Research and Data Governance in Beaumont Hospital

Gillian Vale, 31 May 2021

It continues to be a requirement that a Data Protection Impact Assessment (DPIA) be conducted in respect all research studies taking place in Beaumont Hospital which involve - "processing personal data for health research purposes".

There is currently no policy which requires 'Beaumont Hospital' be named as data controller.

Given the variety of health research projects taking place in the hospital, instigated variously by

- hospital employees,
- university employees,
- university students,
- hospital consultants with a joint academic appointment with a university,
- employees of other public hospitals or the HSE,
- employees of private hospitals,
- commercial companies,
- charities,
- entities (universities, hospitals, charities, commercial companies) based outside the country / EU

many of which are collaborative in nature with multiple stakeholders, it would be extremely difficult for the hospital to put a blanket policy in place.

In addition to this, there is a national impetus for an increasing number of health research studies to undergo research ethics review at national level or regional level. Thus, not all studies are subject to local research ethics committee review. **Hence, the only oversight the hospital has in respect of many research studies is via contract negotiation and site sign off / permission processes.** Having a blanket hospital policy requiring the hospital to be named as a data controller and implementing this at contract sign off stage would also be very difficult – as any change in data controller would necessitate a change in participant information which would necessitate re-review (amendment) to the original reviewing research ethics committee.

It would seem that the only available approach is to continue to assess research studies on a case by case basis, and for researchers to continue to name the data controllers and processors to the best of their ability; and, where local research ethics approval applies, for the Beaumont REC to continue to work closely with the Beaumont Deputy Data Protection Officer (DDPO), and to remain cognisant that even where not named as a data controller or processor, the 'hospital' is implicated, and has a vested interest in ensuring compliance with data protection legislation.

Any processes agreed between the Beaumont REC and Beaumont DDPO are in a challenging space – the REC has a particular role to review research studies from an ethical perspective and uphold the rights and freedoms of participants; the DDPO has a specific and wide-reaching role within the hospital to provide advice, training and develop policies on data protection matters, to report breaches, to maintain a register of data processing activities, to liaise with the Data Protection

Commission (DPC), and to provide advice on Data Protection Impact Assessments (DPIAs) where this is requested.

Neither are in a position to ensure that all health research studies undergoing a local research ethics committee review are fully data protection compliant.

GDPR and the Health Research Regulations are very difficult pieces of legislation to understand, navigate, and implement. There is a wide variety of individual interpretations and organisational-level interpretations in play. It is extremely easy to fall foul of the legislation – and – there is no process which can be put in place which can guarantee compliance.

Where external research ethics committee approval applies, an agreed process will need to be put in place via the proposed new Data Governance Committee. Any such process will also not be a guarantee of compliance. It will serve as evidence of a process being in place to check for compliance in the event such evidence is required by either the DPC or a court of law.

The publication of the proposed HSE Framework for Research Governance may offer additional advice, or a national framework which the hospital can work from going forward.