1. **Background**
   The development and implementation of policies for selection of patients for transplantation and for allocation of donor organs (from living and deceased donors) is a statutory responsibility of NHSBT.

   These policies should be clear and, as far as possible, evidence based and based on the principles of equity, fairness, benefit and utility. All policies should be supported by clinicians and other relevant stakeholders. Criteria for assessment of these policies have been developed and agreed.

   As clinical practice evolves and improves, and as both donor and recipient characteristics change, it is important that these policies are reviewed on a regular basis and revised as necessary.

   Policies are developed and reviewed annually by the relevant Advisory Group and reviewed and approved by the Transplant Policy Review Committee on behalf of the Board of NHSBT before being implemented by NHSBT and partners.

2. **Aim of policy**
   The selection and allocation policies are of relevance both for information and implementation by a large number of stakeholders, including patients and their families, clinicians who refer, assess and manage patients before and after transplant, those in organ donation, organ retrieval and other health care professionals, commissioners and regulators. These may work in different institutions other than NHSBT and in different countries of the UK. Furthermore, implementation of some of these changes may take weeks or months so agreement of changes in policies will not always immediately translate into action.

   The purpose of this document is to define the stages not only when patient selection and organ allocation policies should be reviewed but how such changes are proposed, agreed and implemented.

   The stages are:
   - Proposal for change
   - Consultation
   - Approval of change
   - Implementation of changes
   - Dissemination of changes
3. Clinical Policy Change process

A flow chart detailing the change process is detailed below:

**Clinical Policy Change Process**

- **Policy Change Request instigated following regular review / Advisory Group / Senior Management Team as a result of an incident / Request for Change**
  - **Existing Policy?**
    - Yes: **Associate Medical Director Policy?**
      - Yes: **Statistical Lead reviews change request with Associate Medical Director**
      - No: **Decision**
    - No: **Associate Medical Director or nominee to contact Quality Assurance to raise Document Draft**
  - No: **Owner/Author Produce draft of Policy**
    - **Change Type?**
      - Major: **Prepare draft paper/ policy for review**
      - Minor: **Submit to Clinical & Support Services**
    - No: **Review by Transplant Policy Review Committee**
    - Yes: **Associate Medical Director informs Statistical Lead of Transplant Policy Review Committee Decision**
      - No: **Transplant Policy Review Committee Agreed?**
      - Yes: **Go Live**
  - **Policy Agreed?**
    - No: **Final Draft Policy to be reviewed by Organ Donation and Transplantation Senior Management Team**
    - Yes: **Yes**
  - **Final Draft Policy to be reviewed by Organ Donation and Transplantation Senior Management Team**

**Decision**

- **Statistical Lead to Initiate Change Control with QA, Document Author and Process Owner**
  - **Agree Implementation Plan and Go Live Date**
  - **Follow Change Plan Including Document Updates, Training and Communications**
  - **Upload Documents to Qpulse and ODT Website (if appropriate)**
  - **Go Live**
  - **Review as Required**