Central Remedial Clinic­

**RESEARCH ETHICS APPLICATION FORM**

**PLEASE NOTE THE FOLLOWING:**

* **Incomplete** **applications** **cannot** **be** **processed** and will be returned for completion.
* Forms **without** applicant(s) signature and research supervisor(s) signature (for student applications) cannot be processed.
* Forms **without a completed checklist** (Section 1) cannot be processed.
* Applications must be **typed** and not hand-written.
* If you have any difficulties completing this form, please contact tmackeogh@crc.ie

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| Please complete the application form and return **TWO hard copies** **(one copy to include original signatures)** to:Chair, Research Ethics CommitteeCentral Remedial ClinicVernon AveClontarfDublin 3D03 R973Please also **email** your application in full to: tmackeogh@crc.ie |  Office use only:

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| --- |
| Ref No: |
| *Meeting date:* |
| *Decision:* |
| *Remarks:* |

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| **applicant NAME:** |  |
| **Role in project:** | Principal investigator [ ]  Co-investigator [ ] *List any other researchers involved:* |
| **APPLICANT EMAIL:** |  |
| **CRC STaff MEMBER?** | Yes [ ]  No [ ]  Job title*:* |
| **Student:** | Yes [ ]  No [ ]  College: |
| **STUDENT LEVEL**  | UG [ ]  M.Sc. [ ]  M.Phil. [ ]  M.Litt. [ ]  Ph.D. [ ]  |
| **supervisor NAME:** |  |
| **PROJECT TITLE:****CRC SPONSOR:****(if supervisor above is not CRC based)** |  |
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**Please complete the checklist below before submitting your application to the Research Ethics Committee.**

**SECTION 1: CHECKLIST** (MUST BE COMPLETED)

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| table  | **Yes** | **No** | **N/A** |
| If you are a student, has your CRC clinical supervisor signed this completed form? |[ ] [ ] [ ]
| **If appropriate to your study, have you attached the following?** |
| * 1. The **consent** **form** you propose to use
 |[ ] [ ] [ ]
| * 1. The **participant** **information** **leaflet** you propose to use
 |[ ] [ ] [ ]
| * 1. The **privacy notice** you propose to use
 |[ ] [ ] [ ]
| * 1. **Letter** **seeking** **access** to sample population (if your proposed study requires access to an external research site)
 |[ ] [ ] [ ]
| * 1. A copy of any **data** **collection** **tools** you propose using in your proposed study (i.e. questionnaire, interview questions, observation plans, etc.)
 |[ ] [ ] [ ]
| * 1. A copy of ethical approval for this study received from a college or university or other organisation
 |[ ] [ ] [ ]

**Please note:**

1. Any amendments to the original approved proposal must receive prior Research Ethics Committee approval.
2. As a condition of approval investigators are required to document and report immediately to the Secretary of the Research Ethics Committee any adverse events, any issues which might negatively impact on the conduct of the research and/or any complaint from a participant relating to their participation in the study.

SECTION 2 – DETAILS OF RESEARCH PROJECT AND PARTICIPANT SELECTION

2.1 Working title of project:

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**2.2** Dates & duration of research activities:

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| --- | --- | --- | --- |
|  Proposed start date for fieldwork/data collection: |       | Proposed end date of fieldwork/data collection: |       |

**2.3** What are the primary location(s) for data collection? (E.g. classroom, clinic, lab, participant’s home, place of convenience for participants):

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**2**.**4** Please provide a brief outline of the proposed project (**maximum 850 words in total**). This should include aim(s) and objective(s), background, research question(s) or hypothesis, research design, recruitment and sampling, and data collection procedures/instruments.

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| **(a) Aims/objectives and theoretical background**     **(b) Research question(s) or hypothesis**     **(c) Research design**      **(d) Recruitment and sampling**. Please specify (i) **who** may be contacted by you during fieldwork/data collection, e.g. in seeking access to research population or a gatekeeper, and **how** they will be contacted by you, and (ii) expected sample size and composition.     **(e) Data collection procedures.** Please include (i) a clear outline of the planned research instruments e.g. questionnaire/interview/logbook/experiment – append copies, and (ii) an estimation of the time commitment involved for participants/respondents.     **(f)** **Data processing.** If the project involves the processing of personal data, please describe the processing activity (i) will the data be anonymised, pseudonymised or identifiable (where data has been anonymised, the original information should be securely deleted to prevent any reversing of the ‘anonymisation’ process. If this deletion does not take place then the data is classified as ‘pseudonymised’ (masked) and is still considered personal data), and (ii) Please specify the arrangements to anonymise/pseudonymise.     1. **Specify nature and extent of Patient/Public/Participant Involvement in the study**:

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**2.5** Please provide lay description of study/research proposal **(maximum 300 words in total)**

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**SECTION 3 – CONSENT AND CONFIDENTIALITY (INCLUDING DATA PROTECTION)**

**3.1** Will informed consent be obtained from the adult research participants?

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| --- | --- | --- | --- | --- |
| **YES** |[ ]   | **NO** |[ ]   | **n/a** |[ ]

If **YES**, please give details of who will obtain consent from participants and how it will be done. Please attach a copy of any letters, consent form (if required), privacy notice and information leaflet (where appropriate). Please see the CRC ethics and consent policies for guidance. Template consent and participant information leaflets are provided. Please adapt the templates provided to suit your study and participants.

If **NO**, please explain what alternative approaches are being implemented.

If **N/A**, please comment.

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**3.2** Working with children: will assent be obtained from any children under 16?

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| **YES** |[ ]   | **NO** |[ ]   | **n/a** |[ ]

 Will informed consent be obtained from parents/carers on behalf of any children under 16?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **YES** |[ ]   | **NO** |[ ]   | **n/a** |[ ]

If **YES**, please give details of who will obtain assent from children/consent from parents/carers, and how it will be done. Please attach a copy of any letters, assent/consent form (if required), privacy notice and information leaflet (where appropriate). Please see CRC consent and ethics policies for guidance on how to prepare these documents. Please adapt the templates provided to suit your study and participants.

If **NO**, please explain what alternative approaches are being implemented. (*See CRC consent policy for more information about the difference between assent and consent*).

 If **N/A**, please comment.

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* 1. Please specify if you will allow for a time interval between providing your participants with information about the research and seeking their consent:

*(For example, in some research methodologies, it is recommended that a period of 3 to 7 days be provided for reflection before asking individuals to participate in an experiment.)*

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* 1. Will the participants be from any of the following groups (tick as appropriate):

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|  | **YES** | **NO** |
| Children under 16 years of age |[ ] [ ]
| Adults with learning disabilities |[ ] [ ]
| Adults with language or communication difficulties |[ ] [ ]
| Adults with mental illness  |[ ] [ ]
| Clinical population |[ ] [ ]
| Other groups who may need specific supports in the assent/consent processPlease specify:  |[ ] [ ]

* 1. If participants are to be recruited from any of the groups listed above, please give details of:

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| 1. Any special steps taken to ensure that participants are as fully informed as possible about the nature of their involvement:

   1. Who will give consent:

   1. How consent will be obtained (e.g. will it be verbal, written or visually indicated?):

   1. The arrangements that have been made to inform those responsible for the care of the research participants of their involvement in research:

   1. The use of a gatekeeper in accessing participants:

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* 1. During and after the study, what steps will you take to protect:

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| 1. Participant identities?

   1. Hardcopy records?

   1. Digital data? Please describe measures to be taken during transfer and storage.

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* 1. Will any of the following personal data or special category data be processed (tick as appropriate):

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| --- | --- | --- |
|  | **YES** | **NO** |
| Data Subject Identify (name, surname, DOB) |[ ] [ ]
| PPSN (or other national identification number) |[ ] [ ]
| Contact details |[ ] [ ]
| Identification data (passport, licence data etc.) |[ ] [ ]
| Health data |[ ] [ ]
| Data revealing racial or ethnic origin |[ ] [ ]
| Political opinions, religious or philosophical beliefs |[ ] [ ]
| Sex life data |[ ] [ ]
| Genetic data |[ ] [ ]
| Biometric data (fingerprint/facial/iris recognition) |[ ] [ ]

* 1. If processing special category data (sensitive data), what other person(s) other than the researcher(s) named in this form will have access to the data collected, and what steps will be taken to protect confidentiality?

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| *Please specify the controls in place to log whether and by whom personal data has been consulted, altered, disclosed or erased:*  |

* 1. Will participants be given access to a copy or transcript of any recorded material (including audio or video files), if they so wish?

The participant’s entitlement in this regard should be mentioned in the consent form and participant information leaflet (if these forms are used).

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| **YES** | **NO** | **N/A** | please explain what you will do:     |
|[ ] [ ] [ ]   |

* 1. Who will take responsibility for the secure storage of, and access to, the data generated by the research?

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* 1. Who will be responsible for archiving or destroying the data?

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| *Please provide the name of the person responsible, and details of what will eventually happen to the data including retention periods:* |
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* 1. If processing personal data, describe what mechanisms are in place for providing participants with a copy of their personal data or to stop processing/delete personal data if consent is withdrawn:

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* 1. State how and where participants will be informed of legal limitations to data confidentiality?

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| LEGAL LIMITATIONS TO DATA CONFIDENTIALITY: *Participants need to be made aware that confidentiality* *of information provided cannot always be guaranteed by researchers and can only be protected within the limitations of the law - i.e., it is possible for data to be subject to subpoena, freedom of information claim, data subject access request or mandated reporting by some professions. This information should be included in your Plain Language Statement/Information Sheet and Informed Consent Form. Depending on the research proposal and academic discipline, you may need to state additional specific limitations.* |

###### SECTION 4 - RISK, HARM AND BENEFIT

**4.1** What is the potential for an adverse outcome for research participants? (For example, inconvenience, physical or emotional risk, discomfort, stress, anxiety, fatigue or embarrassment. In low risk projects, adverse outcomes are usually rare.) NOTE: for the protection of both the researcher and participants, this list must appear in full in the participant information leaflet.

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* 1. Please indicate what steps you will take in order to minimize any potential adverse outcomes for research participants:

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**4.3** What risk may be posed to personal data during any data processing activity? (For example, data loss, unauthorised disclosure/access, security issues, storage, retention, secure data destruction. NOTE: in the event of a data breach, CRC’s data breach management policy & procedure must be followed, with notification to CRC’s data protection officer without undue delay. The CRC is obliged to carry out mandatory reporting to the Data Protection Commission within 72 hours of becoming aware of a personal data breach.

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* 1. Please indicate what measures you will take in order to reduce or eliminate any potential risks to personal data:

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**4.5** What is the potential for benefit, if any, for research participants?

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**4.6** Will payment be made to research participants?

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|  | [ ]  YES [ ]  NO [ ]  Minimal payment to cover travel costs etc. |

**4.7** If you answered **YES** to the previous question, please specify for what purpose the payment will be made and the amount per participant:

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* 1. Are you aware of any conflicts of interest that could arise in the course of this project? If your answer is **yes**, please give full details below:

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* 1. Are there any other ethical considerations which you anticipate in relation to your study that have not been covered by the questions above? If so, what steps will you take to address these?

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* 1. Are there any risks to the researcher anticipated and how will these be mitigated?

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* 1. Describe how unexpected and potentially adverse outcomes for research participants will be managed

(if appropriate to study)?

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###### SECTION 5 – RESEARCH FUNDING

5.1 How is this project being funded?

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5.2 PROJECT GRANT NUMBER *(If relevant and/or known – otherwise mark as N/A)*

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5.3 Does the project require ethics approval before consideration for funding by a granting body?

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| Yes [ ]  No [ ]  |

* 1. How will the participants be informed of the source of funding? *(e.g. included in the Plain Language Statement/Information sheet)*

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* 1. Do the funders of this project have a personal, financial or commercial interest in its outcome that might compromise the independence and integrity of the research or bias the conduct or reporting of the research or unduly delay or otherwise affect their publication?

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| Yes [ ]  No [ ]  |

*(If YES, please specify how this conflict of interest will be addressed.)*

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###### SECTION 6 – DECLARATION OF APPROVAL AND SIGNATURES

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| **Personal Data & Compliance with General Data Protection Regulation.** *(Personal data is data relating to a living individual, i.e. the ‘Data Subject’, who is, or can be, identified either from the data itself or from the data in conjunction with other information that is in, or is likely to come into, the possession of the ‘Data Controller’. Please refer to the CRC’s Data Protection Policy.)* Is personal data being processed as part of this project? Y [ ]  N [ ] Name the Data Controller(s) involved in the processing:*(The ‘Data Controller’* *determines the purposes of any personal data and the means of processing it.)* NOTE: if personal data is processed as part of this project, a Privacy Notice detailing the envisaged processing activities must be issued to participants when obtaining explicit consent for the processing of their personal data.If personal data is processed, please indicate your compliance with the following:I/We confirm that we have read and agree to act in accordance with the CRC’s Data Protection Policy, General Data Protection Regulations (GDPR) and Irish Health Research Regulations:Signed:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(to be signed by lead researchers and supervisors) |
| DPO opinion: |
| APPLICANT DECLARATION:I confirm that the information provided in this form is correct, that I am not aware of any other ethical issues not addressed within this form. I understand the obligations to and the rights of participants (particularly concerning their safety and welfare, the obligation to provide information sufficient to give informed consent and the obligation to respect confidentiality).  |
| APPLICANT NAME: |       |
| SIGNATURE (for hard copies) |  | DATE:  |
| CLINICAL SUPERVISOR/CRC SUPERVISOR SIGNATUREStudent applicants are required to have their Research Supervisors complete this section. |
| **SUPERVISOR NAME:****CRC SUPERVISOR NAME (if different from above):** |
| As the student’s supervisor, I have read this document, and to the best of my knowledge, this project conforms to the CRC’s ethics and consent policies and research procedures.**SUPERVISOR’S SIGNATURE & DATE:****CRC SUPERVISOR SIGNATURE (if different) & DATE:** |