



*Blood and Transplant*

## **Research Governance Policy for Supporting Research Proposals – Organ Donation & Transplantation**

---

NHS Blood & Transplant

December 2011

## **1 Executive Summary**

- 1.1 NHS Blood and Transplant (NHSBT) recognises the importance of clinical research and wishes to support all suitably approved research.
- 1.2 The policy outlines the process for ensuring appropriate governance of those research projects relating to the Directorate of Organ Donation and Transplantation that involves
  - Gaining access to human organs, tissues or samples derived from tissues from deceased donors.
  - Gaining access to donors, donor families, carers or friends, ODT staff or aspects of the donation process.
- 1.3 This policy does not cover research using data in the UK Transplant Registry and other NHSBT Databases where separate arrangements apply.
- 1.4 This policy is guided by the principles of the Research Governance Framework for Health and Social Care (2005) and the Scottish Executive Health Department Research Governance Framework (2006) and should be used in the context of NHSBT Research Governance Policies, and should be used in conjunction with the current NHSBT Policies on Research and Development.

## CONTENTS

1. Executive Summary	2
Contents	3
2. Introduction	4
<b>Section One – The NHSBT – ODT Research Approval Process</b>	
3. How to get ODT Support	4
4. Project Registration	4
5. How to Proceed with a Proposal	5
6. Documentation Required	6
7. The Approval Process	7
<b>Section Two – General Advice Supporting the Research Approval Process</b>	
8. Financial Arrangements	7
9. Intellectual Property	8
10. Peer/ Scientific and Ethical Review	8
11. Human Tissue in Research	8
12. Researcher Conduct	9
<b>Section Three - Research Governance Responsibilities</b>	
13. General Responsibilities	9
14. Responsibilities – Clinical Governance Monitoring Group	10
15. Responsibilities – Researchers	10
16. Responsibilities – Principle Investigators	11
17. References	14
18. Appendices	15

## **2 Introduction**

- 2.1 This policy outlines the procedures that all researchers, whether employed by NHSBT or other appropriate agencies (including other NHS Trusts, Health Boards or Universities), should follow before undertaking research associated with any aspect of the work undertaken by the Directorate for Organ Donation and Transplantation (ODT).
- 2.2 This process is required not only to ensure that there is appropriate research governance but also that all those who may be affected by the research proposal are aware of the proposal and that the integrity of the donation and transplantation process is not adversely affected.
- 2.3 The policy is divided into 3 sections:
- 1) The ODT approval process.
  - 2) General Information – in support of the research application.
  - 3) The research governance responsibilities.
- 2.4 The policy covers all research projects involving ODT activities including:
- NHS staff working for NHSBT
  - Patients ( including donors and potential donors)
  - The actual or potential organ or tissue donor, and their family, carers or friends
  - Tissues
  - Organs
  - Blood or blood products
  - NHS facilities within ODT
  - NHS equipment owned by ODT
- 2.5 The policy does not cover research based on data in the UK Transplant Registry or other databases held by NHSBT, for which separate arrangements apply.

## **Section 1: The NHSBT/ ODT Research Approval Process**

### **3 How to get ODT Support**

- 3.1 Anyone considering undertaking a research project that involves any aspect of ODT's activities or requires support from ODT should initially seek advice from the Research Manager – ODT.
- 3.2 See Appendix 1 for over view of the approval process

### **4 Project Registration**

- 4.1 The Research Governance Framework requires that all research must be registered and authorised by the appropriate R&D Department.

- 4.2 Registration and approval from ODT is required in addition to local R&D approvals when the research involves or requires support from ODT staff or any aspect of ODT's activities.
- 4.3 All research proposals submitted to ODT for approval will be given a unique study number and entered onto the ODT Research Register.

## **5 How to Proceed with a Proposal**

- 5.1 All research proposals/projects must meet the criteria set out in this policy in adherence to the Research Governance Framework for Health and Social Care (2005) and Northern Ireland and the Human Tissue (Scotland) Act (2006).
- 5.2 The Principal Investigator (or an authorised delegate, who may be a co-investigator or Research Nurse), should complete and return the Project Registration Form (see Appendix 2) along with the required documentation to the Research Manager – ODT.
- 5.3 In order to minimise delaying the start of a project, submission for approval by ODT may be undertaken alongside other external approval processes (REC, local R&D etc...).
- 5.4 ODT may give provisional approval pending the outcomes of other approvals.
- 5.5 NHSBT may, when appropriate, seek reimbursement of costs for supporting research. This should be included in any funding or grant applications. Advice on potential financial implications should be sought from the Research Manager – ODT.
- 5.6 On receipt of all appropriate documentation the Research Manager - ODT will notify the appropriate Directors at ODT of the research proposal for their initial approval to proceed the application:
- Research studies involving the use of organs or tissues, medical equipment will be directed to the Associate Medical Director (AMD) or Deputy.
  - Research studies involving the donor, donor families, carers or friends, ODT employees or ODT facilities will be directed to the Assistant Director (AD) or Deputy.
  - The Director will respond within 4 working days.
- 5.7 Once ODT managerial approval has been granted, the proposal will be discussed at the appropriate Sub-Group of the ODT Clinical Governance Monitoring Group (CGMG). The purposes of the review include:
- Overview of the project: whether the aims are consistent with the strategic aims of ODT and NHSBT
  - Implications for staff, patients, families and carers
  - Practical and logistic issues
  - Compliance with current legislation and policies

- Training issues
  - Competing projects
  - Informing and/or consultation with other clinicians involved in the donation/transplantation process
- 5.8 Where there are competing research proposals or potential studies investigating similar activities, the CGMG sub-group will apply the ODT R&D prioritisation matrix (see appendix 4) to determine priority.
- 5.9 Where appropriate the CGMG sub-group may seek an agreement of support from the Organ Donation Service Team(s) involved in the research.
- 6 Documentation Required (see appendix 2 for the Project Registration Form):**
- 6.1 **Documentation Required - Always:**
- A copy of the research proposal or protocol
  - Confirmation of the project Sponsor, if this is not NHSBT.
  - Research Ethics Committee approval (or evidence that it is being sought) or a letter confirming REC approval is not required
  - Local R&D approval, if this is not through NHSBT.
- 6.2 **Documentation Required - When Appropriate:**
- The protocol should also include:
    1. A Standard Operating Procedure describing the surgical procedure involved in removing the organ or tissue if this is not covered by existing SOPs.
    2. Names and qualifications of those of personnel who will retrieve the organ or tissue or name of the appropriate NORs team.
    3. Confirmation of Human Tissue Authority Post Mortem Licence.
    4. Process for appropriate storage and disposal of human organ, tissue or samples.
    5. Contact details where appropriate.
    6. Details of the transport arrangements if outside the current agreed processes: this should include details of who is responsible for organising this transport, the details of the transport company and the SLA.
    7. Process of training SN-ODs where appropriate
  - Where appropriate, an agreement in principle from the NHSBT Department of Statistics and Clinical Audit to grant access to or provide data requested for the research proposal/ project. This may also require approval from the relevant Advisory Group.
  - Where appropriate, an agreement in principle from the NHSBT Information Manager that the research proposal/ project has in place the necessary requirements of current information and data legislation.

## **7 The Approval Process**

- 7.1 Proposals/ projects that receive CGMG sub-group approval will be presented at the ODT CGMG for formal approval and final sign off by the AMD.
- 7.2 Confirmation in writing of the outcome of the approval process will be sent to the researcher within 1 week of the CGMG decision. If approval has not been given this letter should include an explanation of why the project was unsuccessful to enable re-submission if appropriate.
- 7.3 All proposals/ projects successfully approved or not will be entered onto the ODT Research Register for record and to aid the monitoring and audit of projects.
- 7.4 The process from initial application to a first decision should take less than 30 working days within ODT.
- 7.5 This time frame will exclude time waiting for a response from ODT to the researcher.
- 7.6 The PI should submit a report to CGMG when the study is completed.

## **Section 2: General Advice – Supporting the Approval Process**

### **8 Financial Arrangements**

- 8.1 Supporting research proposals may incur costs to ODT which may have to be recovered.
- 8.2 Where appropriate NHSBT may seek reimbursement of these costs.
- 8.3 These costs will need to be factored into any research funding or grant applications and advice on these costs should be sought from the Research Manager – ODT.
- 8.4 Financial arrangements need to be agreed in advance of a project submission to ODT for approval.
- 8.5 ODT will develop and publish a tariff of charges

### **9 Intellectual Property**

- 9.1 Intellectual Property (IP) can be defined as any ideas, inventions, technology, software, creative expression (and derivatives thereof), in which a proprietary interest may be claimed and includes those novel ideas or inventions arising from NHS employees.
- 9.2 There are a range of legal rights, Intellectual Property Rights (IPR), that enable the owner of the IP to control or prevent unauthorised use of this IP and include copyright, design rights, trade marks and patents.

- 9.3 In order to retain novelty, and to maintain the possibility of claiming IPR, invention details must not be published or disclosed to any third party without a Confidentiality Disclosure Agreement being agreed and signed by all parties.
- 9.4 NHSBT arrangements for IP are set out in the NHSBT Policy on Intellectual Property.
- 9.5 The Research Manager – ODT should be contacted for any questions about IP.

## **10 Peer / Scientific & Ethics Review**

- 10.1 ODT's role in the approval process does not involve providing any specialist opinion on Research Ethics.
- 10.2 However, ODT may refuse to support any project which might adversely affect the reputation and integrity of the donation and transplantation pathway
- 10.3 Advice on research ethics can be obtained from the [National Research Ethics Service \(NRES\)](#).
- 10.4 Ethical issues relating to Organ Donation or Transplantation may, following consultation, be referred to the independent [UK Donation Ethics Committee](#) for consideration and comment.
- 10.5 Peer or Scientific Review should be arranged by the PI.

## **11 Human Tissue In Research**

- 11.1 The Human Tissue Act (2004) and the Human Tissue (Scotland) Act (2006) has the broad purpose of regulating the storage and use of human tissue from the living, and the removal, storage and use of tissue from the deceased.
- 11.2 Human tissue can be defined as material which has come from the human body which consists of, or includes, human cells.
- 11.3 Cell lines are excluded, as is hair and nail from living people. Live gametes and embryos are excluded as they are already covered by the Human Fertilisation and Embryology Act (1990).
- 11.4 The Human Tissue Act (2004) deems the retrieval of human tissue or organs for the scheduled purpose of research, from a deceased person, as a licensable procedure.
- 11.5 The Human Tissue Act (2004) also established the Human Tissue Authority (The HTA has no authority in Scotland but does carry out some activities on behalf of the Scottish Parliament) to:



- Advise on and ensure compliance with the Act
  - Develop national operational procedures and guidelines
  - Licence activities using human tissue
- 11.6 Any research proposal that involves the retrieval of organs or tissues from a deceased organ donor in theatres, within England, Wales or Northern Ireland, must be covered by a HTA Post Mortem Licence.
- 11.7 No HTA Post Mortem Licence is required if the research proposal requires access to an organ retrieved for the scheduled purpose of transplantation that is subsequently found not suitable for transplant purpose.
- 11.8 It is the responsibility of the researcher to ensure their study fulfils the requirements of the Human Tissue Act (2004) in England, Wales and Northern Ireland and the Human Tissue (Scotland) Act (2006). The Research Manager – ODT can provide advice on related issues.
- 12 Researcher Conduct**
- 12.1 ODT recognises that much of the research that it is involved in or supporting is being carried out by researchers not employed by NHSBT.
- 12.2 Although ODT is not responsible for those researchers' conduct it does have a responsibility to the research participants and may need to work with the researchers' employers if there is a breach in acceptable conduct or their responsibilities relating to good Research Governance as set out in the Good Clinical Practice Guide published by the National Institution for Health Research (2011).

### **Section 3: Research Governance Responsibilities**

#### **13 General Responsibilities**

- 13.1 All staff, including those holding an honorary contract, have the responsibility of being familiar with the principles of Good Clinical Practice (GCP) described in the Research Governance Framework for Health and Social Care (2005) and the Scottish Executive Health Department Research Governance Framework (2006)
- 13.2 Before agreeing to their donors, donor family or other users being approached, all NHSBT staff must satisfy themselves that the research has been approved by the ODT Clinical Governance Monitoring Group (CGMG) and where necessary the appropriate Research Ethics Committee.

#### **14 Responsibilities – Clinical Governance Monitoring Group (CGMG)**

- 14.1 The CGMG or designated sub-group will assess the research application and confirm that:

- Where necessary, an appropriate NHS Research Ethics Committee has approved the research.
- All legal requirements (Human Tissue Act(s); Research Governance Framework(s), Data Protection Act etc) have been addressed.
- There are adequate procedures for ensuring patient confidentiality.
- The study complies with HTA directives and that there are procedures for suitable storage and disposal.
- Ensure that the research proposal :
  - Poses a minimal risk of any adverse affect on organ donation.
  - Has no adverse impact on the retrieval process or quality of organs retrieved.
  - Will not interfere with current or future agreed research.
  - Causes minimal risk to the reputation of NHSBT.
- That all relevant groups (such as SNODs, CLODs, NORS team) have been consulted.
- There are appropriate plans for ensuring that the rights and dignity of the donor and the donor family/ carers or friends are respected.

## **15 Responsibilities – Researchers**

- 15.1 The researcher must ensure there are appropriate arrangements in place to allow them access to relevant patient information and material.
- 15.2 Researchers are responsible for ensuring that:
- The research is conducted in accordance with:
    - The current version of the Research Ethics Committee approval.
    - The approved protocol (this should be the most current version).
    - The Research Governance Framework for Health and Social Care (2005) and/ or the Scottish Executive Health Department Research Governance Framework (2006).
    - Health and Safety legislation.
  - Care professionals (i.e. SN-ODs) are informed of a subject's participation in research (where applicable).
  - The integrity and confidentiality of clinical and other records and data protection legislation and the Caldicott Principles.
  - Any failures to conduct the study in accordance with the above are reported as appropriate.
  - All adverse events are recorded and reported in accordance with the NHSBT R&D Policy.

## **16 Responsibilities – Principle Investigator**

- 16.1 With the exception of student research the Principle Investigator (PI) must be a senior individual, with appropriate experience and training to either:
- Undertake the design, conduct, analyses and reporting of the study to the standards set out in the Research Governance Framework or;
  - Lead and manage others who have been delegated responsibility for some of these aspects.

- 16.2 For student research the student may take on some of the roles of the PI provided the student has a designated supervisor with appropriate experience, expertise and training.
- 16.3 The PI has overall responsibility for the conduct of the research and is accountable for it to their employer, and through them, to the sponsor(s) where the research takes place (or through which the research team has access to participants, their organs, tissues or data). If the research is taking place at more than one site, the PI takes personal responsibility for the design, management and reporting of the study, and co-ordinating the other investigators.
- 16.4 The PI is responsible for ensuring that:
- The research team gives priority at all times to the dignity, rights, safety and well-being of participants.
  - The study complies with all legal and ethical requirements.
  - The research is carried out to the standards in the Research Governance Frameworks.
  - Each member of the research team, including those at collaborating sites is qualified by education, training and experience to discharge their role in the study, and their qualifications are documented and retained in the Investigator Site Files (ISF) at site.
  - All researchers involved in clinical trial of IMPs are aware of their legal duties.
  - Students and new researchers have adequate supervision, support and training.
  - A suitable sponsor or sponsor(s) is secured and agreements are in place detailing the responsibilities of all parties involved in the research.
  - R&D approval is obtained from each care organisation involved prior to commencing the study at that care organisation, including ODT.
  - The protocol is submitted for ethics review, the study does not start without a favourable opinion, and the research team acts on any conditions attached to the ethics opinion.
  - Unless urgent safety measures are necessary, the research follows the protocol or proposal agreed by the relevant ethics committee, by the ODT/ other Trust R&D department and by the sponsor(s).
  - Substantive changes to the protocol or proposal are submitted for ethical review, for the sponsor(s) agreement and for the ODT and Trust/ Hospital Board R&D approval. With exception of urgent safety measures these amendments are implemented only when approved.
- 16.5 The PI is responsible for the conduct of the study at the site where the research is being conducted and must ensure that:
- The research team give priority at all times to the dignity, rights, safety and well-being of participants.
  - The study complies with all legal and ethical requirements.

- The research is carried out to the standards in the Research Governance Framework for Health and Social Care (2005) and/ or the Scottish Executive Health Department Research Governance Framework (2006),.
- Each member of the local research team is qualified by education, training and experience to discharge his/her role in the study, and their qualifications are documented and retained in the Investigator Site File (ISF).
- All local researchers involved in a clinical trial of IMPs are aware of their legal duties.
- Students and new researchers have adequate supervision, support and training. When a study involves participants under the care of a doctor, nurse (including Specialist Nurse – Organ Donation) or social worker for the condition or circumstances to which the study relates, those care professionals are informed that their patients or users are being invited to participate, and agree to retain overall responsibility for their care.
- When a study involves participants under the care of a doctor, nurse (including Specialist Nurse – Organ Donation) or social worker for the condition or circumstances to which the study relates, those care professionals are informed that their patients or users are being invited to participate, and agree to retain overall responsibility for their care.
- ODT approval is obtained prior to commencing the study.
- Unless urgent safety measures are necessary, the research follows the protocol or proposal agreed by the relevant ethics committee, by the Trust/ Hospital Board R&D and ODT and by the sponsor.
- Substantive changes to the protocol or proposal are submitted for ethical review, for the sponsor(s) agreement and for the Trust/ Hospital Board R&D and ODT approval. With the exception of urgent safety measures these amendments are implemented only when approved.
- When the research involves a service user or carer of a child, looked after or reviving services under the auspices of the local authority, the agency director or their deputy agrees to the person (and/or their carer) being invited to participate, and is fully aware of the arrangements for dealing with any disclosures or other relevant information.
- Unless participants or the ethics opinion says otherwise, participants' care professionals are given any information directly relevant to their care that arises in the research.
- For clinical trials involving medicines, the research follows any conditions imposed by the licensing authority.
- Procedures are in place to ensure collection of high quality, accurate data and for the integrity and confidentiality of data during processing and storage.
- Arrangements are in place for the management of financial and other resources provided for the study.

- Arrangements are in place for the management of any intellectual property arising from the research.
- Reports on the progress and outcomes of the work required by the PI, Trust/ Hospital Board R&D and ODT, the sponsor(s), funders, MHRA or others with legitimate interest are produced on time and to an acceptable standard.
- The findings from the work are disseminated promptly and fed back as appropriate to participants.
- There are appropriate arrangements to archive the data when the research has finished, and to ensure it is still accessible. Study documents and source data must be retained in accordance with the local Trust/ hospital Board Health Records Retention/Destruction policy.
- In the event that the PI leaves the local Trust/ Hospital Board or NHSBT/ODT the PI must hand over all site study documentation to the local Trust or Research Manager - ODT, until such time as a replacement PI is identified.
- All data and documentation associated with the study are available at the request of the inspection and auditing authorities.
- Potential participants and other service users and carers are involved in the design and management of the study whenever appropriate.

## 17 References

**Department of Health 2005.** *Research Governance Framework for Health and Social Care 2<sup>nd</sup> Edition.* Department of Health. London.

<http://www.doh.gov.uk/research/rd3/nhsrandd/researchgovernance/worddoc/rgf.doc>

**Scottish Executive Health Department 2006.** *Research Governance Framework for Health and Community Care 2<sup>nd</sup> Edition.*

<http://www.cso.scot.nhs.uk/Publications/ResGov/Framework/RGFEdTwo.pdf>

**Department of Health 2001.** *Governance Arrangements for NHS Research Ethics Committees (GAfREC).* Department of Health. London.

<http://www.doh.gov.uk/research/documents/gafrec.doc>

**National Research Ethics Service (NRES).**

<http://www.nres.npsa.nhs.uk/>

**National Institute for Health Research (2011).** *Introduction of Good Clinical Practice (GCP) A practical guide to ethical and scientific quality standards in clinical research. NIHR CRN Workforce Development. Version 2.1.* Leeds

**The Human Tissue Act (2004).**

<http://www.legislation.gov.uk/ukpga/2004/30/contents>

**The Human Tissue (Scotland) Act (2006).**

<http://www.legislation.gov.uk/asp/2006/4/contents>

## The Data Protection Act (1998).

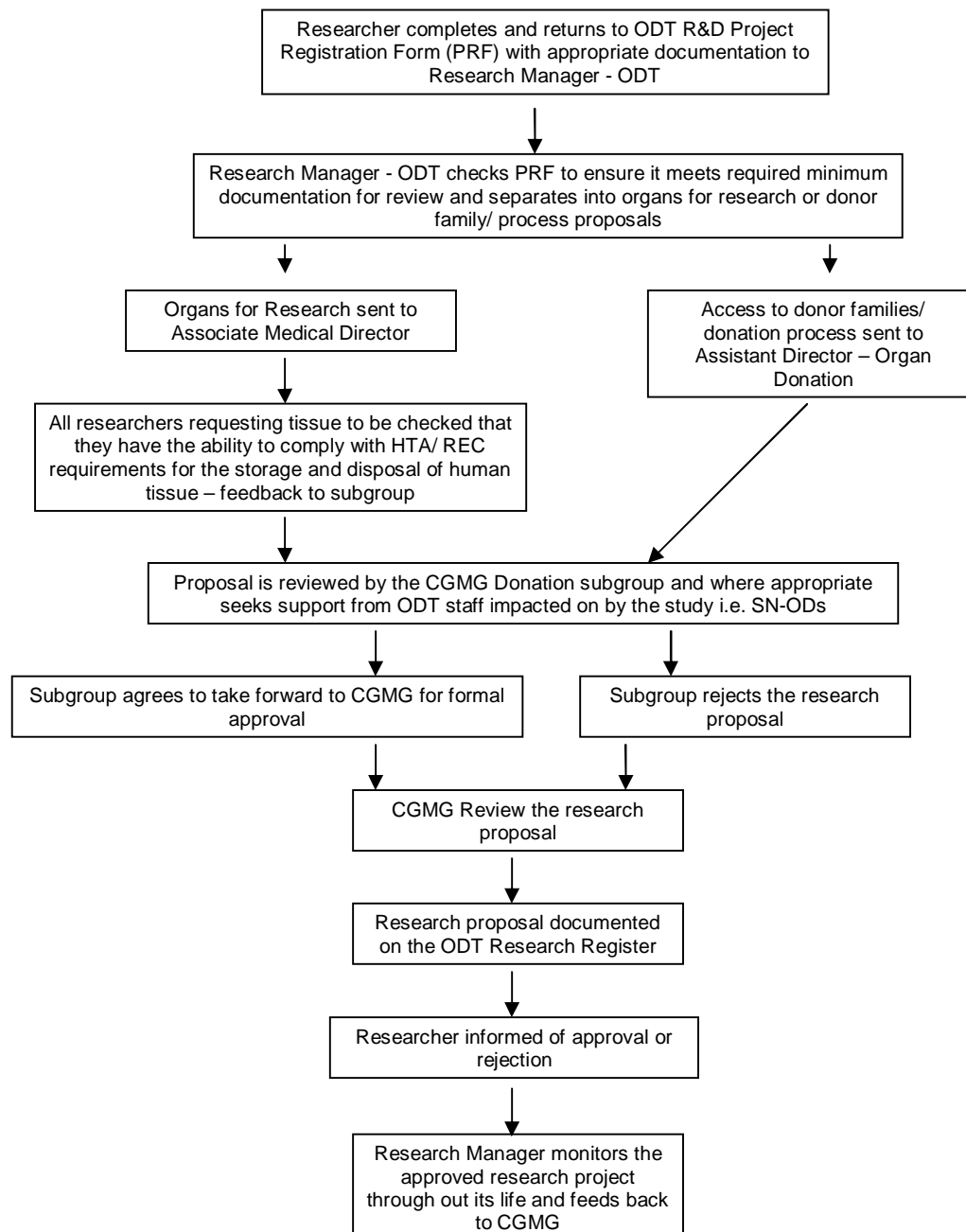
<http://www.legislation.gov.uk/ukpga/1998/29/contents>

## The Human Fertilisation and Embryology Act (2008).

<http://www.legislation.gov.uk/ukpga/2008/22/contents>

### 18 Appendices

#### Appendix 1 - NHSBT ODT R&D Governance Process for New Research Proposals/ Applications



**Appendix 2 – ODT R&D Project Registration/ Approval Form**  
**NHS BLOOD & TRANSPLANT – ORGAN DONATION & TRANSPLANTATION**  
**Research Department**

ODT R&D Project Registration Form (for completion prior to submission to CGMG)

ODT Project No \_\_\_\_\_

<b>CHECKLIST</b>		
<b>ITEM</b>	<b>Tick</b>	<b>WHEN REQUIRED</b>
*Research Protocol		Always
*Confirmation of sponsor		If not NHSBT
*Evidence of REC approval (copy sent or being sought)		Always
*Evidence of local R&D approval (copy sent or being sought)		Always
Independent Scientific Review (file note if accredited)		Always
Letter confirming Research Ethics Committee approval is not required for the study		If applicable
Statistics department approval in principle		If applicable
Information Manager approval in principle		If applicable
NHSBT Approval letter		Always
*Patient Information Sheet (on headed paper or 'to be on headed paper')		If applicable
*Explicit consent/authorisation for the use of human tissue (on PIS/ consent form)		If applicable
*Patient Consent/ Authorisation Form (on headed paper or 'to be on headed paper')		If applicable
*Questionnaire		If applicable
*Letters of invitation to potential participants		If applicable
*Confirmation of funding		If applicable
Honorary contract/ Research Passport/ Letter of Agreement to conduct research		If applicable
*Authorisation by regional SNOD teams involved – signed by TM & RM.		If applicable
SNOD training (completed or intended to be provided)		If applicable
*Evidence of HTA PM licence extension to theatres A Standard Operating Procedure describing: 1. The surgical procedure involved in removing the organ or tissue and who will undertake this. 2. Details on how and when to contact the researcher in the event of suitable organs or tissues becoming available. 3. Details of the transport arrangements for moving a non-transplantable organ or tissue		If applicable  If applicable

from the donor hospital or recipient hospital to the researcher and who is responsible for organising this transport and the SLA with the company employed to undertake this if appropriate.

Comments:

#### Approval Authorisation

National Clinical Lead – Organ Donation / Assistant  
Director – Organ Donation

Signature

Clinical Governance Monitoring Group Approval  
Associate Medical Director - ODT

Signature



## Appendix 3 – ODT R&D – Research Approval Matrix

### NHS BLOOD & TRANSPLANT – ORGAN DONATION & TRANSPLANTATION Research Department

#### Research Approval Study Prioritisation Matrix

Scoring Scale 1-5 (1 is low 5 is high) scores above xxx to be approved

Project Title:		Project Number:	
Criteria	Key themes	Scale	Score
<b>Strategic Objective 1:</b> Does the project enable ODT to fulfil its role as an ODO?	EU Directives; Quality & Governance systems; IT system for allocation & registration	1 2 3 4 5	
<b>Strategic Objective 2:</b> Does the project explore development support for organ donation throughout the wider NHS?	Obstacles to organ donation; Performance manage identification & referral of potential donors.	1 2 3 4 5	
<b>Strategic Objective 3:</b> Does the project explore ways to maximise conversion of potential organ donors into actual donors?	Maximise potential donors into actual donors; Development & implementation of robust, sustainable donor co-ordination service; Development & effectiveness of CLOD network & Donation Committees	1 2 3 4 5	
<b>Strategic Objective 4:</b> Does the project explore ways of ensuring organ retrieval services are sustained through a period of change?	NORS team; Sustained organ retrieval service	1 2 3 4 5	
<b>Strategic Objective 5:</b> Does the project explore ways of changing public behaviour with regard to organ donation?	Social marketing strategies; Promotion of organ donation as 'expected behaviour' amongst UK citizens.	1 2 3 4 5	
<b>Strategic Objective 6:</b> Does the project develop live organ donation?	Develop & implement a strategy for increasing live organ donation	1 2 3 4 5	
<b>Strategic Objective 7:</b> Does the research look at sustainable cornea donation	Develop & implement a robust, sustainable cornea service	1 2 3 4 5	

Does the project explore organ donation amongst the BME population of the UK	BME; Cultural issues; Increase organ donation; Social marketing strategies	1 2 3 4 5	
<b>Project Title:</b>		<b>Project Number:</b>	
<b>Criteria</b>	<b>Key themes</b>	<b>Scale</b>	<b>Score</b>
Does the project explore current practice amongst those involved in organ donation that would influence organ donation rates?	SNOD practice; Clinical staff practice; non-clinical staff practice; Friends & family impact	1 2 3 4 5	
Does the research explore themes that will enhance the service that ODT offers?		1 2 3 4 5	
Does the research offer a low risk impact on organ donation rates and the reputation of NHSBT?		1 2 3 4 5	
<b>Approved: Yes No</b>		<b>Total Score:</b>	