

# Beaumont Hospital

## Ethics (Medical Research) Committee

---

Chairperson: Professor Gerry McElvaney

Convenor: Dr. Peter Branagan

**October - December 2018**

To Whom It May Concern

### **RE. Health Research Regulations 2018**

I am contacting you in your capacity as the principal investigator of a research study in the context of the Health Research Regulations.

**Please begin to complete Section E2 of the most recent ethics application form, dated 31.8.18,** with a view to ensuring that suitable and specific measures are taken to safeguard the fundamental rights and freedoms of the data subject as per Section 3 of the Health Research Regulations 2018

Secondly, please liaise with the relevant Data Protection Officer in relation to the need for a Data Protection Impact Assessment.

If necessary, please submit a Data Protection Impact Assessment to the Data Protection Officer.

Thirdly, please review the participant information leaflets and consent forms for your study with a view to ensuring they meet the requirements for explicit consent as per GDPR 2016.

If necessary, please submit an amendment to the relevant Research Ethics Committee(s) to revise the participant information leaflets and consent forms for your study to bring them in line with the requirements for explicit consent as per GDPR 2016.

This committee has placed adjusted template Patient Information Leaflets & Consent Forms on its website with a view to assisting researchers in meeting the requirements for explicit consent.

Should you decide to submit an amendment to the relevant Research Ethics Committee(s), please ensure you obtain expert legal / data protection advice from your legal department / data protection officer as appropriate.

Kind regards

Yours sincerely

*Administrator*

Ethics (Medical Research) Committee