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| **MATERIAL AND DATA INFORMATION FORM (MDIF)** | **Ref. no.** |
| **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** |
| **Comments**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_**  **PRINT NAME SIGN DATE** |

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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. |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_**  **PRINT NAME SIGN DATE** |

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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:** |  | |
| **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 | 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 | 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 | 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 | 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 text   1. **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 text   1. **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   * **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 |  |

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| 1. **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 text   1. 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 text   1. 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 **☐** |  |
| 1. **Medical malpractice Insurance** |  |
| Please clarify if any member of the study team is going to perform a procedure (including blood draw) or diagnostic as part of the study .  Yes  No  if you selected yes above, for any member of the study team who is not an employee of the hospital where the study is conducted and is conducting an procedure (such as blood draw) as an RCSI employee or student or is self-employed, please complete the information below  Name of the team member: **:**  Click 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)   1. Please describe the procedure performed by the team member named above:   Click here to enter text   1. Is the procedure conducted on children or pregnant participants Yes  No 2. Study area of research:   Bariatrics /  Weight loss,  Neurology,  Cardiology,  Maternity  Antenatal  None of the above  Name of the team member: **:**  Click 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)   1. Please describe the procedure performed by the team member named above:   Click here to enter text   1. Is the procedure conducted on children or pregnant participants Yes  No 2. Study area of research:   Bariatrics /  Weight loss,  Neurology,  Cardiology,  Maternity  Antenatal  None of the above |  |

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| 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.** |  |