

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 – Access Studies

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, as you are relying on consent from another study for the purposes of your research study, please forward the attached letter to the principal investigator of the study in question. This may be the biobank / registry from which you drew material / data down; or another clinical research study. Please forward to the appropriate Principal Investigator as relevant.

Kind regards

Yours sincerely

Administrator

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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.

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