Determining when Ethical Approval is Required; Guidance for Tusla Child and Family Agency staff

Prepared by Dr Edel Tierney National Research Officer

Document Reference Number	
Revision Number	
Approval Date	November 2020
Next Revision Date	November 2023
Document Developed By	Edel Tierney
Document Approved By	
Responsibility for Implementation	National Research Office
Responsibility for Review and Audit	

Table of Contents

1. Introduction

This guidance is situated within the Child and Family Agency Act 2013, which specifies a role of the Agency to undertake or commission research relating to its functions. The National Research Office (NRO) was set up to undertake this role underpinned by Tusla Research Strategy 2015-2017. The NRO also operates within the policy context of Better Outcomes Brighter Futures; the National policy framework for children and young people 2014-2020 highlighting the importance of transforming policies and services through stronger coordination, collaboration and implementation across Government, to achieve the best outcomes for children, young people and families (DCYA, 2014).

More recently, the Tusla Corporate Plan 2018-2020 and in particular, the following strategic objectives are relevant to the role of research in Tusla:

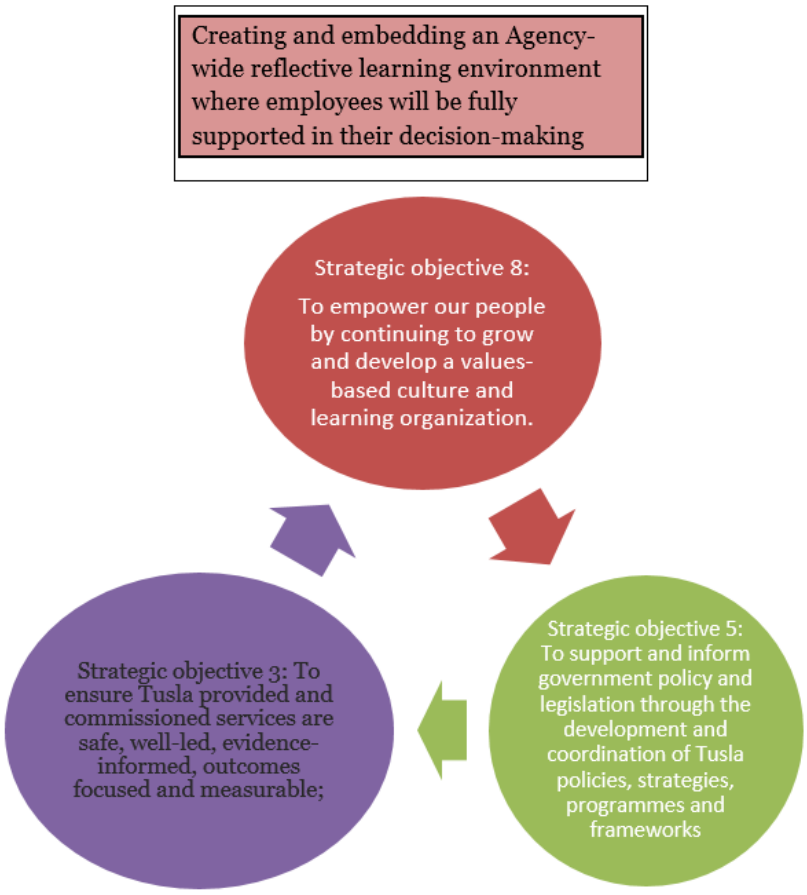

Figure 1: Tusla Corporate Plan 2018-2020 and related objectives which inform this guidance document[1]

[1] https://www.tusla.ie/uploads/content/Tusla_Corporate_Plan_20-18_-_2020.PDF

To support evidence-informed decision-making and ensure that services are designed to deliver improved outcomes for service users, the Agency has increasingly prioritised and invested in research through the Tusla National Research Office.

Within this context, Tusla approved Research Ethics Committee (REC) Guidelines in June 2015[2] and set out the rationale, membership and protocols for the Agency's Research Ethics Committee (REC) and the basis for ethical review of research. Section 4.12 of these guidelines outlines exceptions not considered research; namely routine audit, performance service reviews, quality assurance studies or reviews and testing within normal education requirements[3]. Tusla holds personal sensitive data on children and families and when there is a lack of clarity about what category a data collection project falls into i.e. research, audit, quality improvement or consultation, there is a risk that the work is not conducted to the highest ethical standards. This creates a risk for the Agency and for those involved in the work. This guidance is intended to support such activities to be conducted within an ethical and rights based framework.

2. Purpose

The purpose of this guidance is to support Tusla staff in making decisions about what category their project falls into and whether research ethical approval is required to proceed with their project.

The principles underpinning this document are that research is conducted to the highest standards, the wellbeing and best interests of children and young people are paramount, and that ***all*** *r*esearch participants are protected from harm and exploitation within these processes and children's and young people's participation rights are supported. All users of this guidance will uphold the values of courage, trust, respect, compassion, empathy and inclusion for each other (adapted from Tusla's Corporate Plan 2018-2020).

3. Scope

The scope of this document is for all Tusla staff, involved in projects involving human participants and data collection activities. Data collection activities refer to data collected on or about service users and their families or staff in pursuing quality improvement initiatives, audit or consultation as well as research. The intention of this guidance is to set out clearly the definitions of research, audit, consultation and quality improvement so that the reader is clear about whether or not ethical approval is required for their work to proceed.

---

[2] https://www.tusla.ie/uploads/content/Research_Ethics_Committee_Guidelines_Final_June_2015.pdf

[3] For the purpose of this guidance, and in accordance with Tusla practices, the headings of Research, Audit, Quality Improvement and Consultation, will be utilised.

4. Legislation and Other Related Policies

This paper is also cognisant of other legal and policy contexts such as the United Nations *Convention on the Rights of the Child* (UNCRC 2009)**,** *Children First Act 2015, Children First: National Guidance for the Protection and Welfare of Children (DCYA 2017)*, and the Tusla Child and Youth Participation Strategy 2019 – 2023.

Tusla Research Ethics Committee (REC) Guidelines (2015) and Research Ethics Application form (2019) underpin this guide.

Tusla Child and Family Agency Tusla Quality Improvement Framework 'A Tusla Approach to Improving the Quality and Safety of Services' (2016)[4] and

Tusla Child and Family Agency Quality Assurance Audits (2016) A Guide for Staff[5] are also drawn on.

5. Roles and Responsibilities

5.1 Role of NRO

The Role of the NRO is to support the research activities across Tusla. The NRO have a role in supporting researchers and staff to decide which activity their data collection activity falls into and providing advice about the appropriate actions to take[6]. In addition to a supporting role, the NRO have an oversight role in ensuring best practice in research ethical approval processes are adhered to and providing guidance on processes for access to Tusla data.

5.2 Role of Tusla Research Ethics Committee (REC)

Tusla's Research Ethics Committee is responsible for assessing the benefits and risks of proposed studies for research participants, Tusla Child and Family Agency and wider society. Tusla research ethical approval is required where proposed research relates to the following:

- 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.

The aim of Tusla's REC is to facilitate good quality research that promotes best practice in research in support of securing best outcomes for children and families and to ensure the protection of participants in approved research projects. This promotes a

[4] https://www.tusla.ie/uploads/content/QA_Quality_Improvement_Framework.pdf
[5] Quality Assurance Directorate (2019) Tusla Audit Methodologies A Guide for Staff V0.6
[6] Contact details for the NRO staff are available https://www.tusla.ie/research/tusla-research-office

research culture and ensures public confidence in and about the conduct of researchers and the dignity, rights, safety and well-being of research participants.

5.3 Role of Staff

The role of staff is to familiarise themselves about the difference between the various data collection activities and seek advice from NRO or REC administrator about whether Tusla ethical approval is required for their data collection activity.

5.4 Role of Research Sponsors

As it relates to this guidance, Tusla Research Commissioners/Sponsors[7] are responsible for:

- Identifying and taking responsibility for the initiation, management and financing of a proposed research study.
- Signing off on a proposed research study on behalf of the Agency.
- Dissemination of the findings and learning from the research to relevant stakeholders and audiences.

5.5 Role of Consultation Sponsors

As it relates to this guidance, consultation sponsors[3] are responsible for:

- Identifying opportunities for consultation with children and young people families and staff in an effort to seek advice about a particular service or activity
- Taking responsibility for the initiation of the consultation and identifying how the information gathered may be used to improve the quality of service Tusla provides or how it can inform future projects or activities.
- Determining when ethical approval may be required for their consultation activities as per this guidance.

5.6 Role of Research and Information Mentors

As it relates to this guidance, Tusla Research and Information Mentors (RIMs) can support Tusla staff in the planning or the design stage of data collection, consultation or research and sign-posting to ethical approval processes as and when this is required. They may also support staff by promoting and supporting access to research and information resources on the Tusla Research centre website. More information about the RIM can be found on the Tusla Research Centre[8]

5.7 Role of Quality Assurance

The Quality Assurance (QA) Directorate is responsible for promoting continuous improvement and effective risk management in services for children and families by: Objectively assessing, monitoring and reporting on the quality and safety of services, tracking and driving the reduction of identified risks and providing systems, information and tools that support service improvement.

[7] Research commissioners/sponsors/consultation sponsors in Tusla should be at SMT, Director, Service Director or Area Manager level.

[8] https://www.tusla.ie/research/research-and-information-mentors

As it relates to this guidance, the role of QA is to direct QA staff to this guidance if they are unclear if their project requires research ethics approval

6. Glossary of Terms and Definitions: Defining Research, Audit, Quality Improvement and Consultation

6.1 What is Research?

Research is defined as a "process through which we attempt to achieve systematically and with the support of data the answer to a question, the resolution of a problem, or a greater understanding of a problem" (Leedy, 1997:5). Research aims to extend knowledge and knowledge must be transferrable.

- It takes hypotheses and tests them to either refute them or allow them to be accepted as scientific fact.
- It attempts to establish what is best practice, determines when an intervention will be able to make a real difference or what is the best intervention that can be made.
- It tests the links between processes of care and the outcomes of care (Bull, 1993; National Patient Safety Agency, 2007; Smith 1992).

Research must allow its results to be repeated in other similar situations and thus must treat the study population as a sample of a wider population.

Exploratory research is also applicable here. Exploratory research is not typically generalizable to the population at large and can be used when the topic or issue is new and when data is difficult to collect (Babbie 2007). Exploratory research is flexible and can address research questions of all types.

6.2 What is Audit?

Audit is a component of any good quality assurance system. It seeks to extend the knowledge of a practitioner about their own practice (Bull, 1993). Audit depends on scientific knowledge and assesses whether the knowledge is being applied in a given practice. Audit may be defined as evaluation or review against a defined set of evidence based standards or what is recognised as representing 'best practice' within a specific profession or work setting[9]. Within social work and social care settings, the term 'social care audit'[10] is increasingly used.

In Tusla, audit may be undertaken with reference to the following:

- National Standards for Child Protection, Foster Care, Residential Care, Special Care
- Statutory regulations and legislation (for example: Children First, Child Care Act 1991)

[9]See: http://www.northerntrust.hscni.net/pdf/Definitions_document.pdf;

[10] For example: London Borough of Bexley (2017) *Children's Social Care Quality Assurance Framework*; Social Care Institute for Excellence see: https://www.scie-socialcareonline.org.uk/social-care-audit-in-practice/r/a110f00000NeCTHAA3

- Policies, Procedures, Guidance and protocols
- National approach to practice in social work and social care (e.g., Signs of Safety[11], Well Tree Model[12]).

The aim of audit is to support service and quality improvement within the organisation. See Appendix 1 for further information.

6.3 What is Quality Improvement?

Quality improvement (QI) in health/social care is a process by which individuals work together to improve systems and processes with the intention to improve outcomes. The distinct and fundamental difference between QI and research is the *purpose*. Quality improvement is conducted to improve care for a specific population or service delivery (Cassarett et al 2000).

Although QI initiatives are diverse, they generally can be understood as small-scale cycles of interventions that are linked to assessment and that have the goal of improving the process, outcome, and efficiency of complex systems of health and social care (Cassarett et al 2000).

The Tusla 'Quality Improvement Framework[13] is the principal quality improvement system for the Agency. The Quality Assurance Directorate recommends supporting methodologies and tools to support services review and improve their services, such as specific practice audit tools, appreciative enquiry methodologies and lean practice methods. These initiatives may include satisfaction surveys of stakeholders'/service users.

6.4 What is Consultation?

Consultation involves asking members of the public/stakeholders/service users for their views and then using those views to inform decision-making[14]. More specifically, consultation *with children and young people* refers to the myriad of processes by which children and young people's input and views on matters affecting them are sought (CCYP Ethical Consultation Policy and Procedure 2018). Consultation is more than a one -off event. It involves sustained engagement over time. What occurs before and after the consultations is as important as the consultations themselves (Harris & Mantakis, 2013). The overall aim of consultation is to discover what people know about a service or organizational needs. Stakeholder consultation involves the development of constructive, productive relationships over the long term and has a number of benefits (see INVOLVE 2012, CCYP Ethical Consultation Policy and Procedure 2018) and is important for the long-term effectiveness of an organisation, responsive to the needs of its users (Jarrett and Land 2017). Consultation may form part of research, audit and QI processes. It may also take a variety of forms e.g., meetings or focus groups. However, consultation also bears challenges e.g., consultation fatigue, time

[11]See: https://www.signsofsafety.net/signs-of-safety-adopted-as-national-child-protection-framework-for-ireland/

[12] https://www.tusla.ie/uploads/content/Tusla_2017_Annual_Report_final_13.07.18.pdf: p.21, A.3.4

[13] Tusla Child and Family Agency Tusla Quality Improvement Framework A Tusla Approach to Improving the Quality and Safety of Services (2016)

[14] See https://www.invo.org.uk/

and representation (INVOLVE 2012). There is no one correct way to consult with children and young people but there are key principles and values that may guide consultation exercises (see Department of Children and Youth Affairs, 2015; Harris & Mantakis, 2013)

6.5 What are the similarities and differences between research, audit, QI and consultation?

Research, audit, QI and consultation differ from normal clinical/ professional practice because such 'normal' practice rarely achieves such a high standard of data collection and analysis.

There are many similarities between these activities. They all

- start with a question
- depend on a spirit of inquiry and may use similar methods
- expect the answer to change or influence practice
- require formal data collection
- depend on using appropriate methods and design to reach sound conclusions
- require attention to ethical practice in data collection and analysis
- have common questions which frame the activity involved (see table 1).

Table 1 Common questions in respect of the data collection process across the activities:

What type of data will be collected (quantitative and /or qualitative)?
What data sources will be used to find the data?
What methods will be used to gather data? For example, Document review, Surveys, Interviews, Observation of practice, Focus groups etc.
Will data collection tool (e.g., questionnaire, data collection form) be required and is there one available?
Is a pilot necessary?
Will the exercise require a visit to the sites under investigation or will it be a desk-based exercise?
Who will be collecting the data?
How will I ensure data quality?
Does data collection comply with data protection legislation?

Therefore, while the data collection practices within research, audit, QI, and consultation can overlap, how to decide what category your work fits into can be difficult as sometimes the boundaries are not clear-cut.
This guideline draws from the literature and an adaption of a table developed by the National Patient Safety Agency 2007, to assist Tusla staff /researchers to determine

the similarities and differences between research, audit, QI and consultation (see table 2).

Table 2: Is ethical approval required for your project? How to distinguish research, audit, quality improvement and consultation (adopted from National Patient Safety Agency 2007)

RESEARCH	**QUALITY IMPROVEMENT**	**AUDIT**	**CONSULTATION**
The attempt to derive generalizable new knowledge. Tests the links between processes of care and the outcome of care. Knowledge must be transferrable.	A process by which individuals work together to improve systems and processes with the intention to improve outcomes. Goal is to improve the quality of health/ social care.	Seeks to extend the knowledge of a practitioner about their own practice. Designed and conducted to produce information to inform delivery of best care.	Seeks to discover what people know about a service or organizational needs.
One off activity Change not inevitable.	Small-scale cycles of interventions that linked to assessment with a goal of improving the process, outcome, and efficiency of complex systems of health care.	Usually ongoing Potentially leads to change.	Can take a variety of forms e.g., consultation on specific developments, projects, initiatives or ongoing consultation to track and monitor stakeholder perceptions within the broader environment.
Addresses clearly defined questions, aims and objectives	Designed to answer, "What standard does this service achieve?" Measures current service without reference to a standard.	Designed to answer "Does this service reach a predetermined standard?" Measures change against a standard	Designed to develop a more comprehensive understanding of stakeholders' views of their experiences or about a service. Involves asking members of the public/stakeholders/service users for their views and then using those views to inform decision-making.

RESEARCH	QUALITY IMPROVEMENT	AUDIT	CONSULTATION
Quantitative research – may involve evaluating or comparing interventions, particularly new ones. **Qualitative research** – usually involves studying how interventions and relationships are experienced.	Involves an intervention in use only.	Involves an intervention in use only.	May involve workshops/focus groups meetings with stakeholders to identify key priorities and areas of interest and concern.
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.	Usually involves analysis of existing data but may include administration of interviews or questionnaires. Usually employs limited measures that do not take a long time to complete or are not difficult to administer. These initiatives maybe descriptive, such as satisfaction surveys of stakeholders.	Usually involves analysis of existing data but may include administration of interviews or questionnaires. Usually employs limited measures that do not take a long time to complete or are not difficult to administer.	The method of consultation will need to be identified, balancing the resources available and the level of feedback required. Innovative approaches will assist children and young people's participation in consultations.
The burdens of research to the participant may be time commitment and inconvenience, as well as risk (e.g., physical, psychological, legal, financial), often with no or little prospect of direct benefit.	No additional risk or burden to participants. Informed consent may be required.	No additional risk or burden to participants. Informed consent may be required.	Will deliver strategies to minimise risk, increase engagement and improve outcomes for all the parties. Informed consent from all participants is required. In addition, informed consent is required from parents/guardians of children and young people under 18 years.

RESEARCH	QUALITY IMPROVEMENT	AUDIT	CONSULTATION
Informed consent is necessary. In addition, informed consent is required from parents/guardians of children and young people under 18 years.			
Variety of sampling methods may be employed including randomisation, purposeful sampling, snowball sampling etc.	No allocation to intervention: the health professional and patient have chosen intervention before service evaluation. No randomisation	No allocation to intervention: the health professional and patient have chosen intervention before audit. No randomisation.	Involves sampling a reference or representative group who can speak on the experiences of the user group. Variety of sampling methods may be employed including randomisation, purposeful sampling, snowball sampling etc.
May not benefit service users, patients, staff or providers. Direct personal benefit is not the primary concern.	May benefit service users, patients, staff, or providers. Intention is to improve service delivery	May benefit service users, patients, staff, or providers. Intention is to ensure service delivery meets a required standard.	Represents good governance and transparency, demonstrates a desire to engage in meaningful two-way communication, and recognises the important contribution stakeholders at all levels can make to future changes which will directly or indirectly affect them.
Results of the project will be publishable or generalizable outside their institution.	Results of the project may be publishable or generalizable outside their institution.	Results of the project will not be publishable or generalizable outside their institution.	Results of the project will not be publishable or generalizable outside their institution but may inform future initiatives.
Requires Research Ethics Committee review.	Does not usually require Research Ethics Committee review	Does not require Research Ethics Committee review	Does not usually require Research Ethics Committee Review.

7. Guidance on the research ethics approval process

Sometimes determining the intent of a data collection activity is difficult, but the study objective should provide insight.
If the project seeks to test an existing data collection process, it is most likely QI or audit.
If it seeks information to further plan a research project or QI initiative, then it is consultation.
If, however, the aim is to evaluate an innovation to an existing process, to study something completely new, or to analyse a process that has not yet been subjected to rigorous scientific analysis, then the project is defined as research.
A project may have more than one intent; in such a case, a judgement is needed as to what the primary aim is. This determines what category it fits into and what process needs to be followed.
This section examines the ethical concerns which need to be considered for research, audit, QI and consultation and provides advice on the appropriate processes for each to ensure best ethical practice is upheld.

The following questions may help to tease out if ethical approval is required.

- How much does this project or activity deviate from current normal (accepted, local, clinical/service practice?
- What is the (additional) burden imposed on the participants or others?
- What (additional) risks are posed to the participant or others?
- What benefit might occur for the participants or others?
- What are the potential benefits to society (for stakeholders'/future clients/patients/service users)?

(Wade 2005)

A staff member may contact the REC Administrator in the first instance if they have a query about their project. They may also consult these guidelines especially Table 2 to determine if their project requires ethical approval.

7.1 Ethical considerations for research

Research practice requires particular attention to data collection and analysis and the ethical considerations for research activity require additional ethical scrutiny. Therefore, ethical approval by a Research Ethics Committee (REC) is required.

If ethical approval is determined necessary, then the applicant can submit a research proposal on the Agency approved ethics application form and submit to the REC for approval. The REC will review the research proposal in terms of ethical appropriateness and will consider the design of the research, the outputs of the research and the proposed conduct of the research. Following review of the proposal at the REC meeting, discussion will take place and a decision will be made to (1) grant

approval, (2) approve with clarifications, (3) request a resubmission or (4) withdraw the application. All applicants will be informed of this decision within 10 working days and any follow up actions required.
All information on the Research ethics approval process can be found on the Research Centre website[15].

In the main, ethical approval is not required for quality improvement initiatives, audits or consultation. However, some ethical considerations need to be taken into account when undertaking these activities. These are outlined below.

7.2 Ethical considerations for audit

By definition, audit does not involve anything being done to service users beyond 'normal' service provision and therefore does not require formal ethical approval (UHB 2005). However, audit methodology should be appropriate to the objectives of the audit. Methods used need to be clearly documented to answer any future queries and to be able to replicate the audit elsewhere or at re-audit stage. Some issues to consider when conducting an audit include consent, data protection and involvement of service users in audits (See Appendix 1)[16].

Where children and families are involved in audit programmes their role needs to be clearly defined and appropriate support and guidance provided to enable participation. This should include the provision of information and guidance in relation to data protection requirements. Refer to the staff guide for information on the inclusion of children and families in audit.

7.3 Ethical considerations for consultation

In the main, ethical approval is not required for consulting with stakeholders in quality improvement initiatives, audits or in the planning or the design stage of research. Involving stakeholders in the design and development of research does not generally raise any ethical concerns. This is because they are not acting in the same way as research participants. They are acting as advisers, providing valuable knowledge and expertise based on their experience of a health condition, and/or use of social care or public health services or in their role as a carer (INVOLVE 2012). For consultation more broadly i.e., on service design and delivery, opinion differs about whether ethical approval should be sought (see CCYP Ethical Consultation Policy and Procedure, 2018).

Activity where the risk level is higher than 'low risk' may involve discussions with Tusla REC. The REC Administrator, in consultation with REC Chair will ask the Consultation sponsor to devise a consultation proposal, and the activities involved, so that the risk level can be determined or seek advice and direction from the full REC, if appropriate. Where advice and direction is sought from REC, they may advise on how the risk could be fully mitigated or minimised, whether the risk is justified in the context of the

[15] https://www.tusla.ie/research/tusla-research-office/research-ethics-committee/
[16] Quality Assurance Directorate Tusla Audit Methodologies: A GUIDE FOR STAFF

benefits of the consultation, and/or whether the risk can be appropriately managed to ensure that the participants are not harmed in any way.

If Tusla staff are unclear about whether they need ethical approval for their consultation activity, the consultation sponsor should develop a consultation proposal.

A consultation proposal should provide an outline of:

- The purpose of the consultation
- The mandate for the consultation
- The intended consultation process, including details of actual project activities; and
- An assessment of risk to children, young people and other participants in the consultation.

Further ethical considerations in Audit, QI and consultation are discussed in Appendix 2.

8. Conclusion

Research is essential to a modern and effective health and social care system. Research also contributes to the efficiency and effectiveness of the content, planning, delivery and monitoring of health and social care and plays an important role in the knowledge economy (HIQA 2012). Research governance is principally concerned with improving research through the regulation and assurance of research quality and research ethics. However, the difference between QI, consultation, research and audit is not always clear. A clear understanding of the differentiation between audit, QI, consultation and research will enhance evidence-based practice.

9. Guideline review

This guideline will be reviewed by the National Research Office Research Policy Working Group every 3 years. The updated document will then be submitted to NPOC for approval and upload onto Tusla's Policy Catalogue

10. References

Babbie, E. (2007) The Practice of Social Research. 11th edition. Belmont CA: Thompson - Wadsworth. pp. 87-89.

Bull, A.R. (1993) Audit and Research: Complementary but distinct. Annals of the Royal College of Surgeons of England; 75, 308-311

Casserat D, et al. (2000) Determining when Quality Improvement Initiatives should be considered research. Journal of the American Medical Association; 283: 2275.

CCYP Ethical Consultation Policy and Procedure (2018) Commissioner for Children and Young People Tasmania https://www.childcomm.tas.gov.au/wp-content/uploads/2018/04/Ethical-Consultation-Policy-and-Procedure-Version-1.0_16-March-2018-APPROVED.pdf

Data Protection Act (2018) (Health Research) Regulations 2018 (Section 36(2)): Available at: http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf

Data Protection Commissioners (2007) Data Protection Guidelines on research in the Health Sector. Dublin: Data Protection Commissioners. Available at: https://www.dataprotection.ie/documents/guidance/Health_research.pdf

Department of Children and Youth Affairs (2017) Children First: National Guidance for the Protection and Welfare of Children, Dublin: Dublin: Department of Children and Youth Affairs.

Department of Children and Youth Affairs (2015) A practical guide to including seldom heard children and young people in decision making. Dublin: Dublin: Department of Children and Youth Affairs. Available at: https://www.comhairlenanog.ie/wp-content/uploads/2014/10/Seldom-Heard-toolkit.pdf

GDPR guidelines (2018) Data Protection and the General Data Protection Regulation (GDPR) https://dbei.gov.ie/en/Data-Protection/

Government of Ireland (2015) Child Care Act. http://www.irishstatutebook.ie/

Hanley, B. et al (2004) 'Involving the public in research and development in the NHS, Public Health and Social Care: Briefing Notes for Researchers' INVOLVE.

Harris, P., & Manatakis, H. (2013) Children's Voices: A principled framework for children and young people's participation as valued citizens and learners. University of South Australia in partnership with the South Australian Department for Education and Child Development, Adelaide

Health Service Executive (2013) A Practical Guide to Clinical Audit. Available from http://www.hse.ie/eng/about/Who/qualityandpatientsafety/Clinical_Audit/clauditfilespdfs/practicalguideclaudit2013.pdf

HSE National Consent Policy (HSE 2013) https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/consent/national-consent-policy-august-2017.pdf

HIQA (2012) International Review of Ethics Structures https://www.hiqa.ie/system/files/Intl-Review-Research-Ethics-Structures.pdf

INVOLVE (2012) Briefing notes for researchers: involving the public in NHS, public health and social care research. INVOLVE, Eastleigh

INVOLVE (2019) https://www.invo.org.uk/current-work/involving-children-and-young-people/

INVOLVE (2009) Patient and public involvement in research and research ethics committee review www.involve.nihr.ac.uk/resource-centre/publications-by-involve/

INVOLVE, Health Research Authority (2016) The impact of public involvement on ethical aspects of research, INVOLVE: Southampton.

Jarrett, C and Land, N. (2017) Doing Research with People Who Are Not Users: Consultation https://www.uxmatters.com/mt/archives/2017/08/doing-research-with-people-who-are-not-users-consultation.php

Kirby P. (2004) 'A Guide to Actively Involving Young People in Research: For researchers, research commissioners, and managers'. INVOLVE: Southampton.

Laura Lynn Children's Hospice Guidelines for Applicants to the Laura Lynn Research Ethics Committee.

Leedy P.D. (1997) Practical Research: Planning and Design (6th Edition). Upper Saddle River; New Jersey: Prentice- Hall.

Morgan, C.A. (2018) Stakeholder Research & Consultation: Keep Your Ears to the Ground https://www.b2binternational.com/publications/stakeholder-research

National Patient Safety Agency (2007) Defining Research, National Research Ethics Service, National Patient Safety Agency; London. http://www.pi.nhs.uk/data/consent/NRES_leaflet_Defining_Research.pdf

Newhouse, R; Pettit, J C. Poe, S, Rocco, L. (2006) The Slippery Slope: Differentiating Between Quality Improvement and Research. The Journal of Nursing Administration Issue: Volume 36(4), pp 211-219

Smith R. (1992) Audit and Research. British Medical Journal 305: 905. Available at: www.bmj.com

Schutt, Russell K. (2011) Investigating the social world: The process and practice of research. Pine Forge Press.

Tusla Child and Family Agency Tusla Corporate Plan 2018-2020 https://www.tusla.ie/uploads/content/Tusla_Corporate_Plan_20-18_-_2020.PDF

Tusla Child and Youth Participation Strategy 2019 - 2023 https://www.tusla.ie/uploads/content/tusla_child_and_youth_participation_strategy-2019-2023.pdf

Tusla Child and Family Agency (2016) Tusla Quality Improvement Framework: A Tusla Approach to Improving the Quality and Safety of Services. https://www.tusla.ie/uploads/content/QA_Quality_Improvement_Framework.pdf

Tusla Child and Family Agency (2016) Quality Assurance Audits: A Guide For Staff http://hsenet.hse.ie/childfamilyagency/QA_Assurance_Audits.pdf

Tusla Child and Family Agency (2017) Tusla Organisation Risk Management Policy and Procedure
http://hsenet.hse.ie/childfamilyagency/QA_Org_Risk_Management.pdf

Tusla Child and Family Agency (2015) *Research Ethics Committee Guidelines*. Tusla Child and Family Agency: Dublin.

http://www.tusla.ie/uploads/content/Research_Ethics_Committee_Guidelines_Final_June_2015.pdf

Tusla Child and Family Agency (2015) *Research Strategy 2015-2107*. Tusla Child and Family Agency: Dublin.
http://www.tusla.ie/uploads/content/Research_Strategy_Final_09.02.pdf

Tusla Child and Family Agency (2018) Data Privacy Policy. Tusla Child and Family Agency: Dublin.
https://www.tusla.ie/uploads/content/Tusla_Privacy_Policy.pdf

Child and Family Agency (2017) Record Management Policy. Tusla Child and Family Agency: Dublin.
http://hsenet.hse.ie/childfamilyagency/Risk_Records_Management_Policy.pdf

University Hospitals Bristol NHS Foundation Trust (2005). Clinical Audit 'How to Guides'. http://www.uhbristol.nhs.uk/for-clinicians/clinicalaudit/how-to-guides

UN Committee on the Rights of the Child (2009) General Comment no. 12: The Rights of the Child to be Heard. Geneva: UN.

Wade D. (2005) Ethics audit and all shades of grey. British Medical Journal. 330: 468.

Appendices

Appendix 1 Audit Methodologies in Tusla

Two distinct Audit methodologies are used within Tusla:

1. Audit (measurement of compliance with standards, policies and procedures).
   Audit involves tracing activities and systems along 'audit paths' to see if things happened the way they should have e.g., tracing a complaint received from a child/family from the initial letter of complaint through to resolution to establish if recommended procedures were followed appropriately.
2. Collaborative Case Audit (in accordance with Tusla's National approach to practice, Signs of Safety).
   The collaborative case audit approach, in contrast to a traditional audit provides a qualitative and collaborative focus in exploring best practice in more depth through a process of self-assessment, engagement and individual discussion with staff in relation to their work, utilizing the principles and 'questioning' approach of Signs of Safety.

Appendix 2: How to distinguish research from audit, QI and consultation

There are two factors that help distinguish QI, consultation, audit and research.

The first factor is **the intent** of the investigator as defined by the expressed purpose of the proposed project, specifying who may benefit from the project. The second major factor concerns the **risks and burdens** imposed on the participants in the project.

	Intent	**Risks and burdens**
Research	Research is intended to provide knowledge that is generalizable to populations for use by clinicians, researchers, practitioners or the broader scientific community, not to assess the success of an existing process for purposes of system improvement.	In research, the participants are at greater risk of harm knowing in advance that personal benefit may not result. They must understand that they are volunteers in the project. The burdens of research to the participant may be time commitment and inconvenience, as well as risk (e.g., physical, psychological, legal, financial), often with no or little prospect of direct benefit.
QI and Audit	The purpose of QI and audit is to improve care processes within a specific unit or organization.	In QI and audit, the objective is to benefit those who are served by the sector/service area; thus, the risk of

Consultation	The intent of consultation is to discover what people know about a service, or organizational needs.	"participation" is the same as the risk of receiving clinical or social care. To minimise risk in consultation a consultation proposal may be developed. A consultation proposal will assess the risk to children, young people and other participants associated with the consultation e.g., gauging their probability and severity; assessing the extent to which they can be minimised; and determining how they can be managed.

Appendix 3: Other ethical issues to consider in Audit, Consultation and QI initiatives

Consent: In terms of consent, guidance from the HSE National Consent Policy states: "…an integral component of modern health and social care is the use of audit and quality assurance programmes to ensure that the care provided is of the highest quality when benchmarked against national and international standards. Consent from the service user is not usually sought in these circumstances except where identifiable data is being made available to a third party. However, it is good practice to make service users aware that such practices occur and that safeguards exist to ensure that their personal information is protected" (HSE 2013 page 40).

Data Protection: Legislation regarding data protection and service user record confidentiality must be complied with when performing audits, QI initiatives and consultation (Data Protection Acts 1988, 2003, and 2018 and Tusla's staff guide on data protection legislation, 2015 GDPR guidelines 2018). Methodologies should be designed so that the confidentiality of personal information is not compromised. When reporting, data should be completely anonymised in every case. No link between conclusions, children/families or individual staff members should be possible.

Involvement: When planning any audit, QI initiative or consultation, the team should consider the possible benefits of including children and families in the process. For example, would it be beneficial to consider their experience of receiving a service? Some common methods for including children and families in the audit process for example, include:

- Gathering feedback from children and families, for example letters of complaint
- Analysis of comments made at forums where children and families are present
- Interviews with children and families

- Surveys
- Focus groups
- Expert user groups
- Examining serious incidents