**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**.** Staff or students planning to undertake research should complete the Research Ethics Checklist in order to determine if their study requires ethical approval. 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. Complete the ‘Research Ethics Checklist’ section.** If the study is deemed not to require ethical approval, then the study can proceed without the approval of an ethics committee. If the study is deemed to require ethical approval, then the applicant should proceed to the Checklist for School REC suitability in order to determine if the proposal should be evaluated by a Level 1 or Level 2 committee. Checklists for student projects must be endorsed by their supervisor.

**3.** **Complete the ‘Checklist for School REC suitability’ to determine if the application is suitable for consideration by the school REC.** Completion of thechecklist indicates whether the study is suitable for consideration by a Level 1 committee. If the study is suitable for evaluation by a Level 1 committee, the researcher should complete the application form for ethical approval from the Dental School REC. Students should ensure that this is approved by the project supervisor before being sent to the Chair of the Research Ethics Committee (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).

**4. Submit sample Patient information leaflet and Patient informed consent form.**

**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 on the Dental School Research pages.

**Research Ethics Checklist**

**School of Dental Science, Trinity College Dublin**

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

**Section 1: All students and staff planning research activity must complete the initial checklist below:**

DOES YOUR RESEARCH PROJECT FALL CLEARLY UNDER ANY OF THE FOLLOWING CATEGORIES

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| 1. Quality assurance study (e.g. assessment of teaching practice)\* |  |  |
| 2. Audits of standard practice (not involving identifiable records)\* |  |  |
| 3. Research on publically available information, documents or data |  |  |
| 4. *In vitro* research on cell lines, microorganisms or non-biological materials ***that does not*** involve primary biological material from humans or animals |  |  |

**If you have answered YES to one or more of the above questions**, your research project can proceed without the need for ethical approval from the School REC. Please be aware that all researchers have a responsibility to follow TCD’s Policy on Good Research Practice, (available at <https://www.tcd.ie/research/dean/TCDGoodResearchPractice.pdf>) as well as any academic or professional code of practice or guidelines relevant to the specific research project.

**If you have answered NO to all of the above questions**, proceed to Section 2 to determine whether your application is suitable for consideration for the School REC or if the application needs to be evaluated by a Level 2 committee.

*\*Quality assurance and audit studies do not routinely require ethical approval.*

*However, if following the study there is scope to publish the findings of a study*

*an REC may grant a letter of approval if required.*

**Checklist for School REC suitability**

**School of Dental Science, Trinity College Dublin**

**Section 2: This checklist needs to be completed in order to determine whether your application is considered “low risk” and is suitable for consideration by the School REC.**

**Please indicate if your application falls into any of the categories below:**

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| **1.** A survey asking questions of a sensitive or private nature |  |  |
| **2.** A questionnaire or observational studies involving children or vulnerable adults. |  |  |
| **3.** Research where there is a risk of a participant feeling undue pressure to participate by virtue of his/her relationship with the researcher (e.g. student/supervisor; patient/clinician). |  |  |
| **4.** A project involving a justifiable degree of deception. |  |  |
| **5.** Aclinicaltrial of medicines or medical interventions |  |  |
| **6.** Analysis of archival irrevocably anonymised human tissue samples for which consent for research was not originally given, and was not for a previous research study must always get new ethical approval). |  |  |
| **7**. Research involving collection of invasive biological samples or tissues (excluding saliva, plaque, epithelial cells or small volumes of blood <10 ml from volunteers [see point 3]). |  |  |
| **8.** Research on biological samples yielding information that could impact upon treatment (e.g. Human DNA sequencing) |  |  |
| **9.** Research where identifiable information obtained may have legal, economic or social consequences for research subjects. |  |  |
| **10.** Research that may identify illegal activity. |  |  |
| **11.** Projects where each subject is paid (over and above token gestures). |  |  |
| **12.** Research that may potentially endanger the subjects, and/or researchers, and/or 3rd parties, and/or the environment. |  |  |
| **13.** Research that may have a direct military role. |  |  |
| **14.** Research involving humans conducted outside Ireland. |  |  |
| **15.** Research involving psychological intervention. |  |  |

**If you have answered YES to any of the above questions**, then the application is deemed to be of moderate or high risk and should be submitted to an appropriate level 2 Ethics Committee.

**If you** **have not answered YES** to any question in Section 2, your application can be submitted for consideration by the School REC.

**Ethical Approval Application Form**

**School of Dental Science, Trinity College Dublin**

**This application form can be submitted following completion of the ‘Research Ethics Checklist’ and if the ‘Checklist for School REC suitability’ indicates that the proposal is suitable for consideration by a level 1 committee.**

**All student applications should be reviewed and approved by the project supervisor prior to submission.**

**Part I (Declaration)**

|  |
| --- |
| **Name of Applicant (**Student/lead researcher**)** |
|  |
| **Name(s) of Additional Researcher(s)** |
|  |
| **Name of Supervisor** (for students) |
|  |
| **Academic Division** |
|  |
| **Has this application been submitted to another Ethics Committee for approval?** |
|  |
| **Title of project** |
|  |

|  |  |
| --- | --- |
| **Signature of applicant**  *I declare that the information given herein is accurate. I have read the Ethics Policy and will follow the guidelines therein.* | **Signature:**  **Date:** |
| **Signature of Supervisor (in case of postgraduate students)**  *I declare that the information given herein is accurate. I have read the Ethics Policy and will follow the guidelines therein.* | **Signature:**  **Date:** |

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

**Part II (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. |
| **Informed consent** |
| Outline the information that will be provided to potential participants, and procedures for gaining consent (if this will be in printed form, please supply a copy of it). Please indicate if a gatekeeper will carry this out. |
| **Methods** |
| Outline the methods that will be used for data collection and analysis and provide interview or survey questions where these are being used. |
| **Confidentiality, anonymity, and data storage** |
| Provide an explanation of any measures that will be put in place to preserve confidentiality and anonymity, including an explicit explanation of secure data storage and disposal plans. Note that there may be a need to store data for 10 years after completion of the project. If this is a student project, please confirm that all data will be given to the project supervisor for long-term storage. |
| **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* |

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

# Appendix I

# Sample Consent Forms

**Title of research study:**

This study and this consent form have been explained to me. My doctor/dentist has answered all my questions to my satisfaction. I believe I understand what will happen if I agree to be part of this study.

I have read, or had read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I have received a copy of this agreement and I understand that, if there is a sponsoring company, a signed copy will be sent to that sponsor.

Name of sponsor:

**PARTICIPANT’S NAME:**

**PARTICIPANT’S SIGNATURE:**

**Date:**

**Date on which the participant was first furnished with this form:**

**Statement of investigator’s responsibility:** I have explained the nature, purpose, procedures, benefits, risks of, or alternatives to, this research study. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

**Doctor’s/Dentist’s signature:**

**Date:**

(Keep the original of this form in the participant’s medical record, give one copy to the participant, keep one copy in the investigator’s records, and send one copy to the sponsor (if there is a sponsor).

**Appendix II**

**Sample Patient Information Leaflets**

**Patient Information Leaflet**

A Patient Information Leaflet and Consent Form must be submitted to the committee. The leaflet should be written in clear non-technical English and aimed at the potential subjects in the project, and not at members of the Research Ethics Committee. All the headings in the following outline should be included. For several of the headings, recommended wording is provided in *italics* and should be used if appropriate for the particular study.

1. **Title of study:**

**2. Introduction:** Provide a brief description of the research project, stating the purpose of the study, the drug or procedure being tested, and the extent of the participant’s involvement, e.g. time span of participation, expected number of visits to the doctor or to the clinic.

**3. Procedures:** List the criteria for selection for participation in the study, e.g. that the participant has a particular complaint, is between certain ages and is not covered by the criteria for exclusion. Then detail the nature of the participant’s involvement, e.g. that the participant will undergo initial tests and will have return visits to the doctor and subsequent examinations, etc.

**4. Benefits:** List any benefits to participants in the study. These may include more intensive medical supervision. The study may have no direct benefit to the individual participant but the results may benefit subsequent patients.

**5. Risks:** List the material risks, discomforts and side effects involved in participating in the study. If the risks attaching to a treatment are unknown this should be stated.

**6. Exclusion from participation:** *Your doctor/dentist has told you that you cannot be in this study if any of the following are true*: (list the criteria excluding an individual from participating in the study).

**7. Alternative treatment:** *You do not have to be a part of this study to be treated. There are other medications available that can be used to treat your complaint and your doctor/dentist has discussed this with you.*

1. **Confidentiality:**

*Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the hospital.*

**9. Compensation:**

*Your doctors/dentists are covered by standard medical malpractice insurance. Nothing in this document restricts or curtails your rights.*

**10. Voluntary Participation:** *You have volunteered to participate in this study. You may quit at any time. If you decide not to participate, or if you quit, you will not be penalised and will not give up any benefits which you had before entering the study.*

**11. Stopping the study:** *You understand that your doctor or the sponsoring company may stop your participation in the study at any time without your consent.*

**12. Permission:** State that the trial has School of Dental Science Research Ethics Committee approval.

**13. Further information:** *You can get more information or answers to your questions about the study, your participation in the study, and your rights, from Dr….........who can be telephoned at …............ If your doctor/dentist learns of important new information that might affect your desire to remain in the study, he or she will tell you.*

# 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:

**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: