section to be completed if prospective data is being collected for the purpose of the study**.** If data is newly generated as a result of analysis of material only, please complete section 6 below instead of this section 5.  **Does the research study require access to/use of newly generated personal data:**  Yes  No  **If YES,**   1. **Please clarify the data type:**   Non-sensitive personal data  Health data  Genetic data  Biometric data  Other - Pls clarify Click or tap here to enter text.  **(b) Please clarify whether the newly generated data 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.  **(c) Please name the institution(s)/organisation(s) where this data is generated, the individual representing that Institution and his/her role in the study (if any):**   * **Organisation name:**  Click or tap here to enter text.   **Name of the scientists/clinician representing the Organisation:**  Click or tap here to enter text.  **Representative role in the study (if any):** Click or tap here to enter text.  **Representative email**: Click or tap here to enter text.  **Representative Involvement in the study design** Yes  No  **(d) Please select the data processing activities which will be performed by the organisation named above for the purpose of the study:**   * **Collection** Yes  No * **Data Storage** Yes  No * **Data Analysis**  Yes  No * **Data Pseudonymisation**  Yes  No * **Data Transfer** Yes  No * **Other: pls clarify**  Click or tap here to enter text.   **(e) If data is being transferred under (d) above, please describe the method of transfer:**  Click or tap here to enter text.  **(f) 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 name:**  Click or tap here to enter text.  **Name of the scientists/clinician representing the Organisation:**  Click or tap here to enter text.  **Representative role in the study (if any):** Click or tap here to enter text.  **Representative email**: Click or tap here to enter text.  **Representative Involvement in the study design** Yes  No  **(g) Please select the data processing activities which they will perform for the purpose of the study:**   * **Collection** Yes  No * **Data Storage** Yes  No * **Data Analysis**  Yes  No * **Data Pseudonymisation**  Yes  No * **Data Transfer** Yes  No * **Other: pls clarify**  Click or tap here to enter text.   **(h) If data is being transferred under (g) above, please describe the method of transfer:**  Click or tap here to enter text. |  |
| **6. 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 below in relation to each organisation involved in the collection and/or analysis and/or storage of the material**   1. **MATERIAL TYPE** (e.g. blood, saliva,urine etc.): Click or tap here to enter text.  * **Please name the Organisation where the biological samples are/were originated:**   Click or tap here to enter text.   * **Name of the scientists/clinician representing the Organisation:**   Click or tap here to enter text.   * **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 or tap here to enter text.   * **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 or tap here to enter text.  **Name of the scientists/clinician representing the Organisation:**  Click or tap here to enter text.  **Analysis being conducted on the samples:**  Click or tap here to enter text.  **Please clarify if the analysis is going to generate genetic data or other data that can be regarded as personal data:** Yes  No  **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  **Organisation name:**  Click or tap here to enter text.  **Name of the scientists/clinician representing the Organisation:**  Click or tap here to enter text.  **Analysis being conducted on the samples:**  Click or tap here to enter text.  **Please clarify if the analysis is going to generate genetic data or other data that can be regarded as personal data:** Yes  No  **If yes, please clarify what is going to happen with the newly generated data**:   * **It will be sent to the organisation owning the samples** Yes  No * **It will be retained by the organisation carrying out the analysis** Yes  No * **It will be shared with another organisation for further analysis**  Yes  No * **Organisation name:**  Click or tap here to enter text.   **Upon completion of the analysis, please 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     1. **MATERIAL TYPE** (e.g. blood, saliva,urine etc.): Click or tap here to enter text.  * **Please name the Organisation where the biological samples are/were originated:**   Click or tap here to enter text.   * **Name of the scientists/clinician representing the Organisation:**   Click or tap here to enter text.   * **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:**   * **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 or tap here to enter text.  **Name of the scientists/clinician representing the organisation:**  Click or tap here to enter text.  **Analysis being conducted on the samples:**  Click or tap here to enter text.  **Please clarify if the analysis is going to generate genetic data or other data that can be regarded as personal data:** Yes  No  **If yes, please clarify what is going to happen with the newly generated data**:   * **It will be sent to the organisation owning the samples** Yes  No * **It will be retained by the organisation carrying out the analysis** Yes  No * **It will be shared with another organisation for further analysis**  Yes  No * **Organisation name:**  Click or tap here to enter text.   **Upon completion of the analysis, please 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  **Name of the scientists/clinician representing the organisation:**  Click or tap here to enter text.  **Analysis being conducted on the samples:**  Click or tap here to enter text.  **Please clarify if the analysis is going to generate genetic data or other data that can be regarded as personal data:** Yes  No  **Upon completion of the analysis, please 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 |  |
| 1. **Other Organisation(s) Involved in the Study Not Identified Above** | **I**nstitutional comments and/or requirements |
| **Please name any other organisation(s) involved in the study.**   * **Organisation name:**  Click or tap here to enter text.   **Name of the individual representing the organisation:**  Click or tap here to enter text.  **Representative role in the study (if any):** Click or tap here to enter text.  **Representative involvement in the study design** Yes  No |  |
| 1. **Ethics/DPIA Status** | Institutional comments and/or requirements |
| 1. **Have you submitted an ethics application for the study?**   Yes  No   1. **If YES, has ethics been approved \*?**   Yes  No  **Please provide date of ethics submission:**  Click or tap here to enter text.  **Ethics reference number:**  Click or tap here to enter text.  **If NO, please provide date planned for ethics submission:**  Click or tap here to enter text.   1. **Have you completed a DPIA for the study?**   Yes  No  **If YES, please provide a copy of the DPIA when returning this form**   1. **Type of DPIA:**   RCSI template  RCSI/Beaumont joint template  Other  **If, yes has the DPIA been approved by the relevant DPO?**  Yes  No  **\* For future studies, please ensure that you engage with Clinical Research Contracts team and  complete this form before submitting your ethics application and DPIA to the hospital and/or RCSI DPO. RCSI Clinical Research Contracts to be notified once ethics approval has been obtained.** |  |
| 1. **Additional Details** | **I**nstitutional comments and/or requirements |
| 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. |  |