Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

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IBTS/RD/SOP/0001
IBTS/RD/POL/0001
IBTS/DP/POL/0001

SmartSolve Roles

LAB SCIENTIFIC STAFF MRTC	MED CON MRTC
LAB SCIENTIFIC STAFF NBC	MED CON MSD IBTS
DC DON IBTS	MED CON MV NBC
DC ADON NBC	MED SMO MRTC
DC PDC IBTS	MED SMO NBC
DC CF IBTS	MED SPEC REG NBC
MED CON BMR HLA NBC	QA THOD NBC
MED CON DON NBC	RD LEAD FACILITATOR IBTS
MED CON IH NBC	RD RACO IBTS
MED CON MICRO NBC	TDOQ

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Category	Mobile	Cryobiology	Website	GDP
Yes / No	No	No	Yes	No

TITLE: RESEARCH ETHICS POLICY

Table of Contents

1 INTRODUCTION

This policy describes the research ethical considerations, guiding legislation and internal processes for ensuring all research is carried out in an ethical way. By ensuring that health research is underpinned by ethical principles, we:

- Comply with the principles for good clinical practice
- Promote confidence in our health research,
- Specifically promote confidence within our donors regarding our health research
- Provide reassurance that the interests, dignity, welfare, rights and well-being of research participants are protected
- Ensure participant interests and legal rights take precedence over those of science and society.

2 OBJECTIVES

- To describe the mechanisms required to ensure research is conducted to the highest ethical standard and is in accordance with all legal, health and safety, ethical and regulatory requirements.
- To outline the guiding legislation and best-practice guidelines for ensuring research is carried out in an ethical way
- To outline the process for collecting, storing and protecting data generated from and during research projects.
- To outline our processes for making our own research ethical requirement determination.

3 SCOPE

The purpose of this policy is to outline the mechanisms and guidance necessary to determine whether ethical approval is required for a given project overseen by the Research & Development department.

4 ROLES AND RESPONSIBILITIES

The following are the general Roles and Responsibilities within the organisation associated with the implementation and operation of the Research Practice and Integrity Policy.

Role	Definition	Responsibility
Research Development Committee (RDC)	Sub-committee of the board for all of research activity at the IBTS	The RDC reports directly to the IBTS Board which is tasked with ensuring that there is accountability for nature of R&D within the organisation.
Data Protection Officer (DPO)	Oversees implementation of data protection regulation	All research activity is covered by GDPR, Data Protection Act 2018 and the Health Research Regulation. Oversee Research Ethics Committee applications
Medical and Scientific Director (MSD)	Oversight on the nature of all IBTS research	Interacts directly with RDC and Board of Management. Contribute to an ethical pre-review of research projects
Research and Development Lead Facilitator (RDLF)	Oversight and on-going monitoring on all research activity	The inception, progression and completion of all R&D projects will be centrally monitored through the RDLF. The RDLF is tasked with providing local R&D governance, expert leadership and support within the organisation. Implementing, writing and reviewing the Research practice and integrity policy Devising the Research & Development strategy Determining the framework for conducting research Oversee Research Ethics Committee applications
Principal/Lead investigator (PI)	Individual who supervises / who may have given significant intellectual inputs to the work, but might not actively conduct the experiments	Updates on project progression to 1. RDLF 2. MSD
Researcher	Any individuals involved in a research project	Updates on project progression to: 1. PI 2. RDLF 3. MSD

5 RESEARCH ETHICS POLICY

5.1 Research Ethics definition

Ethical research conduct means applying the relevant fundamental ethical principles and legislation to all aspects of research. The most common ethical issues in research include the following:

- involvement of children, patients and other vulnerable populations
- use of human embryonic stem cells
- concerns regarding privacy and data protection
- research on animals and non-human primates
- impact of research outputs on the environment
- Genetic data

5.2 Principles of Research Ethics

There are a number of health research ethical frameworks from which to base a review of a proposed project. Outlined below are the main principles which are used to provide coherent guidance for applying ethics to clinical research:

Honesty	Being honest: ➢ With the beneficiaries and respondents. ➢ About the findings and methodology of the research. ➢ With other direct and indirect stakeholders.
Integrity	Ensuring honesty and sincerity. Fulfilling agreements and promises. Do not create false expectations or make false promises.
Objectivity	Avoiding bias in experimental design, data analysis, data interpretation, peer review, and other aspects of research.
Informed consent	Informed consent means: ➢ A person knowingly, voluntarily and intelligently gives consent to participate in a research. ➢ The autonomous right of the individual to participate in the research are protected. ➢ Informing the participant about the research objective and purpose, their role, benefits/harms (if any) etc.
Autonomy	Requires that those who are capable of deliberation about their personal goals should be treated with respect for their capacity for self-determination. Protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse.

Beneficence	Maximize the benefits of the participants. Maximize the possible benefits to the respondents. Minimize possible harms to the respondents.
Non-maleficence	Do no harm. Minimize harm/s or risks to participants. Ensure privacy, autonomy and dignity.
Responsible publication	Responsibly publishing to promote and uptake research or knowledge. No duplicate publication.
Protecting anonymity	This involves keeping the participant anonymous by not revealing the name or any other personal information about the participants that may reveal his/her identity.
Non-discrimination	Avoid discrimination on the basis of age, sex, race, ethnicity or other factors that are violation of human rights, and are not related to the study.
Openness	Be open to sharing results, data and other resources. Accept encouraging comments and constructive feedback.
Intellectual property	Respect the licenses of the content used Be careful about possible error and biases. Give credit to the intellectual property of others. Never plagiarize.
Justice	Distribute benefits and burdens fairly. Treat equals equally Give reasons for differential treatment based on widely accepted criteria for just ways to distribute benefits and burdens.

Implementing these ethical principles may be effectively done by considering the following:

Value	Research should: ✓ Have a social, scientific and/or clinical value. ✓ Be important, generalisable, and include a plan for sharing results so that society can benefit. Research should not ✗ waste resources on studies without integral value. ✗ Expose individuals to risk without some scientific or social value.
Validity	Research should: ✓ Be scientifically and methodologically sound and valid. ✓ Be able to answer the research question. ✓ Be practically feasible and possible to execute

Fair subject selection	➢ Scientific goals of the study should determine who the participants or subjects are ➢ Subject exclusion should not depend on convenience but on scientific objectives. ➢ Subjects should be selected in a manner that minimises risks and enhances benefits. ➢ Those who bear the risk of the research study should enjoy its benefits ➢ Those who benefit should share the risk of the research ➢ Including a group of participants because they are either vulnerable or privileged providing 'ease-of-access' is not appropriate
Favourable risk–benefit ratio	The requirement for a favourable risk–benefit ratio embodies the principles of non-maleficence and beneficence, long recognised as fundamental values of clinical research. ✓ Potential risks to individual subjects should be minimised ✓ Potential benefits to individual subjects should be maximised ✓ Potential benefits to individual subjects and society should be greater than or equal to the risks.
Independent review	✓ By am independent committee thereby minimising the impact of potential conflicts of interest. ✓ Reassures the public and potential participants of the validity of the research.
Respect for persons	✓ Respect for individuals throughout study. ✓ Regard for their welfare, rights, beliefs, perceptions, and customs, both individual and collective, of individuals involved in research studies. ✓ Manage personal data in accordance with confidentiality and privacy rules. ✓ Permission and procedure to withdraw from the study without penalty. ✓ Participant welfare should be monitored throughout project. ✓ Appropriate treatment and corrective actions must be provided for adverse reactions ✓ Mechanism to inform participants of what was learned from the research.
Informed consent	✓ Participants accurately informed of the purpose, methods, risks, benefits and alternatives to the research study. ✓ Participants must understand this information ✓ Participants must have the capacity to understand the study and its bearing on their own situation. ✓ Decision to participate is voluntary, un-coerced and autonomous

5.2.1 IBTS Ethical pre-review (Attachment 7.3)

The ethical considerations for a project will be reviewed as part of the research project proposal by one or more of the following:

- IBTS Research Ethics and Data Protection Working group
- Research and Development Lead Facilitator
- Medical and Scientific Director
- Research & Development Board sub-committee
- IBTS Research Meeting Attendees
- Research Collaborators

5.3 Types of Projects

Refer to Attachment 7.1 IBTS Research Ethics Algorithm

5.3.1 Usual practice

- Usual practice may involve systematic, quantitative or qualitative methods.
- Assesses choices of intervention, treatment, care or services based on best public health evidence or professional consensus.
- May involve analysis of existing routine data or administration of interview or questionnaire to those in the population of interest.
- May involve a review of existing evidence.
- Addresses questions such as:
  - "what are the health issues in this population and how do we address them?
  - "what is the cause of this disease outbreak or incident and how do we manage it?"
- Examples include:
  - E.g. Investigations designed to determine donor infectious disease epidemiology
  - E.g. Investigations designed to determine population health related behaviours.

5.3.2 Service evaluation

- Designed and conducted solely to define or assess current care.
- Addresses the question "what standard does this service achieve?"
- Assesses choices of treatment, care or services that are currently available according to guidance, professional standards and/or patient/service user preference.
- Service Evaluations do not usually require research ethics approval , as it is necessary to meet accreditation standards and to ensure optimum quality in our services.
- Service evaluation conference presentations and peer-reviewed publications do not require participant explicit consent.
- Examples include:

- E.g. evaluations performed to assess current care of donors or recipients
- E.g. evaluations of the standard of care a service achieves
- E.g. evaluations aimed at determining or choosing appropriate procedures or service options.

5.3.3 Clinical audit

- Clinically led quality improvement process that seeks to improve donor and/or patient care and outcomes through systematic review of care against explicit criteria.
- Measures the delivery of an intervention against a standard.
- Designed to answer the question: "does this service reach a predetermined standard?"
- The Health Research Regulations, Data Protection Act 2018, stipulate that Irish data protection legislation relevant to 'health research', only applies to the activities within the concept of ‘health research’ according to its Section 3(2). This concept does not include audit and/or service evaluation (Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018).
- Assesses choices of treatment, care or services that are currently available according to guidance, professional standards and/or patient/service user preference.
- Clinical audit does not usually require research ethics committee approval, as it is required by accreditation standards, health professional bodies and to ensure optimum quality in our services.
- Audit conference presentations and peer-reviewed publications of do not require participant explicit consent.
- Examples include:
  - E.g. evaluations designed to inform best service or care delivery
  - E.g. evaluations of whether or not a care or service meets required standards
  - E.g. evaluations relating to current treatments or interventions

5.3.4 Case Studies / Case Reports

- Written consent should be obtained directly from the individual case.
- Authors should seek the patient's (the cases) consent to publication before submitting any article.
- Research Ethics Committee approval is not required in respect of a single case study or case report, or in respect of a case series, which involves less than five reports.

5.3.5 Health research

Research is designed and conducted to generate new generalisable or transferable knowledge and can includes quantitative and/or qualitative studies that aim to generate new hypotheses, as well as studies that aim

to test existing or new hypotheses. Research may have the following goals:

- Goal of understanding normal and abnormal functioning, at the molecular, cellular, organ system and whole body level.
- Goal that is specifically concerned with innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury
- Goal of improving the diagnosis and treatment of human disease and injury and of improving the health and quality of life of individuals
- Goal of improving the efficiency and effectiveness of health professionals and the health care system
- Goal of improving the health of the population as a whole or any part of the population through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status

It is often the underlying goal or reason resulting in the project data collection and processing that determines whether the project is defined as 'Research' (as per HRR) or a 'Service Evaluation' or 'Audit' etc. It still may be prudent to submit for a Research Ethics Committee review but the requirements for participant explicit consent will vary. Health research can include:

- experimental, translational and clinical research
- public health and social care research
- population health research
- basic and translational health research
- research into treatment strategies, medical device or product development
- Actions taken to establish whether an individual may be suitable for inclusion in the research

5.3.5.1 Retrospective chart review

This is a type of research design in which pre-recorded, patient-centred data are used to answer a research question. Chart review studies facilitate the rapid collection of clinical, safety, and healthcare resource utilisation data.

- Retrospective chart review studies for health research purposes are mostly low risk, particularly as these are typically conducted by a healthcare practitioner working in a particular health care delivery context and by fully supervised healthcare students.
- Retrospective chart reviews do not usually require explicit consent from study participants, as it is required to ensure optimum quality in our services and continued development.

- The Data Protection Act 2018, Health Research Regulations 2018, Amendment 2021 allows for the processing of personal data to establish suitability or eligibility for inclusion in health research carrying out low risk retrospective chart reviews; if the following criteria are met:
  i. REC approval
  ii. Data protection risk assessment indicates a low risk to the rights and freedoms of the data subjects whose data will be accessed and used in the study
  iii. Carried out by a health practitioner employed by the data controller only
  iv. Transparency of initiative through the IBTS Research and Development | An Information Booklet for Blood Donors (Attachment 7.4)

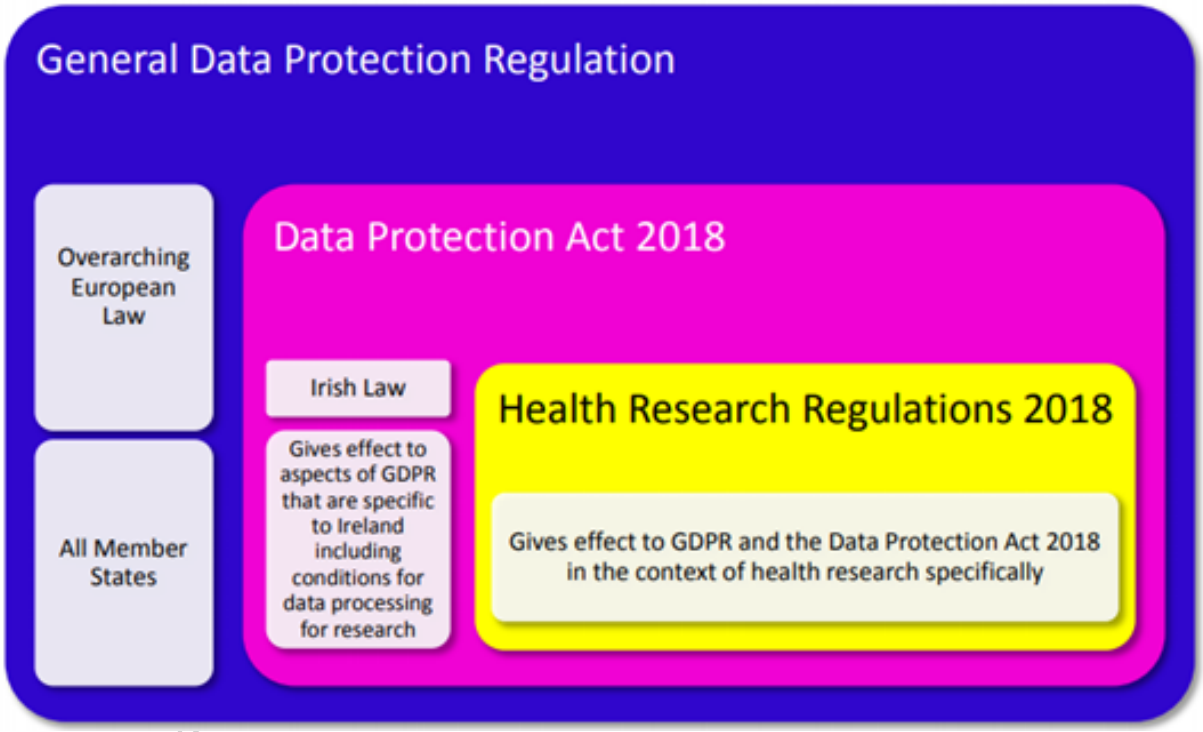
5.3.6 Is my project research, evaluation or audit?

- The definition of the type of project informs the researcher as to which laws are applicable (see section 5.3 on legislative framework)
- The NHS Health Research Authority & UK Medical Research Council have developed a useful decision making tool to help you decide if your activity is a research project, clinical audit, evaluation study or usual practice. http://www.hra-decisiontools.org.uk/research/index.html
- Also refer to Attachment 7.2 - NOCA GDPR Assessment Table for Clinical Audit

5.4 Legislative Framework

It is important to determine the appropriate legislative basis for decision making surrounding research practices and ethics; however there is a lack of standardisation, and different interpretations of the requirements have been made by different institutions. The current research legislative framework is underpinned by a number of contributing laws:

Figure 5.3; Summary of legislation underpinning processing data for projects overseen by the Research and Development Department



5.4.1 General Data Protection Regulation (GDPR) 2016

GDPR outlines the different lawful basis under which personal data may be processed and the obligations that the Data Controller must fulfil. Please refer to the more specific and comprehensive IBTS data protection policies for a detailed description of GDPR (IBTS/DP/POL/0001).

5.4.2 Data protection act 2018,

This legislation provides a basis for defining ‘research’ and differentiates this from ‘usual practice’, ‘service evaluation’ and ‘clinical audit’ and encompasses the Health Research Regulation 2018, amendments 2021).

Specifically for projects overseen by the Research and Development department, the data protection act and health research regulations:

- Define requirements necessary for study participant lawful consent, and especially explicit consent
- Where explicit consent is not required, ***Transparency*** regarding the project and its associated data processing is necessary. This is achieved by:

  i. Privacy notices for donors through the Data Protection donor clinic leaflet
  ii. www.giveblood.ie website which lists full privacy notice
  iii. The IBTS Research and Development | An Information Booklet for Blood Donors (Attachment 7.4)
  iv. Social media research updates through Twitter @IBTS_Education.

5.4.3 Health professional regulation, 2018

Medical professionals' practices are guided by specific Health Professional Regulation, 2018. Furthermore maintaining professional registration as Health and Social care professionals requires involvement in certain initiatives such as clinical audit and service development.

5.4.4 The Health and Social Care Professionals Act (2005)

- Section 27 (1) of the Health and Social Care Professionals Act states that the object of the registration board of a designated profession is to protect the public by fostering high standards of professional competence among registrants of that profession.
- Section 27 (3)(c) states that one of the functions of a registration board is to give guidance to registrants concerning ethical conduct and give guidance and support to them concerning the practice of the designated profession and continuing professional development
- Medical Scientists Registration Board Code of Professional Conduct and Ethics (www.coru.ie).

5.4.5 Irish Blood Transfusion Service Statutory Instrument (SI) No. 78 of 1965 and No. 209 of 1988

Processing data for research and development is legally permitted if it is to:

(i) Help protect our vital interests
(ii) We are legally obliged to as part of carrying out our service or
(iii) For the provision of Healthcare (e.g. Clinical Audit)

Specifically for projects overseen by the Research and Development department, one of the functions of the IBTS as set out in Statutory Instrument is "**To organise, provide, assist or encourage research and the training and teaching of persons in matters relating to blood transfusion and preparation of blood products"**.

5.4.6 Clinical trials

A clinical trial may only be carried out in collaboration with a designated clinical research facility /centre (CRF/C). The CRF/C will 'sponsor' the proposed trial and takes the responsibility for the initiation, management and reporting of the clinical trial and interventions. Clinical trials are subject to specific regulation and ethics, which are beyond the scope of this policy.

5.5 Legal Rationale for Processing Personal Data for Projects overseen by the Research & Development Department

GDPR Article 6 establishes the legal basis under which a data processing activity is lawful. Processing shall be lawful only if and to the extent that at least one of the legal basis established by GDPR Article 6 applies.

Those legal basis are:

- Consent
- Performance of a contract
- Compliance with legal obligation
- Protect vital interests
- Performance of a task carried out in the public interest or in the exercise of official authority vested in the controller
- Legitimate interest

5.5.1 Public Interest

Processing personal data for research projects, service evaluations and clinical audits is permitted if it is deemed in the public interest.

- ***GDPR Article 6 (1)(e) processing is necessary for the performance of a task carried out in the public interest*** or in the exercise of official authority vested in the controller; The **purpose** of the processing shall be determined in that legal basis or, shall be necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller. The Union or the Member State law shall meet an objective of public interest and be proportionate to the legitimate aim pursued.

In the scenario that special/sensitive categories of data are going to be processed, GDPR Article 9 must be observed:

- ***GDPR Article 9.1*** **Processing of personal data revealing** racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of **genetic data**, **biometric data** for the purpose of uniquely identifying a natural person, **data concerning health** or **data concerning a natural person's sex life or sexual orientation shall be prohibited**

Although, there are exceptions to the general prohibition set in GDPR Article 9.(1) one of them is:

- ***GDPR Article 9 (2)(g): processing is necessary for reasons of substantial public interest***, on the basis of Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data

The distinction between GDPR Art 6 and GDPR Art 9 remains in the fact that for processing personal data, the processing has to be based in one of the legal basis established by GDPR Article 6; all processing activities not based on one of those legal bases are illegal and can't be carried out.
But according to GDPR Article 9, processing activities which involve special categories of data are forbidden and only can be carried out IF one of the exceptions in GDPR article 9 (2) applies (For example GDPR Article 9 (2)(g)).
So, for processing special categories of data, a lawful basis under GDPR Article 6 is needed AND one of the exceptions in GDPR Article 9(2) may apply.

<u>However, there must have a legal basis that indicates processing is in the public interest</u>

- E.g. Public Health legislation supporting COVID-19 pandemic activities

5.5.2 Service Evaluation

Processing personal data for service evaluations is permitted as part of quality assessment, service improvement and strategic development.

- ***GDPR Article 6 (1)(h) processing is necessary for the purposes of preventive or occupational medicine, medical diagnosis, the provision of health*** or social care or treatment or the management of health or social care systems
- ***GDPR Article 9 (2) (i) processing is necessary for ensuring high standards of quality and safety of health care and of medicinal products or medical devices.***
- ***Data Protection Act 2018 (DPA 2018) (Section 42) (Section 54)*** provisions for the processing of personal data for the purposes of archiving in the public interest; scientific or historical research purposes; or statistical purposes.

<u>However, it's important to reference IBTS Statutory Instrument and/or strategy as a basis indicating that processing is a necessary step for service provision</u>

- ***IBTS S.I. No. 78/1965 Article 4*** (b) to organise and administer a blood transfusion service (c) to make available, blood and blood products; (f) to furnish advice, information and assistance in relation to any aspect of the service (h) to organise, provide, assist or encourage research and the training and teaching of persons in matters relating to blood transfusion and the preparation of blood products.
- E.g, Expanding the donor pool to include more donors of African ancestry.

5.5.3 Clinical Audit

Processing data for clinical audit is permitted as part of clinical quality assessment, health professional best practice and strategic development.

- ***GDPR Article 6 (1)(h) processing is necessary for the purposes of preventive or occupational medicine, medical diagnosis, the provision of health or social care*** or treatment or the management of health or social care systems
- ***GDPR Article 9 (2) (i) processing is necessary for ensuring high standards of quality and safety of health care and of medicinal products or medical devices***
- ***IBTS S.I. No. 78/1965 Article 4*** (b) to organise and administer a blood transfusion service (c) to make available, blood and blood products; (h) to organise, provide, assist or encourage research and the training and teaching of persons in matters relating to blood transfusion and the preparation of blood products
- ***The Health and Social Care Professionals Act 2005 Section 27 (1)*** states that the object of the registration board of a designated profession is to protect the public by fostering high standards of professional competence among registrants of that profession.
- ***Royal College of Physicians*** continuous professional development includes clinical audit and quality improvement.

5.5.4 Health research

Processing data for Health Research projects is permitted if consent has been obtained for this purpose as part of ethical approval, following review by a Research Ethics Committee (REC)

5.6 Research Data Format

The research data format directly influences the ethical assessment of the project (Attachment 7.1). Research participants must be advised on the following:

- Data collection format (anonymous / pseudonymous / identifiable)
- Genomic information and its impact on anonymisation
- Control and processing of the research data.

5.6.1 Anonymous Data

- Data is considered anonymous if it is NOT possible to identify an individual from that data under any circumstances.
- Anonymous data is not considered to be Personal Data, and therefore its use in a project is *not subject to GDPR or HRR legislation*
- The anonymisation process must be robust enough to eliminate the singling out or linkability of data. This is critical for sensitive personal data.

5.6.2 Pseudonymous Data

- Data is considered to be pseudonymous if it no longer allows the identification of an individual without additional information.
- Pseudonymous data is considered to be Personal Data and users should ensure that any 'key' necessary to identify data subjects from the coded data is kept separately, and is subject to technical and organisational security measures to prevent inadvertent re-identification of the coded data.
- Where personal data is given to an IBTS researcher for use, they should pseudonymise the data set and work on the pseudonymised data set to
    - ensure that the original data is not duplicated and
    - ensure security and control of the personal data is maintained.
- This is *Personal Data*, and therefore its use in a project is *subject to GDPR and potentially HRR legislation*.
- However processing pseudonymous data for the purposes of *service evaluation, clinical audit or in the public interest i*t is *permissible under GDPR and not subject to HRR legislation. Explicit consent is NOT required.*

5.6.3 Identifiable Data

- A person proposing to process personal data for health research purposes requires the *explicit consent* of the study participant.
    - This is personal data and therefore its use in a project is *subject to both GDPR and HRR legislation*.
    - Approval from a REC is required.

5.7 Research Data Protection

5.7.1 Personal data

Personal data is any information relating to an identified or identifiable natural person as defined in Art 4 (1) of GDPR.
Within the concept of "personal data", GDPR establishes a difference between categories of data and requires some specific obligations when the personal data is included in "special categories of personal data" according to the Regulation.
Examples of categories of personal data: Financial (bank account number, credit card number, mortgages, tax) Identification (name, surname, phone, email) Professional (job, college degree), etc.

It is likely the research projects will involve different categories of personal data

Special category of Personal data includes the data pertaining to:

- Racial or ethnic origin
- Political opinions
- Religious or philosophical beliefs
- Trade union membership
- Genetic data
- Biometric data for the purpose of uniquely identifying a natural person,
- Health
- Person's sexual behaviours
- Sexual orientation

5.7.2 Research data manipulation

The following manipulations of research data may be required as part of conducting a project overseen by the Research and Development department:

- Collection
- Generation
- Processing
- Combining
- Transferring
- Analysing
- Archiving
- Accessing
- Storing
- Protecting
- Destroying

5.7.3 Planning required prior to commencing a project

It is important to consider and resolve the following prior to commencing agreed initiative:

- **Rationale:** What is the rationale for collecting the research data and the legal bases underpinning this process?
- **Variables:** What specific information is required to answer the research question(s)? Only the minimum amount of personal data necessary for the study should be sought.
- **Sources:** Where and how will the variables be sourced?
- **Format:** What format will the data variables be collected, processed and stored etc.?
- **Security:** What data security measures are in place?

5.8 Research Data Controller

- The data controller for a research study is the organisation/person that determines the purpose and the manner by which personal data are processed for the research study (i.e. 'Whom', 'Why', 'How'). If the organisation/person takes these decisions with another organisation, they must specify the nature of their respective controllership (i.e. separate or joint controllers).
- This may be a fluid position as the data is collected and subsequently processed for research.
    - For example: Donor infectious disease results are controlled by IBTS. However, once collected in an anonymised format and transferred to a collaborator for research purposes, the collaborating institution or the researcher is now the research data controller.
    - Example: Clinical Trials - A health care provider (the investigator) and a university (the sponsor) decide to launch together a clinical trial with the same purpose. They collaborate together to the drafting of the study protocol (i.e. purpose, methodology/design of the study, data to be collected, subject exclusion/inclusion criteria, database reuse (where relevant) etc.). They may be considered as joint controllers, for this clinical trial as they jointly determine and agree on the same purpose and the essential means of the processing.
      The collection of personal data from the medical record of the patient for the purpose of research is to be distinguished from the storage and use of the same data for the purpose of patient care, for which the health care provider remains the controller.
      In the event that the investigator does not participate to the drafting of the protocol (he just accepts the protocol already elaborated by the sponsor), and the protocol is only designed by the sponsor, the investigator should be considered as a processor and the sponsor as the controller for this clinical trial.

5.9 Data Protection Impact Assessments (DPIAs)

The National Office for Research Ethics Committees has published Guidance on Data Protection for Research Purposes for Applicants and requires that Data Protection Impact Assessments (DPIAs) are submitted with an application for research ethics review. Alternatively, applicants may submit a statement outlining why a DPIA is not required. The DPIA will need to be completed by the Data Controller of the research study and reviewed by its Data Protection Officer (DPO).

The following is required:

- The advice of the DPO must be documented as part of the DPIA process.
- The Participant Information Leaflet should include the names and contact details of the Data Controller(s), Data Processor(s) and the DPO associated with the research study.

- Where there are Joint Data Controllers, the advice of the DPOs from all of the data controllers is required.
- Where the Data Controller is based in a non-EU country, DPIAs should be reviewed by a person with equivalent roles and responsibilities to a DPO.
- If the Data Controller is situated outside Ireland, it is advised that the DPO of the lead-Irish based institution be given the opportunity to review the DPIA, thereby safeguarding the rights of Irish research participants.

Refer to the more specific and comprehensive IBTS data protection policies for a detailed description of DPIA (IBTS/DP/POL/0004).

5.10 Participant Consent

The Health Research Regulations 2018 and 2021 amendment stipulate that "**explicit consent"** must be obtained from the data subject, prior to the commencement of the health research, for the processing of his or her personal data for the purpose of specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof."

- 'explicit consent' relates to the processing of personal data and differs from informed consent to take part in the research project. In order to meet the threshold for 'explicit consent' under GDPR, the consent for processing must be **freely given, specific and informed**.

Freely given

- It must involve a clear affirmative action, such as ticking a box and can be done electronically, online, on paper etc.
- A record of the consent must be retained by the data controller.
- A copy of the consent should be given to the individual.
- The consent must convey clearly that it can be withdrawn and how to do so.
- There can be no adverse impact on an individual that does not consent to participating.
- There must be no attempt to access data without consent, or for individuals that have not consented.

Specific

- Consent captured must be specific. The processing activity must be carried out for a specific purpose.
- The scope of the consent should be clear e.g. specific consent for project X, broader consent for research purposes, future consent for X.
- It cannot be bundled with other consents, explicit consent for the processing of personal data for the research purposes should be kept separate and distinct from informed consent to take part in the research or from consent to other purposes.
- Blanket consents must be avoided.

Informed

- The principle of transparency under GDPR applies here, the individual must be given sufficient information in relation to the nature and purpose (what data will be processed, how and why) of the personal data processing to be able to make an informed decision about whether to consent.
- The individual should be provided with information about who to contact if they have questions in relation to their personal data processing.

The individual should be informed about his/her data protection rights and about the details established in GDPR articles 12, 13 or 14

5.11 Research Ethics Committees

5.11.1 Research Ethics Committee functions and activities

Research Ethics Committees (RECs) are a cornerstone in the governance of health research. A REC is the acknowledged international best practice structure for overseeing the conduct of ethical standards in healthcare research and has three main functions:

- ***Protection:*** To contribute to safeguarding the dignity, rights, safety and well being of all actual or potential research participants (WHO 2002), to weigh the risks and benefits for research participants, to protect the rights of researchers to carry out legitimate investigation; and our reputation for conducting and sponsoring research.
- ***Advice:*** To advise individual researchers on whether a research project requires research ethics review, if it is likely to be harmful or offensive to participants or the broader community.
- ***Research quality:*** Research must be scientifically sound and carried out to the best possible standard for it to be ethical.

The role of the REC is to provide an independent opinion in relation to the ethical aspects of research proposals. Before the research commences all the necessary ethical, legal and regulatory requirements must be in order and approved. Ethical approval should be sought at the collaborating or affiliated hospital/ university/ institution prior to the commencement of a project, if deemed necessary. The IBTS does not ethically approve its own work.

REC approval may be required for:

- Research designed and conducted to generate new generalisable or transferable knowledge that generate new hypotheses or test existing hypotheses.
- Observational clinical research.
- Qualitative research involving access to personal information by means of questionnaires, interviews or focus groups
- Clinical trials involving human participants
- Testing of new treatment or interventions or medical devices
- Research involving human remains, cadavers, tissues, discarded tissue (e.g. placenta), biological fluids
- Testing innovative practices in health and disability services
- Research involving the secondary use of data.

5.11.2 Activities that do not usually require REC review

- Research utilising existing publicly available documents or data
- Observational studies in public places in which the identity of the participant remains anonymous

- Case study of one patient with the proviso that written informed consent has been obtained from the relevant study subject/participant
- Quality assurance studies
- Clinical Audits
- Service Evaluations
- More information can be found on the HSE website at https://www.hse.ie/eng/services/list/5/publichealth/publichealthdepts/research/rec.html

5.11.3 Specific activities requiring Research Ethics Review

- Clinical trials involving human participants.
- Testing of new treatment or interventions or medical devices.
- Observational clinical research.
- Research involving human remains, cadavers, tissues, discarded tissue (e.g. placenta), biological fluids.
- Testing innovative practices in health and disability services.
- Qualitative research involving access to personal information by means of questionnaires, interviews or focus groups.
- Research involving the secondary use of data (use of data not collected for that research purpose), if any form of identifier is involved and/or if personal health information pertaining to individuals is involved.
- Physiological studies.
- Comparing an established procedure, whether therapeutic, non-therapeutic or diagnostic, with other procedures which are not recognised as established by virtue of their recent development, discovery or use in a new or unfamiliar way.
- Research conducted by students, which include all activities that meet the definition of research with human participants. The Irish Council for Bioethics state that RECs should review research protocols with a view to contributing to the student's education in scientific and ethical principles governing research.
- Case studies, when a series of subject observations allow possible extrapolation or generalisation of the results from the reported cases and when there is an intent to publish or disseminate data.

6 REFERENCES

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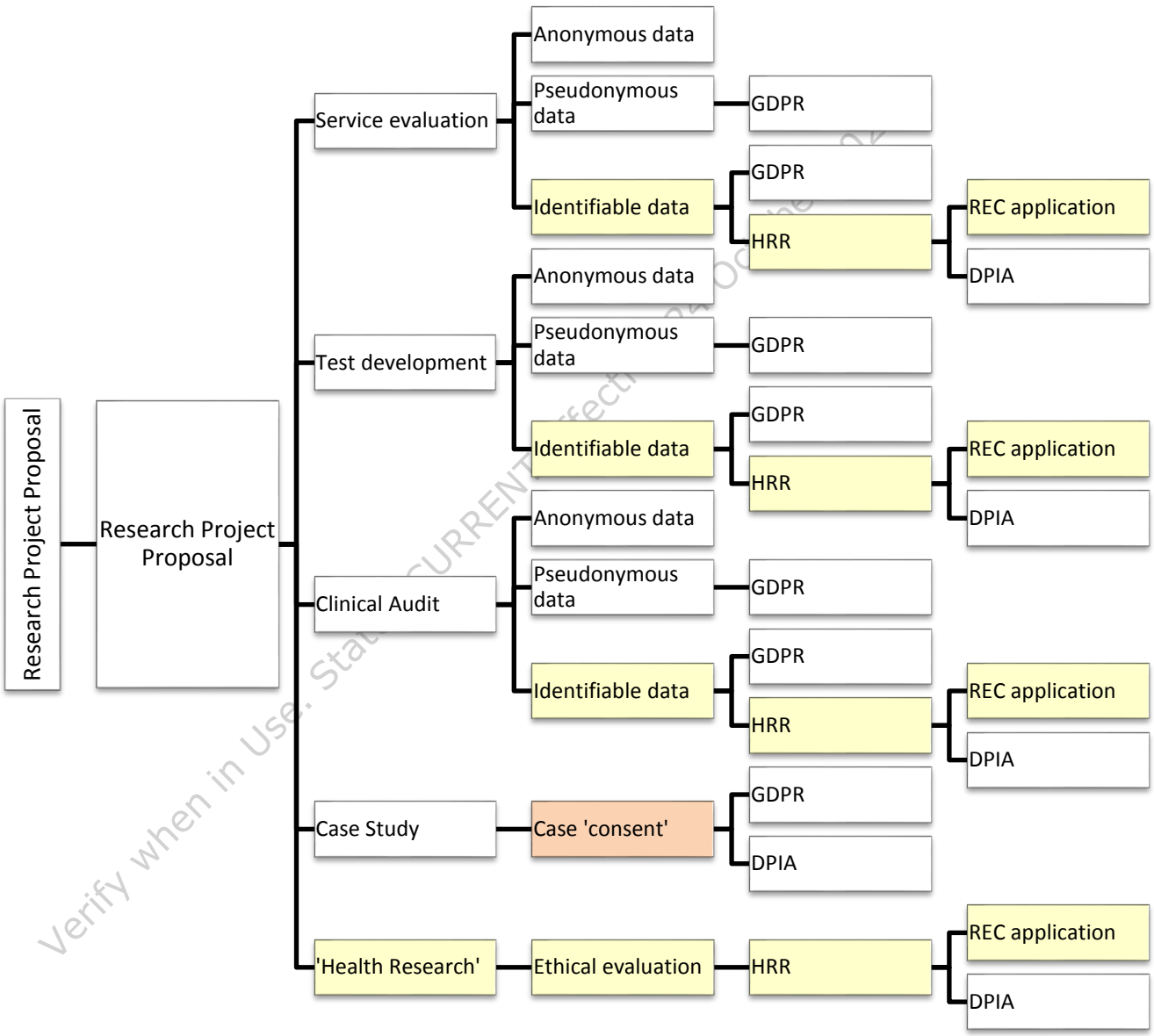
- S.I. No. 18/2021 - Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021 https://www.irishstatutebook.ie/eli/2021/si/18/made/en/print
- National Office of Clinical Audit. GDPR Assessment Table - to assist in determining if you are conducting Clinical Audit, Service Evaluation, Research, Healthcare Record Review or collecting data for a Clinical Register and how the purpose relates to GDPR, Data Protection Act 2018 (including the Research Regulations 2018) https://www.beaumontethics.ie/docs/application/NOCA_GDPR_Assessment_Table_Clinical_Audit.pdf
- HSE National Framework for Governance, Management and Support of Health Research September 2021 https://hseresearch.ie/wp-content/uploads/2021/09/HSE-Framework-for-the-Governance-Web-Optimised.pdf
- REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0679
- Data Protection Act 2018 https://www.irishstatutebook.ie/eli/2018/act/7/enacted/en/html
- Guidelines 07/2020 on the concepts of controller and processor in the GDPR
- Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art 70.1.b))

7 ATTACHMENTS

Attachment 7.1 IBTS Research Ethics and Data Protection working group Ethical Pre-review Algorithm.
Attachment 7.2 National Office of Clinical Audit. GDPR Assessment Table
Attachment 7.3 IBTS Ethical Pre-Review
Attachment 7.4 IBTS Research and Development | An Information Booklet for Blood Donors

Attachment 7.1 IBTS Research Ethics Algorithm



Attachment 7.2 National Office of Clinical Audit. GDPR Assessment Table

NCCA National Office of Clinical Audit

GDPR Assessment Table - to assist in determining if you are conducting Clinical Audit, Service Evaluation, Research, Healthcare Record Review or collecting data for a Clinical Register and how the purpose relates to GDPR, Data Protection Act 2018 (including the Research Regulations 2018)

	Clinical Audit	Service Evaluation	Health Care Record Review	Clinical Registers	Research
Definitions	'Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria, and acting to improve care when standards are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit criteria. If required, improvements should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements.' DOHC (2008)	'Service evaluation seeks to assess how well a service is achieving its intended aims. It is undertaken to benefit the people using a particular healthcare service and is designed and conducted with the sole purpose of defining or judging the current service'. Shorten & Twycross (2014 p.65)	A Healthcare Record Review is where pre-recorded, person-centred data are used to answer one or more questions. The review is not part of direct patient care. A healthcare record review may be carried out for a number of purposes including clinical audit, research, or incident review. The purpose will dictate the governance structures to be followed. It may be also be referred to as a chart review or case review.	'A registry (in a clinical setting) is described as a system which collects a defined minimum data set from patients with a particular disease, undergoing a particular procedure or therapy, or using a health care resource'. Hoque et al (2019)	Research is designed and conducted to generate new generalisable or transferrable knowledge. It includes both quantitative and qualitative studies that aim to generate new hypotheses as well as studies that aim to test existing or new hypotheses'. HRB (2019)
Assessment Criteria	Did care meet the standard yes/no? • Measuring against explicit standards Non randomised population (all patients meeting criteria of audit) • No allocation to intervention - change to care of the patient	Did the service meet your expectations e.g. Patient Experience Survey • No explicit standards • Non randomised population (all patients meeting criteria of audit)	Why are you going into the chart? • Assessing the context of care, peer review, look back review, incident review, judging the context of care • The purpose will dictate the assessment steps to be followed.	System for collecting data on patients who meet criteria of register • List of patients who meet criteria for the register. Their consent status and their clinical information • Non randomised population	A research question exists that may generate new knowledge • Can be randomised • The outputs from clinical audit and/or service evaluation do not answer the research question without further analysis or additional information from other sources

	Clinical Audit	Service Evaluation	Health Care Record Review	Clinical Registers	Research
GDPR and DPA 2018 **Legal Basis**	• Article 6(1)(c) GDPR "processing necessary for performance of contract" with the data subject, or Article 6(1)(e) – 'processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller, or Article 6(1)(f) – processing is necessary for the purposes of legitimate interests. • Article 9(2)(h) GDPR– 'processing is necessary for the purpose of preventative…medicine…the provision of health or social care or treatment or the management of health or social care systems and services…' or Article 9(2)(i) – 'processing is necessary for reasons of public interest in the area of public health, such as…ensuring high standards of quality and safety of health care…' • Consent is not required if there is another other legal basis more appropriate to use • Data Protection Act 2018, Section 52(1) (a) – 'for the purposes of preventative or occupational medicine', Section 52(1) (d)' for the provision of medical care, treatment or social care' and/or Section 52(1)(e) for the management of health or social care systems and services' which allows patient information to be used for clinical audit provided that appropriate measures are taken to safeguard the fundamental rights of the data subject. • Data Protection Act 2018, Section 53(b) – 'ensuring high standards of quality and safety of health care…'			Consent is required unless a mandatory register with an opt out option	Consent is required unless HRBCDC exemption received
Research regulations	Not applicable in gathering the data for Clinical Audit	Not applicable in gathering the data for Service Evaluation	Yes - Depends on the purpose the health care record review is performed	Not applicable in gathering the data for Clinical Register	Yes
Research Ethics Committee (REC) Approval	Not required	Not required	As above	Not required	Yes
Presenting findings	Findings should be aggregated and not identify individuals				As per Research Ethics Committee Approval
Using the Data collected for Clinical Audit, Service Evaluation for Research?	• If data is totally anonymous then GDPR and/or Research Regulations do not apply as the data is no longer considered personal data. • If the data is held in pseudonymised format then consideration needs to be given to who holds the key (link back) to identify the patients. If the person carrying out the research has access link datasets or to re-identifying the patients then this would fall under the Research regulations and consent or consent exemption would be required. • If data is identifiable then GDPR and Research Regulations do apply.				

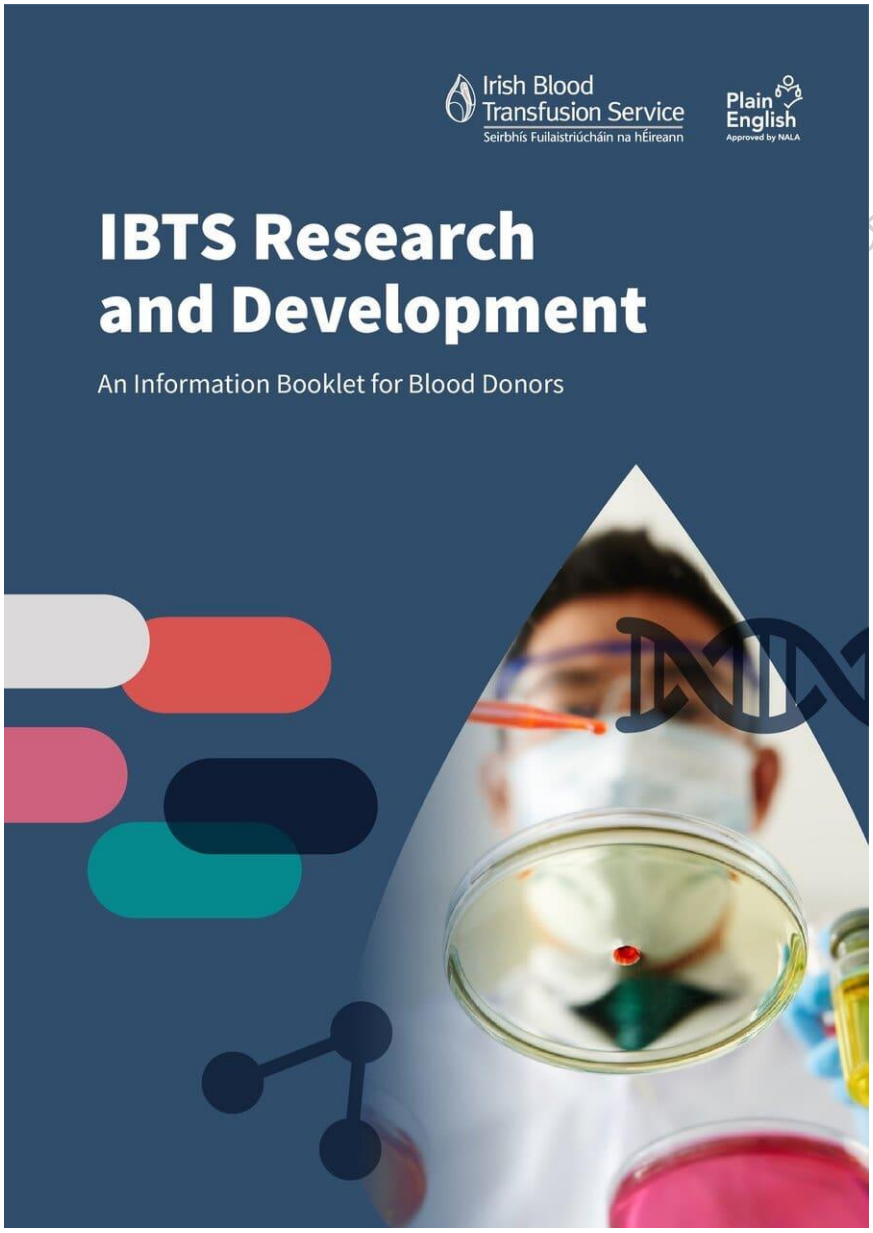
Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

IBTS Research & Development

RESEARCH PROJECT ETHICAL PRE-REVIEW

Ethical Principal	***Description***
Autonomy *Decision-making process is free of coercion or coaxing. Participant understand can make an informed decision*	Choose an item. Click here to enter text.
Justice *The burdens and benefits of research is distributed equally among all groups in society.*	Choose an item. Click here to enter text.
Beneficence *The intent of doing good for the participants involved. Consider the balance between developing and maintaining the service, skills and knowledge with the individuals circumstances of the participants*	Choose an item. Click here to enter text.
Non-maleficence *Are there any research outcomes that could impact directly or indirectly on a participant's health*	Choose an item. Click here to enter text.
Project type	Choose an item.
Consent	Choose an item.
Data format	Choose an item.
Explain why identifiable data, and therefore explicit consent, is required	Click here to enter text. N/A ☐
How consent can be withdrawn?	Click here to enter text. N/A ☐
Is a follow-up with the data subject required?	Click here to enter text. N/A ☐
Outcome of Ethics discussion with R&D team	Click here to enter text.
Ethical approval required?	Choose an item.
Name of Chosen Research Ethics Committee:	Click here to enter text.

Attachment 7.4 IBTS Research and Development | An Information Booklet for Blood Donors \\ibtsnbcsvr79\ctxfolders$\watersa\Desktop\ibts-research-and-development_an-information-booklet-for-blood-donors_june-2022.pdf



About this booklet and the IBTS

This booklet is for blood donors interested in learning more about the IBTS's research and development.

At the IBTS, we are responsible for the national blood supply. This includes managing blood products such as red and white blood cells, platelets and plasma.

The booklet explains how we develop research for both blood transfusion and how blood products are prepared. It provides examples of research projects and outlines how we protect your data (information) when using it in our research.

The IBTS carries out research and development to make sure healthcare professionals and researchers use donated blood and tissue in the best possible ways.

We thank you for donating and enabling us to carry out our work.

Types of research and development projects

Our research and development includes:

- **Audits or checks on our services**
  Do our services meet international standards?
- **Service evaluation**
  What factors impact how we deliver our services?
- **Public Health**
  What are the health issues for our donors and what can we learn from them?
- **Health Research**
  We try to answer research questions about blood donation, transfusion and related fields. This may involve collecting information or carrying out testing in addition to our everyday services.

IBTS Values

- **Strive for excellence**
  Use the minimum information required to complete our audits, service evaluations and address public health concerns.
- **Lead by example**
  We are open and transparent in all our research activities. We are accountable for our actions and decisions from the start to the finish of a project.
- **Love our donors**
  We respect one another, the research process and hold our donors and the products we work with in the highest regard.
- **Improve patients' lives together**
  We work with clinical and academic colleagues to ensure the best research outcomes.

How we protect your data

We will always:

- ✓ Use the minimum information needed to do our work to address public health concerns and complete our service audits and evaluations.
- ✓ Train our staff on data protection and research ethics.
- ✓ Ask for your explicit consent to use your identifiable data in our health research.

Explicit consent means we will fully inform you of how we plan to use any data that could identify you, so you can decide if you want to allow us to use it. You can give consent in writing with a signed consent form or online.

Without your explicit consent we will never:

- × Send your identifiable data or blood products for research purposes outside of the IBTS.
- × Process (use) your identifiable data or blood products within the IBTS for research purposes.
- × Use your genetic information for any purposes, other than those our service needs.

If you have any doubt about how we process your personal information or you want to exercise your data rights, please email our Data Protection Officer at dpo@ibts.ie

How your donation helps us

With your donation and information, we can do the following:

- **Monitor donor behaviours and disease risks**
  We monitor trends in donor lifestyle and behaviours to identify and minimise risks to our donors and recipients. We analyse donor laboratory results to get insights into our current donor population, and what is required for matching donor blood with transfusion recipients.
- **Understand the impact of donations on the health of our donors**
  We aim to understand how factors like donor nutrition and lifestyle affect who is eligible to give blood. We compare the evidence we find with similar organisations internationally in order to develop our services and improve donor health.
- **Be world experts in blood and tissue testing and production**
  We aim to improve the process of donation, testing, and blood production. We look to gain insights into the biological factors such as donor age, blood group or storage conditions that may affect the quality of blood products.
- **Collaborate with clinical research facilities on clinical trials**
  We contribute to clinical trials (medical research) to help us ensure the best use of blood products such as platelets and plasma.
- **Continue to monitor blood components and tissue**
  This monitoring is known as haemovigilance. It means that we monitor poor reactions to blood donation and transfusion. This helps us limit risks to donors and transfusion recipients.
- **Provide biological material for research**
  We provide biological material for researchers. This can include blood parts that can't be used for treatment, and other products of the donation process such as immune cells. These products help advance many types of biological research.

Specific examples of research projects

Below are examples of research projects which show how donations contribute to our work.

Public Health Research:

- Estimate level of antibodies (disease-fighting proteins) in donors' blood. This helps us understand outbreaks of disease, and immune response to infection and vaccination.
- Identify the blood groups, and other blood associated proteins in donors to investigate if there are any specific groups associated with disease risk.
- Contribute to clinical trials which use our products to treat patients.

Service Evaluation:

- Analyse donor health and lifestyle behaviours for trends, such as donor travel or sexual activity.
- Evaluate donor recruitment methods to ensure our donor population reflects the general Irish population.
- Find the best approach to match donor blood groups for people who need multiple transfusions, such as more detailed genetic testing.
- Compare iron levels in donors to evaluate the impact of repeated donation on donor health.
- Evaluate blood components stored under different conditions.

Clinical Audit:

- Review any negative reactions after a transfusion. Review transfusion outcomes in those with rare blood groups, especially during pregnancy.

Legal basis

- **Our legal responsibility**
  We must 'organise, provide, assist or encourage research and the training and teaching of persons in matters relating to blood transfusion and preparation of blood products' (IBTS Statutory Instrument No. 209 of 1988).
- **Work in the public interest**
  We need to process your personal data to perform analyses that are carried out in the public interest to inform Public Health (General Data Protection Regulation Article (GDPR) 6(1)(e)).

For example, to support the COVID-19 pandemic by providing information on infection rates in donors.

2022

- **Follow legal definition of personal data**
  We understand personal data as 'any information relating to an identifiable natural person' [you] (GDPR Article 4(1)). We can legally process personal data to help us with our service audit and evaluation as long as it is anonymised (without any identifying information). We can do this as this data is outside the GDPR.
- **Always get your consent when required**
  We may need to process your personal data for scientific research purposes (GDPR Article 9(2); Health Research Regulation 2018, amendment 2021). We will always ask for your explicit consent in this case.
- **Legal surveillance work**
  When carrying out our services with donors or recipients, we always monitor for any serious or unexpected reactions in donors or recipients (EC Directive 2002/98/EC).

Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

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Web: www.giveblood.ie
Donor Infoline: 1800 731 137