Dear Colleagues

We are writing to update you on progress made within St Vincent's University Hospital regarding the  implementation of the General Data Protection Regulation (GDPR) and the Health Research Regulations. As you will know, the changes in the regulations have had a significant national impact on research and presented significant challenges to the research community. We are working closely with our colleagues in partner hospitals and universities to address these challenges.

By way of update

1. The new GDPR compliant version of the Standard Ethics Application form is attached to this email. This has been reviewed and approved by the hospital and should be used for all new applications

 2. A new standard Patient Information Leaflet (PIL) concerning data sharing has also been produced and is attached here. This can be used for all new applications and will ensure compliance with the changed regulations

 3. These documents should be used for all new applications, and the Ethics office staff are available to guide you with any queries on the forms

 4. We are creating a new research GDPR section on the hospital intranet to deal with these issues - included in this area will be template documents, FAQs, advice from the Department etc etc- This intranet section will launch ASAP.

 5. We understand from the Department of Health that the consent declaration committee will be established imminently. Applications for consent waivers etc will be available to download- We will notify you when this goes live

 6. In terms of retrospective chart reviews, the Department have consulted with the Office of the Data Protection Commissioner and it has been determined that the requirement for explicit consent will commence on 1 May 2019.  This is to allow hospitals and other data controllers who carry out such reviews to adapt their procedures to capture the relevant explicit consent from patients.  We will be working on putting this in place over the coming months to ensure explicit consent is captured from patients at registration

 7. In terms of previously approved and  ongoing studies, (before new documentation) we are developing our internal process for audit of these to determine compliance, as required by the regulation. The documentation for this review is being finalised and we will hold a workshop in January to outline the process.

In addition to the above , we continue to work internally and externally to clarify the remaining outstanding items We will continue to update you as this progresses.

 Best wishes

 Dermot Cullinan- Director of ICT

Dr Rachel Crowley - Chair REC

Prof Peter Doran- Director of Research