**Application Process for School of Dental Science REC**

**Procedures for Research Ethics Review**

All staff and students conducting research are required to ensure that their research is carried out in compliance with the School research ethics policy. If the study is deemed to require ethical approval, the Checklist for School REC suitability should be completed to determine whether the study is suitable for consideration by the School level 1 committee or needs to be submitted to an appropriate level 2 committee.

The process for applying for ethical approval is outlined in the following steps:

**1. Review the Trinity College Dublin ‘Policy on Good Research Practice**’

This is available from the following link: <http://www.tcd.ie/about/policies/assets/pdf/TCDGoodResearchPractice.pdf>

**2. Determine whether ethical approval is required and whether the application is suitable for consideration by the school “level 1” REC**

<https://www.tcd.ie/dental/research/research-ethics/Correct-Committee-Selection.pdf>

If the study is suitable for evaluation by a Level 1 committee, the researcher should complete this application form for ethical approval from the Dental School REC. Students should ensure that this is approved by the project supervisor before being submitted (as indicated on the form). Applications should be sent to the ethics committee administrator, Ms. Anne Kenny (anne.kenny@dental.tcd.ie) for review by the School’s Research Ethics Committee.

If the checklist indicates that the study requires the approval of a Level 2 committee, the applicant should download the application and procedures for the appropriate REC (e.g. the Faculty of Health Sciences REC, the Joint REC or another suitable Level 2 committee).

**Please note that all research involving non-human animals must be approved by the Animal Research Ethics Committee**

**4. Submit sample Patient information leaflet and Patient informed consent form.** Applicants must use the consent form template provided (Appendix I) to comply with the Health Research Regulations (2018).

**5. Respond** if necessaryto any requests for further information, or clarification, that the Committee mightmake in relation to the approval request. In some cases, this may include a request for further information. Discuss these with your supervisor if necessary, **and confirm to your supervisor when the approval has been granted**.

**6. All applicants must submit an annual report for ongoing projects and an end of project report upon completion of the study.** Templates for project reports are available in Appendix II and III.

**Completed Applications should be sent by email to the REC administrator, Ms. Anne Kenny (****anne.kenny@dental.tcd.ie****)**

**Section 1: Research Ethics Checklist**

**RESEARCH APPLICATION CHECKLIST**

**Please answer all question yes, no or not applicable as appropriate to the following questions. If you answer no to any question, please explain why and the relevant question number in the comment box at the end of the form**

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| 1. Is this a level 1 application (as per website insert link)?
 |  |  |
| 1. Is this a level 2 application (as per website insert link)?
 |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Please tick the appropriate box | **Yes** | **No** | **NA** |
| 1. Are you undertaking the proposed research study in your capacity as a staff member of the School of Dental Science*?*
 |  |  |  |
| 1. Are you undertaking the proposed research study in your capacity as a student of the School of Dental Science?
 |  |  |  |
| 1. If you are a student, has your **supervisor read, approved and signed** the completed form?
 |  |  |  |
| 1. Have you **signed** the application form?
 |  |  |  |
| 1. Have you **checked** that your application meets the criteria for this research ethics committee?
 |  |  |  |
| 1. Are you recruiting participants for this study?
 |  |  |  |
| 1. Are the participants purposefully recruited from a vulnerable group?
 |  |  |  |
| 1. Is this a health research study?
 |  |  |  |
| 1. Does the study include a health intervention?
 |  |  |  |
| 1. Are you collecting personal or sensitive data?
 |  |  |  |
| 1. Have you **completed** and **included** a risk assessment (for data) for this study ([Risk Assessment Link](https://www.tcd.ie/info_compliance/data-protection/dpias/))?
 |  |  |  |
| 1. Do you require a Data Protection impact assessment?
 |  |  |  |
| 1. If applicable (yes to Q8), have you completed a Data Protection impact assessment ([DPIA link](https://www.tcd.ie/info_compliance/data-protection/dpias/))?
 |  |  |  |
| 1. If accessing personal or sensitive data have you successfully **completed Trinity GDPR** online course? [LINK](https://www.tcd.ie/itservices/vle/kb/overview-GDPRtraining.php)
 |  |  |  |
| 1. If accessing collecting personal or sensitive data, and you are an undergraduate or master’s student has your **supervisor successfully completed** Trinity GDPR online course?
 |  |  |  |
| 1. If accessing collecting personal or sensitive data, have all Trinity members of the research team listed, successfully completed Trinity GDPR online course? [LINK](https://www.tcd.ie/itservices/vle/kb/overview-GDPRtraining.php)
 |  |  |  |
| 1. Have you **included** a copy of the questionnaires, interview template, data extraction list?
 |  |  |  |
| 1. Are you collecting samples, no matter how small, that could be used for genetic testing?
 |  |  |  |
| 1. If applicable, have you **included** the consent form and participation information leaflet?
 |  |  |  |
| 1. If applicable, have you **included** all relevant letters of permission /access from external agencies/organizations/ schools/ industry / clinical site hosting the study, from the appropriate responsible people agreeing access included including access to databases?
 |  |  |  |
| 1. If applicable, have you **included** the letter to the participants?
 |  |  |  |
| 1. If applicable, have you **included** any posters/other material used to advertise the study?
 |  |  |  |
| 1. If collecting personal or sensitive data, have you included detailed information on how you will implement security measures to protect the personal data in all its forms and all types e.g. device encryption?
 |  |  |  |
| 1. Have you **included** any other documents that are needed for your study i.e. Garda clearance, debrief documentation?
 |  |  |  |
| 1. If collection personal or sensitive data do you agree to only use the minimum data necessary to carry out the research?
 |  |  |  |
| 1. Have you put in all the necessary security arrangements required to collect, process store and destroy any personal or sensitive data required for this study?
 |  |  |  |
| 1. Are there any contractual arrangement required in order to carry out this study?
 |  |  |  |
| 1. Have you read and will abide by the requirements regarding research reporting, data storage and reporting of adverse events ?
 |  |  |  |

**If you have answered NO to any of the above questions (except 1,2, 6, 23) please explain:**

|  |
| --- |
|  |

**Section 2: Project Description**

|  |
| --- |
| **Name of Applicant**  |
|   |
| **Academic Supervisor/Lead Researcher** |
| For students this is the name of your supervisor. For staff this should be the lead researcher (if any) |
| **Academic Division**  |
|  |
|  **Title of project**  |
|  |
|  **Timeframe of research**  |
| Provide a brief timetable of the proposed research, particularly indicating data collection.  |
|  **Purpose of research**  |
| Provide a summary of the research, written in terms that a non-specialist would understand. |
|  **Participants in the research**  |
| Provide details of the population to be studied, and sampling procedures to be used.  |
|  **Recruitment procedures**  |
| This should include an explanation of any incentives and/or compensation (financial or otherwise) to be offered to participants.  |
|  **Methods** |
| Outline the methods that will be used for data collection and analysis and provide interview or survey questions where these are being used. |
|  **Ethical considerations and potential risks to participants**  |
| Where potential risks to participants may be present, explain any steps that will be taken to minimize these and any additional support services that might be used should the need arise. |
|  **Published ethical guidelines to be followed**  |
| Identify professional code(s) of practice and/or ethical guidelines relevant to the research.  |
|  **Signature of applicant:** |
| *I declare that I have read the TCD Ethics Policy and will follow the guidelines therein.****For student applications****: I also confirm that this application has already been reviewed and is supported by my supervisor.* |
| **Signature of the Chair of the School’s Ethics Committee** *In my capacity as Chair of the School’s Ethics Committee, I confirm that this project has been approved by the School’s Ethics Committee* |

**Section 3: Consent**

|  |
| --- |
| 3.1 Will you obtain consent for this research?  |
|   Yes NoIf the answer is **no,** please skip to section 4.  |
| **3.2 Please specify the type of consent:** |
| **Informed consent (from an ethical perspective)** **Explicit consent (for health research only)***Explicit consent: informed consent that is documented, (you must maintain evidence that it has been recorded). Please note that explicit consent is now a mandatory safeguard under the Health Research Regulations unless data are irreversibly anonymized (no key held ) or a consent declaration has been obtained from the health research consent declaration committee HRCDC) See* [*here*](https://hrcdc.ie/apply/) *for further information.****NB****: Consent to the use of personal data is not an appropriate legal basis for health research or any other research given the imbalance which exists between the data subject and the researcher.* **Please ensure you use scientific research[[1]](#footnote-1) in the public interest[[2]](#footnote-2) as your legal basis.** |
|  **3.3. How will you ensure informed / explicit consent is obtained from the research participants?**  |
| *Please attach a copy of invitation letter, consent form and participant information leaflet.* ***See Appendix and*** <https://www.tcd.ie/info_compliance/data-protection/health-research/> |
|  **N.B. Please indicate if you have modified the consent form and/or the participant information leaflet included in the link above?** Yes No If **yes** please highlight the changes made and why these were necessary.*If template is changed substantially - this will need to be reviewed by Deputy DPO for Research: email:* *researchDPO@tcd.ie* |

|  |
| --- |
| 3.4 What is the time interval between giving information and seeking consent or participation? |
| *During this time prospective participants should receive a letter of invitation, PIL and Consent Form to consider. It is recommended that a period of seven days be provided for reflection. If less than this, please justify.* |
| 3.5 Will the participants be purposefully recruited from any of the following groups (tick as appropriate) (i.e. children, prisoners, adults with mental illness where having/had a mental illness is an inclusion criterion of the study population)  |
|

|  |  |  |  |
| --- | --- | --- | --- |
|  | **YES** | **NO** | **Not known** |
| Children under 18 years of age |  |  |  |
| Adults with learning disabilities |  |  |  |
| Adults with communication difficulties |  |  |  |
| Adults who are unconscious or very severely ill |  |  |  |
| Adults who have a terminal illness |  |  |  |
| Adults with mental illness  |  |  |  |
| Adults suffering from dementia |  |  |  |
| Prisoners |  |  |  |
| Young Offenders |  |  |  |
| Those who could have been considered to have a particularly dependent relationship with the investigator, e.g. those in care homes, students, line manager of participants  |  |  |  |
| Other groups who may be considered vulnerable(Please specify below) |  |  |  |
| *NB: Inclusion of these groups will likely raise the risk level of the project to Level 2 and as such,* *Should be submitted to a level 2 committee.* |

 |

|  |
| --- |
| 3.6 If participants are to be recruited purposefully from any of the potentially vulnerable groups listed above, please complete the following: |
| (a) The extra steps taken to ensure that participants from any of these vulnerable groups are as fully informed as possible about the nature of their involvement |
| (b) Who will give consent |
| (c) How consent will be obtained (e.g. will it be verbal, written or visually indicated?) |
| (d) When consent will be obtained   |
| (e) The arrangements that have been made to inform those responsible for the care of the research participants of their involvement in research |
| 3.7 Will participants include women of childbearing potential? |
|   Yes NoIf No, please explain Why*Note: This information is required regardless of whether there are potential implications for the well-being of participants* |
| 3.8 If women of childbearing potential are to be involved, do the study design and the Participant Information Leaflet address the 9 essential points listed in the linked checklist, found here: <https://www.tcd.ie/dental/research/research-ethics/Research-on-women-of-childbearing-potential.pdf> |
|   Yes NoIf No, please explain Why*Note: This information is required regardless of whether there are potential implications for the well-being of participants* |

**Section 4: Confidentiality, data protection, data processing and data storage**

|  |
| --- |
| **4.1 Does the study involve collecting, using, accessing or sharing personal data[[3]](#footnote-3)?***Please read footnotes 1 & 2 to ensure you are answering this question correctly*  |
|  Yes No If you are not collecting personal data, please skip to question 4.2If yes please give details of the personal data to be collected and list all media/ forms utilised: online, hard copy, audio, video, photographs etc. and processing activity. Finally, please indicate how the personal data being collected relate to the aims and objectives of the study. (Justification) |
| **Data Collected** | **Justification** | **Processing Activity** |
| *EXAMPLE: Participant names* | *Identification, so that we can apply matching codes across data sets.* | *Excel database, situated in ‘X’ Drive on ‘X’ desktop computer at ‘X’ site.* |
| *EXAMPLE: Written consent* | *Legal basis for processing.* | *Paper forms, stored in locked filing cabinet at ‘X’ site. Access restricted to [detail] only.* |
| *EXAMPLE: code keys* |  |  |
|  |
| **4.2 Does the study involve collecting, using, accessing or sharing sensitive data[[4]](#footnote-4)?** |
|  Yes No If you are not collecting personal or sensitive data, please skip to question 4.14.If yes please give details of the sensitive data collected. Please indicate below how collecting such data is relevant to the aims and objectives of the study.  |
| **Data Collected** | **Justification** | **Processing Activity** |
| *See questionnaire appendix xxx question 12-17*  |  |  |
|  |  |  |
|  |  |  |
| **4.3 Who will determine the ‘how’ and ‘why’ the data is used? (i.e. data controller or joint controllers if more than one)** |
| *Employees and students of TCD/DDUH are not data controllers. TCD or DDUH are the data controllers (Insert this here). However, if other institutes are involved, they should be noted as controllers here.*  |
| **4.4 Specify the name/s of any personnel who will have access to the personal and/or sensitive data? Please list all individuals including those who are employees or students of other institutes/hospitals etc. Indicate the format in which they will receive the data i.e. identifiable or pseudonymised?**  |
| *(For other personnel working under contract - such as data inputters and transcribers see 4.5)* |
| **Personnel names**  | **Data access to**  | **Format available to these**  |
| *EXAMPLE: member of research team TCD affiliated name*  |  |  |
| *EXAMPLE: member of research team non TCD affiliated name* |  |  |
|  |  |  |
|  |
| **4.5 Specify the name/s of any service providers such as transcribers, third party’s carrying out analysis, data collection etc.?**  |
| *Indicate the format in which they will receive the data i.e. identifiable or pseudonymised? Please confirm and attach the agreement that is in place with the service provider.* |
| **Personnel names**  | **Data access to**  |  **Format available to these**  |
| *EXAMPLE: Transcribers names* | *EXAMPLE: Participant names* | *original, anonymised, non-anonymised or pseudonymised.* |
| *EXAMPLE: Statisticians name*  | *EXAMPLE: Written consent* |  |
| *EXAMPLE: data collector name (hired personnel or companies that are not members of the research team )* | *EXAMPLE: participant names and contract details, written consent*  |  |
|  |
| **4.6 During and after the study, what steps will you take to protect the confidentiality of personal or sensitive personal data collected as part of the project? (e.g. Participant identities, contact details, consent forms, code keys that link personal or sensitive personal data to other data, data collected from patient/client records). Please specify details for all that apply and likewise for all media forms utilised (online, hard copy, audio etc.)**  |
|  Please note: Double encryption is required on all computers, laptops and mobiles devices. Personal data should not be stored on portable devices unless absolutely necessary and it should be stated here if this is necessary and why. Cloud storage of personal data require secure clouds as recommended by TCD and if cloud storage is used it should be indicated here.  |
| **Personal/sensitive data type**  |  **Media Format**  | **Storage Details:**  |
| *EXAMPLE: contract details, telephone*  | *Original hard copy*  |  |
| *EXAMPLE: consent*  | *Original Hard copy*  | *Stored in locked cabinet with access solely by x* |
| *EXAMPLE: sensitive data* |  *Original Hard copy*  |  |
|  |
| **4.7 Please specify that you have a log and controls in place to record who accesses, changes, discloses or erases all personal data collected. In the case of repository data, changes and erasures only need to be logged**  |
|  |
| **4.8 Indicate clearly when processing (i.e. pseudonymisation, anonymization, deletion) will occur.** Please indicate who will be responsible for these processes and who will retain the key code if applicable |
|  |
| **4.9 Accepted best practice recommends secure retention of personal non-anonymised (of all the types listed previously) for 7 years. If there is any reason to apply for a variation from these guidelines, please give details and provide a justification.**  |
| *Consent forms used for research must be retained for 7 years, as evidence of consent in compliance with GDPR. Students must handover to supervisor when they leave Trinity.*  |
| **Personal/sensitive data type and media format**  |  **Format**  | **Retention time, when it will be destroyed**  |
| *EXAMPLE: contract details, telephone*  | *original, anonymised, non-anonymised or pseudonymised.* |  |
| *EXAMPLE: consent form* |  |  |
|  |  |  |
|  |
| **4.10 If identifiable data or material (photographs etc.) will be retained after the study is completed, is it stated on the informed consent form that this will be done and that material will not be used in future unrelated studies without further specific permission being obtained?** |
|  Yes No  |
| **4.11 Researchers must allow the participant access to their personal data including their transcript if they so wish (right of access and right of rectification). Please give details of these arrangement.** |
|  |
| **4.12 How will you ensure the participants can use their other rights as required under GDPR?** **These include:*** right to erasure;
* right to object to processing based on public interest;
* right to data portability;
* right to object to profiling or making decisions about individuals by automated means?
 |
|  |
| **4.13 Do you have a procedure in place if a data subject wishes to withdraw from the study for example? Please expand.**  |
|  |
| **4.14 Are there any potential confidentiality issues through identification of the study site?** |
| Yes No  If yes, please expand.  |
| **4.15 Are there elements of genetic testing involved in the proposed project? If yes please explain. If yes, please note that you must contact** **researchDPO@tcd.ie** **and conduct a DPIA.**  |
|  **Yes No**If yes, please explain and please note that you must contact researchDPO@tcd.ie and conduct a DPIA . [here](https://www.tcd.ie/info_compliance/data-protection/assets/docs/TCD_DPIA_Research_Template_V.02.docx).  |

SECTION 5 - RISK, BENEFIT AND HARM

|  |
| --- |
| 5.1 What is the potential for an adverse outcome (for example, illness, pain, discomfort, distress, inconvenience) for research participants? *NOTE: for the protection of both the investigator and the participant, this list must be suitably comprehensive and must also appear in full in the participant information leaflet.* *Any substantive adverse events must be reported to the Dental School Ethics Committee.* |
|  |
| 5.2 Will individual or group interviews/questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting*If Yes, give details of procedures in place to deal with these issues. Give specific names of counselling or other support services that might be offered to participants.* |
|  |
| 5.3 Is it possible that criminal or other disclosures requiring action could take place during the study *If yes, please provide specific detailed procedures in place to deal with these issues and who will be informed if disclosures occur. This information needs to be also included in the participant information leaflet.* |
|  |
| 5.4 If participants are to undergo a clinical assessment, what is the nature and extent of this assessment? |
|  |
| 5.5 If applicable will there be ongoing clinical supervision of the participants by a duly insured clinical practitioner during the study? |
|  |
| 5.6 Will the research participant’s General Practitioner be informed that they are taking part in the study? |
|  |
| 5.7 Will permission be sought from the research participants to disclose information  |
|  |
| 5.8 What is the potential for benefit for research participants? please outline only the direct benefits.  |
|  |

SECTION 6 - FUNDING & PAYMENT

|  |
| --- |
| 6.1 Outline sources of funding for the study if applicable and how you will manage possible conflict between the funders of the study and the aims and results of the study (if applicable). |
|  |
| * 1. **6.2 Will the results of the study will be used or disclosed for commercial purposes? If yes please also indicate in the participant information leaflet and indicate that the participant will not commercially benefit.**
 |
|  |
| 6.3 Will payment be made to research participants? |
|  |
| 6.4 If you answered YES to question 6.3, please specify for what purpose the payment will be made and the amount to be provided to each participant. |
| e.g. minimal expenses to cover travel etc. |

SECTION 7 – ETHICAL APPROVAL FROM OTHER COMMITTEES, FROM NON-TRINITY FACILITIES

|  |
| --- |
| Ethical approval from Trinity research committees if granted, does not supersede any requirements that outside bodies which may have the need for similar applications to be made to local ethical approval bodies in advance of the study commencing.  |
|  |
| 7.1 Has ethical approval been sought from any other organisation(s) in which the study will take place? |
| YES | NO | **NA** : *If NA, please explain why.* |
| If you answer YES go to question 7.2  |
| If you answer NO go to question 7.3 |
|  |
| 7.2 If you have answered YES to question 7.1, where has approval been sought from and has ethical approval been given? If a DPIA was required for this application please insert as an appendix to this application.  |
| **YES** | **Awaiting Reply** | **NO** | *If No, please explain why* |
| 7.3 If you have answered NO to question 7.1, is it your intention to seek ethical approval from the organisation(s) in which the study will take place? |
|  |
| 7.4 Do you require, and have you sought access to collect data from specific groups either within or outside Trinity to conduct your research please list them here and attach the letter(s) of permission to your application. This includes sports clubs, hospitals, care facilities, community services, etc. |
|  |
| Facility/Institute | Responsible Contact |
|  |  |
|  |  |
|  |  |
|  |  |

SECTION 8 - DECLARATION OF APPROVAL AND SIGNATURES

The lead investigator/student (if applicable) must provide all data below and sign:

8.1 If applicable please state briefly what preparatory work you will need to undertake to become competent in your chosen method of data collection (e.g. training in the use of a standardised schedule/test, clinical procedures, or practice in conducting an interview).

|  |
| --- |
|  |

8.2 LEAD INVESTIGATOR / STUDENTS DECLARATION:

 I confirm that the information provided in this document is correct and that I am not aware of any other ethical issue not addressed within this form. I understand the obligations to and the rights of participants particularly concerning their safety and welfare and their data protection.

I undertake to provide an annual report within 12 months of the date of approval to the Dental School Research Ethics Committee with details of the number of participants who have been recruited, the number who have completed the study and details of any adverse effects. Any serious adverse effects will be reported immediately to the Dental School Research Ethics Committee, and, if involving medication this will also be reported to the Irish Medicines Board.

|  |  |
| --- | --- |
| NAME: (BLOCK CAPITALS) |  |
| STAFF / STUDENT I.D. No. |  |
| SCHOOL / DEPARTMENT: |  |
| COURSE OF STUDY: (if appropriate) |  | YEAR |  |
| SIGNATURE: |  | DATE: |  |

**Please insert details of all co applicants**

|  |  |
| --- | --- |
| NAME:(BLOCK CAPITALS) |  |
| STAFF / STUDENT I.D. No. |  |
| SCHOOL / DEPARTMENT: |  |
| COURSE OF STUDY:(if appropriate) |  | YEAR |  |
| SIGNATURE: |  | DATE: |  |

|  |
| --- |
| RESEARCH SUPERVISORStudent applicants are required to have their Research Supervisor complete this section.Name of Supervisor:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(BLOCK CAPITALS)Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_State the educational value of this research:I confirm that I have reviewed this application and I am not aware of any ethical issue not addressed within this form.I undertake to ensure that the student provides an annual report within twelve months of the date of approval, yearly thereafter and a final project report within 6 months of the completion of the study to the xxx Ethics committee with details of the number of participants who have been recruited, the number who have completed the study and details of any adverse effects, complaints and the date of completion of the project.Any serious adverse effects must also be reported immediately to the  **Dental School Research** Ethics Committee I undertake to make arrangements with the student regarding the storage and destruction of the data . Signature of the Supervisor:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

Office Use Only:

|  |  |
| --- | --- |
| Reference Number |  |
| XXX Research Ethics Committee Meeting Date |  |
| Approved |  |
| To be resubmitted |  |
| Date |  |

# APPENDIX I

**GUIDANCE ON PREPARING A CONSENT FORM AND TEMPLATE**

**GUIDANCE ON PREPARING A CONSENT FORM**

This is a sample consent form has been developed to help researchers create their own consent form for research studies and is to be used for example purposes only. It does not constitute legal advice and should be read in conjunction with guidance from the relevant research ethics committee.

The Principal Investigator and the research team must prepare a consent form which meets the exact needs of the research study that is being carried out.

Please note the following:

* The consent form should be prepared in conjunction with the Information Leaflet for the research study.
* This template has been created to assist researchers to design consent forms for research studies involving participants
* Not all sections and phrases in this template will apply to your particular study. Sections on Biological Samples, Biobanking and Genetic testing should be deleted if they are not relevant to your study. Each of the consents should be reviewed to determine if they are required for a particular research study and should be amended to take into consideration any specific requirements and/or details of the research study.
* If your study does not involve patients, watch out for words like ‘patient,’ ‘future care,’ ‘medical care,’ ‘medical records,’ and ‘storage’ and as they may not apply and may need to be deleted/amended as appropriate.
* Ensure that consent for the **processing of personal data** should be distinguished from other consent requirements that serve as an ethical standard.
* Please ensure that the consent form is clear, concise and as easy to read and understand as possible. Legal jargon or medical terms that a participant may not understand should not be included in the consent form.

**SAMPLE CONSENT FORM**



|  |
| --- |
| **STUDY NAME:** **Centre ID:****Identification Number for study:** |
| **Consent Form** |
| **The below section should always be included in consent forms. The consents should be reviewed by the Principal Investigator and research team and amended as appropriate in line with the specific requirements and consents being sought from participants.**  |
| **There are X sections in this form. Each section has a statement and asks you to initial if you agree. The end of this form is for the researchers to complete.** **Please ask any questions you may have when reading each of the statements.** **Thank you for participating.** **Please Initial the box if you agree with the statement. Please feel free to ask questions if there is something you do not understand.** |
|  |  |
| **General**  | **Tick box** |
| I confirm I have read and understood the **Information Leaflet** for the above study. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction. |  |
| I understand that this study **is entirely voluntary,** **and if I decide that I do not want to take part, I can stop taking part in this study at any time without giving a reason**. I understand that deciding not to take part will not affect my future medical care. |  |
| I understand that my [**medical/dental] notes and records** may be looked at by my [Study Doctor/Dentist and his/her study team] at [hospital] where it is relevant to the research. I agree that these individuals can access my records. I understand that all information will be kept private and confidential and that my name will not be disclosed. |  |
| I understand that I **will not be paid for taking part in this study**[[5]](#footnote-5).  |  |
| I know how to contact the research team if I need to. |  |
| I agree to take part in this research study having been fully informed of the **risks, benefits and alternatives** which are set out in full in the information leaflet which I have been provided with. |  |
| [I agree to being contacted by researchers by [email/phone[[6]](#footnote-6)] as part of this research study][[7]](#footnote-7).  |  |
| **Data processing**  | **Tick box** |
| I agree to allow personal information about me to be shared with third parties including; national and international hospitals, and academic research institutions for the purpose of [INSERT DETAILS OF RESEARCH AREA] research, as described in the Information leaflet[[8]](#footnote-8).  |  |
| I agree to allow personal information about me to be shared with for-profit commercial research or biopharmaceutical companies for the purpose of [INSERT DETAILS OF RESEARCH AREA] research, as described in the Information leaflet[[9]](#footnote-9). |  |
| I understand that personal information about me, including the transfer of this personal information about me outside of the EU, will be protected in accordance with the General Data Protection Regulation.  |  |
| [I understand that there are **no direct benefits to me** from participating in this study. I understand that **results from analysis of my personal information will not be given to me]**.  |  |
| I understand that **I can stop taking part in this study** at any time without giving a reason and this will not affect my future medical care.  |  |

|  |
| --- |
| **Remove the table below if it does not apply to your study – this table will only apply if you placed the paragraph entitled ‘Consent to Future Uses’ in your Information Leaflet** |
| **FUTURE USE OF INFORMATION**  |
| **RETENTION OF RESEARCH SAMPLES IN THE FUTURE [please choose one or more as you see fit]** | **Y** | **N** |
| **OPTION 1:** I give permission for my biological samples/personal information to be stored for *possible future research* ***related*** to the current study [INSERT DETAILS OF RESEARCH AREAS] ***only if consent is obtained*** at the time of the future research and the research is approved by a Research Ethics Committee. |  |  |
| **OPTION 2:**  I give permission for my biological samples/personal information to be stored for *possible future research* ***related*** to the current study [INSERT DETAILS OF RESEARCH AREAS] ***without further consent*** being required but only if the research is approved by a Research Ethics Committee. |  |  |
| **OPTION 3:** I agree that future research projects into [INSERT AREA OF RESEARCH] may be carried out by researchers working for **commercial/pharmaceutical companies.** |  |  |
| **OPTION 4:** I understand **I will not be paid for any** future use of my samples/personal information or products derived from it. |  |  |

|  |  |
| --- | --- |
| **The following section of this consent form is relevant if you are collecting biological samples each element of the consent should be reviewed to determine if relevant to the particular research study.**  |  |
| **BIOLOGICAL SAMPLES**  | **Y** | **N** |
| I agree to provide a sample or samples [DETAIL OF THE SAMPLES BEING SOUGHT SHOULD BE INCLUDED E.G. BLOOD, TISSUE, SALIVA, URINE AND DETAILS OF THE SPECIFIC QUANTITIES OF THE SAMPLES BEING SOUGHT SHOULD BE INCLUDED I.E. 32 MLS OF BLOOD] for use in this study as described in the Information leaflet. The risk of taking samples has been explained to me.  |  |  |
| [I agree to allow [INSERT DETAILS OF RESEARCH TEAM] to access and use my previous samples (stored by [hospital]) for this study][[10]](#footnote-10). |  |  |
| I agree for my biological samples (including DNA samples) to be shared with authorised third parties including; national and international hospitals, and academic research institutions [INSERT DETAILS OF RESEARCH AREA] research, as described in this Information leaflet. I for research, [including genetic research[[11]](#footnote-11)], into [INSERT DETAILS OF RESEARCH AREA], for use in this study as described in the information leaflet.  |  |  |
| I agree for my biological samples to be shared with commercial/biopharmaceutical companies for this study. |  |  |
| I understand that my biological samples will be disposed of in a lawful and respectful way. |  |  |
| I understand that I can **stop taking part in** this study and **request withdrawal of my biological** **samples** and requested that my biological samples are destroyed at any time without any negative impact on my medical care. |  |  |
| I agree to allow my biological samples (including DNA samples) to be shared with for-profit commercial research or biopharmaceutical companies] for the purpose of [INSERT DETAILS OF RESEARCH AREA] research, as described in this information leaflet.  |  |  |
| [I understand that results from the **analysis of my samples will not be given to me.[[12]](#footnote-12)**]  |  |  |
| I understand that I will not be paid for the use of my samples. |  |  |

|  |  |  |
| --- | --- | --- |
| **The sections below relate to entry of data/samples into a biobank[[13]](#footnote-13). Please remove the sections below if this does not apply to the research study.**  |  |  |
| **BIOBANK** | **Y** | **N** |
| I agree for entry of my **clinical personal information/samples into the biobank/registry** [INSERT DETAILS OF THE BIOBANK AND THE PURPOSE OF THE BIOBANK].I agree to have my personal information processed as part of any future research studies approved by ethics committees[[14]](#footnote-14) in the field of [X] by academic institutes.  |  |  |
| I agree that my medical records can be accessed as part of any future research study in the field of [INSERT DETAILS OF AREA OF HEALTH RESEARCH] relating to the biobank/registry.  |  |  |
| I agree to have personal information about me processed as part of any future research studies approved by ethics committees in the field of [INSERT DETAILS OF AREA OF HEALTH RESEARCH] by commercial entities.  |  |  |
| I understand that I will not be paid for any future research.  |  |  |
| I know who to contact if I change my mind about my samples and information being used in the [X] biobank for future research. |  |  |

|  |  |
| --- | --- |
| **Please remove the sections below if genetic testing will not be carried out as part of this research study.**  |  |
| **GENETIC TESTING**  |  |
| I agree to take part in this research study which involves genetic testing having been informed of all of the risks, benefits and alternatives. | **Y** | **N** |
| The following relates to what you wish us to do if we discover a genetic disorder on genetic testing. If you do wish to be informed, you will need to attend a genetics clinic and have a second blood sample taken to confirm the diagnosis. |  |  |
| **Optional:** I want to learn about results found about me related to the [INSERT AREA OF HEALTH RESEARCH] disorders studied as part of this project[[15]](#footnote-15). | **Y** | **N** |
| **Optional:** I understand that results related to disorders in the area of [INSERT AREA OF HEALTH RESEARCH] will be returned to me. OrI understand that results related to disorders in areas other than [INSERT AREA OF HEALTH RESEARCH] may be returned to me if possible.[[16]](#footnote-16) | **Y** | **N** |
| **Optional:** I understand that if my data has been anonymised then it will not be possible to return results related to disorders in the area [INSERT AREA OF HEALTH RESEARCH,] or in any other area, to me. | **Y** | **N** |

---------------------------------------------------- ---------------------------------------------------------------

Patient Name (Block Capitals) Patient Signature Date

--------------------------------------------------- ----------------------------------------------------------------

Witness Name (Block Capitals) Witness Signature Date

**To be completed by the Principal Investigator or nominee.**

I, the undersigned, have taken the time to fully explain to the above patient the nature and purpose of this study in a way that they could understand. I have explained the risks and possible benefits involved. I have invited them to ask questions on any aspect of the study that concerned them.

I have given a copy of the information leaflet and consent form to the participant with contacts of the study team

Researcher name

Title and qualifications

Signature

Date

 | | |

**3 copies to be made: 1 for patient, 1 for PI and 1 for hospital records.**

# APPENDIX II

**Participant Information Leaflet - Template**

The Trinity College Dublin Research Ethics Committee has prepared a Participant Information Leaflet template to aid researchers prepare the participant information leaflet for their own research studies.

The form provided is a template **only**: researchers will need to **tailor** this template to their own research studies.

* Some *sections* in the template may not apply depending on the research study. Sections are typically may not apply are highlighted. However, in general, most of the sections specified on the template should be included.
* Some studies may require *items* not stated in the template and other studies may not require some items stated in the template. However, in general, most of the items specified in the template should be included.

Researchers should pay attention to:

* + The **content** of the leaflet particularly the importance of using plain English.
	+ The **appearance** of the leaflet particularly the font and font size used.
	+ The National Adult Literacy Agency have provided useful advice on how to ensure the leaflet is suitable for your target audience and is available at [www.simplyput.ie](http://www.simplyput.ie).

It is critical that the contents of the Participant Information Leaflet **match** the details provided in the Application Form.

**Participant Information Leaflet**

**Name of Study: [INSERT STUDY TITLE HERE]**

|  |  |
| --- | --- |
| Site |  |
| Principal Investigator(s) and Co-Investigator(s)(insert names, titles and contact details) |  |
| Study Organiser/ Sponsor (if applicable) |  |
| Data Controllers | **Trinity College Dublin (for research data)** **[HOSPITAL SITE] (for hospital medical records) (if applicable)** |
| Data Protection Officer | **Data Protection Officer****Secretary’s Office** **Trinity College Dublin****Dublin 2****Data Protection Officer of [hospital]: [INSERT CONTACT DETAILS HERE].** |

You must provide an introductory statement.

**SAMPLE TEXT**:

*Example: You are being invited to take part in a research study that is being done by [insert location] by [insert Principle Investigator’s name] at [insert hospital site].*

*Before you decide whether or not you wish to take part, please read this information sheet carefully. Ask [Principle Investigator] any questions. Don’t feel rushed or under pressure to make a quick decision. You should understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. You may wish to discuss it with your family, friends or GP.*

*This leaflet has five main parts:*

*Part 1 – The Study*

*Part 2 – Data Protection*

*Part 3 – Costs, Funding and Approval*

*Part 4 – Future Research*

*Part 5 – Further Information*

|  |
| --- |
| **Part 1 – The Study** |

**Why is this study being done?**

* Provide an outline of the purpose of your study in lay language. Do not cut and paste directly from the protocol. Pay particular attention to aspects that are experimental e.g. new medicinal products or medical devices or drugs being used outside their existing product licence.

*We are doing this study to …*

**Why have I been invited to take part?**

* Explain specifically why that person has been invited (e.g. because they have a specific condition, or because they are a healthy individual).
* State how many participants you are intending to involve and their characteristics (e.g. healthy volunteers, people with a specific condition or demographic).
* Make sure that people with no medical training or background understand the words you use. Do not assume patients will understand words and terms such as ‘inclusion’, ‘exclusion criteria’ and ‘control’.

**Do I have to take part? Can I withdraw?**

Explain:

* that participation is **voluntary**;
* that a decision not to consent will have **no adverse consequences**;
* that consent can be withdrawn at any time. Advise when and how consent can be **withdrawn** (e.g. before anonymisation of the data or publication of results) and the effect of any such withdrawal.
* the process of withdrawal, i.e. *contact XXX on 01-XXXXXX*

**SAMPLE TEXT:**

*Example (for studies based in clinical care setting): You don't have to take part in this study. It is entirely voluntary. If you decide not to take part it won’t affect your current or future medical care. You can change your mind about taking part in the study and opt out at any time even if the study has started. If you decide to opt out, it won’t affect your current or future medical care. You don't have to give a reason for not taking part or for opting out. If you wish to opt out, please contact [insert name, role and contact details] who will be able to organise this for you.*

|  |
| --- |
| **What happens if I change my mind?** |

* Make it clear that participation in the study is voluntary and that participants may change their minds at a later stage if they so wish.
* Inform participants that withdrawal will not in any way affect the care they receive from any relevant service (e.g. for patients, from the HSE).
* Check as to what procedure is in place in case of withdrawal:
	+ Are there any safety implications? Will participant involvement be followed up and a final visit arranged?
	+ Will samples and data collected to point of withdrawal be retained for the study, removed, or will the participant have a choice?
	+ If the study intends to bank tissue or data for future research, specify the effect of withdrawal on future use.
	+ Make it clear that it may not be possible to destroy samples and data already used in research studies prior to withdrawal of consent.
	+ Make it clear to participants if their data will continue to be processed for reasons other than health research (i.e. to provide critical care) if they withdraw consent to their data being processed for health research purposes. Where such data processing will occur the legal basis for such processing should be set out.

**SAMPLE TEXT**:

*You can change your mind at any time by contacting your study Doctor at [INSERT CONTACT DETAILS]. If you choose not to continue to take part, this will not affect your medical care in any way. If you choose not to take part any more, you will be asked to fill in a withdrawal form. If you wish, you can ask for your samples and/or data stored to be destroyed. If you request this, we will destroy all samples and data that are still in our possession. We will no longer use or share your samples or data for research from this point onwards. However, it will not be possible to destroy samples and data already used in research studies prior to this time.*

|  |
| --- |
| **How will the study be carried out?** |

Provide a general overview of the study.

Important questions to address in this section include:

* **When** will the study take place?
* **Where** will the study will take?
* **What** will happen in general terms?
* **How** many patients will be taking part in the study?

**What will happen to me if I decide to take part?**

* This is a very important section.
* Participants need to know exactly what they are consenting to. Keep the language simple.
* This section details what will be involved in your research study from a participant’s point of view, and in the order they will experience it.
* Details of the procedures and tests that will be performed – and by whom.
* If there are multiple study visits, describe them in turn.
* If research is taking place in the context of clinical care, make clear which parts are research and which standard care.
* A table or flow chart can provide clarity when describing a complex series of interventions.
* Clearly state what will be expected of the participant if s/he takes part with adequate detail regarding procedures, duration and location of testing/interviews etc.
* Any procedures which are experimental should be identified and alternative procedures or courses of treatment disclosed.
* Where involvement in the research involves a change to the ‘usual care’ this individual would receive, this should be specified.

Consider:

1. Where will the participant have to go?
2. How long the participant will be involved in the research, how often they will need to attend a research session and how long visits will be.
3. If you will be allocating participants randomly to study medication(s) and/or placebo, describe what it means in lay terms.
4. Are any of the tests invasive?
5. If you will be collecting samples, give an idea of amounts. Blood volume may be more meaningfully expressed in tablespoons: 5ml is equivalent to 1 teaspoon, 15ml is 1 tablespoon. Biopsies may be compared to grains of rice.
6. If you will be using tissue samples, state whether the tissue will already be collected as part of clinical care. Are you requesting use of tissue surplus to diagnostic need, or collecting additional samples?
7. Outline any plans for long-term monitoring/follow-up.
8. If the study involves the use of any ionising radiation (e.g. x-rays) or non-ionising radiation, such as MRI scans.

**What will happen to my Samples and Data?**

* State how the samples and data will be used in the research (where they will be transferred or held, what analysis will take place) and in what form (anonymous, identifiable, pseudonymised (coded)). Publications?
* Include information on sharing of samples and data, including details of partner hospitals, universities and commercial partners.
* Information on how the data will be kept secure should be provided, and who is responsible for ensuring data security. This should include details of restricted access to the data, use of software encryption, firewalls etc.
* If your study involves the analysis or use of DNA, limits on anonymity should be made clear to participants. For example:

*Your DNA and blood sample will be assigned a code and your data will also be identified only by this number. The material given to researchers will not have information that identifies you. However, your DNA is unique to you so it can never be completely anonymous.*

* You should also give potential participants information on your plans for any samples remaining after your specific piece of research has ended, such as whether they will be destroyed or stored, with consent, for future use.
* If samples are intended to be retained for future use, it is worth ‘future proofing’ by indicating that this research may happen outside of the EEA (and potentially outside of the scope of GDPR). Consider whether the samples may be used by commercial companies. For example:

*Your pseudo anonymised/anonymised samples will be used mainly by local researchers (if applicable), but ethically approved research projects may also take place in hospitals, universities, non-profit institutions or commercial laboratories worldwide.*

**Note, it is important to be as specific as possible, as broad ‘catch all’ consent is not permissible under GDPR and HRR.**

* It will also be necessary to retain the Consent Form (personal data) until the sample has been depleted or destroyed in order to provide evidence of consent in accordance with Article 7 GDPR requirements. Please add a statement in the PIL. For example:

*Biobanks - If you agree to your samples being used in future research, your consent form will be held until the samples have been used up.*

**Are there any benefits to taking part in this research?**

* Provide information on potential benefits if any, to the participant or others, through taking part.
* If there is no direct benefit to the participant, then this should be stated.

**SAMPLE TEXT**:

*Taking part in this study will not directly benefit you. However, research performed with your coded/uncoded samples and information may help us to better understand [INSERT RESEARCH AREA] and may result in new tests, drugs or treatment approaches. This is a long-term research project, so the benefits of the research may not be seen for several years. By participating, you are helping to advance science and medicine for future generations.*

**Are there any risks to me or others if I take part?**

* This paragraph **always applies**. Provide a fair and honest evaluation of the possible consequences of key research procedures and drugs. Remember if you mentioned a risk to the research ethics committee, the participants also need to know about it.
* Risks, including any discomforts must be clearly explained. All medications have the potential to cause side-effects. Precautions taken to minimise risks should be stated.
* The patient should be advised that he/she is entitled to seek a second opinion.
* Potential breach of patient confidentiality should be considered as a risk.

**SAMPLE TEXT (in relation to data risks)**:

**Note, there can be considerable variety in respect of data risk, depending on the nature of the study and type of data that is captured and subsequently processed as a consequence.**

* ***Health Information (Data):*** *There is a risk that a connection to your identity could be made. Great care will be taken to ensure the confidentiality of all data and the risk to participants of a breach of confidentiality is considered very low [AMEND AS APPROPRIATE].*
* ***Genetic Testing:*** *There are some risks to genetic testing. The greatest risk is that genetic testing may reveal that you are not related to one or more of your family members, for example we might discover that your father is not the person you expected him to be. There is also the possibility of social and economic disadvantages. Genetic information shared in the wrong way could affect you and your family, such as if an employer or insurance company was to obtain the information. This is termed ‘genetic discrimination’. We will do our utmost to guarantee complete confidentiality, but there is a theoretical risk of this information becoming available to others.*

**What happens if something goes wrong when I’m taking part in the study? *(May not apply)***

* This paragraph may not apply to your study.
* If your study involves a risk and you have measures in place if the risk does materialise, let the participant know; e.g. counselling in case of psychological distress, genetic counselling in case of certain genetic results, referral to a **named** specialist or **named** counselling service if something clinically relevant is discovered etc.
* If your study is sponsored by a company, and they have signed an indemnity agreement, let the participant know.

**SAMPLE TEXT**:

*In the unlikely event that you are harmed in any way, the researchers on this study are covered by insurance through [INSERT DETAIL]. This insurance will cover you if you are injured as a result of taking part in this study.*

**What other treatments are available to me? (May not apply)**

* Outline any alternative treatments if relevant including the option not to treat.

|  |
| --- |
| **Will I be told the outcome of the study? Will I be told the results of any tests or investigations performed as part of this study that relate to me?** |

* Provide clarification whether:
	+ Any outcome from the research that would **impact directly or indirectly on the participant’s health** will be reported to him/her.
	+ The **results of the research** will be reported to the participant.
* Important items to address in this section include:
	+ How the **results of the research** will be disseminated e.g. medical journals, medical conferences.

**SAMPLE TEXT**:

*The results of the study will be reported in medical/scientific journals and disclosed at medical/scientific conferences. No information which reveals your identity will be disclosed.*

|  |
| --- |
| **Part 2 – Data Protection** |

The following information should also be included as standard in Participant Information Leaflets, in order to ensure compliance with the 2018 Health Research Regulations.

|  |
| --- |
| **What information about me (personal data) will be used as part of this study? Will my medical records be accessed?** |

Provide a description of the **personal data** to be collected and used. List each item you intend to record. Identify each of the healthcare providers or other persons that the personal data will be sought from.

* Important items to address in this section include:
	+ Whether the participant’s **medical records** will be accessed.
	+ Why **identifiable data** rather than anonymised data is required.

|  |
| --- |
| **What will happen to my personal data?** |

Outline **what will happen** to the participant’s personal data. Include details of other data controllers, data processors, third parties that will have access to the personal data.

* Confirm that arrangements are in place so that personal data will be processed **only as is necessary** to achieve the objective of the health research and will not be processed in a way that damage or distress will be caused to the participant.
* State the **length of time** the personal data will be kept (in an identifiable or pseudonymised format) and why it is necessary to keep it for that period.
* State the arrangements to be made for the personal data to be **archived or destroyed.**
* State whether the personal data collected will leave the **State** and if so what countries it will go to and why it is going to those countries.
* If applicable, state the existence of automated decision-making, including profiling and information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject.

|  |
| --- |
| **Who will access and use my personal data as part of this study?**  |

* Name the **individuals** (i.e. PI, Co-Investigator, TCD/SJH study team etc.) who will access (or have access to) the participant’s personal data as part of this study including those who will access their medical records (if relevant).
* Identify any **healthcare providers** or other persons from whom personal data will be sought.
* Specify any person to whom it is intended to **disclose** the personal data collected (whether in an identifiable, pseudonymised or anonymised form).
* Will the data leave the site/Ireland/ the EU?

|  |
| --- |
| **Will my personal data be kept confidential? How will my data be kept safe?**  |

Outline the **confidentiality and security measures** in relation to the participant’s data.

* Describe the **data security arrangements** in place.
* Confirm that a **Risk Assessment** of the **data protection implications** of the health research and /or a **Data Protection Impact Assessment** was carried out and an indication of the level of risk identified by either or both.
* State whether any **presentation or publication** in relation to the study could identify the participant.
* Confirm that the persons carrying out the research or otherwise having access to the personal data are **bound by a professional code of secrecy** (like doctors) or a **contractual code of secrecy** (that would mean disciplinary action for employees who disclosed or facilitated unauthorised access to the personal data) or some other arrangement that emphasises confidentiality (this may be applicable in the case of medical students).
* Confirm that **training in data protection law** and practice has been provided to those individuals involved in carrying out the research.

**SAMPLE TEXT:**

*Your privacy is important to us. We take many steps to make sure that we protect your confidentiality and keep your data safe. Here are some examples of how we do this:*

*However, if something did go wrong we …..*

|  |
| --- |
| **What is the lawful basis to use my personal data?** |

State the **lawful basis** for the use of the participant’s personal data.

* Identify the lawful basis for the processing of data by reference to Article 6 and Article 9 of the GDPR.

**SAMPLE TEXT:**

By law,[[17]](#footnote-17) we can use your personal information for scientific research[[18]](#footnote-18) (in the public interest[[19]](#footnote-19)). We will also ask for your explicit consent to use your data as a requirement of the Irish Health Research Regulations.

|  |
| --- |
| **What are my rights?** |

State the **rights** individuals have regarding their **data**.

* Right to access data held
* Right to restrict the use of the data held
* Right to correct inaccuracies
* Right to have information deleted
* Right to data portability
* Right to object to profiling

**SAMPLE TEXT:**

 You are entitled to:

* The right to access to your data and receive a copy of it
* The right to restrict or object to processing of your data
* The right to object to any further processing of the information we hold about you (except where it is de-identified)
* The right to have inaccurate information about you corrected or deleted
* The right to receive your data in a portable format and to have it transferred to another data controller
* The right to request deletion of your data

By law you can exercise the following rights in relation to your personal data, unless the request would make it impossible or very difficult to conduct the research. You can exercise these rights by contacting your study Doctor [INSERT CONTACT DETAILS] or the Trinity College Data Protection Officer, Secretary’s Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: [www.tcd.ie/privacy](http://www.tcd.ie/privacy).

|  |
| --- |
| **Part 3 – Costs, Funding and Approval** |

**Has this study been approved by a research ethics committee?**

Provide details of the **research ethics committee** that gave ethical approval to the research including:

* The **name and contact details** of the committee that gave ethical approval to the research (does not need to be a named individual);
* Whether any of the persons carrying out the research have **a link** to the committee or the institution behind the committee;
* The **date** ethical approval was given by the committee;
* **Reporting arrangements** agreed with the committee;
* Any **conditions** attached to the research by the committee.

**SAMPLE TEXT**:

*Yes, this study has been approved by [INSERT NAME(S) OF HOSPITAL(S)] [JOINT, IF APPROPRIATE] Research Ethics Committee. Approval was granted on [INSERT DATE].*

**Who is organising and funding this study? Will the results be used for commercial purposes?**

Outline the funding for the study

Questions to consider answering in this paragraph:

* Who is conducting the research?
* Who is funding the research?
* Are you getting a grant to do this research?
* Are you conducting the research for the purposes of obtaining an academic qualification?
* Is a pharmaceutical company funding this study?
* Are you being paid to recruit patients to this study?
* Will the results be disclosed for commercial purposes?

**Is there any payment for taking part? Will it cost me anything if I agree to take part?**

State the costs of participation and any reimbursements or compensation to be provided (if any).

**SAMPLE TEXT**:

No, we are not paying patients to take part in the study. However, you will be reimbursed for travel expenses if you need to make any visits that you would not normally have made as part of your routine clinical care.

|  |
| --- |
| **Part 4 – Future Research** |

**Will my personal data and/or biological material be used in future studies? (May not apply)**

* State whether you intend to seek the participant’s consent for use of his/her data in **future research studies** and, to the greatest extent possible, describe in lay terms the intended future uses of the research participants’ data/biological material.
* Explain to participants they have **only given permission** for their data and/or biological material to be used for the current study and that you are seeking permission to store the data and/or biological material for possible future use in research.
* Explain if this will be your research or it could be **someone else’s research**.
* Make it clear this participation is voluntary and they can withdraw their consent to future research at any time.
* Make it clear that this research will only take place if it has research ethics approval.

Note: The Health Research Regulations state that in order for a researcher to conduct health research ‘explicit consent has been obtained from the data subject, prior to the commencement of the health research, for the processing of his or her personal data for the purpose of specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof’.

In relation to the use participant personal data as part of future research studies, the TCD Research Ethics Committee interprets the Health Research Regulations **as allowing** researchers to seek participant consent to use his/her personal data for future health research purposes providing that:

* The future health research is, at a minimum, **specified** to the general area or a health-related area of the original research and
* The **data processing measures and safeguards** in existence for the original study are in place for any future studies (in addition to any future data processing regulations that may be introduced);
* The participants are **informed as much as possible** when obtaining consent for future use of their personal data.

Although the Health Research Regulations apply to data processing only, the same standards are applied for research intending to use biological data in future studies.

|  |
| --- |
| **Part 5 – Further Information** |

**Who should I contact for information or complaints?**

**SAMPLE TEXT**:

If you have any concerns or questions, you can contact:

* Principal Investigator: [INSERT CONTACT DETAILS HERE].
* Data Protection Officer of [hospital]: [INSERT CONTACT DETAILS HERE].
* Data Protection Officer, Trinity College Dublin: Data Protection Officer, Secretary’s Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: [www.tcd.ie/privacy](http://www.tcd.ie/privacy).

Under GDPR, if you are not satisfied with how your data is being processed, you have the right to lodge a complaint with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: [www.dataprotection.ie](http://www.dataprotection.ie).

|  |
| --- |
| **Will I be contacted again?** |

State whether you intend to **contact** the participant following their participation in the study (as outlined previously) and the circumstances under which this contact will be made e.g. clinically-relevant results, future research.

**SAMPLE TEXT**:

*If you would like to take part in this study, you will be asked to sign the Consent Form on the next page. You will be given a copy of this information leaflet and the signed Consent Form to keep.*

**APPENDIX III**

# Annual Report Template

**School of Dental Science Research Ethics Committee**

**Project Annual Report Form**

Name of applicant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title of project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |
| --- | --- | --- |
| **Questions:** | **YES** | **NO** |
| Is the study continuing? If so, please provide the anticipated date of completion in the space below. | □ | □ |
| Have there been any modifications to the procedures for which approval was granted? If so, please provide details in the space below.  | □ | □ |
| Have there been any adverse outcomes associated with the conduct of the research? If so, please provide details in the space below. | □ | □ |
| Is all data being stored in accordance with Trinity’s data storage policy, in adherence to the Freedom of Information Act, and in compliance with the requirements of the Data Protection Commissioner? | □ | □ |
| Will all data be kept for 10 years in accordance with Trinity’s data storage policy? | □ | □ |

If the study is continuing, what is the anticipated date of completion?

Modifications to the procedures for which approval was granted:

Adverse outcomes associated with the conduct of the research:

**APPENDIX IV**

**End of Project Report Template**

**School of Dental Science Research Ethics Committee**

**End of Project Report Form**

Name of applicant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title of project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |
| --- | --- | --- |
| **Questions:** | **YES** | **NO** |
| Is a summary of the outcomes of the project either 1) provided in the space below, or 2) attached (e.g. thesis or published work)? | □ | □ |
| Were there any modifications to the procedures for which approval was granted? If so, please provide details in the space below.  | □ | □ |
| Were there any adverse outcomes associated with the conduct of the research? If so, please provide details in the space below. | □ | □ |
| Is all data being stored in accordance with Trinity’s data storage policy, in adherence to the Freedom of Information Act, and in compliance with the requirements of the Data Protection Commissioner? | □ | □ |
| Will all data be kept for 10 years in accordance with Trinity’s data storage policy? | □ | □ |

Summary of the outcomes of the project

Modifications to the procedures for which approval was granted:

Adverse outcomes associated with the conduct of the research:

1. Article 9, 2, (j) [↑](#footnote-ref-1)
2. Article 6 [↑](#footnote-ref-2)
3. Personal data is information which can identify a person – in particular: a name, address, email, telephone number,  an identification number, location data, an online identifier, or and IP address. [↑](#footnote-ref-3)
4. Sensitive personal data means genetic, biometric and health data, as well as personal data revealing racial and ethnic origin, political opinions, religious or ideological convictions or trade union membership. [↑](#footnote-ref-4)
5. Amend as appropriate. [↑](#footnote-ref-5)
6. Please include the appropriate relevant details. [↑](#footnote-ref-6)
7. Please delete as appropriate. [↑](#footnote-ref-7)
8. This section of the consent should be amended in accordance with the information leaflet to detail those third parties that data will be shared with. [↑](#footnote-ref-8)
9. This section of the consent should be amended in accordance with the information leaflet to detail those third parties that data will be shared with. [↑](#footnote-ref-9)
10. Amend or delete as appropriate. [↑](#footnote-ref-10)
11. Delete as appropriate. [↑](#footnote-ref-11)
12. Delete or amend as appropriate. [↑](#footnote-ref-12)
13. A description of the Biobank and what a Biobank is should be set out in the Information Leaflet. [↑](#footnote-ref-13)
14. Details of the research ethics committee and what a research ethics committee is should be set out in the Information Leaflet. [↑](#footnote-ref-14)
15. Delete or amend as appropriate. [↑](#footnote-ref-15)
16. Delete or amend as appropriate. To be reviewed by the PI in each research study to determine what results relating to disorders will be returned to participants involved in that particular study. [↑](#footnote-ref-16)
17. The European General Data Protection Regulation ( GDPR) [↑](#footnote-ref-17)
18. *Article 9(2) (j))* [↑](#footnote-ref-18)
19. *(Article 6(1)(e)* [↑](#footnote-ref-19)