GUIDANCE ON BROAD CONSENT AND THE HEALTH RESEARCH REGULATIONS ISSUED BY THE DEPARTMENT OF HEALTH

The following guidance is an addendum to the guidance on 'Informed Consent obtained in the time of EU Directive' (Amendment to Regulation 6 of the Health Research Regulations, under S.I. 18 of 2021)

The purpose of the Health Research Regulations is to support and facilitate health research and, at the same time, to promote public confidence, trust and participation in research through appropriate data protection safeguards.

A key safeguard is informed consent of the data subject that is then properly recorded (explicit consent). In that regard, the Health Research Regulations allow the data controller seeking the informed consent to frame the consent request to extend beyond the particular study into related areas of health research. That is the concept of broad consent.

While broad consent is acceptable, blanket consent is not and should not be sought.

These principles are consistent with the opinion of the European Data Protection Board[1]:

> '*broad consent' cannot be asked and relied on for processing health data for 'any kind of - unspecified -future research purposes'. However the concept of broad consent could be relied on for different research projects that fall within the scope of that broad consent and that meet certain additional safeguards'*

However, it is recognised that during the time of the EU Data Protection Directive (1995 to May 2018) that data controllers may, in good faith, have sought and obtained informed consent from data subjects in respect of i) a particular study and ii) further related research and iii) unrelated research (essentially blanket consent). In that scenario, the Department wishes to clarify and advise as follows: the fact that blanket consent was obtained does not invalidate the consent but rather the consent is limited to the particular study and further related research. That will be so where (a) it is the data controller who obtained the consent that is seeking to further use the personal data for the related research and (b) the new related research study is the subject of a separate or amended REC approval.

It is important to note that where consent was obtained **solely for a specific study,** and **not more broadly for related research,** the data controller cannot process data for related research studies. It is up to the data controller to ensure it is processing data within the scope of the consent obtained.

July 2021

[1] https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf at Section 31.