**IMPORTANT NOTICE**

**Health Research Regulations 2018**

**Matters being considered by the Department of Health that may lead to amendments**

The main purpose of the Regulations is to promote health research by promoting public confidence in and support for health research having regard to the applicable legal framework, accepted best practice and the need to give effect to patient empowerment in relation to a patient’s own information.  It has always been the publicly stated position of the Department of Health in relation to the HRR that the Department would monitor them to ensure that their application was in line with meeting their policy objective.

At the seminar last October where the Department introduced the GDPR/HRR, the Department stated its aspiration to have the Health Research Consent Declaration Committee (HRCDC) established by January 2019. However, officials also stated that an extension would be sought to the HRR should the necessity arise due to any delays with putting the HRCDC in place. Therefore, following the recent establishment of the HRCDC and with planning underway to consider applications from April 2019, **the Department wishes to advise that it is in the process of seeking an extension to the period under Regulation 6 for consent in relation to ongoing research and related applications to the HRCDC**. Extending the specified date requiring explicit consent for ongoing research beyond 30 April would allow for applications for a consent declaration to be made in an orderly and timely way to the Committee and importantly will allow the recently appointed Committee appropriate time and space to conduct its deliberations.

Furthermore, at the October seminar and subsequent events, the Department pro-actively flagged a number of areas based on learning from other countries. The Department committed to continued engagement with the research community, data controller organisations and the Data Protection Commission regarding these areas (e.g. retrospective chart reviews, pre-screening for eligibility for research studies) and others raised at the seminar in order to resolve any underlying uncertainty or confusion and to suggest acceptable and appropriate approaches to ensure that such research activity can continue while fully aligning with the principles set out in GDPR and maintaining public confidence.

Accordingly, over the past number of months, the Department has engaged with researchers, research ethics committees and institutions and bodies that support health research in Ireland. In line with that open approach, the Department can now state that it is consulting with the Data Protection Commission on certain specific matters. That engagement **may** lead to amendments to the Health Research Regulations where any such amendments are sound from a policy perspective and legally feasible.

The areas under consideration are:

-An amendment which wouldseek to optimise the use of **administrative data for health research purposes** – by facilitating disclosure (in the absence of explicit consent) of pseudonymised personal data for secondary health research purposes where re-identification by the recipient is not permitted.

 - An amendment which seeks to provide a mechanism for **retrospective chart reviews studies** carried out in a data controller’s organisation by health practitioners and employees of that organisation (that are low risk and have high transparency). This acknowledges the challenges of obtaining valid, explicit consent for such research and would also represent an alternative to the vast majority of such studies having to be submitted to the HRCDC.

-An amendment which seeks to provide greater clarity regarding **pre-screening** for assessing eligibility and suitability of individuals for inclusion in health research. The current position as set out in Regulation 3 (2)(b) has led to confusion. If accepted, the amended HRR will state explicitly that healthcare staff involved in the care and treatment of individuals and other employees of the data controller organisation with a duty of confidentiality can engage in pre-screening without the explicit consent of the individuals concerned. In addition, drawing on approaches which evolved over time in other jurisdictions, the amendment under discussion will go further and set out a mechanism which could facilitate other “approved” researchers to engage in pre-screening subject to a number of safeguards.

-An amendment which seeks to address the challenge of explicit consent versus “deferred” consent in **emergency care intervention studies**.

-An amendment aimed at finding a workable basis for the processing of personal data for health research **where an adult lacks capacity to consent**. The Department is of the view that the requirement for explicit consent in the case of someone who lacks capacity to consent means that the very people who might benefit from particular research studies will not be able to allow their personal data to be used for such research and that is not consistent with public policy and the values underpinning a patient centred health system. An amendment has therefore been prepared reflecting the core principles set out in the Assisted Decision-Making (Capacity) Act 2015 and the HSE National Consent Policy.

Next Steps

It should be noted that the process of making any amendments to the Health Research Regulations requires, by law, formal consultations not only with the Data Protection Commission but also the Department of Justice and Equality to ensure that anything contemplated is consistent with the Data Protection Act 2018. The Attorney-General’s Office is also directly involved to ensure any proposed amendments would be properly drafted and legally sound. Equally, amendments may not be sound or feasible or alternatives approaches might emerge.

The Department will keep the research community informed as a matter of urgency through the HRCDC website.

 8 April 2019