Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

RESEARCH & DEVELOPMENT STRATEGY

2021 TO 2023

Contents

Foreword

I am delighted to present our first-ever dedicated IBTS Research & Development strategy. We have always been committed to providing an excellent service to our donors and all the communities we serve; however, this strategy will provide a framework for by embedding research as a core activity throughout our whole organisation. It is essential that we are prepared for new and emerging opportunities or threats in the blood sector, as well as meeting the challenges of changing therapies, blood component production and laboratory testing. Importantly, we will support our staff in their research endeavours, celebrate our achievements and promote a culture of continuous improvement and collaboration. Research thrives on innovation and questions, and we aim to be research leaders, at the forefront of blood transfusion medicine, providing the answers and the evidence that will ultimately benefit our donors and patients.

Prof. Stephen Field | Medical & Scientific Director | January 2021

Research vision

Researching, developing and innovating our blood and tissue services by harnessing the expertise of our people, and through collaboration with clinical and academic partners.

Research mission

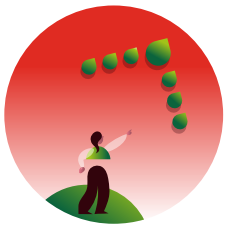
We are committed to providing the research evidence for improving and developing our blood and tissue services to patients, through collaboration with our donors, the expertise of our people and of our clinical and academic partners.

WE ARE
THE IBTS

Research values

- **We strive for excellence**
  We continuously improve our research capacity by learning from each other, building on our findings and working with our collaborators

- **Lead by example**
  We are open and transparent in all our research activities, and are accountable for our actions and our decisions from project inception to completion.



- **We love our donors**
  We respect one another, the research process and hold our donors and the products we work with in highest regard

- **We improve patients lives, together**
  We work together and collaboratively with clinical and academic colleagues to ensure the best research outcomes

Developing our research strategy

The Connections that Count strategy for 2021 to 2025 provides a framework for us to deliver programmes of change, including the implementation of a research and development strategy which is built into the pillar of *Supporting Better Healthcare.*

We are responsible for the national blood supply for Ireland and therefore our coordinated research activities must be informed by emerging risks and opportunities which ultimately optimise patient care and help position us at the forefront of blood transfusion medicine and science.

The rapidly evolving fields of transfusion, transplantation and laboratory diagnostics mean it is imperative that upcoming changes to clinical practice, testing, production and donation, are always considered and prepared for. One of our core functions, as set out in the IBTS Statutory Instrument is a remit to 'organise, provide, assist or encourage research and the training and teaching of persons in matters relating to blood transfusion, transplantation and preparation of blood products'.

It is, therefore, essential that a comprehensive research and development programme underpins our services to donors, patients and hospitals.

This strategy was developed over the course of 5 months, during which regular consultations with the Chief Executive Officer, Medical and Scientific Director and senior research staff were carried out. The complimentary expertise of our scientific and clinical teams means we already have a wealth of talent with the capacity for progressing the proposed research and development programme. This strategy demonstrates our on-going commitment to supporting research, and outlines the necessary steps for the development and implementation of a structured and progressive research programme within our organisation. A summary of the strategy developmental process is outlined in Figure I.

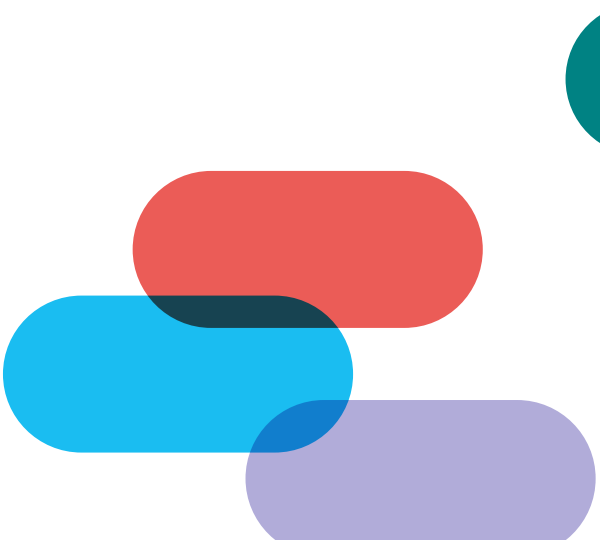
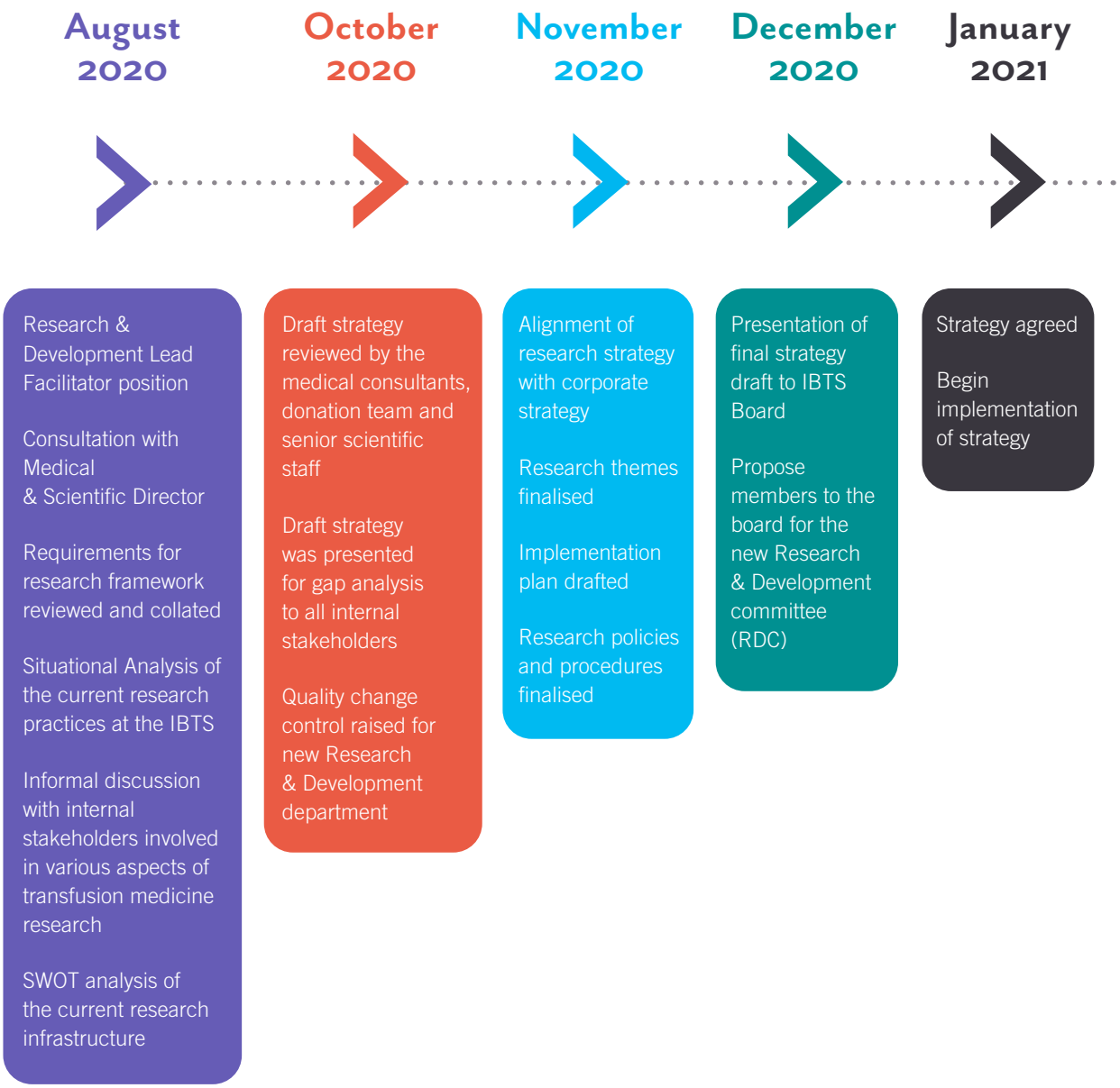


Figure I: Strategy developmental process



Our research and development strategy is ambitious, reasoned and relevant to all of our service users, and aims to capitalise and develop previously untapped expertise of staff and clinical colleagues.

Research will be supported at all levels throughout the organisation and its outcomes tools that lead to a deeper understanding of blood donation and the clinical application and utility of blood and tissue. The fundamental drivers required for a successful research strategy identified during the situational analysis and consultation process, were as follows:

- **Research pathway provision**
  A clear and well-defined research governance structure for all staff and external collaborators engaging in research is required to support and provide oversight from project proposal to completion.

- **Community engagement**
  The transfusion and transplantation communities comprise of donors, recipients and the medical communities regularly engaging with our services. Research should be primarily focused on improving the lives and experiences of the communities that we serve.

- **Build on research strengths**
  We already have a strong presence in the academic literature, particularly in the field of donor screening and disease epidemiology. This is a solid foundation from which to progress further our footprint in academia.

- **Technological advancements**
  Our blood and tissues services must continue to develop and progress methodologies, especially in the areas of molecular diagnostics and blood component production. The clinical application and publication of new products evaluations and service developments should be considered during where possible.

- **Academic affiliation**
  A progressive, influential and sustainable research programme requires strong links with third-level institutions, which can provide access pathways for collaboration, training, funding and ethical approval.

- **Economic value**
  It is crucial that research costs are supplemented through grant funding. In addition, applied research solutions must be deemed economically viable for the communities that we serve.

- **Leadership**
  Our profile can be further enhanced by collaboration, publication and national and international engagement through conferences, working groups and networks.

- **Showcase**
  The research projects in which we are directly / indirectly involved should be showcased in a symposium, and easily accessible through a specific research module on our website and intranet.

- **Research culture**
  The success of the research strategy will be greatly enabled by the people and culture in within the organisation. A value must be placed on technical writing, publication strategy, presentations skills and research outputs to encourage research involvement and dissemination of data.

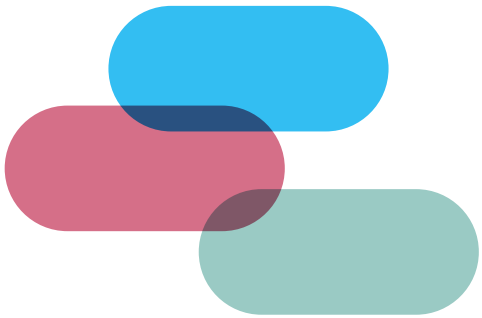
Research objectives

The overarching goal of our research programme is to provide the evidence-base for improving the donation process, developing blood testing services and determining the optimum use of blood and tissue. All of our research endeavours should strive to maximise the ability of blood and tissue donation to improve the health of patients.

It is envisioned that by the completion of this strategy we will have:

- Positioned ourselves as a key research leader in the fields of transfusion, transplantation screening and blood science
- Provided insights on the parameters affecting donor health and welfare
- Evaluated evidence for donor testing methodologies and algorithms
- Implemented improvements to blood component and tissue production
- Assessed the clinical utility of blood component transfusion in recipients
- Proven through our research endeavours our ability to attract and retain the brightest clinical, medical and scientific staff and experts.

Working closely with our partners and capitalising on the all the research resources available within our organisation are key to achieving success. Furthermore, the effective implementation of research best-practice, defined governance structures and a supportive culture will enable the creation of a positive and innovative environment for staff engaging in research. All of these changes will facilitate advancements in the knowledge and practice of transfusion medicine, and simultaneously build our research reputation. The three core research objectives underpinning this strategy are as follows:



Improved Donation and Donor Care
Applied research & insights

It is imperative to gain a deeper understanding into the dynamics of the donation process in order to have a measurable positive impact on the donation community that we serve. Insight into the factors motivating and preventing people donating blood will provide an evidence base from which to develop and improve blood collection policies, testing algorithms and clinical guidelines. This will be achieved by investigating the sociological and epidemiological factors influencing donation, as well as monitoring the effects of changes in donor deferral, testing and clinical practices. Specifically, it is crucial that donation behaviours and donor welfare are risk-assessed against emerging threats to this process, and that research evidence is used to underpin contingency plans and solutions.

Progressive Blood Service
New products and services

A critical part of this mission must be to future-proof the service in relation to changing technologies, blood demands and blood component usage, thereby optimally serving transfusion and transplant recipients. Furthermore, the delivery of Good Manufacturing Practice, the development of regenerative medicines and other cellular solutions to disease management requires translation from the research benches to recipients.

Clinical Leadership
Advocacy, advice and guidance

We aim to position ourselves as a research leader in the field of transfusion medicine through participation in national and international networks, and through collaboration with clinical colleagues, international blood services and commercial partners for research endeavours and clinical trials.

Research Priorities & Framework

The outcomes of high-quality research may positively impact a broad range of health-related fields including blood science, transfusion, transplantation, public health policy, clinical interventions and epidemiology. We must provide the framework for carrying out applied research, communicating insights and to help position us as a key leader for advocacy, advice and guidance.

Governance and Infrastructure

A successful Research and Development programme requires a centralised research system that is underpinned by a clear governance structure, national and international research policy and guidance, as well as internal local leadership driving the departmental structure, providing research supports and fostering new collaborative relationships. The governance infrastructure for the Research & Development department is summarised below in Figure II.

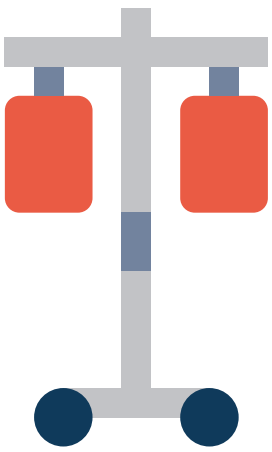
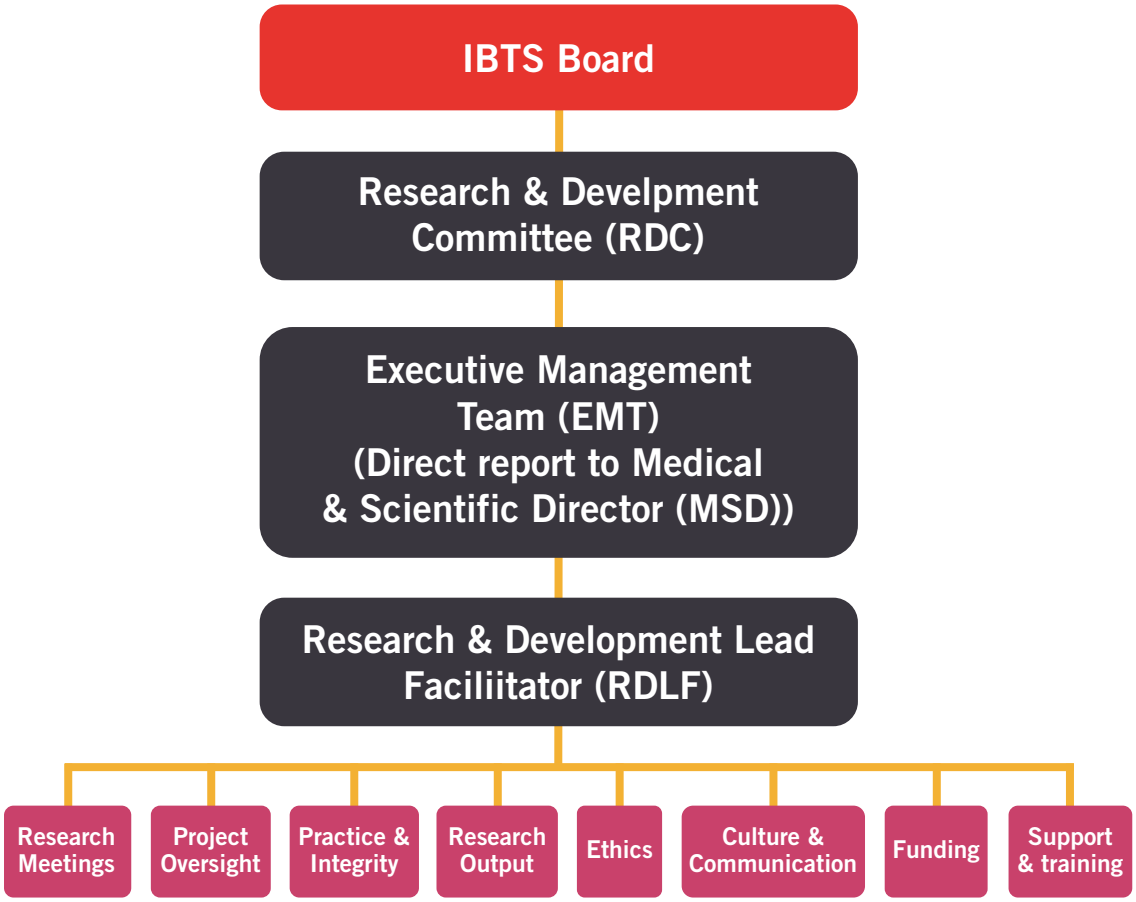


Figure II: Research infrastructure



Research & Development committee

Projects and spending will be overseen by a newly formed sub-committee of the IBTS Board, the Research and Development Committee (RDC) under agreed Terms of Reference. The RDC consists of members of the Board and external experts that can provide valuable and insighful contribution to its proceedings. This committee is an essential component of our research governance as it reports directly to the IBTS Board and is tasked with ensuring that there is accountability for both the funding and the nature of research within the organisation.

Research & Development Lead Facilitator

The inception, progression and completion of all research projects will be centrally monitored through Research and Development Lead Facilitator (RDLF). The RDLF is tasked with providing local governance, expert leadership and research support throughout

the whole organisation using a range of research methodologies. Over the course of this strategy, the RDLF will oversee the set-up and managing of a separate Research & Development deparment. The RDLF, under the guidance of the Medical and Scientific Director (MSD), will liaise regularly with the EMT & RDC, ensuring all monies are spent optimally, research projects are aligned with our values and missions, and the work carried out is in line with the relevant guidance, policies and procedures. The RDLF is responsible for administering the agreed budget and supplementing spending through applications for external funding, where possible.

Executive management team

The MSD is a member of the Executive Management Team (EMT) and will relay research strategy progress and key research findings to the EMT on a quarterly basis. Research outputs are a key tool that can inform decision-making on service developments and changes.

Research Practice & policy

Research carried out internally, or in collaboration with colleagues, must be practiced in accordance with the relevant national and European laws, policies and guidelines. Our research must be performed to the highest standards of professionalism and rigour, ensuring accuracy, quality and trustworthiness in all outputs. It is recognised that education, training, support and promotion of good research practice are the foundations of research integrity and all practices must be transparent and robust from project proposal to completion. The ethical implications for all projects must be considered and ethical approval granted prior to commencement of the work. Furthermore, the health research data protection regulations should be closely linked with all ethical applications. Lastly, striving to perform research in a sustainable way is also a consideration. Leadership, collaboration and project oversight aim to maximise output whilst limiting project overlap, and unnecceary data collection and storage. Our research policy will describe the criteria and guidance for (i) research integrity and practices, (ii) research ethics, sustainability and data protection, (iii) research outputs, (iv) research learning and development (v) research culture and (vi) research communication.

Research scope

The essential basis of all research projects is a unique research question, the answer to which may directly advance or inform academic knowledge, practices or guidelines. Projects that fall within the categories outlined below are within the scope of the Research and Development department and subject to the governance and procedures outlined in this strategy.

- Projects with a clear well-defined research question relevant to blood transfusion and transplantation.
- Grant-funded projects
- Studies funded directly by RDC
- Studies requiring ethical approval
- Laboratory developments, audits and case studies suitable for peer-reviewed publication

Collaboration

Effective collaboration and partnerships are a crucial component of research, and essential to increasing our research reputational footprint. Research and innovation thrives on collaborative and beneficial relationships with academic, clinical and commercial colleagues, which are greatly valued, and should be encouraged.

Academic affiliation and collaboration:

Coordinating with universities and educational institutions that have research interests in transfusion medicine is an essential way to support research projects. Already, we provide surplus blood components to a number of academic research teams. There is a need to grow the number of our staff with formally recognised third level institution affiliation. This will be achieved through increasing the number of staff with adjunct staff recognition and principal investigator approval. In addition, once affiliated, direct involvement in lecturing to scientific and medical students is another avenue for haematology training and for deepening our ties with academia.

Clinical collaboration:

Collaboration and cooperation with hospital-based clinicians and through international networks will enable our involvement with trialling new blood component treatments and clinical therapeutic evaluations. It's critical that functioning clinical relationships are in place for developing strategies that best serve critical patient groups such as those with sickle cell anaemia. Crucially, clinical trial protocol development for blood components will greatly aid our participation in trials. Lastly, we refer donor specimens for confirmatory and genetic testing and collaborating with referral laboratories on retrospective and prospective studies gather evidence for referral policies and interpretation of results.

Commercial collaboration:

There is a potentially beneficial relationship between our services to donors and hospitals, and a commercial entity's need to develop, validate and clinically evaluate their products. This strategy will capitalise on existing commercial relationships through formal research partnership to specifically progress diagnostic methodologies and blood component development.

Leadership

One of our over-arching strategic goals is to position ourselves, nationally and internationally, as a credible sector leader at the forefront of the field of blood transfusion. Leadership in the field of research is largely measured by peer-reviewed publication, conference contribution and subsequent policy and algorithm development. In addition, communication of research outputs is required to maximise the impact of research findings and drive further innovation. Building our research reputational footprint and increasing its visibility will be achieved by concentrating on the following:

Conference and committee participation:

A continued engagement and involvement with the wider transfusion, transplant and public health communities through project collaboration, conference attendance and committee contribution is essential. This will enable us to lead and influence the development of national and international clinical guidelines for blood services, donor screening and blood component production development. There will be a further focus on local engagement in order to increase our profile with national institutions, groups and societies such as the National Transfusion Advisory group (NTAG), the Irish Society of Haematologists and the Academy of Clinical Science and Laboratory Medicine.

Peer-reviewed publications:

There will be an initial focus on preparing manuscripts from data already gathered from previous research work, and specifically on data describing the epidemiology and pathogenesis of the SARS-CoV-2 virus. This publication drive will subsequently be expanded into all areas of transfusion medicine as projects are completed. All research work must be deemed relevant to the wider academic community prior to commencement. The RDLF may also collaborate on significant laboratory and service developments, audit findings and interesting case studies, if peer-reviewed publication is a possible outcome from the work.

Culture and Engagement

An intrinsic part of this strategy is to embed research as a core activity throughout our whole organisation. The situational analysis determined that the majority of staff members are excited and energised by the introduction of a separate research and development department. However, there is some confusion around the definition of a research project. It is anticipated that embracing new research practices and procedures, as opposed to the previous informal structure, may also be a barrier to successful engagement with the governance strategy. Lastly, a lack of centralised knowledge and access to on-going research has led to the coexistence of pockets of staff that are highly exposed to and active in research, or research unaware and inexperienced. It is recognised that a major motivator of research is observing the applied impact of one's research outputs. The current research culture will initially be assessed as part of a wider organisational culture audit. These findings will inform strategies for research culture improvement. The creation of a positive research culture is crucial and must support research ideas and researchers through of the entire process from research project inception to completion. It is hoped that research engagement will build as research outputs are celebrated, communicated and promoted. Research thrives on collaborative thinking and therefore a value is placed on a culture that is supportive of staff 'speaking-out' and sharing their ideas and suggestions.

Communication

Effective communication of research findings is paramount to building our research reputation and creating a positive research culture. It is also a valuable and respected way of connecting with all the different communities engaging with our services.

Internal communication:

Regular communication of on-going research findings and academic studies may be accessed internally through attendance at monthly research meetings, staff presentations and newsletters. In addition, a continuation of the research communication pathways that are already in place is essential, such as the medical journal club, Haemovigilance workshop and a presence at appropriate national and international meetings.

External communication:

The primary research communication goal is to develop a research component of the **www.giveblood.ie** website. This will showcase the research, and the researchers, as well as being a repository for our peer-reviewed publications and conference presentations. A secondary aspect to the website is an IBTS research social media presence targeting the wider lay community. Lastly, a symposium showcasing research and development through posters and presentations is proposed. The location of the National Blood Centre provides a huge opportunity to collaborate with our co-located clinical and academic partners, ensuring that our research data is communicated to the medical and scientific communities that engage our services on a daily basis.

Research Themes

Our chosen research themes, summarised in Figure III, underpin our mission of providing the research evidence for improving and developing our blood and tissue services to patients. It is essential to prioritise areas for further research, in order to capture and disseminate relevant research data in a timely manner.

Our research findings may directly progress the field of testing and use of blood components, contribute to the development of new transfusion therapies, transplant supports, and inform technical and policy service enhancements and developments. Focused research will drive forward our objectives of improved donation and donor care, progressing our blood services; and becoming a key research leader in the field of transfusion science and medicine.

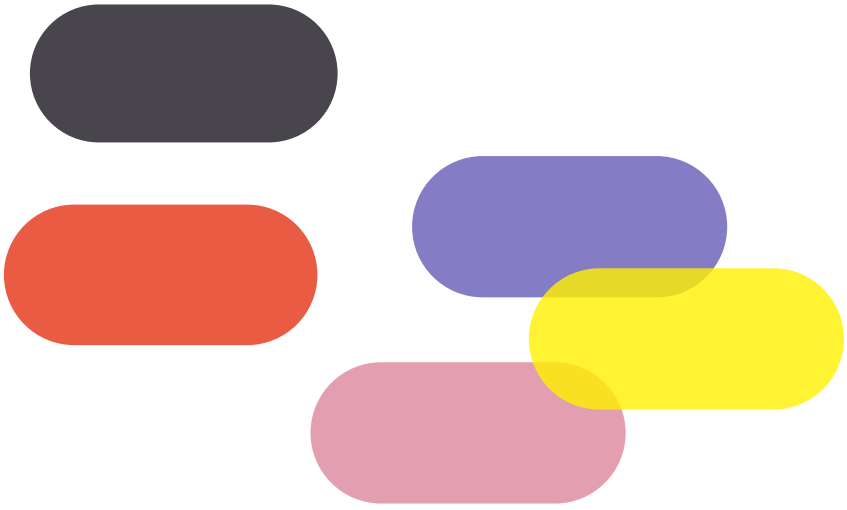


Figure III: Our Research Themes

Disease epidemiology & genetic susceptibility

- Infectious Disease Epidemiology
- Genetic associations with disease

Donation & deferral policy

- Changes in donation and deferral policy
- Donor health, welfare and selection

Applied diagnostics & technical advancement

- Immunohaematology
- Tissue and blood component production

Clinical evaluation of blood & tissue transfusion

- Clinical application and trials
- Case studies & clinical audit
- Haemovigilance

Disease Epidemiology & Genetic Susceptibility

Our Ambition:

- To capture and monitor donor infectious disease and genetic epidemiology.

Our Focus:

- **Infectious Disease Epidemiology:** Continued surveillance and epidemiological research is critical in order to identify and mitigate microbiological risks to transfusion. We will initially focus on SARS-CoV-2 seroepidemiology and on the risk of transfusion-transmitted HTLV infection in a low prevalence region such as Ireland. This data will build on that already published on donor hepatitis E virus epidemiology and the impact of infectious disease screening using nucleic-acid amplification testing.
- **Genetic associations with disease:** Donor genetic polymorphisms may provide valuable information on the genetic variability within the current donor pool for transfusion and transplantation. In addition, specific genetic polymorphisms have been linked with disease manifestations and progression. This area will investigate disease associations with blood groups, Human Leukocyte Antigens and other blood-related genetic markers. Initially, research projects will explore associations between genetic markers and COVID-19 disease susceptibility and severity.

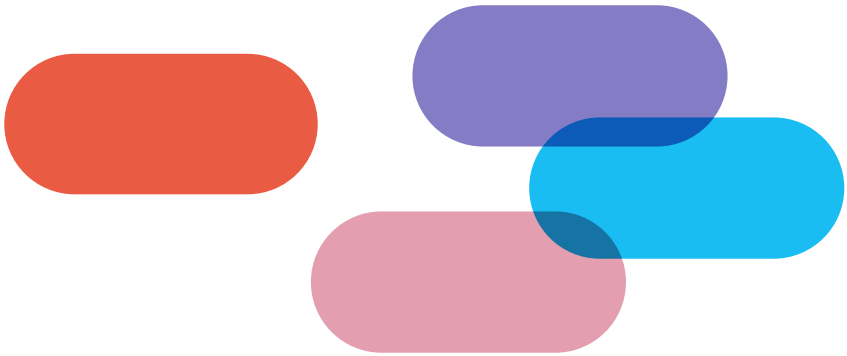
Donation & Deferral Policy

Our Ambition:

- To gain a deeper understanding of the sociological dynamics of the donation through behavioural scientific and sociological research
- To improve donor welfare
- To analyse the effects on donation following changes in deferral and screening policies

Our focus:

- **Changes in donation and deferral policy:**
  The donor deferral policy has had two significant changes in recent years; the reversal of variant CJD deferral guidelines and the inclusion of donations from men who have sex with men. Temporal changes in the donor pool, the donor deferral rates and the subsequent laboratory test results need to be evaluated.
- **Donor health:**
  Recent studies have shown that iron deficiency may be undetected using the standard haemoglobin testing criteria and a potentially more effective way of determining donor iron stores is based on blood ferritin levels. Furthermore, donor nutrition, behaviours and lifestyle have direct an impact on the interpretation of screening test results and eligibility.
- **Donor selection:**
  There are a number of different policies throughout Europe for assessing a donor prior to donation. Our initial assessment for donation is based on the donor health and lifestyle questionnaire; however, the compliance level of Irish donors has never been assessed. Furthermore, targeting and building a more ethnically and genetically diverse donor population is critical in order to optimally care for individuals with the sickle cell anaemia.



Applied Diagnostics & Technical Advancement

Our Ambition:

- To ensure we are at the forefront of blood and tissue testing and production technological advancements
- To harness the scientific capabilities within the laboratory and continuously improve donation, testing and blood production procedures
- To drive peer-review publication of laboratory developments through collaborate with validation teams

Our focus:

- **Immunohaematology:**
  This broad field encompasses both serological and molecular blood antigen profiling of antigen-antibody reactions, and their potential for pathogenesis and clinical manifestations of blood disorders. Detailed molecular genotyping of red-blood cell antigens, and other blood components, is often crucial for transfusion and transplant in clinically significant patients such as neonates and multi-transfused individuals. Determining the profile and incidence of blood antigens and antibodies in Irish donors and recipients will directly inform testing and screening algorithms.
- **Tissue and blood component production:**
  The development of blood component and tissue production methodologies and gaining a deeper understanding of the underlying mechanisms that affect the viability of these processes is essential. Specifically, the development of novel components such as cold stored platelets and use of whole blood in trauma, as well as deeper insights into platelet aggregation and pathogen reduction. Lastly the reopening of the Irish eye bank is envisioned during the time-frame of this strategy, which will likely drive research and development in the areas of cornea manipulation and regeneration.

Clinical Evaluation of Blood & Tissue Transfusion

Our Ambition:

- To collaborate on clinical trials assessing the clinical application and utility of blood components and tissue
- Continued Haemovigilance of blood component and tissue administration
- To drive peer-review publication of audit and clinical case studies through collaboration with our scientific and clinical teams

Our focus:

Clinical application and trials: Studies in this area required firm collaborative links with clinical research centres/facilities which are capable of overseeing clinical trials. Initially a clinical trial protocol that encompasses the production, administration and efficacy of COVID-19 convalescent plasma will be used a platform to establish these necessary links.

Case studies & clinical audit: Clinically significant donor case studies and audit outcomes that may be relevant to the wider academic community should be identified and published where possible. Currently, we are closely aligned with the clinical interpretative work of the National Transfusion Advisory Group (NTAG) and the research of the newly appointed Aspire fellow in Neonatal Transfusion and Haemovigilance.

Haemovigilance: A retrospective analysis of serious adverse reactions and events following blood transfusion or blood component administration will add to understanding of the risks and outcomes of transfusion.

Key milestones for 2021 and 2022

The strategy implementation ambitions and key milestones for 2021 and 2022 are listed below. Please see below for a summary of the on-going research projects and time-lines for completion.

2021 Ambition

- Implementing the Research and Development governance and infrastructure
- Publication drive on data previously analysed but still awaiting publication
- Key contributor to BEST collaborative

Critical for success

- Research Information Technology infrastructural support

Key deliverables:

Q1

1. Set-up of Research and Development Committee (RDC)
2. Begin monthly internal research meeting Completion of Research Practice and Integrity policy
3. Introduce new Research practice standard operative procedure
4. Agree Research key-performance indicators
5. BEST collaborative membership & contribution to on-going BEST studies

Research Implementation Plan

Q2

1. Research practice and integrity e-training module
2. Donor blood antigen publication
3. SARS-CoV-2 studies publication
4. Publication and presentation repository & system for review
5. Design research presentation and poster templates

Q3

6. Academic staff adjunct affiliation for RDLF
7. Donor infectious disease epidemiology publication
8. Research grant information and funding plan

Q4

9. Research culture audit findings
10. Central list of conference, society, network and group membership & participation

2022 Ambition

- Strong focus on research communication

Key deliverables:

11. IBTS Research module on Website
12. IBTS Research Social media
13. IBTS Research Symposia
14. Medical Fellowship
15. Presentations at BEST collaborative
16. Presentation at International Society of Blood Transfusion
17. Presentation at two national conferences or society meetings

Irish Blood Transfusion Service
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