Príomhoifigeach Cliniciúil
Oifig an Phríomhoifigigh Cliniciúil
Ospidéal Dr Steevens, Lána Steevens
Baile Átha Cliath 8 , D08 W2A8

Chief Clinical Officer
Office of the Chief Clinical Officer
Dr Steevens Hospital, Steevens Lane
Dublin 8, D08 W2A8

www.hse.ie
@hselive
t 01 635 2000
e cco@hse.ie

BY EMAIL ONLY

Deputy Tom Brabazon
Dáil Éireann
Leinster House
Kildare Street
Dublin 2

14th October 2025

PQ52918/25- To ask the Minister for Health the way in which the country's main neurological hospitals (including Beaumont) select patients to participate in clinical research

Dear Deputy Brabazon,

Many thanks for your representation.

Each clinical research study must be approved by the relevant Research Ethics Committee (REC) for conduct at a specific research site before it can commence. For research regulated under the Clinical Trial Regulation[1], Medical Device Regulation[2] or In-Vitro Medical Device Regulation[3] REC approval must be granted by a National Research Ethics Committee and notification to or approval by the Health Products Regulatory Authority. The protocol and other study documentation are reviewed as part of the approval process.

Each clinical research study is conducted according to its own specific protocol which as well as describing the objective, design, purpose, organisation etc. of the clinical trial will also include a description of the inclusion and exclusion criteria for enrolment in a study, the procedures for inclusion of participants and shall provide a clear indication of what the first act of recruitment is. The inclusion and exclusion criteria are commonly known as the eligibility criteria.

Researchers will seek to identify individuals who potentially may meet these eligibility criteria and invite them to consent to participate in the clinical study. Both the identification and consent process must be in compliance with the approved study documentation, relevant regulations such as GDPR and HSE policies such as HSE National Policy for Consent in Health and Social Care Research (2024)[4]. Only once a fully informed and explicit consent has been provided and it is confirmed that the eligibility criteria has been meet can an individual be enrolled in a clinical research study.

[1] Regulation (EU) 536/2014 REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

[2] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

[3] Regulation (EU) 2017/746 relating to in vitro diagnostic medical devices (IVDR)

[4] https://www2.healthservice.hse.ie/organisation/national-pppgs/hse-national-policy-for-consent-in-health-and-social-care-research/

Participant identification for enrolment in a clinical study typically follows a structured process to ensure individuals are recruited ethically and scientifically. A number of factors are at play during this process:

Defining Eligibility Criteria

Researchers begin by establishing **inclusion** and **exclusion criteria which protect the safety of participants and the scientific rigour of the study. These** may include:

- **Demographics**: Age, sex, ethnicity
- **Medical history**: Diagnosis, stage of disease, prior treatments
- **Lifestyle factors**: Smoking status, alcohol use
- **Lab values or biomarkers**: e.g., HER2 status in breast cancer

These criteria are outlined in the study protocol and approved by ethics committees.

Recruitment

Once criteria are set, participants are identified through various channels:

- **Clinical databases**: Electronic health records (EHRs) or disease registries
- **Referrals**: From clinicians or specialists
- **Advertisements**: Online, print, radio, or social media
- **Patient advocacy groups**: Especially for rare diseases
- **Previous trial participants**: If appropriate and ethical

Pre-screening and Screening

Potential participants undergo:

- **Pre-screening**: Often via phone or online questionnaire to assess basic eligibility
- **Screening visit**: Informed consent, in-person assessments, and lab tests,

Informed Consent

Before enrollment, participants must:

- Receive detailed information about the study
- Understand risks, benefits, and their rights
- Sign an informed consent form

Enrollment

Once consent is given and eligibility is confirmed , participants are officially enrolled and, if applicable, randomised.

I hope this provides you with some assistance.

Yours sincerely

Ana Terres
Head of Research and Evidence
Health Service Executive