

Studies submitted for review to Beaumont Hospital Research Ethics Committee (GUIDANCE FOR USE BY THE REC)

When should BH REC refer a study to the BH Data Protection Officer (BH DPO)?

13 September 2021

Referral is not required in the case of:

1. Anonymous Survey Studies; or
2. Studies involving analysis of anonymised datasets

Where the REC / or REC Chairperson (in case of Chairperson's approval) has concerns that the study is not in fact 'anonymous', the REC/REC Chairperson may involve the DPO in the review process.

The REC / REC Chairperson may use the HSE R&D Department Ethical Risk Self-Assessment Tool to assess if an anonymous survey study warrants full REC review or Chairperson's review

https://www.beaumontethics.ie/home/ethical_risk_self_assessment.htm

Referral is required in respect of all other studies:

The REC will ensure that where significant data protection concerns are identified that these are flagged to the DPO.

Similarly, the REC will inform the DPO where no concerns are raised.

The following study types are deemed to ones which require a DPO opinion in all cases:

1. Low Risk Retrospective Chart Reviews as defined in the Data Protection Act 2018 (Section 36 (2)) (Health Research) (Amendment) Regulations 2021

Rationale: assessment of data protection risk is required under the in the Data Protection Act 2018 (Section 36 (2)) (Health Research) (Amendment) Regulations 2021

2. Studies which involve the USE of TECHNOLOGY
e.g. 'app', cloud storage, online portal, wearable tech, remote monitoring etc.

Rationale: IT expertise needed to make an assessment of data protection risk

3. GENETIC / GENOMIC STUDIES which involve: -
genetic testing, genetic analysis, whole genome sequencing, processing of genetic data

Rationale: Special Category Data – higher risk in nature