**Amendment of the Health Research Regulations**

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**29 April 2019**

This explanatory note relates to Regulation 6 of the Health Research Regulations made by the Minister on 7 August last year as amended by the Minister on 29 April 2019.

Regulation 1(2) of the Health Research Regulations provides that they came into effect on 8 August 2019.

Regulations 3 (1) provides that a data controller who is processing or further processing personal data for the purposes of health research must ensure that specified suitable and specific measures are taken to protect data subjects. One of those safeguards is that the explicit consent of the data subject is obtained.

**What is Regulation 6 about?**

The original Regulation 6 provides for a transition period to enable a data controller who is carrying out health research that commenced prior to 8 August 2018 who processes or further processes personal data for the purposes of that health research after 8 August 2018 must, as soon as practicable and no later than 30 April 2019, have explicit consent of the data subject for the processing of his or her personal data for the purpose of the specified health research.

‘Processing’ under the General Data Protection Regulation includes obtaining, using, disclosing and storing. Storing is important because it means that even if the personal data concerned is not currently being actively used for health research it is nonetheless encompassed by the definition.

Where it is not possible to obtain explicit consent, this transition period enabled data controllers to make other appropriate arrangements to ensure compliance with GDPR (e.g. anonymisation of a dataset).

Two specific scenarios were considered in framing Regulation 6;

1. where no consent was obtained;
2. where consent was obtained in line with the previous EU Data Protection Directive, but the data controller is of the view that that prior consent obtained would, in some material way, not be consistent with the consent requirement of GDPR for the ongoing and further processing of that data.

If the data controller believes obtaining the explicit consent, re-consenting or anonymisation of the data is not possible or practicable, Regulation 6 provides that the data controller can apply to the Health Research Consent Declaration Committee (HRCDC) for a consent declaration. Where the HRCDC grants a declaration in relation to such an application on or before 30 April 2019 then the requirement in Regulation 6 for explicit consent to be in place by that date would be met by the declaration.

However, the HRCDC itself was not established until March 2019 and it was recognised that the longer than anticipated establishment of the HRCDC should be reflected in an amendment to Regulation 6That change was carried through in the amendment made by the Minister on 29 April.

**What does the amendment to Regulation 6 mean?**

There following key points should be noted regarding the amendment:

1. It extends outwards the timeline by which explicit consent must be in place or a consent declaration granted by the Committee, from 30 April to 7 August 2019 –which is effectively a total period of 12 months from the time the Regulations were made on 8 August 2018. After 7 August 2019 the requirement for explicit consent in relation to research falling under Regulation 6 will be fully in effect.
2. Applications submitted to the HRCDC on or before 7 July 2019, will not be considered in breach of the requirement to have explicit consent in place, until such time as the Committee has made a decision on an application. Accordingly, as a practical matter, all applications under Regulation 6 should be made before 7 July rather than after that date and before 8 August.
3. The Committee will not be able to consider applications purporting to be made under Regulation 6 if they are submitted after 7 August 2019, since any such application would be breach of the requirement to have explicit consent in place by that date.

Department of Health

3 May 2019