

*This Management Process Description replaces
NEW*

Copy Number

Effective

DRAFT

Summary of Significant Changes

N/A

Policy

The mission statement of this group is to provide support and encourage NHSBT's researchers to actively seek patient and public involvement and engagement in their research at all stages. The role of the Patient and Public Advisory Group (PPAG) is to bring together expertise, insight and experience in the field of public involvement in research, with the aim of making it an essential part of the process by which NHSBT research is identified, prioritised, designed, conducted and disseminated.

Purpose

The purpose of this document is to provide the reader with background information on the management and processes of the NHSBT Patient and Public Advisory Group. It outlines the rationale and importance of a PPAG and provides information on the process of applying for PPAG input in research related projects including but not limited to protocol development, patient information sheet reviewing, research management and dissemination of research results at the end of a study (Appendix 1').

Responsibilities

R&D Office – Coordination and management of PPAG activities including linking PPAG members with NHSBT researchers for research specific tasks, provide update to Clinical Directorate Senior Management Team (CDSMT) and Research and Development Committee (RDC).

PPAG Management Group – Develop and manage PPAG, to meet every 2 months and support all group activities.

Clinical Trials Unit (CTU) – A representative will be a member of the PPAG management group and provide support to group activities.

NHSBT Researcher - Engage with R&D Office to involve PPAG members in research project and support PPAG members throughout duration of involvement.

PPAG members – Provide appropriate support to researchers in the development and management of research projects.

Components development Laboratory (CDL) - A representative will be a member of the PPAG management group and provide support to group activities.

NHSBT Patient and Public Advisory Group for research projects

RDC – Approves NHSBT PPAG activities.		CDSMT – Approves NHSBT PPAG activities.
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Definitions (please refer to appendices)

PPAG – Patient and Public Advisory Group

CTU – Clinical Trials Unit

R&D – Research & Development

CDSMT – Clinical Directorate Senior Management Team

RDC – Research and Development Committee

CI – Chief Investigator

PI – Principal Investigator

PPIE – Patient and Public Involvement and Engagement

CDL – Components Development Laboratory

Applicable Documents

Patient and Public Advisory Group Registration Form	Researcher Registration Form
Researcher Request Form for PPAG member involvement	Patient and Public Advisory Group Member Feedback Form
Confidentiality Statement	Researcher feedback Form
PPAG Lost Link Form	Expenses Claim Form

Background Information

NHS Blood and Transplant (NHSBT) has the responsibility for optimising the supply of blood, organs, tissues and raising the quality, effectiveness and efficiency of blood and transplant services for the public. One way that NHSBT achieves this is by commissioning and conducting research and development (R&D). Working in collaboration with leading universities, public and private industry, the R&D programme guides international transfusion and transplantation practice to benefit healthcare in the UK and beyond. Within the public, private and academic sectors in the UK, there are no other organisations capable of delivering an R&D programme that spans our range of products and services.

Our current research consists of a portfolio which is funded across a number of themes (Appendix 2), both internal and external to NHSBT. Each project is aligned with one of our nine research themes. We are also supported by the National Institute for Health Research Blood and Transplant Research Units (NIHR BTRUs) for research to improve the supply of blood, blood products, stem cells and tissues.

We also provide core funds to our Principal Investigators for research prepared in conjunction with NHSBT Research Strategy Groups. This approach has increased alignment with operational requirements and improved translation of results into service delivery.

NHSBT Patient and Public Advisory Group for research projects

More people than ever before are taking part in research studies, which has led to new and better treatments and services. Members of the public are also getting involved in advising us about what research should be funded and helping to design research studies.

Public involvement in research is defined as research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them. This includes, for example, working with research funders to prioritise research, offering advice as members of a project steering group, commenting on and developing research materials.

The term 'public' includes patients, potential patients, carers and people who use health and social care services as well as people from organisations that represent people who use services. There is an important distinction to be made between the perspectives of the public and the perspectives of people who have a professional role in health and social care services.

The mission statement of this group is to provide support and encourage NHSBT's researchers to actively seek public involvement and engagement in their research. The role of the group is to bring together expertise, insight and experience in the field of public involvement in research, with the aim of making it an essential part of the process by which NHSBT research is identified, prioritised, designed, conducted and disseminated.

The need for Patient and Public Involvement and Engagement (PPIE)

Prior to September 2018 NHSBT did not have a central Research Patient/Public Advisory Group (PPAG) that could provide the support our researchers need to fulfil the PPIE requirement needed in research. PPIE support includes but is not limited to:

- Study design;
- Implementing managing the study;
- Disseminating research results;

PPIE is important to ensure research quality and relevance as well as being part of public accountability and transparency.

The impact of creating and sustaining an NHSBT PPAG will be to actively support patient/public involvement and engagement in NHS Blood and Transplant research activities.

Patient and Public Advisory Group Members

A diverse PPAG will ensure that patients and the public are systematically involved and embedded in all aspects of the research process. This group and list of contacts will be a resource for NHSBT researchers to draw upon to support them with research questions or tasks (Appendices 3-5). A range of patient and public representatives will be invited to join. The role and structure of this group is dynamic and fluid and may consist of:

- A database of already established patient groups willing to be contacted to offer support to NHSBT researchers;

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- a. people with specific expertise/experience or medical conditions;
 - b. people willing to support research but with less time available;
 - c. representatives of charities or local communities/networks.
- A register of patients and members of the public willing and able to meet researchers either physically or virtually to discuss strategic issues and to support research at various stages. These volunteers are drawn from across the country.

Interested parties will register via the [PPAG Member Registration Form](#) on Cognito forms which is a password protected site with limited access; please see Privacy Policy for more information. This database of contacts will be developed and maintained with appropriate permissions by the R&D Office. Compliance with the Data Protection Act 2018 and the General Data Protection Regulation (GDPR) will be achieved via Informed consent and Privacy Policy at registration on Cognito (approved by NHSBT Information Governance).

Registered PPAG members will be required to sign an electronic [Confidentiality Statement](#)* if they agree to support a research project.

*Please note this is a Memorandum of Understanding only therefore all care must be taken when information is shared with PPAG members.

PPAG Member responsibilities if you agree to support a research project include:

- Prepare in advance for meetings, please note frequency and dates of meetings will vary depending on the need for PPAG member input in research projects;
- Respond in a timely manner to all email communication as required;
- Share your views in a considered and constructive manner;
- Treat all research related documents that you review as confidential (except already published materials);
- Provide ongoing feedback to help further develop and refine the process for involving patients in the review of clinical research.

Skills and Experience required:

- Ability to listen and to express own views about issues concerning research;
- Ability to work as part of a group with people from a wide range of different backgrounds;
- A commitment to diversity and equality of opportunity;
- A commitment to seeking the views of a range of stakeholders;
- Perspectives beyond personal experience;
- Be enthusiastic about research, and willing to familiarise yourself with medical and research language (Appendix 6);

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- Good communication skills with an ability to listen to and to respect differing opinions, and to express your own view clearly and appropriately;
- It is desirable that some PPAG members have experience of taking part in a clinical trial.

Length of membership

- Membership to PPAG is open; if you would like to leave the group please email the R&D Office at PPAG.Research@nhsbt.nhs.uk

Time commitment

- Online registration;
- Annual PPAG management meeting;
- The time it takes to review research documents, attend research specific meeting and provide feedback as applicable; this will vary depending on the research project.

Expenses

- Expenses for NHSBT activities will be covered either by the R&D Office when attending events organized by us or you will be reimbursed by the research team that you are supporting (please see Patient and Public Advisory Group Member Expenses Reimbursing Policy);

NHS Blood and Transplant researchers

To register for PPAG involvement please complete the [Research Registration Form](#) to register your research project.

To help you plan and undertake PPAG involvement in your research we suggest that you consider the following points:

- Involve people as early as possible;
- Be clear with the R&D Office and PPAG members of what is needed from them;
- If the research project is confidential, please ensure that PPAG members are aware;
- Be accessible i.e. named individual on research project team that will lead and organize PPIE work;
- Reimburse PPAG members' expenses for research specific tasks in a timely manner (please see Patient and Public Advisory Group Member Expenses Reimbursing Policy);
- Document and record PPAG involvement in your research.

Please visit <http://www.invo.org.uk/resource-centre/resource-for-researchers/> for more information

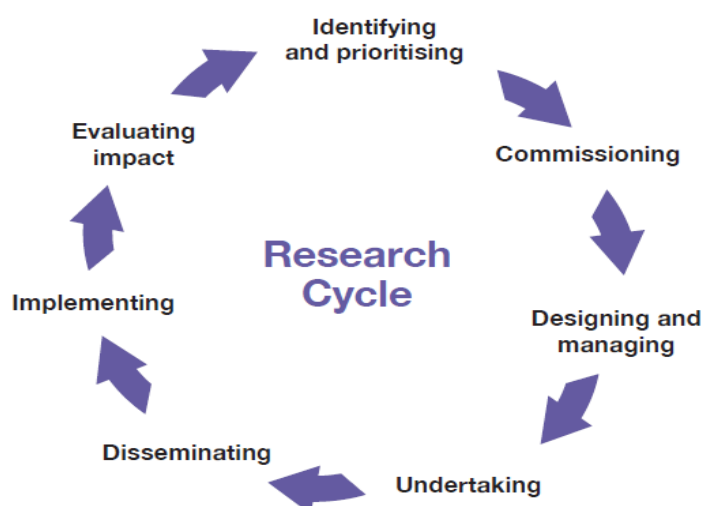
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NHSBT PPAG management group

Chair	National Research Manager (R&D Office)
Deputy Chair	Research Governance Manager (R&D Office)
Secretariat	R&D Administrator (R&D Office)
Contributors	<ul style="list-style-type: none">• Medical Director of Clinical Trials Unit (CTU)• Trial Manager/Research Nurse (CTU)• Component Development Scientist• Senior Information Scientist• Specialty Doctor

Appendices

Appendix 1: Ways the PPAG members can be involved in research projects

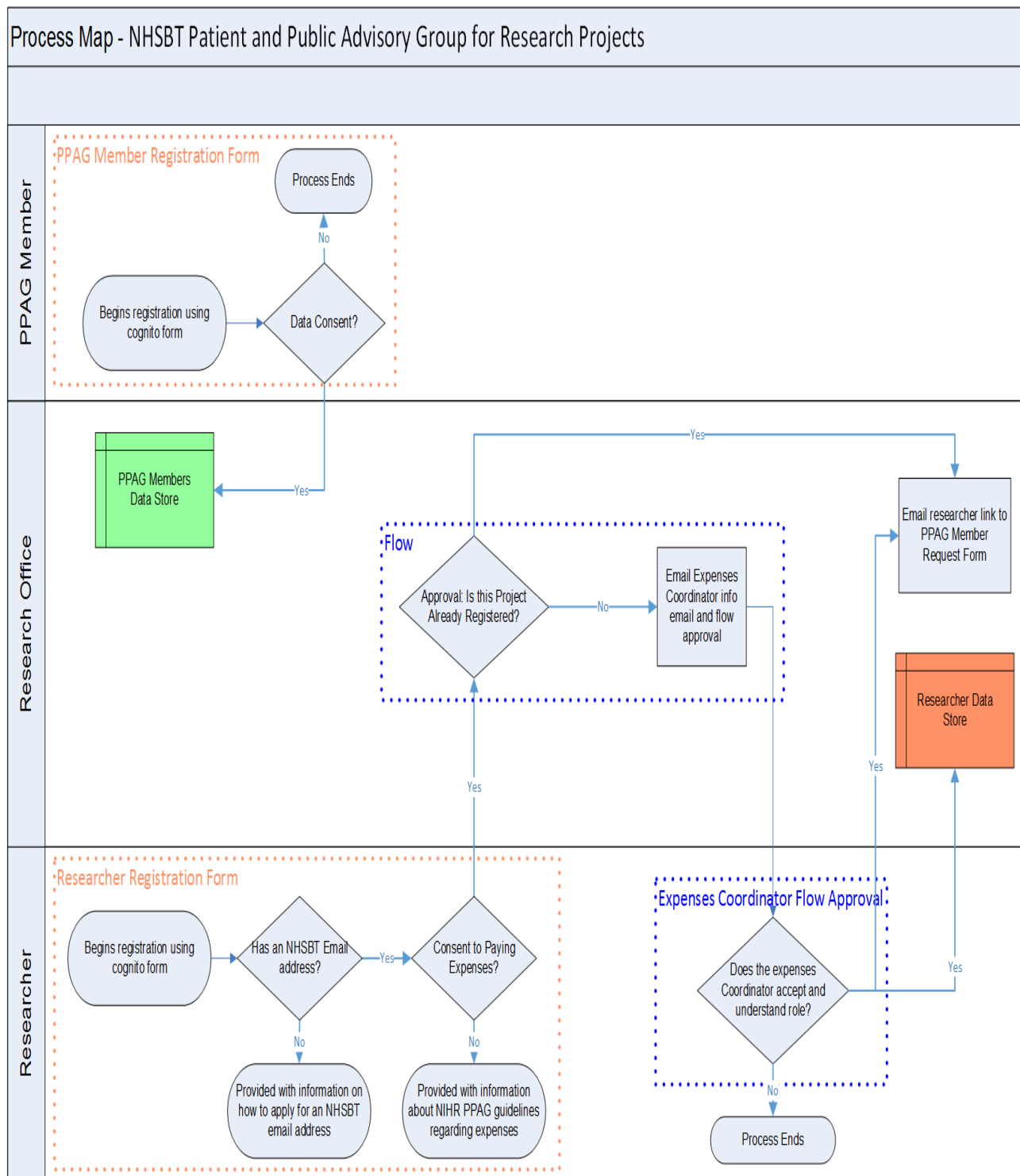


Appendix 2: NHS Blood and Transplant Research Themes

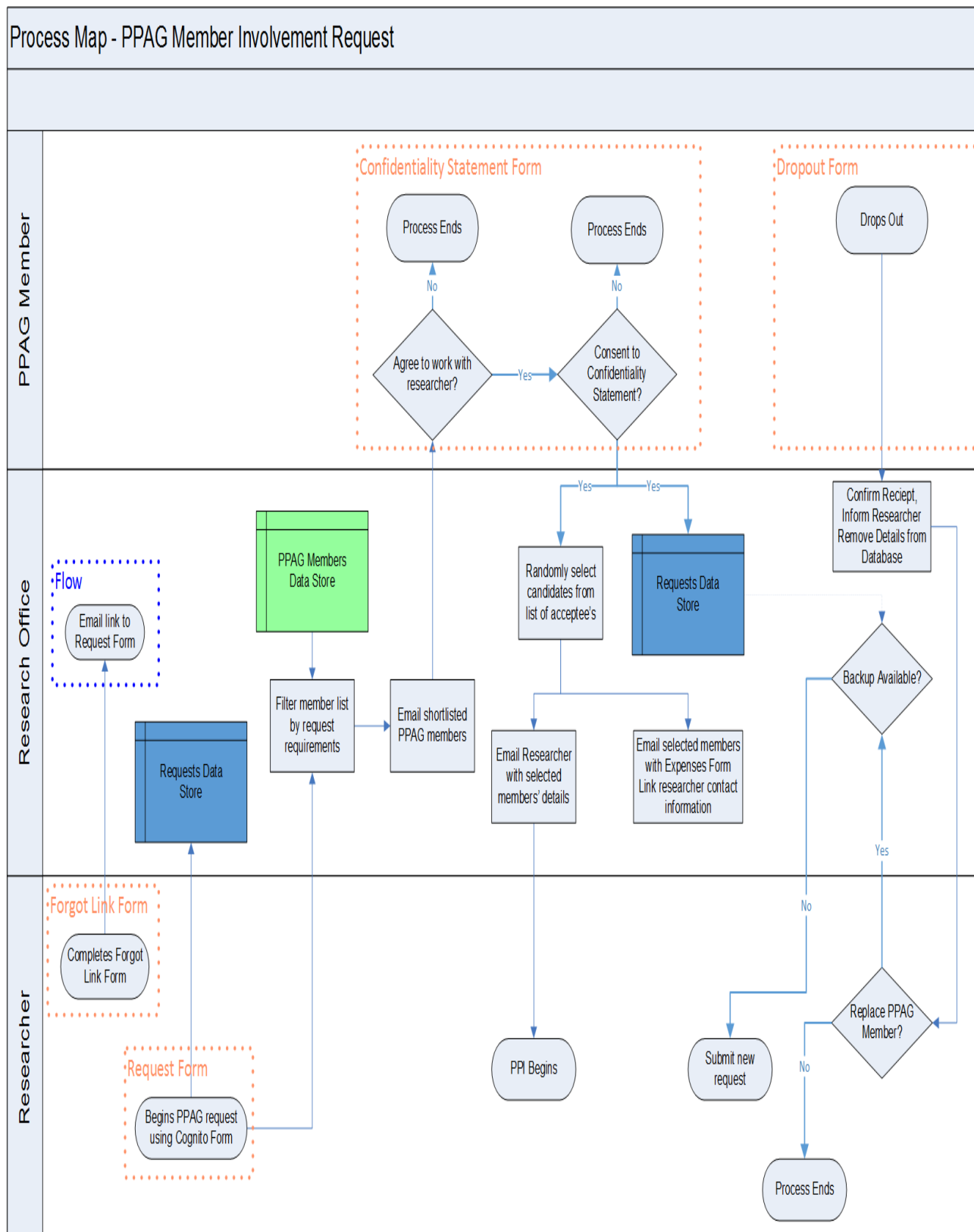
1. Blood Donor Health
2. Transfusion/Transplantation Virology and Microbiology
3. Patient Blood Management
4. Advanced Blood Components
5. Organ Donation and Transplantation
6. Stem Cells and Immunotherapies
7. Tissue Engineering
8. Behavioral Research
9. Translational Data Science

Appendices 3-5: Process flow chart for requesting PPAG member for research related work

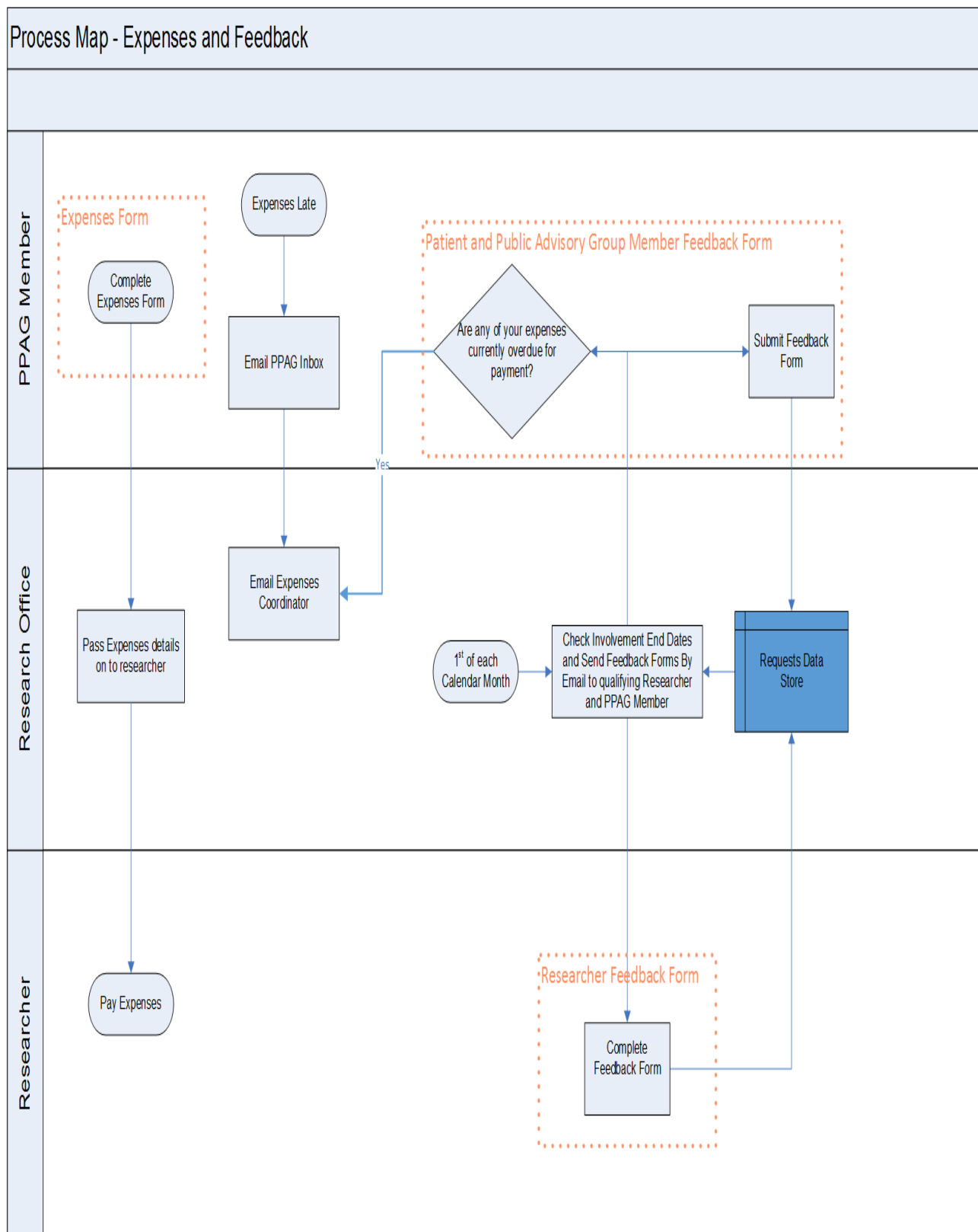
Appendix 3: Registration



Appendix 4: Involvement request



Appendix 5: Expenses and Feedback



Appendix 6: Research terminology glossary

AE	Adverse event
A&E	Accident & Emergency
AR	Adverse reaction
ATU	Advanced Therapies Unit
BP	Blood Pressure
BTRU	Blood and Transplant Research Unit
CB	Cord blood
CDL	Components Development Laboratory
CDSMT	Clinical Directorate Senior Management Team
CI	Chief Investigator
CRF	Clinical Research Facility
CTIMP	Clinical Trial involving an investigational medicinal product
CT	Computerised tomography
CTU	Clinical Trials Unit
DH	Department of Health
DMC	Data Monitoring Committee
DNA	Deoxyribonucleic acid
EDTA	Ethylenediaminetetraacetic acid
EudraCT	European Clinical Trials Database
FBC	Full Blood Count
FDA	US Food and Drug Administration
(ICH) GCP	(International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) Good Clinical Practice
GP	General Practitioner
IMP	Investigational Medicinal Product
IMPD	Investigational Medicinal Product Dossier
IPSC	Induced Pluripotent Stem Cells
ISRCTN	International standard randomised controlled trial number
IRAS	Integrated Research Application System
MHRA	Medicines and Healthcare Products Regulatory Agency
MPD	Management Process Description
NHS	National Health Service
NHSBT	NHS Blood and Transplant
NIHR	National Institute for Health Research
PPAG	Patient and Public Advisory Group
PB	Peripheral Blood
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
QP	Qualified Person
R&D	Research and Development
RBC	Red Blood Cell
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RDC	Research and Development Committee
RNA	Ribonucleic acid
SAE	Serious adverse event
SABRE	Serious Adverse Blood Reactions & Events
SAR	Serious adverse reaction

NHSBT Patient and Public Advisory Group for research projects

SUSAR	Suspected Unexpected Serious Adverse Reaction
TMG	Trial Management Group
TSC	Trial Steering Committee
UAR	Unexpected Adverse Reaction

Additional information

NHSBT is committed to being inclusive in all that we do, and we will therefore make any reasonable adjustments required to enable you to fulfil this role.

Please visit the NHSBT Research and Development corporate page for updates on PPIE activities and the quarterly newsletter.

ⁱ http://www.invo.org.uk/wp-content/uploads/2014/11/9938_INVOLVE_Briefing_Notes_WEB.pdf