

ICGP Research Ethics Committee position on HSE National Policy for Consent in Health and Social Care Research

April 2023

The Irish College of General Practitioners Research Ethics Committee welcomes the recent publication of the HSE's National Policy for Consent in Health and Social Care Research. The policy has been developed based on national and international codes, standards, and regulations and with extensive stakeholder consultation.

Although the policy only applies to health research activities taking place in the HSE, or in HSE-funded or affiliated healthcare organisations, its principles can be applied to health research being conducted in other settings in Ireland.

The committee would encourage applicants to draw on information contained in the policy in order to develop plans for consent procedures within their study, with due regard for the particular topic and context of their study, and any specific considerations this may present.

In response to enquiries, the committee's view on particular points are outlined below.

- With respect to who should obtain consent in unregulated studies, the committee's view is that subject to appropriate justification of the suitability of any individual and with due regard for the context and topic of the study, a trained and authorised member of the research team may consent prospective participants.
- In relation to pre-screening, the committee's view is that the policy reflects the January 2021 amendment to the Health Research Regulations (Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021) which relates to pre-screening. Guidance on this amendment is available at <https://hrcdc.ie/guidance/>. The committee's view is that any proposed pre-screening must adhere to the provisions outlined in this amendment, and any proposed pre-screening described within an application to the committee should confirm this, and provide appropriate justification in the particular context of the study.