ODTI Guideline for Opt-Out Register Verification

1. INTRODUCTION

1.1 PURPOSE

The Human Tissue (Transplantation, Post Mortem, Anatomical Examination and Public Display) Act 2024) was signed into law on 28th February 2024. Part two of this legislation will commence on June 17th 2025.

Key Provisions of the Act:

- **Deemed Consent**: The Act facilitates the opt-out model, meaning that all competent adults over the age of 18, who are ordinarily resident in Ireland for 12 months are deemed to consent to organ donation unless they have explicitly opted out.
- **Respecting the Wishes of Individuals**: If an individual has opted out, their wishes must be respected, and organ donation will not take place.
- **Family Consideration**: The Act allows for a 'soft opt-out' meaning that consent is required from the individual's next of kin to proceed with organ donation. The Act continues to recognise the role of the family in organ donation but emphasises that a patient's decision to Opt-Out must take precedence. If a person has opted out, healthcare professionals will not approach an individual's next of kin in relation to organ donation.
- **Duty of Healthcare Professionals**: The new provisions of the Act will require healthcare professionals to verify that an individual is not on the Opt-Out Register before approaching families in relation to organ donation.

ODTI is required to provide and maintain a National Opt-Out Register for Organ Donation. This guideline will outline the steps required to verify an individual's Opt-Out status, on identification of potential organ donor in the critical care areas.

1.2 SCOPE

This guideline applies to healthcare professionals involved in the assessment and management of a potential organ donor. It covers the steps required for obtaining a search result from the National Opt-Out Register to confirm an individual's decision regarding organ donation. The guideline is intended to ensure:

1. **Accurate Searches**: Healthcare professionals understand the minimum information that is required to perform a search of the opt-out register and how this information will be received and communicated.
2. **Confidentiality and Data Protection Act 2018**: All searches and interactions with the opt-out register will be conducted by authorised personnel, solely for the purpose of checking the Opt-Out status of the individual in question.
3. **Legal and Ethical Compliance**: The guideline aims to ensure that all actions taken during the search process align with the requirements of The Human Tissue Act 2024.

1.3 PERSONNEL

This guideline applies to Healthcare Professionals, involved in the identification and care of potential organ donors.

1.4 REFERENCES

This guideline is informed by the following references:

- Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024
- ODTI, A framework for Quality and Safety of Human Organs Intended for Transplantation, Version 1 December, 2014.
- S.I. No: 325 of 2012, European Union (Quality and Safety of Human Organs Intended For Transplantation)
- S.I. No: 198 of 2014, European Union (Quality and Safety of Human Organs Intended for Transplantation (Amendment) Regulations 2014
- Commission Directive 2010/53/EC of 7 July 2010 of the European Parliament and the Council of the European Union on standards of quality and safety of human organs intended for transplantation
- Guide to the quality and safety of Organs for Transplantation, (2022) 8th Edition, European Directorate for the Quality of Medicines & Healthcare (EDQM), France.
- HSE National Framework for developing Policies, Procedures, Protocols and Guidelines (PPPGs) (2016)
- Data Protection Act 2018

2. DEFINITIONS

CLOD	Clinical Lead Organ Donation
Consent	Under the Human Tissue Act 2024 in relation to transplantation, consent refers to the voluntary permission or agreement for the use of human cells, organs, and tissues for purposes such as transplantation.
DOH	Department of Health
HTA	Human Tissue Act
NODTAG	National Organ Donation and Transplant Advisory Group
NOPS	National Organ Procurement Service
ODNM	Organ Donation Nurse Manager
ODTI	Organ Donation Transplant Ireland
OOR	Opt-Out Register

3. GUIDELINE

3.1 CRITICAL CARE HEALTHCARE PROFESSIONAL

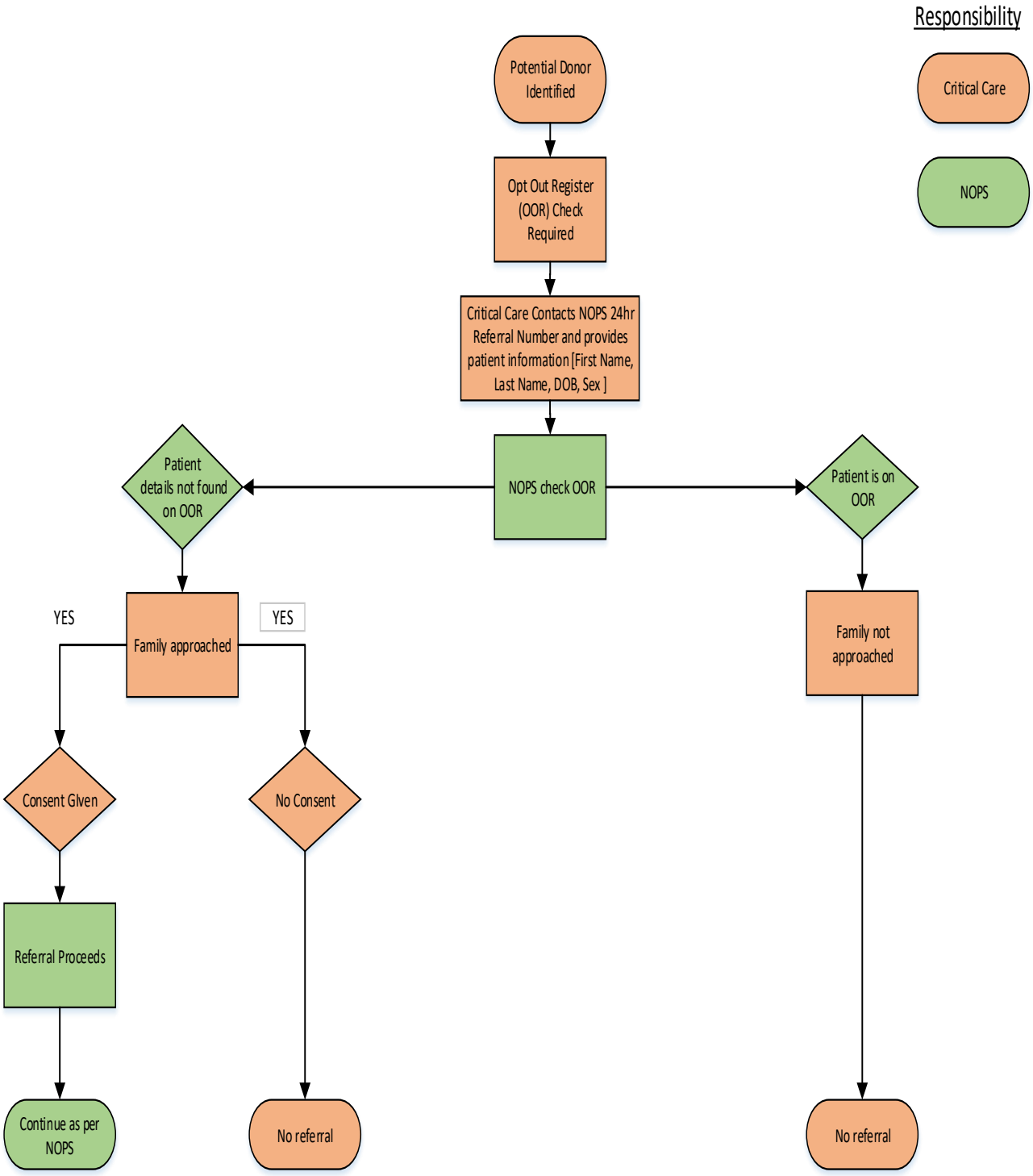
This section applies to all critical care Healthcare Professionals involved in the identification and care of patients who may be potential organ donors. The purpose of the check is to confirm whether or not an individual is on the opt-out register.

As the designated body, the National Organ Procurement Service (NOPS) will perform the requested check against the Opt-Out Register. It is important to note that this register check is not a formal notification of a potential organ donor.

It is important to note the Opt-Out Register check does not provide any clinical or medical information about the individual's eligibility or suitability for organ donation. The formal process of determining clinical suitability for organ donation will only begin once characterisation is initiated.

Figure 1 below outlines the process of the Opt-Out register check.

Figure 1 – Process Flow



3.1.2 Identification of a Potential Donor

On identification of a patient who may be a potential organ donor and before discussing organ donation with the family, the healthcare professional must check the patient is not on the National Opt-Out Register.

3.1.3 Opt-Out Register contact

On identification of a potential donor, at any time the healthcare professional must contact the National Organ Procurement Service (NOPS) on 1800 100 016. NOPS will facilitate the register check on behalf of ODTI.

3.1.4 Required Information for the Opt-Out Register Check

On contacting the National Organ Procurement Service, the healthcare professional must provide the following required mandatory and where available the supplementary information listed below in the Table 1 below.

Table 1

Mandatory	Supplementary
Forename	PPS Number
Surname	Mother's Birth Surname
Date of Birth	Home Address
Sex at Birth	Eircode
	Mobile Phone
	Nationality
	Place of Birth

The healthcare professional must also provide their details including a contact email address to facilitate the return of the search results of the Opt-Out Register Check from NOPS.

3.1.5 Opt-Out Register Results Check Response

As soon as possible on completion of the Opt-Out Register search NOPS must contact the healthcare professional initially by telephone and immediately by email with the search results response.

NOPS must provide the search result on a NOPS template email document.

The healthcare professional should file the search result with the patient's notes, either in digital or paper format as appropriate to the clinical area.

The healthcare professional must provide a response on the NOPS template via email confirming the details searched are correct, as soon as possible.

The healthcare professional must communicate the search and the response on the Opt-Out Register search to the local ODNM.

3.1.6 Follow Up Action if the patient IS ON the Opt-Out Register

If the patient **is on the opt-out register** (i.e., they have opted out), the family may not be approached for consent, and organ donation will not proceed.

3.1.7 Follow Up Action if the patient IS NOT ON the Opt-Out Register

If the patient **is not on the opt-out register** (i.e., they are deemed to be a potential organ donor), then the family can be approached when appropriate to raise the possibility of organ donation.

3.1.8 Family Approach

On confirmation that the patient is not on the Opt-Out Register when appropriate, the healthcare professional family approach and family conversations can be conducted as per local unit's Policy / Procedure(s) where available.

3.1.9 Formal Referral to National Organ Procurement Service

On receipt of verbal consent to proceed to organ donation, the process of referring the patient as a potential donor can commence by contacting NOPS on 1800 100 016.

3.2 National Organ Procurement Service – Opt-Out Register Verification Checks

This section applies to the National Organ Procurement Service (NOPS). The following are the verification checks required to be in place in a NOPS Standard Operating Procedure for the confirmation that a patient is not on the Opt-Out Register.

3.2.1 Initial Opt-Out Register Call and Search

On receipt of a call requesting an Opt-Out Register Check from a healthcare professional, NOPS will require the mandatory plus supplementary information as listed above in order to undertake a search of the Opt-Out register.

NOPS will undertake the search of the Opt-Out Register and return the results of the search to the requester via email. NOPS will require confirmation from the requester that the information searched and returned is accurate and reflective of the patient in question.

3.2.2 NOPS Onsite at Potential Donor Hospital

If after a search of the Opt-Out Register is performed and it is confirmed that the patient did not 'Opt-Out', then the healthcare professionals may approach the patients family to raise the possibility of organ donation. If verbal consent is given by the family to proceed with organ donation, a referral will be received by NOPs and characterisation begins.

If the referral progresses and NOPS travel to the potential donor hospital, a second identification check is required, whereby NOPS must re-confirm the patients details with the bedside nurse or clinician responsible for the patient. A signature for this is required from the bedside nurse or clinician and will be countersigned by the NOPS Coordinator present. This signature is confirming the ICU team are satisfied that the information provided and searched in the initial register search remains accurate.

If there are any discrepancies in the patients details noted in this second check, then a new search of the Opt-Out Register must be undertaken by NOPS.

3.2.3 NOPS FAMILY CONVERSATION

Where a referral progresses to the family meeting, encompassing the written consent process for organ donation, a final identity check is required to be undertaken by the NOPS coordinator.

The NOPS Coordinator will discuss the Opt-Out Register check that has been completed returning no results, implying deemed consent. The NOPS coordinator should reconfirm the patient details with the family, confirm that they are not known by any other aliases.

If there are any discrepancies in the patients details noted in this third check, then a new search of the Opt-Out Register must be undertaken by the NOPS Coordinator.

4. GUIDELINE APPROVAL

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REFERENCE NUMBER	ODTI-C-GDE-0010	
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APPROVAL		
RESPONSIBILITY	NAME	POSITION
APPROVED BY	Dr Brian O'Brien	On Behalf of NODTAG Director of ODTI
VERSION	DOCUMENT REVIEW HISTORY	
1	New Guideline	

5. COMMUNICATION AND DISSEMINATION

These guidelines will be disseminated to the circulation list identified below following approval.

GUIDELINE CIRCULATION
Director ODTI
Chief Operations Officer ODTI
Director of Quality ODTI
Quality and Biovigilance Manager ODTI
Clinical Leads Organ Donation
Organ Donation Nurse Managers
Responsible Person National Organ Procurement Service
Donor Coordinators National Organ Procurement Service
Quality Manager National Organ Procurement Service
NOPS Medical Clinical on Call Personnel
ICU Distribution List

6. IMPLEMENTATION

This guideline, once approved, will be disseminated through the Opt-Out Register Professional Education and Development Group to relevant healthcare professionals in critical care areas. It will also be shared with the NOPS Quality Management System via the NOPS Quality Manager, and with the ICU community through the ODNM Network.

7. MONITORING, AUDIT, AND EVALUATION

The efficacy of this guideline document will be reviewed after three months of the implementation of the Opt-Out Register, through ODTI QMS, Opt-Out Register Project Team, NOPS QMS and relevant clinical programs. This will be reviewed through the ODTI Quality Improvement Group.

8. REVISION OF DOCUMENT

The Guideline will undergo periodic review within three years of its implementation. This process will be managed through the ODTI document management process.