Beaumont Hospital
Ethics (Medical Research) Committee

October - December 2018

To Whom It May Concern

RE. Health Research Regulations 2018 – Clinical Trials of Medicines

I am contacting you in your capacity as the chief investigator / principal investigator of a clinical trial in the context of the Health Research Regulations.

In the case of sponsored clinical trials, I would be grateful if you could bring the following information to the attention of the trial sponsor.

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 this clinical trial 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 Recognised Research Ethics Committee to revise the participant information leaflets and consent forms for this clinical trial 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 Recognised Research Ethics Committee, 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