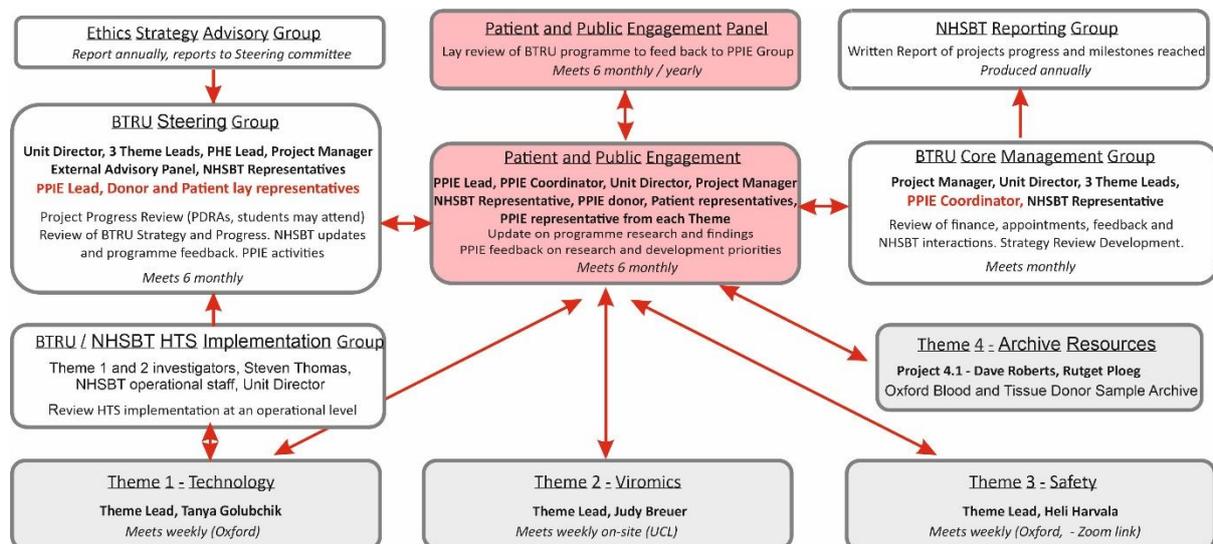


NIHR Blood Transfusion Research Unit
Genomics to Enhance Microbiology Screening (BTRU-GEMS)
Patient and Public Involvement and Engagement (PPIE) Strategy, 2022-2027

Involvement, engagement and participation

We recognise that public involvement in research is carried out in collaboration with patients, carers, representatives of specific communities and health service users, and those with first-hand experience of specific health conditions related to the BTRU-GEMS theme. For the current programme, the main stakeholders are therefore blood donors, blood, organ and transplant recipients and multi-transfused individuals, such as people with sickle cell disease or Thalassaemia or those undergoing treatment for cancer, who have specific concerns and involvement in transfusion risk, including most relevantly for this BTRU, transfusion and transplant transmitted infections (TTTIs). Wider representation will also include representatives from groups representing patients with specific infections, including hepatitis B virus (HBV) and human immunodeficiency viruses (HIV).

The BTRU is structured to include public / patient engagement in all key decision-making committees and structures (see Organogram below). PPIE representation (highlighted in red) is planned for the Ethics Strategy Advisory Group, the BTRU Steering Group and the BTRU core Management Group.



Objectives and Measuring success

Our objectives are aligned with National Institute for Health and Care Research (NIHR) and NHS Blood and Transplant (NHSBT) and will be reviewed periodically to ensure it meets the needs of our research and NHSBT. Our objectives and success criteria are:

Objectives	Success criteria	Measured by	Monitored by
To align our research with the needs of blood or organ donors (donors) and blood or organ recipients (recipients) and NHSBT.	<p>PPIE training of BTRU staff and supervisors,</p> <p>Advice on PPIE planning</p> <p>Developing PPI panels and processes</p> <p>Delivery of PPIE focus group for research needs.</p>	Monitoring PPIE work data	PPIE advisory committee meeting, meets quarterly and will include reporting from the BTRU
To involve donors, recipients and other key stakeholders in the design, ethics discussions and reporting of our research from the start through to implementation.	<p>Increased interest and trust of researchers to work with more diverse communities and disadvantaged groups</p> <p>Increase number of diverse organisations</p>	Monitoring PPIE work data	<p>Through the PPIE advisory committee</p> <p>Report our PPIE activities by our PPIE representatives in annual meeting</p>
To establish a culture where ethical issues substantially contribute to research planning and decision making.	<p>Involve donors and recipients in our Ethics Strategy Advisory Group</p> <p>Members of the Ethics Strategy Advisory Group will review protocols and ethics applications, participate in the development of participant information and consent forms</p>	Evaluation of individual projects	Reporting from the Ethics Strategy Advisory Group
To actively involve donors, recipients and the public to increase understanding of	Increased interest and trust of researchers to work with more diverse communities	Community led PPIE	PPIE advisory committee meeting

medical research techniques.	and disadvantaged groups		
To create a process to support and encourage the involvement of donors and recipients to participate in discussions impacting the research that is conducted by our researchers.	Increase number of staff reporting to PPIE advisory committee Increase knowledge, skills and confidence.	Survey and interview at induction for new starters Annual survey and follow up interviews of research staff	PPIE advisory committee meeting

PPIE lead and coordinator

To develop active PPIE engagement, we are appointing a full-time PPIE Lead / coordinator who will coordinate a range of PPIE activities and programme engagement priorities.

The appointee will play central roles in the interface between scientists, clinicians and those drawn from donor and patient groups and members of the public. He/she will play a central role in the coordination of these activities to ensure that PPIE representation significantly guides the BTRU programme in directions of most benefit to the main stakeholders affected by TTTIs.

Committee representation of Patients and Public within the BTRU

More specifically, the following guidelines for involvement will be followed in the BTRU programme:

- PPIE should be accessible to everyone and participation in research should be accessible to all groups who are relevant to our study. To achieve this, we will create a diverse PPIE Advisory Committee following the guidelines provided in the INVOLVE 2012 document ‘Strategies for diversity and inclusion in public involvement: Supplement to the briefing notes for researchers. We will additionally assign one PPIE member from each Theme in the PPIE Advisory Committee. Engaging regularly (quarterly) with the PPIE Advisory Committee members through virtual and in person meetings will enable us to identify and address barriers to underrepresented groups involvement and engagement. We will reach out to underrepresented groups by going through community contacts or social media, and through the NHSBT networks.
- The PPIE appointee will be asked to formally chair and administer the PPIE Advisory Committee (pink box in the Organogram). This committee incorporates PPIE representatives from different

donor and patient groups, the PPIE coordinator, the Unit director, project Manager and representatives from NHSBT. This committee will report to the Director and BTRU core management group. It will also coordinate PPIE panels that provides lay review and opinions on selected area of the BTRU programme where they have donor, patient or wider societal implications. The group will meet 6 monthly with a remit to provide regular updates on programme research and findings and provide formal feedback on research and development priorities to the Management Group and wider Steering Group.

- PPIE Advisory Committee members will be involved in all stages of the research cycle of all three themes to provide opportunities for a range of PPIE activities. This includes prioritisation, study design, and conduct of our research work. We will share our study documentation with our PPIE Advisory Committee to ensure the language and content is accessible and suitable for patients, donors and a wider general audience.
- We will ask a sub-committee, the Patient and Public Engagement Panel, to formally review programme plans and to formally report back to the PPIE committee on a 6-12 month cycle to ensure that project plans have received the appropriate scrutiny from relevant lay parties. PPIE representatives will therefore play a number of roles in these groups, including identifying research priorities, providing insights into the use of patient information leaflets, consent procedures, interviews and other forms of donor and patient interactions and insights into how such group conceive of the value and applicability and public benefit of research and development programmes performed by the BTRU.
- The PPIE appointee will act as primary links between the research groups, NHSBT and UKHSA representatives and patient/donor/public representatives. They will help to recruit those and make sure they feel included and acknowledged
- There will be PPIE representation in the BTRU Steering Group that reports directly to NIHR on an annual basis. Their involvement will help develop avenues for implementation, reporting and reviewing impacts of donors, patients and other stakeholders.
- PPIE representation (involving a blood donor and a blood recipient) in the BTRU Ethics Strategy Advisory Group has been organised and representatives will provide essential knowledge and insights in public and patient perception of advances and associated information and

communication issues that arise. We are working together on ways to increase the contribution of donors and recipients to the BTRU activities by developing learning and development opportunities. For example, we will organise face-to-face meeting with PI's and visit to research facilities and BTRU Ethics Strategy Advisory Group will provide feedback on the study plans.

- The PPIE appointee will engage directly with our NHSBT partners, in the engagement and recruitment of new donor and patient groups, that those previously to review broader aspects of transfusion practice, including the formulation of FAIR guidelines for donor selection and longer-term impacts of ATMP therapy.
- Involvement in the commissioning of data acquisition in areas of transplant and transfusion practice and opinion, through creation of wider surveys of patient and professional groups. Information gained from such activities will provides essential guideposts for BTRU project development and understand its impacts.
- Interaction and knowledge exchange with PPIE leads across NHSBT, BTRU programmes and with the PPIE in the two other Oxford BTRU units. Once this network is in place, we envisage the PPIE leads would meet to share good practice and experiences at least twice a year.
- Researcher colleague will receive PPIE training within the BTRU-GEMS. This will heighten researcher awareness of PPIE and help instil public involvement. To maximise PPIE's potential benefits, it is important to understand the role of PPIE in research. We will provide training for our Researcher colleagues through our NIHR representatives such as Oxford Biomedical Research Centre and Nuffield Department of Primary Care Health Science. We will implement appropriate policies, procedures and guidelines including the 2022 NIHR guidance for remuneration of individuals who participate in PPIE activities.
- Coordination of public and patient engagement events arranged by the BTRU e.g. open days, science café's. Where possible using available infrastructure in Oxford University but also creating bespoke events when appropriate. Activities will also be combined with public outreach and communications by the other BTRU units in Oxford.
- We will develop online resources for patients, donors and the public through our project website. Our website will also provide support to researchers on PPIE. Public engagement of agreed social media outputs from the Unit. For example, they (along with the PPIE committee)

will regularly contribute to the BTRU-GEMs website with information and articles written in plain interest:

<https://www.medsci.ox.ac.uk/research/networks/blood-and-transplant-research-units/genomics-to-enhance-microbiology-screening>

There will be active contributions and conversation on the twitter account established for the Unit (@BTRU_GEMs), and which will inform the public and encourage involvement about the Units research.

- The Programme will fund participant time, expenses and other costs based on the following NIHR guidelines:

<http://www.invo.org.uk/posttypepublication/budgeting-for-involvement>

This provides funding for patient, donor and public engagement activities at a level that represents realistic costs for engagement of patient and donor panels. It will additionally fund a series of outreach, events, public meetings, participation in NHSBT external events (£2000/year) and dissemination (£1000/year), including the extension and use of the BTRU-GEMs website for plain English description of BTRU-GEMs activities, progress and translation into benefits for patients and donors.

In terms of monitoring, PPIE activity will be monitored, reviewed and reported across the BTRU-GEMs through the management structures shown in the organogram and will be reported to NIHR in the BTRU annual reporting. Our PPIE strategy will be designed and implemented by our PPIE Lead and coordinator and we will make this document publicly available and reassess it each year on a dedicated BTRU website. It is important to evaluate and report the impact of PPIE in research to strengthen the patient, donor and public involvement. We will evaluate and report the impact of PPIE in research across all the themes to NIHR.

Specific examples of PPIE involvement early in the BTRU Programme

- The development and application of high throughput sequencing for donation screening presents enormous ethical and confidentiality issues, referral decisions and potential future medical interventions for donors. These are not encapsulated in existing donor consent forms

and result reporting associated with current screening. Substantial assistance in meeting these challenges can be achieved through the involvement of donor and patient representation in a BTRU-GEMS group, the Ethics Strategy Advisory Group, to develop robust guidelines for the use of these technologies and to help anticipate the ethical issues, consent requirements and operational impact of the introduction of novel technologies in donation screening. This process is currently ongoing with guidance expected later in 2022.

- The positive steps towards transfusion and transplant safety and use of advanced therapeutic medical products (ATMPs) requires a degree of patient and public engagement in conveying the potential improvements in the safety of NHSBT practice to wider groups of both patients and clinicians.
- In Theme 3, we will investigate the natural history of occult hepatitis B virus infections, its ethnic and demographic associations, and establish how these may impact on maintaining an effective BAME (Black, Asian, and Minority Ethnic) donor cohort through better prediction of infectivity. This requires considerable public involvement into how research is conducted, interpreted and communicated.
- Surrogate marker testing for groups assessed at greater risk for HIV infection and also investigation of effects of changes in donor selection criteria as part of FAIR requires substantial donor and other stakeholder engagement. Implementation of appropriate oversight will ensure that public and patient views are central to BTRU research and integrated into BTRU outputs. Some of the stakeholder groups representing newly eligible donors will be approached to support this work.

Rolling programme of projects and activities

	Year 1 April 2022- March 2023	Year 2 April 2023- March 2024	Year 3 April 2024- March 2025	Year 4 April 2025- March 2026	Year 5 April 2026- March 2027
PPIE recruitment	PPIE lead, coordination and PPIE advisory committee	PPIE advisory committee meetings quarterly			

PPI	Donors and recipients involvement in Ethics Strategy Advisory Group to feedback on study design Community-led PPIE	
		Established patient panel (including blood and organ donors and blood and organ recipients)
People engagement	Social media such as Twitter Utilise the monthly bulletin highlighting upcoming events, training and funding	
		Key members of the team to undertake additional training on PPIE to support the programme. Connecting with the local Series of organised events, with the aim of engaging public in our research
Building capacity and capability of lay representatives		Allocated a “science partner” for each member for all meetings for pre and or post meeting discussion and content review.
Partners and collaborators	NHSBT UCL UKHSA	
Leadership and lines of reporting	Outcomes will be presented to the BTRU-GEMS Management team, NHSBT and NIHR	
Monitoring, review and reporting	Regularly review our PPIE strategy to ensure effective use of resources Report our PPIE activities by our PPIE representatives in annual meeting	

Summary aims of the PPIE Strategy

We believe the extensive structural involvement of PPIE in the BTRU-GEMS will substantially improve the focus and outcomes of the research and development programme for the benefit of donors, patients and other stakeholders in the blood services. Their engagement will increase the accountability and transparency of the research themes and aid in their public dissemination and ultimate real-world benefit. It will additionally help articulate a rationale for the work done in the programme and the targeted benefits that the research accrues.

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16th December, 2022

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16th December, 2022