

The logo for TUSLA, featuring the word 'TUSLA' in a bold, white, sans-serif font. The letter 'U' has a unique design with a dot above it and a horizontal bar across its middle. The background of the logo is a gradient of green and blue.

An Ghníomhaireacht um  
Leanaí agus an Teaghlach  
Child and Family Agency

## **Tusla Research Ethics Committee**

**Tusla Child and Family Agency Research Ethics Committee**

**Standard Operating Procedure**

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# Privacy Notice - Research Ethics Committee

The Child and Family Agency – Tusla, has responsibility under Part 2 Section 8 (1)(f) of the Child and Family Agency Act 2013 to “undertake or commission research relating to its functions”.

In support of this function, Tusla’s Research Ethics Committee (REC) reviews research applications in order to provide ethical approval and the Committee’s decisions are independent of any other RECs. The review of applications is carried out for, but not limited to, Tusla staff (including Tusla commissioned research), academics from national and international institutions, research institutes, consultants, multi-centre studies, and students qualifying at National Framework of Qualifications (NFQ) levels 8, 9 and 10.

The legal basis for applicants sharing personal information, and information relating to their application with Tusla, is consent. Applicants will be explicitly asked in the privacy notice within the Tusla Research Ethics Application Form, to consent to their application being shared with members of the REC and the Tusla National Research Office, for the purposes of better co-ordination and avoidance of over-research.

Tusla’s Research Ethics Committee is responsible for assessing the benefits and risks of proposed studies for research participants, the organisation and wider society. Review is required where proposed research relates to the following criteria:

- Tusla Commissioned research
- Potential research participants identified from, or because of their past or present use of services provided by Tusla (including services provided under contract with the private, voluntary or community sectors).
- Potential research participants identified because of their status as relatives or carers of past or present users of services provided by Tusla.
- Potential research participants identified because of their status as providers of Tusla’s services.

See Appendix 1 for the Constitution of the Research Ethics Committee.

The Agency’s REC Standard Operating Procedure asks for the following personal information from REC members:

- First name
- Last name
- Address
- Phone number
- Email address
- Profession and professional affiliation
- Recruitment Application Form
- Written terms of appointment
- Financial information for remuneration, Travel and Subsistence claims where applicable and where members are eligible to claim for remuneration, travel or subsistence (copy of Car Logbook and Insurance Policy for Travel Claims where the committee member uses their own car will be required but will not be necessary where the claim is for use of public transport)
- Non-disclosure agreement

Please note that this personal information is required for the purpose of recruitment and carrying out the members role and function on the REC and will not be shared with any third-party external to the Agency. Personal data is stored electronically on a secure server. Personal data is only shared with Tusla HR, Tusla Finance and Tusla’s National Research Office and its staff. With the members explicit consent, their profile will also be published on the Tusla Research Centre webpages.

Further information is available from Lynn Hirtes, Research Ethics Administrator: [recadmin@tusla.ie](mailto:recadmin@tusla.ie). REC members are asked to consider and answer the following statement before taking on the role, by initialling the boxes:

- I have read the privacy notice – Research Ethics Committee – and I have been given an opportunity to ask questions in relation to the information within it
- I understand the purpose for the collection of personal information and how the information will be processed
- I consent to my personal information being stored on a secure server for the Child and Family Agency in accordance with Tusla’s Record Management Policies
- I consent to my personal details being stored by Tusla HR, Tusla Finance and Tusla’s National Research Office for the purpose of recruitment and carrying out my role and function on Tusla’s REC.
- I understand that my profile will be published on Tusla’s Research Centre webpages that will include my name, profession and professional affiliation(s)
- I understand that my personal information will not be shared with any third party without my explicit consent to do so
- I understand that I can request to see my personal information at any stage by writing to the Independent REC Chairperson and making a data request
- I understand that I can request for my personal information to be rectified and/or erased by writing to the Independent REC Chairperson and making a data request

Signed by:

REC Member

Date:

# Glossary of Terms

The definitions provided within this glossary apply to terms as they are used in these Standard Operating Procedures and Tusla's Research Ethics Committee Guidelines<sup>12</sup>.

**Adverse event**

An incident which resulted in harm experienced by a research participant engaging in a research study.

**Advice**

Non-constraining suggestions or considerations adjoined to a decision in assistance to those involved in the research.

**Amendment**

A written description of changes to an application.

**Applicant**

A researcher undertaking the scientific and ethical responsibility for a study, either on his/her own behalf or on behalf of a research team or organisation, seeking a decision from a Research Ethics Committee through formal application.

**Benefit**

A favourable consequence arising from a study for the participants involved, for organisations and to the wider public.

**Child**

The HSE Consent in Health and Social Care Research Policy (2024) defines a child as a person up to the age of 16.

**Commissioned research**

Research commissioned by Tusla where external organisations are invited to undertake research into a clearly expressed question and need related to the development of practice or business within the agency.

**Community**

A group of people understood as having a certain identity due to the sharing of common interests, experiences, heritage or to a shared proximity. This includes identified social, cultural, ethnic or religious groups.

**Community advisors**

Community members who provide contextual advice to the Applicant and to the Research Ethics Committee.

**Compensation**

That which is given in recompense or remuneration in the context of the Research Ethics Committee.

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<sup>1</sup> Glossary of terms are based on the glossary provided within the NUIG Research Ethics Committee Standard Operating Procedures and the World Health Organisation (2011) *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*. Geneva: Switzerland.

<sup>2</sup> Glossary of research methods available from the Tusla Research Centre: [https://www.tusla.ie/uploads/content/Research\\_Methodologies.pdf](https://www.tusla.ie/uploads/content/Research_Methodologies.pdf)

**Conflict of interest**

A conflict of interest arises when a member (or members) of a Research Ethics Committee holds interests with respect to specific applications for review that may jeopardise his/her ability to provide a free and independent evaluation of the research focused on the protection of the research participants. This includes actual and perceived conflicts of interest. Conflicts of interest may arise when a REC member has financial, material, institutional or social ties to the research which must be declared<sup>3</sup>.

**Consent**

The HSE Consent in Health and Social Care Research Policy (2025) defines consent as ‘the informed and explicit agreement of a prospective research participant to take part in a research study and, when relevant, to the use of their personal data for such research. The agreement for both must be ethically obtained, recorded, and retained; the proposed consent protocol must be approved by an appropriate Research Ethics Committee (REC) and, when applicable, comply with Irish data protection legislation.’

**Decision**

The response by a Research Ethics Committee to an applicant following the review of the application in which the Research Ethics Committee’s position on the ethical validity of the proposed research is stated.

**Ethics**

Pandya-Wood et al (2017)<sup>4</sup> defines ethics as the “the rules of conduct and moral principles recognized in respect to a class of human actions or a group, culture, etc.”

**Ethical Guidelines**

Guidance documentation that assists with decisions relating to the responsibility to adhere to established and relevant standards of ethical principles and practice.

**Evaluation**

A service evaluation seeks to assess how well a service is achieving its intended aims. The results of the service evaluation help towards producing internal recommendations for improvements that are not intended to be generalised beyond the service area. (McHugh et al 2015).

**Expedited Review**

Review of proposed research application by the Research Ethics Committee Chair and Vice-Chair, rather than by the entire Research Ethics Committee outside a scheduled REC meeting.

**General Data Protection Regulation**

The General Data Protection Regulation (GDPR) replaces the existing data protection framework under the EU Data Protection Directive. It outlines the enhanced rights and responsibilities which must be complied with under the new legislation the Data Protection Act 2018, which was ratified on 24<sup>th</sup> May 2018<sup>5</sup>.

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<sup>3</sup> Guidance is available at: <https://www.nice.org.uk/about/who-we-are/policies-and-procedures>

<sup>4</sup> Pandya-Wood, R., Barron, D.S. & Elliott, J. A framework for public involvement at the design stage of NHS health and social care research: time to develop ethically conscious standards. *Res Involv Engagem* **3**, 6 (2017). <https://doi.org/10.1186/s40900-017-0058-y>

<sup>5</sup> Tusla’s Data Privacy statement is available at: <https://www.tusla.ie/about/privacy-statement/>

**Minor**

The HSE Consent in Health and Social Care Research Policy (2025) states that minor is the formal legal description of someone under the age of majority which in Ireland is 18 years.

**Multi-centre studies**

A research study conducted according to a single application but at more than one site, and therefore, may be carried out by more than one Applicant.

**Principal Investigator**

A researcher who undertakes scientific and ethical responsibility, either on his/her own behalf or on behalf of an organisation, for the scientific and ethical integrity of a research study at a specific site or group of sites. In some instances, a coordinating investigator may be appointed as the responsible leader of a team of sub-investigators.

**Public Contributors**

- REC Members of the public who have an interest in research pertaining to child and family welfare and /or in the areas of services which Tusla provide
- REC Members of the public who have lived experience and/or have availed of any of Tusla services in the past

**Public and Patient Involvement (PPI)**

By public and patient in this context we mean everyone; children and young people, those attending Tusla services including potential users of services. We also include parents, carers, guardians, staff members or anyone involved in the care and protection of children and young people.

By 'involvement' we mean the active involvement between children and young people/people who use services/parent/guardians/carers/staff/the general public and researchers. It does not include the use of people as participants in research (or as research 'subjects') and does not generate data for individual research projects.

**Participation**

The process by which children and young people have active involvement and real influence in decision-making on matters affecting their lives, both directly and indirectly<sup>6</sup>

**Quorum**

A quorum is the minimum number of members that must be present to constitute a valid REC meeting where decisions can be taken concerning applications put forward for research ethical review. A meeting is quorate when a quorum is present.

**Requirements**

In the context of decisions, requirements are constraining elements that express ethical considerations that the Research Ethics Committee requires or views as obligatory in pursuing the research.

**Research ethics**

Pandya-Wood et al (2017)<sup>7</sup> refers to research ethics [as] "the moral principles guiding research from its inception through to completion and publication of results" which can also be defined as the "fostering of research that protects the interests of the public" and includes research participants and the researchers themselves".

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<sup>6</sup> Department of Children and Youth Affairs (2015) National Strategy on Children and Young People's Participation in Decision-Making 2015–2020. Dublin.

<sup>7</sup> Pandya-Wood, R., Barron, D.S. & Elliott, J. A framework for public involvement at the design stage of NHS health and social care research: time to develop ethically conscious standards. *Res Involv Engagem* 3, 6 (2017). <https://doi.org/10.1186/s40900-017-0058-y>

**Research Ethics Committee (REC)**

An independent body constituted of professionals, experts and public contributors, whose responsibility it is to safeguard the welfare and the rights of research participants engaging in research studies, taking into account the scientific procedures and the concerns of the local community.

**Research Participant**

An individual who participates in a research study.

**Research Proposal**

A document that provides the background, rationale and objective(s) of a research study and describes its design, methodology and organisation, including ethical and statistical considerations. Some of these considerations may be provided in additional documentation referred to in the proposal.

**Risk**

Risk refers to potential harm (physical, psychological or social) that may arise from the research. Research could result in different types of harm, for example, mental distress or the stigmatising of certain social, cultural, racial or religious groups. Degrees of risk may vary for participants. Applicants must assess and put in adequate protection measures to mitigate against potential harm to research participants.

**Sponsor/Funder**

An individual or organisation that takes on the scientific and ethical responsibility for the initiation, management, and/or financing of a research study.

**Young person**

The HSE Consent in Health and Social Care Research Policy (2025) defines a young person as someone aged 16 or 17 years.

# 1 INTRODUCTION

The Child and Family Agency's (Tusla) Research Ethics Committee (REC) is a group of people appointed by the Agency to review research ethics applications to assess formally if the research is ethical (see Glossary of Terms for definition of research ethics). A REC provides an independent review to participants, researchers, funders, sponsors, employers, care organisations, and professionals on the extent to which applications for research studies comply with recognised ethical standards (HIQA, 2012).

The REC is an impartial and independent committee of the Agency, formally approved by the Tusla Board. The independent REC Chairperson will report into the Quality and Service Sub Committee of the Tusla Board. The REC's implementation and operations will be supported by Tusla's National Research Office, currently based within the Quality & Regulation Directorate.

One of the specific functions of the Agency, as set out in the Child and Family Agency Act, 2013 Part 2 Section 8 (1)(f) is to "Undertake or commission research relating to its functions". The establishment of Tusla's REC directly supports the Agency's statutory function in this regard.

Tusla's REC Standard Operating Procedures (SOPs), which outline the remit and scope of the REC for REC members, sit within the context of Tusla's Corporate Plan 2024 - 2026 and Tusla's Research Strategy 2024 - 2029<sup>8</sup>. Tusla's current Research Strategy 'Driving Innovation and Continued Service Improvement', acknowledges the central importance of the Tusla's Independent REC to drive quality in research and ethical oversight, which facilitates better co-ordination and oversight for stakeholders and provides assurance that Tusla research is ethically reviewed and approved. Within the Strategy's strategic objective: Co-ordination and oversight there is a specific commitment to: Promote knowledge of the role of the Tusla Independent REC and its application to both research and practice. The REC also works within the context of the HSE National Policy for Consent in Health and Social Care Research (2025) which has been adopted by Tusla, the Department of Children, Disability and Equality ethical guidelines for research with children and young people and Tusla's Research Ethics Committee Guidelines (2015)<sup>9</sup>.

Tusla's REC acts in accordance with the *Declaration of Helsinki*, and statements of appropriate ethical practice produced by relevant professional organisations. This includes adherence to the GDPR regulations, Data Protection legislation, Health Research Regulations 2018<sup>10</sup>, the Health Research Consent Declaration Committee<sup>11</sup>, and requirements and to Codes of Professional Conduct and Ethics such as the Health and Social Care Professionals' Registration Board. It follows international good practice guidelines, relevant EU Directives, national guidelines and national draft and enacted legislation pertaining to the ethical conduct of research such as the National Research Ethics Committee Bill General Scheme 2019<sup>12</sup>, with respect to both applicants and the community, which includes guidelines for declaring and managing conflicts of interest. Tusla also recognises the commitment within the research community to actively involve members of the public as partners in the research process (Public and Patient Involvement) and builds on this commitment and includes members of the public as members of the REC.

The 'Bibliography' provides further information.

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<sup>8</sup> Tusla Research Strategy 2024-2029: Driving Innovation and Continued Service Improvement. [http://www.tusla.ie/uploads/content/Research\\_Strategy\\_Final\\_09.02.pdf](http://www.tusla.ie/uploads/content/Research_Strategy_Final_09.02.pdf)

<sup>9</sup> These REC SOPs should be read in conjunction with Tusla's Research Ethics Committee Guidelines (2015)

[http://www.tusla.ie/uploads/content/Research\\_Ethics\\_Committee\\_Guidelines\\_Final\\_June\\_2015.pdf](http://www.tusla.ie/uploads/content/Research_Ethics_Committee_Guidelines_Final_June_2015.pdf)

<sup>10</sup> <http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf>

<sup>11</sup> <https://hrcdc.ie/>

<sup>12</sup> <https://www.gov.ie/en/publication/08835e-general-scheme-of-the-national-research-ethics-committees-bill/>

## 1.1 Remit and Scope

Tusla's REC SOPs set out procedures for the ethical review of research applications within Tusla's research and evaluation remit (see criteria below). Tusla's REC reviews research applications for ethical approval and REC decisions are independent of any other RECs. The SOPs apply to research applications carried out by, but not limited to, Tusla staff (including Tusla commissioned research), academics from national and international institutions, research institutes, consultants, multi-centre studies, and students qualifying at National Framework of Qualifications (NFQ) levels 8, 9 and 10.

Tusla's REC is responsible for assessing the benefits and risks of proposed studies for research participants, the organisation and wider society. REC review is required where proposed research relates to the following criteria:

- Tusla Commissioned research
- Potential research participants identified from, or because of their past or present use of services provided by Tusla (including services provided under contract with the private, voluntary or community sectors).
- Potential research participants identified because of their status as care leavers, relatives or carers of past or present users of services provided by Tusla.
- Potential research participants identified because of their status as providers of Tusla's services.

The REC also has the discretion to review applications outside this scope on a case-by-case basis where the Chair notes there is an overlap with Tusla services.

Section 7.7 of the Tusla Service Level Agreement (SLA) for Section 56 agencies funded by Tusla, states: 'Funded services may require ethical approval for their research. Services may already have ethical approval processes in place for undertaking and commissioning research. If this is not the case, or if ethical approval processes are not of the standard required by Tusla, the Tusla ethical approval process should be adhered to. Services should assure themselves of this requirement and contact Tusla REC Administrator ([recadmin@tusla.ie](mailto:recadmin@tusla.ie)) and Tusla Independent Research Ethics Committee, Tusla Child and Family Agency'.

Potential applicants are advised to contact the Tusla National Research Office: <http://www.tusla.ie/research/tusla-research-office> prior to submitting to enquire whether the proposed research adheres to the remit and scope outlined.

## 1.2 Terms of Reference of the Research Ethics Committee

The Terms of Reference were agreed in April 2019 and April 2021 and are reviewed as part of the overall review of this SOP document every two years or when otherwise stated. The current Terms were reviewed in 2025.

The aim of Tusla's REC is to provide ethical review of research which involves those who use Tusla services and Tusla staff. The primary responsibility is to ensure the protection and safeguarding of participants in approved research studies. Ethical review aims to ensure research integrity and, by providing an ethical opinion, facilitate good quality research that promotes best practice in research in support of securing the best outcomes for children and families. This promotes a research culture and ensures public confidence in and about the conduct of researchers and the dignity, rights, safety and wellbeing of research participants. For any research application to gain ethical approval, it must be deemed worthwhile as well as demonstrating a standard of research design that minimises predictable risk to both the research participant and the researcher.

The REC will:

- Review research applications within Tusla's remit and scope.
- Provide timely, comprehensive and independent reviews of the ethics of proposed studies in line with Tusla's approved Research Ethics Review Standard Application Form. An online version of the Research Ethics Review Standard Application Form is utilised.

- Have authority to approve (with or without revisions) or decline applications for research, on the basis of ethical considerations only.
- Advocate and encourage ethical and integrity standards of practice in research<sup>13</sup>.
- Protect research participants from unnecessary harm.
- Preserve the research participants' rights.
- Through its operation, promote responsible research practices.
- Assess the potential benefits and risks of proposed studies to research participants, the organisation and to wider society.
- Liaise, where necessary, with appropriate community advisors and/or practitioners to gain contextual understanding.
- Through its functions, provide reassurance to the public that best practice is being applied.
- Submit an annual report to the Services and Quality Committee as delegated by the Board of Tusla.

In carrying out its role, Tusla's REC respects academic freedom and operates from the understanding that research is an important activity considered to be a public good, and that applications are reviewed in accordance with this objective.

All members of the REC are required to comply with the standard operating procedures and Tusla's Research Ethics Committee Guidelines (2015) and any other Tusla policies and procedures, that are relevant to their role.

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<sup>13</sup> Good research practices include research environment; training, supervision and mentoring; research procedures; safeguards; data practices and management; collaborative working; publication and dissemination; reviewing, evaluating and editing. For further information on research integrity: Irish University Association (2013) *National Policy Statement on Ensuring Research Integrity in Ireland*. Dublin.

## 2 MEMBERSHIP OF THE REC

The REC will be led by a Chair and a Vice-chair. The Chair will be approved by the Services and Quality Committee as delegated by the Board of Tusla. The Vice-chair will be agreed by members of the REC.

Candidates for the role of Chair will need to have at least one-year's minimum experience as a member of a REC.

Candidates are appointed for specified periods not exceeding three years and may resign in writing to the Chair. The resignation notice period required is a minimum of four weeks and a maximum of eight weeks.

A member should not serve more than two consecutive terms.

Renewal of membership for a second consecutive term will be the decision of the SQ Committee delegated by the Board of Tusla, on the recommendation of the REC Chair.

Membership for the REC will be advertised publicly in the press, local professional and other networks, and /or through Tusla recruitment processes.

As per Tusla Research Ethics Committee Guidelines (2015):

- The Committee composition will be in line with international best practice<sup>14</sup>
- The Committee will comprise a maximum of 21 members.
- The Committee will be multi-disciplinary and where possible achieve a gender balance.
- At least one-third of the members will be public contributors who will be people who are not from a professional health or social care background.
- The remainder of the committee will be expert members who are specialists, or other relevant professionals and academics. A specified number will also be staff from Tusla recruited for their knowledge and experience of research and Tusla services.
- The Committee will be supported by an administrator who acts as Business Support to the Committee and who will be an employee of the Agency. The administrator plays no role in approving research applications.

The Committee will seek broad representation and may potentially include the following categories of members:

- Child and Family Agency Researchers
- Data Protection Specialist
- Public contributors
- Primary Care representative from a primary care setting
- Social Work representative
- Social Care representative
- Mental Health Service representative e.g., CAMHS
- Tusla Education Support Service (TESS) representative
- Family Support Services representative
- Research Academic representative (external representative)
- Workforce Learning and Development representative
- Domestic, Sexual and Gender Based Violence Services representative
- Child advocacy representative
- Family advocacy representative
- Early Years (Pre School) Inspectorate representative

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<sup>14</sup> This includes the World Health Organisation (2011) *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*. Geneva: Switzerland; Economic and Social Research Council (2015) *Framework for Research Ethics*.

The committee may refer to other non-committee members for specialist advice (e.g. legal, data protection) where this is deemed necessary to the review process.

# 3 PROCEDURES FOR SUBMITTING AN APPLICATION

## 3.1 Application Procedure

All applications will be reviewed in accordance with the application processes and procedures outlined below. See also Appendix 2 flowchart.

1. Applicant should consider if they need to seek Research Ethics review and approval for their project. In doing so they may:
  - Speak to the REC Administrator
  - Work with their research supervisor, if relevant, prior to submission
  - Review relevant material e.g., Research Ethics Guidelines, data protection requirements
  - Seek pre-application support from the National Research Office (NRO). In accordance with the NROs coordination mandate, any plan for Tusla services to commission research must be discussed in advance with the NRO.
2. Check dates of REC meetings and submission dates
  - Download the Standard Research Ethics Application form<sup>15</sup> <https://www.tusla.ie/research/tusla-research-office/research-ethics-committee>
  - Complete an application form
  - Complete an Applicant Checklist
  - Contact the REC Administrator for advice or assistance if needed
  - Submit an application to the REC Administrator at least 21 working days before the next REC meeting
3. On receipt of an application the REC Administrator will:
  - Date all incoming material
  - Acknowledge receipt of the application and advise the applicant of the expected date of review by the REC
  - Will alert the applicant if the application is invalid (i.e. incomplete)
  - Will provide the chair with a copy of the application for the chair to undertake a preliminary review
  - With the chair, allocate the review of the applications to REC members
  - Will inform REC of review date for application
  - Will take responsibility for organising the REC meetings
4. REC meets every four to six weeks
  - The Administrator confirms the agenda and attendance with all members and ensures a quorum is present
  - Ensures members have full documentation for the meeting via secure means e.g., Tusla email.
  - The applicant will be informed if required to attend
5. REC reviews applications in advance of the meeting and discusses applications at the meeting

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<sup>15</sup> Forthcoming

- Feedback is captured on a feedback form by each reviewer s, for each applicant. The reviewers present their review at the REC meeting where all members are able to make comments and recommendations.
  - The feedback from the reviewers and from the REC discussion is coordinated into a single feedback document by the chair
  - Decisions about applications are made and fall into one of the categories: approved, approved subject to clarifications; decision deferred, re-submission; or not approved.
6. The outcome of the application is notified to the applicant by email, with the review feedback form, within 10 working days and includes any follow up actions that are required. Following receipt of the feedback the applicant will either:
- Commence their research if given full approval
  - Submit clarifications for further review or
  - Resubmit their full study documentation with required amendments for further review at a full committee meeting
  - Withdraw their application.

On completion of the study a report of the study findings<sup>16</sup> should be submitted to the Research Office for publication in the Tusla Research Centre

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<sup>16</sup> Reporting of findings can include summary report, full report, thesis, articles, presentations, among others.

# 4 RESEARCH APPLICATION REVIEW MEETING PROCEDURE

## 4.1 Meeting Procedure

### **Schedule**

- This schedule will be reviewed on an annual basis.

### **Agenda**

- Meetings will follow a previously scheduled agenda, amended where appropriate, and including at least the following:
  - The date, time, and venue of the meeting
  - Declarations of interest relating to items on the agenda. If a member(s) of the REC declares a conflict of interest, the Chair will exclude the member(s) from the part of the meeting where the application is being discussed. This will be recorded in the minutes.
  - Minutes of the previous REC meeting
  - Matters arising at the previous meeting(s) that the Committee specifically indicated that it wished to consider again
  - Applications for ethical review to be considered at the meeting
- The agenda may also include for discussion, where appropriate, general ethical issues (e.g., new guidelines), matters relating to the membership of the committee and matters relating to Committee procedures. Member information and training sessions may be included when the main business of the meeting is completed.

### **Minutes**

- The minutes of the meeting will be prepared by the REC Administrator, in consultation with the Chair, and other members as necessary.

### **Other procedural items**

- Where required, the applicant may be invited to present the application or to elaborate on specific issues. The decision to do so will be taken by the Chair or, in their absence, the Vice-Chair, in advance of the scheduled meeting.
- Where required, people with additional expertise, including community advisors or practitioners, will be invited to the meeting or will be asked to provide written comments, subject to applicable confidentiality agreements.
- Where the REC needs legal advice or opinion in relation to an application this will be sought from Tusla's Office of Legal Services and Tusla Data Protection Unit by the Chair.

### 4.1.1 Quorum Requirements

- The REC must have a quorum in order to proceed with a meeting
- To be quorate the REC must have a third of its current membership in attendance, including the Chair or Vice-Chair and at least one public contributor. The Administrator is not included as part of the quorum.
- Where a quorum is not present, the REC will not proceed.

All research applications will be reviewed in accordance with the meeting procedure outlined below.

## Meeting Procedure

### **Administrator's duties**

- Confirm agenda and attendance with all members
- Ensure that a quorum of members will be present (if a quorum is not present the meeting will not proceed)
- Ensure that all attendees have full documentation via Tusla email, or through a Tusla IT system (if acceptable to the counterparty).
- If required to attend, inform the Applicant

### **Chair facilitates meeting**

- Previous Minutes and Matters arising are discussed.
- Each research application is discussed in detail, and a list of ethical issues is compiled.
- The REC Administrator records and makes clear how the REC came to its decisions.

## 4.2 Expedited Review

- A request for an expedited review can be made by the applicant through the REC Administrator (see Appendix 3 for expedited review request form).
- Expedited reviews of research applications only occur when there is a time constraint issue.
- Research applications must include the same details as for a full review.
- *If a request is approved by the Chair, the application does not go to the REC for full review. The research application is reviewed by the Chair and Vice-Chair.*
- If the decision of the Chair is to decline the research application for specified reasons, a new application can be submitted to the next REC meeting.
- Research applications that have been approved by expedited review are listed for brief discussion on the agenda of the next scheduled meeting.

In general, it is preferred that the full REC reviews all research applications in accordance with these Standard Operating Procedures.

If request is approved by the Chair, the application does not go to the REC for full review. The research application is reviewed by the Chair and Vice-Chair or another nominated member of the REC. The Chair and Vice-Chair may also decide to nominate a member of the committee to review the application, where and when relevant subject matter expertise is identified.

# 5 DECISION-MAKING PROCEDURE

Research applications are reviewed by REC members prior to the meeting. The decision-making procedure is as follows:

- Research applications are assigned by the Chair (or Vice-Chair in the Chair's absence) and Administrator to members for review and subsequently discussed at the meeting.
- Decisions are arrived at through consensus where possible; under this model the applications will be approved when all members present are willing to allow the applications to proceed.
- Members who have conflicts of interest must declare these at the meeting as per the procedure in section 4.1, and these must be recorded in the minutes.
- In cases of approval pending revision(s) or re-submission of application suggested by the REC, clear suggestions for revision and the procedure for having the application re-evaluated are specified (see 5.1.2)
- Declined applications are supported by clearly stated reasons.
- All terms and conditions of ethical approval must be adhered to by applicants. Tusla's Research Ethics Committee approval is provided on the basis of the information received. If applicants have used Artificial Intelligence (AI) tools in the development of their application, they must declare this and provide details of how it has been used and what programmes or tools have been utilised. Applicants must adhere to any Tusla guidance relating to the use of AI and the EU Ethics Guidelines for the Trustworthy Use of AI in Research. Applicants who do not adhere to the Tusla REC approval are in breach of the agreement. Tusla REC may decide to withdraw ethical approval, depending on the issues identified in any breach of terms and conditions.

See also Appendix 2 flowcharts.

## 5.1 Research Ethics Committee Decisions

### 5.1.1 Approval

The research can commence on the provision of full approval, which the applicant is informed of in writing. Applicants can begin the research as outlined in the research application submitted to the REC.

### 5.1.2 Approval with revisions and re-submission

Approval with revisions or clarifications may be granted, which is subject to the recommended revisions or clarifications to the application or answers to questions posed to the applicant. In this case the applicant is requested to submit a cover letter along with a modified application and supplemental information if requested, highlighting any changes in line with the REC's recommendations/queries. The REC Chair can decide whether the modified application and supplemental information require full review at a future REC meeting or review between REC meetings. Decisions of this nature will depend on whether the modified application is approved with revisions or is a re-submitted application. The applicant is informed of the decision in writing. The applicant must not commence any research activity until they have been issued with full approval by the REC. To do so would contravene the principles of research integrity and, should it come to the notice of the REC, could be considered research misconduct. The REC reserves the right to inform the research supervisor and/or sponsor if misconduct comes to light.

A re-submitted application may be required whereby the application is incomplete and therefore the standard of ethical review cannot be fully met by the REC. No research may be started until all conditions have been met and final approval has been granted. The applicant is informed of the decision in writing.

### 5.1.3 Approval declined

Applications may be declined by the REC. This may occur if the proposed research is not justified and/or poses unnecessary risk to research participants or if it does not meet the required standard of research ethical practice. A

declined application should be supported by clearly defined reasons. The applicant is informed of the decision in writing.

The applicant can avail of a Tusla appeals procedure and/or its Feedback and Complaints Policy and Procedure 'Tell Us'<sup>17</sup>, if they are not satisfied with the decision or procedures of the REC.

## 5.2 COMMUNICATION OF A REC DECISION

### 5.2.1 Post-Meeting Procedure

The post-meeting procedure is as follows:

- The REC Administrator ensures that the minutes of meetings are agreed with the Chair, and other members as necessary.
- Recorded minutes are filed in accordance with the 'Documentation and Records Management' procedure as outlined in Appendix 6.
- REC review forms are compiled by the REC Chair or Vice Chair based on members reviews and the decisions made at the REC meeting. The forms are filed and stored securely in accordance with the 'Documentation and Records Management' procedure.
- The REC Administrator informs the applicants of the REC's decision in writing within 10 working days of the meeting at which the decision was taken and no later than 60 days<sup>18</sup> (in accordance with the *Declaration of Helsinki*) after the REC's decision.

All correspondence is signed and dated by Chair or his/her nominee.

Template letters for communicating REC decisions to applicants are included in Appendix 3.

## 5.3 Procedure for Receiving and Considering Appeals to a REC Decision

In the case of the applicant wishing to appeal the decision of the REC, the procedure for the applicant outlined in Appendix 4 must be followed.

## 5.4 Procedure for Receiving and Considering Complaints

In the case of the applicant wishing to complain in relation to the REC's conduct and/or complaints of research misconduct, Tusla's *Tell Us* Feedback and Complaints Policy and Procedure *Feedback and Complaints Policy and Procedure* (Tusla, 2021) must be followed.

## 5.5 Research Ethics Committee Distress Protocol

A tailored and specific distress protocol (see Appendix 8) will be available to REC members in the event that any member of the REC experiences distress during the process of engaging in REC activity. It will be the responsibility of the REC Chairperson to ensure full implementation of the protocol.

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<sup>17</sup> <https://www.tusla.ie/about/feedback-and-complaints/>

<sup>18</sup> Unless there are reasonable and evidenced reasons for delay by either the REC or the applicant e.g., where the REC makes a request for additional information for the consideration of the application, the number of days shall be suspended from the time the REC makes the request up until the time the information is provided within a period specified by the REC or agreed with the applicant.

# 6 PROCEDURES FOR MONITORING ONGOING RESEARCH

Applicants will be asked for their consent to include information about their research study within Tusla's National Research Database (forthcoming).

## 6.1 Reporting requirements

The REC requests an annual statement of compliance (see sample template in Appendix 5) from the applicant but the Committee can agree more frequent reporting at the time of approval of the application.

The applicant is also requested to submit a final statement of compliance (see sample template in Appendix 6).

## 6.2 Additional Reporting Requirements

The REC is responsible for responding to all notifications of instances or events reported by the Applicant affecting the progress of an approved study. The Chair reserves the right, depending on the nature and seriousness of notifications, to make a judgement on how to respond to the notification received from the Applicant. Measures can include on-going formal communication between the Applicant and the Chair or pausing the approved study until mitigating measures have been put in place by the Applicant to the satisfaction of the REC. If the Chair deems that the study should be terminated, the study will be paused and a decision on study termination will be brought to the REC for further deliberation.

A decision by the REC on notifications and additional reporting requirements is to be issued and communicated to the applicant by the REC Administrator.

### 6.2.1 Instances requiring additional reporting requirements

The following instances or events require additional reporting requirements of a study:

- Any amendments to the application likely to affect the rights, safety and/or well-being of the research participants, the researcher(s) or the conduct of the study
- Any event or new information that may affect the benefits/risks ratio of the study
- Any adverse events or untoward incidents
- Data protection breaches. Applicants must comply with all reporting requirements arising out of Data Protection legislation, GDPR and Health Research Regulations 2018.

### 6.2.2 Amendments

Any alterations to a previously approved application must receive prior approval from the REC before implementation. An amendment request form is available from the REC Administrator.

### 6.2.3 Adverse Events

Serious and unexpected adverse events related to the conduct of the study and the response taken by regulatory agencies, investigators and sponsors must be reported.

The REC Chair or vice-Chair must follow the policy and procedures as outlined in Tusla's Incident Management Policy and Procedure (2016)<sup>19</sup>.

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<sup>19</sup> [https://www.tusla.ie/uploads/content/QA\\_Incident\\_Management\\_Policy.pdf](https://www.tusla.ie/uploads/content/QA_Incident_Management_Policy.pdf)

All applicants are required to immediately report to the REC any serious or unexpected adverse events involving research participants or researchers or events that might affect the benefits/risks ratio of the application.

A serious adverse event is defined as any occurrence that:

- Results in death
- Is life threatening
- Creates harm, distress and or stigmatisation to research participants and to identified communities above and beyond natural day to day occurrences

An unexpected event is an adverse reaction, the nature and severity of which is not consistent with relevant information available at the time of original approval.

Applicants must take urgent safety measures to eliminate immediate jeopardy to the research participants prior to consideration of the event(s) by Chair or the REC. However, applicants should provide the REC with a written report of any mitigating action taken at the earliest opportunity. The REC will review the new material and decide whether there are sufficient grounds for changing its initial decision to grant approval to the application.

### 6.3 Study Termination

In the case of the premature suspension/termination of a study, the applicant should notify the REC of the reasons for the suspension/termination. This should be accompanied by a summary of results obtained in a study up to the point of suspension/termination.

### 6.4 Final Reports

All applicants of approved studies are requested to submit an abstract to the REC summarising the main findings on completion of the study. With the applicant's consent this will be uploaded onto the Tusla Research Centre web pages and/or included in the Agency's National Research register and the internal electronic library management system.

# 7 RESEARCH ETHICS COMMITTEE ANNUAL REPORT

An annual report for the Services and Quality Committee as delegated by the Board of Tusla is submitted by the REC Chair containing information relevant to its procedures including, but not limited to:

- Membership and membership changes.
- Number and dates of meetings held.
- Attendance of members; confirmation of participation by required categories of members
- Substantive changes to the Standard Operating Procedures (SOP).
- List of training undertaken by members.
- A list of applications considered, and the decision reached on each.

Annual reports are public documents and are available on request.

## 8 EVALUATION OF REC PROCEDURES

In line with all functions of the Agency, the REC will be quality assured and evaluated as part of the Agency's policies and procedures and further guidance from HIQA, as directed.

The SOP is subject to review by the Chair/Vice-Chair in consultation with members, and further change as the Services and Quality Committee on behalf of the Board may be determined necessary.

Where the Services and Quality Committee on behalf of the Board forms a view that the REC is not performing its functions properly, it shall notify the REC Chair setting out its concerns and the reasons for those concerns. Informal engagement between the Services and Quality Committee and REC Chair will be utilised before any formal approach is considered.

The SOP was approved in April 2021, and an updated version was reviewed in May 2022 and reviewed again in 2025. Usual practice is to review it on a bi-annual basis.

## 9 Revision History

Version Number	Nature of Changes (Page Number if Relevant)	Author of Change	Date	Approved By	Date of Approval
1.0	New document	REC establishment group	April 2019 - 2021	NPOC	April 2021
2.0	Revision to Section 4.2 Expedited Review	REC	May 2022	NPOC	May 2022
3.0	<p>The aims reflect the RECs primary role to safeguard and protect research participants</p> <p>The review processes and procedures are clearly outlined</p> <p>The distress protocol for members</p> <p>References to Tusla policies and procedures</p> <p>Applicant decision letters</p>	REC	January to December 2025	NPOC	February 2026

## 10.0 Appendices/References

### APPENDIX 1: Constitution of the Research Ethics Committee

Membership of the Research Ethics Committee is on a voluntary basis. RECs are independent and impartial. A REC's opinion must be free, and must be seen to be free, from conflicts of interest. This includes freedom from pressures of:

- Political influence
- Institutional affiliation
- Trade union or profession-related interests
- Direct or indirect financial inducement or any impression thereof
- Coercion
- Strategic concerns
- Market forces
- Agency, discipline or topic related bias (Department of Health, UK, 2011, p 15)

In line with recommendations from HIQA's (2012) international review of research ethics structures, membership for the REC will be advertised publicly in the press and/or local professional and other networks such as Tusla Recruit, internally via Tusla communication channels including Newscast, and via social media. Potential candidates will be required to complete an application form and will be interviewed. The following expertise will be sought:

- Relevant methodological and ethical expertise in clinical, non-clinical qualitative and other research methodologies in health and social science fields
- Practice experience
- Statistics related to research.

The State Claims Agency (SCA) confirms that Tusla its servants and/or agents, will be indemnified by the State in respect of any claims for personal injury and third-party property damage, arising from the negligence of Tusla, its servants and/or agents, in respect of the REC established under the control and direction of Tusla. Servants and/or agents are persons who perform tasks on behalf of Tusla and includes: all employees, persons on a contract of service, volunteers and those on placements/work experience.

All appointed REC members, formally approved by the Board, will have sufficient baseline knowledge of ethical issues.

All REC members will be required to undergo induction training prior to becoming a member of the REC and ongoing training, as required, in fulfilment of REC membership requirements. Induction training will be provided by Tusla or other appropriate providers.

Agreed minimum standards of training and competence (which should be kept up to date with the changing ethics issues within the research lifecycle) will be developed.

Members of the REC must maintain confidentiality and comply with all data protection legislation and regulations regarding applications, meeting deliberations, information about research participants and related matters.

The membership of a REC should allow for a sufficiently broad range of experience and expertise to provide competent and rigorous ethics review of the submitted research proposals (ESRC, 2015). The composition and independence of the REC is important in establishing the legitimacy of the opinions expressed and the decisions made, in the eyes of the community and wider society as well as the researchers and funders of research.

Written terms of appointments for REC members will include the following:

- Duration of appointment
- Terms and conditions
- Renewal policy
- Disqualification and resignation procedures
- Policy concerning declarations of interest
- Details of allowable expenses
- Remuneration policy and guidance
- References

Garda vetting is only required for those who will have direct contact with children and/or minors.

## Conditions of Appointment

### Term of Appointment

- The term of appointment will be 3 years.
- A member should not serve more than two consecutive terms.
- Renewal of membership for a second consecutive term will be the decision of the SQ Committee as delegated by the Board of Tusla, on the recommendation of the Research Ethics Committee Chair.
- Members who do not attend a number of meetings, or do not attend three consecutive meetings, may at the discretion of the Chair or Vice-Chair, be asked to step down and a replacement member may be sought.
- Should a member wish to resign from the Research Ethics Committee, they should inform the Chair in writing of their intention. The resignation notice period required is a minimum of four weeks and no more than eight weeks.
- The procedure for replacement of members at the end of the term of appointment will be the same as for initial appointment of members.
- Where a replacement is required mid-term, the Chair will seek to appoint from those held on any panel resulting from the initial interviews. Failing this, or having appointed all panel members, the process for recruiting will be determined in consultation with the SQ Committee as delegated by the Board of Tusla. There may also be circumstances where the REC require a member with specific expertise or experience in which case, bespoke recruitment may take place.

### Conditions of Appointment

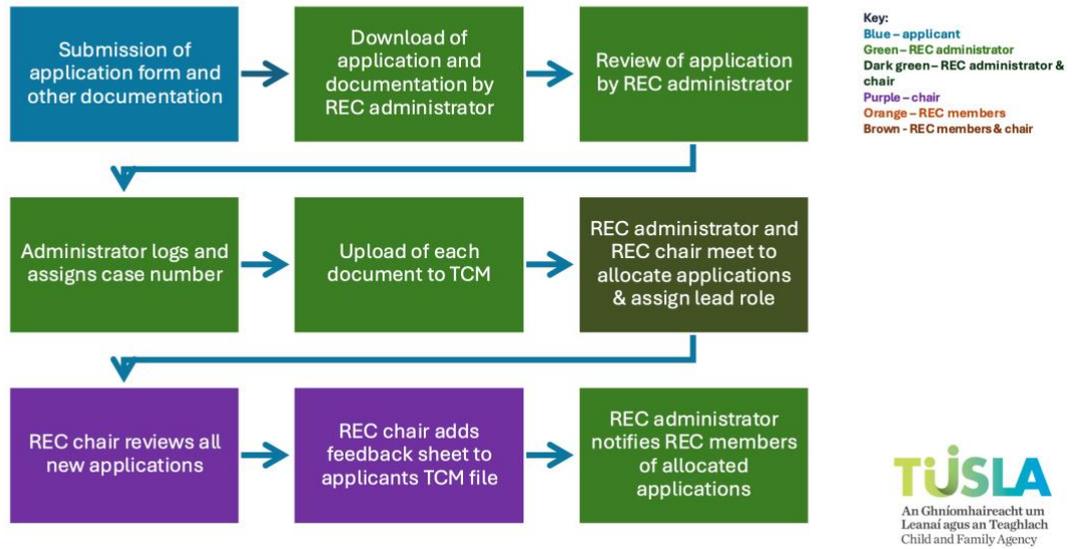
- Members must be willing to have their name, profession and affiliation published on the Tusla Research Ethics Committee webpage
- Members are expected to treat as confidential all applications, meeting deliberations, information on research participants/volunteers and related matters. A non-disclosure agreement must be signed by all members.
- A member must agree to take part in education and ongoing training appropriate to their role on the Research Ethics Committee.
- Members will receive limited reimbursement of expenses for travel in line the Agency's financial regulations and policies (TFR02). A remuneration policy is in place and members who are not employees of Tusla, or related agencies are eligible to claim. Management of taxation and eligibility for social welfare payments is the responsibility of the REC member and Tusla cannot provide advice about a member's personal circumstances.

## Chairperson

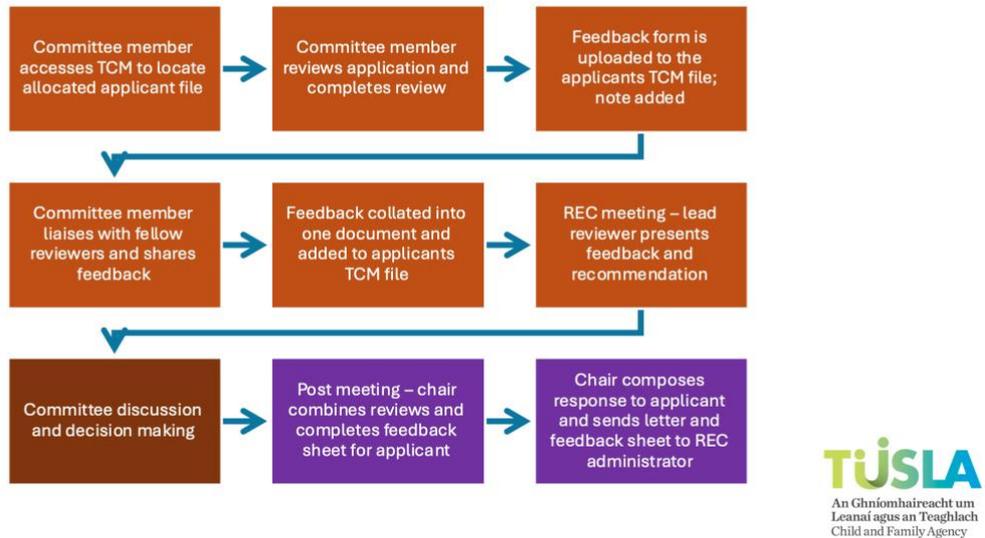
- The Chair is appointed by the Tusla Board
- Remuneration may be considered on a case-by-case basis.
- The duties of the Chair are:
  - Chair meetings of the REC
  - Ensure that the Standard Operating Procedures are followed
  - Liaise with the relevant research and other structures within Tusla
  - Liaise with relevant academic institutions
  - Report to the CEO any decisions or issues likely to impact on the resources of the Agency or the reputation of the Agency
  - Ensure an annual report is issued

# APPENDIX 2: Process for reviewing applications

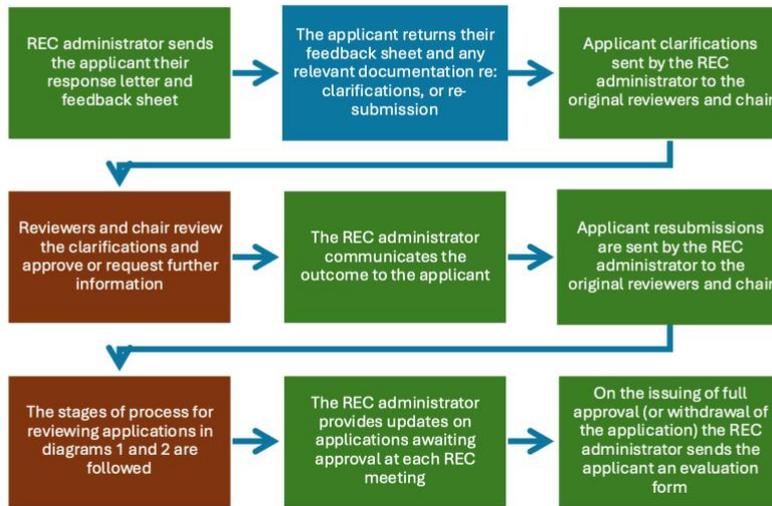
## Process for reviewing applications for REC approval (pre -review)



## Process for reviewing applications for REC approval (review)



### Process for reviewing applications for REC approval (post review)



# APPENDIX 3 - REC Decision templates

## Approval Letter Template

Chair of Tusla Research Ethics Committee

Tusla Child and Family Agency

Brunel HQ

Military Road

Dublin 8

Date:

Name and title of applicant:

Address:

REC Reference Number:

Title of Application Reviewed:

Date of submission:

Dear

Re:

I write to you regarding the above application which was submitted for ethical review.

Thank you for your application. The committee recognised the hard work that had been put into the preparation of your application. Your topic is a valuable one and the reviewers read it with interest.

I wish to inform you that at the meeting of the Tusla Research Ethics Committee held on [date] in [venue], it was the decision of the Committee to grant this application APPROVAL.

All Tusla Research Ethics Committee approval is given subject to the applicant submitting annual and final statements of compliance. The first statement is due on or before X. Annual and final statement of compliance forms are attached below.

It is also the responsibility of the applicant to notify the committee in the case of amendments to the application likely to affect its decision. This includes serious or unexpected adverse events, unforeseen circumstances, termination of the study, the outcome of the study, or of any significant decisions by other Research Ethics Committees. Section 6 of the REC's Standard Operating Procedures provides further details.

Yours sincerely,

Chair of REC

## REC Decision templates

### Approval Subject to Revisions Letter Template

Chair of Tusla Research Ethics Committee

Tusla Child and Family Agency

Brunel HQ

Military Road

Dublin 8

Date:

Name and title of applicant:

Address:

REC Reference Number:

Title of Applications Reviewed:

Date of submission:

Dear

Re:

I write to you regarding the above application which was submitted for ethical review.

Thank you for your application. The committee recognised the hard work that had been put into the preparation of your application. Your topic is a valuable one and the reviewers read it with interest.

I wish to inform you that at the meeting of the Tusla Research Ethics Committee held on [date] in [venue], it was the decision of the Committee to grant this application APPROVAL SUBJECT TO CLARIFICATIONS as noted below.

The main areas to be addressed are listed below and we also attach the reviewers report. The report is intended to assist you in making your amendments and clarifications. The reviewers have made a number of points and recommendations for clarifications which are outlined in their review. Responses to the points and recommendations should be made using the review template and highlighting the changes made to the application. The points to be addressed are listed in the report and include:

You have the option of the application being re-evaluated by the Tusla Research Ethics Committee at a future meeting, or between meetings, subject to the revisions being made.

**PLEASE NOTE YOU MAY NOT COMMENCE YOUR STUDY UNTIL THE REC REVIEWS AND APPROVES YOUR CLARIFICATIONS.**

We look forward to hearing from you.

Yours sincerely,

Chair of REC

## REC Decision templates

### Re-Submission Letter Template

Chair of Tusla Research Ethics Committee  
Tusla Child and Family Agency  
Brunel HQ  
Military Road  
Dublin 8

Date:

Name and title of applicant:

Address:

REC Reference Number:

Title of Application Reviewed:

Date of submission:

Dear

Re:

I write to you regarding the above application which was submitted for ethical review.

Thank you for your application. The committee recognised the hard work that had been put into the preparation of your application. Your topic is a valuable one and the reviewers read it with interest.

I wish to inform you that at the meeting of the Tusla Research Ethics Committee held on [date] in [venue], it was the decision of the Committee to seek a RE-SUBMISSION of the application as noted below. The reasons for this decision were as follows:

The reviewers have made a number of points and recommendations for amendments and clarifications which are outlined in their review. The review is detailed and intended to help you in making the required amendments. Responses to the points and recommendations should be made using the review template and highlighting the changes made to the application in the application form and accompanying documentation.

You have the option of the application being re-submitted to the Tusla Research Ethics Committee at a future meeting, with the following revisions made:

Please contact the Tusla REC Administrator for the next steps in the process, such as appeals and complaints processes.

Yours sincerely,

Chair of REC

## REC Decision templates

### Decline Approval Letter Template

Chair of Tusla Research Ethics Committee  
Tusla Child and Family Agency  
Brunel HQ  
Military Road  
Dublin 8

Date:

Name and title of applicant:

Address:

REC Reference Number:

Title of Application Reviewed:

Date of submission:

Dear

Re:

I write to you regarding the above application which was submitted for ethical review.

Thank you for your application. The committee recognised the hard work that had been put into the preparation of your application. Your topic is a valuable one and the reviewers read it with interest.

I wish to inform you that at the meeting of the Tusla Research Ethics Committee held on [date] in [venue], it was the decision of the Committee to DECLINE APPROVAL. Approval was declined on the following basis:

You have the option of submitting a new application for review by the Tusla Research Ethics Committee at a future meeting.

Please contact the Tusla REC Administrator for the next steps in the process, such as appeals and complaints processes.

Yours sincerely,

Chair of REC

## REC Decision templates Expedited Review Request Form

Chair of Tusla Research Ethics Committee

Tusla Child and Family Agency

Brunel HQ

Military Road

Dublin 8

Date:

Name and title of applicant:

Address:

REC Reference Number:

Title of Application Reviewed:

Date of submission:

Dear Chair,

I am requesting an expedited ethical review of my research application by the Tusla Research Ethics Committee.  
The reasons for my request are as follows:

I look forward to hearing from you.

Yours sincerely,

Applicant

c.c. Supervisor (if applicable)

# APPENDIX 4: Research Ethics Committee Appeals Procedure

## Tusla Research Ethics Committee Appeals Procedure

This appeals procedure is designed to deal with the following two outcomes of the Research Ethics Committee decision-making process:

1. Where the Research Ethics Committee has declined an application for ethics approval, for reasons other than an incomplete application, and the applicant wishes to appeal.
2. Where the Research Ethics Committee has approved an application for ethics approval subject to stipulated revisions being made and the applicant disagrees with the changes.

### Appeals procedure

1. If an applicant wishes to appeal the decision of the Agency's REC, he or she should notify the REC Administrator within 10 working days of being notified of that decision.
2. An appeal must be submitted in writing and must include the reference number of the application, the title of the research application, and name of supervisor if appropriate. The reasons for challenging the decision of the REC must be clearly defined in the notification and based on one or more of the following conditions:
  - 2.1. Criteria used for ethical review
  - 2.2. Material fact pointing to unfairness of decision
  - 2.3. Procedural error pointing to unfairness of decision
3. Requests for appeal will be dealt with all reasonable expedition and will be heard normally within 15 working days of receipt of notification. The REC Administrator shall set a deadline for the completion of the appeal process.
4. A standing Appeals Committee will be established and will be convened on a case-by-case basis. This standing Appeals Committee will comprise a:
  - Tusla National Research Office member
  - Independent academic
  - External member of Tusla's Research Advisory Group
  - A public contributor representative from the REC (who has not been involved in the ethical review of the application in question)
5. The appellant may attend before the Appeals Committee in person
6. The final decision by the Appeals Committee of whether the appeal has been successful or not will be communicated in writing to the applicant within five working days.

# APPENDIX 5: Annual Statement of Compliance

**Name:**

**Research Study Title:**

**REC Reference Number:**

I confirm that the above referenced study (including any amendments hereto) is currently underway in accordance with the approval granted by Research Ethics Committee (REC) at Tusla Child and Family Agency.

An interim report has been sent to the Administrator of the Research Ethics Committee (REC) at Tusla Child and Family Agency.

**Applicant Signature:**

**Date:**

# APPENDIX 6: Final Statement of Compliance

**Name:**

**Research Study Title:**

**REC Reference Number:**

I confirm that the above referenced study (including any amendments hereto) has been carried out in accordance with the approval granted by the Research Ethics Committee (REC) at Tusla Child and Family Agency.

A final report and /or summary report has been sent to the Administrator of the Research Ethics Committee (REC) at Tusla Child and Family Agency.

I consent to the final report and/or summary report, or version therein with my agreement to be uploaded onto the Tusla Research Centre.

**Applicant Signature:**

**Date:**

# APPENDIX 7: Documentation and Records Management Procedure

All documentation and communications of Tusla's Research Ethics Committee are to be dated, filed and archived in accordance with Tusla's Record Management Policies, such as Tusla's data protection privacy statement and Tusla's Data Management Policy 2025<sup>20</sup>. Documents to be filed and archived include, but are not limited to:

- The constitution, historical documents, and SOPs of the Research Ethics Committee (from current up to 5 years, then archived)
- The completed EOI of all Research Ethics Committee Members on a standardised template (in accordance with Human Resources Directorate retention schedule)
- A record of all reimbursements of the Research Ethics Committee (in accordance with Finance Directorate retention schedule)
- All material submitted by an applicant e.g., Applicants' Annual Statement of Compliance /Final Statement of Compliance (from current up to 5 years, then archived)
- All correspondences by Research Ethics Committee members with applicants or concerned parties regarding applications, decisions and follow-up (through the REC Administrator: from current up to 5 years, then archived)
- The notification of adverse effects, the completion or premature termination of a study and a summary of the reasons (from current up to 5 years, then archived)
- The agenda of all Research Ethics Committee meetings (from current up to 5 years, then archived)
- The minutes of all Research Ethics Committee meetings which should include members present, third parties present, time, date and place of meeting (from current up to 5 years, then archived)
- Annual reports of the Research Ethics Committee (from current up to 5 years, then archived)

Master copies of documents should be kept by the REC Administrator in accordance with Tusla's Data Protection Policy and Retention schedules for the periods noted above.

All hard copy documentation held by REC members should be returned to the REC Administrator and destroyed, upon review of applications.

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<sup>20</sup> [https://www.tusla.ie/uploads/content/Tusla\\_Data\\_Management\\_Strategy\\_2019-2022.pdf](https://www.tusla.ie/uploads/content/Tusla_Data_Management_Strategy_2019-2022.pdf)  
<https://www.tusla.ie/about/privacy-statement/>

# APPENDIX 8: Distress Protocol for Research Ethics Committee members

This distress protocol is designed for members of the Tusla Independent Research Ethics Committee (REC). The content should be adapted according to the specific circumstances, constraints and risks for each REC meeting.

## Introduction

Tusla Child and Family Agency adhere to the highest possible standards in research to maximise benefit of our research and its wider contribution to society. We wish to ensure that research is conducted to the highest standards, the wellbeing and best interest of children and young people are paramount, and that all research participants are protected from harm and exploitation within these processes and children's and young people's participation rights are supported. All members of the Tusla Independent REC will uphold Tusla's values of courage, trust, respect, kindness and empowerment.

When involving and/or engaging members of the REC in approval processes, Tusla acknowledges that it has a duty of care to provide a safe, supportive environment for everyone. The principles underpinning this document are built on the foundation of autonomy, beneficence (and non-maleficence), and justice and Tusla's values.

Whilst it is unlikely that involvement on the REC will result in a distressing situation, it is important to consider any emotional upset or distress that may arise from reviewing applications and/or discussing sensitive research topics that are close to an individual's lived experience. This protocol outlines the procedures in place should any member of the committee become upset or experience distress whilst in their role on the committee.

## Roles and responsibilities

It is the responsibility of the Chair of the REC to ensure that all REC members are fully informed about the procedures and are working in a safe environment during their involvement with the REC committee.

## Recruitment to the REC

Before joining the REC, it is recommended that a personal statement be completed as part of the skills match process for all new members. This may include information about a person's motivations for becoming a REC member and any additional information, including conflicts of interest, which may impinge on their participation on the REC.

## Supporting information

All members will be supplied with an information sheet with details of support, which they can access if they experience distress as a result of their role on the REC. The Chair of the REC will strive to ensure that the committee operates as a positive and supportive environment upholding the values of Tusla and will encourage members of the REC to support each other via peer support mechanisms.

## The protocol

The majority of the REC committee meetings are held online, with a small number of meetings being in person. It is recognised that this brings particular challenges in terms of a REC member being able to report within an online meeting that they are experiencing distress. It is also potentially more challenging for other members to recognise signs of distress. This protocol will set out separate processes and procedures for online and in person meetings though it is recognised there will be commonalities.

**During involvement on the REC**

A REC member may experience distress or feel uncomfortable as part of the review process (before a meeting) or during their involvement in a meeting. This could be demonstrated by the person making statements or showing behaviours that:

1. Show they are feeling uncomfortable, upset or distressed.
2. Reveal that they may be considering hurting themselves.
3. Reveal that they are considering hurting someone else.
4. Reveal that they may be in danger if another person found out about their role on the REC.

**Online meeting procedure**

In the event of any concerns becoming apparent, or in the event of a member either personally raising their distress, or another member raising concerns about a distressed member, the Chair will suggest they take a break from the meeting. The Chair or REC administrator will contact the person as soon as practicable to check on their welfare and to listen and offer support. If the person has peer support from another member of the committee, then it may be appropriate to link them with that person.

If the person wishes to rejoin the meeting, they should be allowed to do so if the source of their distress has been identified and is no longer an issue. The Chair will monitor the conduct of the meeting and continue to offer support. The person should be told that they can withdraw from the meeting at any time.

After the meeting, the Chair will discuss options for continued support with the person. The options are:

- Encourage the member to speak to another committee member for support.
- For the person to contact a member of the Tusla Psychology committee so they can act as triage and signpost the person to the most appropriate and available support.
- To call a family member, a friend, or the emergency contact to ask them to make contact or visit the person.
- In cases of high distress, to call for emergency help from the ambulance or police service, or other if the person is in current contact with services.

**In-person meeting procedure**

In the event of any concerns becoming apparent, or in the event of a member either personally raising their distress, or another member raising concerns about a distressed member, the Chair will suggest they take a break from the meeting. They may be encouraged to go to another room in order to take time out. The chair or the administrator should check on their welfare should they choose to leave the meeting or another member of the REC, known to them, may wish to offer support. The person should be asked about their feelings and listened to. If the person wishes to continue in the meeting, they should be told that they can take a break from the meeting at any time they wish

The Chair will discuss options for continued support with the person. The options are:

- Encourage the member to speak to another committee member for support.
- Continued support from the Chair who might signpost them to other support such as the Tusla Psychology committee so they can act as triage and signpost the person to the most appropriate and available support.
- To offer the opportunity to set out a plan of support that enables their continued participation, to withdraw from the REC for a period of time, or to fully withdraw from the REC if they feel that is the best course of action.
- To call a family member, a friend, or the emergency contact to ask them to make contact and attend the meeting venue to meet the person.
- In cases of high distress, to call for emergency help from the ambulance or police service, or other if the person is in current contact with services.

**Follow up actions**

It is the responsibility of the Chair to follow up with the REC member after the meeting. The following actions may be taken:

- A phone call the following day.
- The opportunity to develop a support plan to enable them to continue to participate in the REC.
- Withdrawal from the REC for a specified time period or full withdrawal from the REC if they feel that is the best course of action.
- The member contacts external support services as identified by the Tusla Psychology committee and obtains continued support. Tusla staff members may access EAP services.
- Consideration should also be given to whether any other members of the REC have been impacted and need support or peer support.
- In advance of the next REC meeting, the person should be contacted and any support they require to attend should be identified.

**Distress Protocol - on line meetings**



**Distress protocol – in person meetings**



**Review of Distress Protocol:** The Chair of the REC will continue to monitor the wellbeing of committee members in collaboration with the REC administrator. Any incidents of distress or upset will be anonymously recorded and reviewed and the provision of support will be reviewed when the SOP is reviewed. If more support is deemed necessary for the REC committee, then a suitable approach (e.g., procurement of a bespoke support service for the committee) will be considered and explored.

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The logo for TUSLA, featuring the word 'TUSLA' in a bold, white, sans-serif font. The letter 'U' is stylized with a white dot above it, resembling a child's head or a specific character.

An Ghníomhaireacht um  
Leanaí agus an Teaghlach  
Child and Family Agency