

## DEADLINE REMINDER

### Expiration of Transition Period under the Health Research Regulations for a health research project that commenced prior to 8<sup>th</sup> August 2018

- The Health Research Regulations made under the Data Protection Act 2018 came into effect on August 7<sup>th</sup>, 2018<sup>1</sup>
- The time frame for obtaining explicit consent or a consent declaration from the Health Research Consent Declaration Committee (HRCDC) for the processing of personal data for a health research project that commenced prior to August 7<sup>th</sup> 2018 was due to expire on 30<sup>th</sup> April 2019. This has subsequently extended to 7<sup>th</sup> August 2019<sup>2</sup>.
- Where an application is made for a consent declaration to the HRCDC before 7<sup>th</sup> July this will mean that the processing concerned will not be in breach of the Regulations up until the time a decision is made by the Committee.

#### **For your attention:**

- All data controllers currently using personal data for health research, which commenced prior to August 8<sup>th</sup>, 2018, should consider whether they are currently compliant with the Health Research Regulations;
  - are you processing identifiable or pseudonymised<sup>3</sup> personal data for health research?
  - have you obtained explicit consent<sup>4</sup> from the data subject?

If you cannot obtain explicit consent and continue to process (which includes collecting, using, storing and disclosing) identifiable or pseudonymised personal data; You may need to consider applying to the HRCDC, for a consent declaration. Please see [www.hrcdc.ie](http://www.hrcdc.ie) for more details, and/or contact [secretariat@hrcdc.ie](mailto:secretariat@hrcdc.ie)

- After August 7<sup>th</sup>, 2019, the HRCDC **cannot** consider applications made in relation to research that commenced prior to 7<sup>th</sup> August 2018.
- After this time, data controllers are likely to be in breach of the Health Research Regulations if they continue to process identifiable or pseudonymised personal data, without explicit consent.
- Further information from the Dept. of Health can be found [here](#).
- All applications for a consent declaration made to the HRCDC must be as complete as possible upon submission, with confirmed research ethics approval and completed data protection impact assessment.

**\*\*SUMMARY \*\***

#### Submissions pre July 7th

- Applications submitted & pending a HRCDC decision - will not be in breach of the requirement to have explicit consent

#### Submissions between July 7th - Aug 7th

- Applications submitted & pending a HRCDC decision - may be in breach of the requirement to have explicit consent **after 7th August**

#### Submissions post August 7th

- Applications **CAN NOT BE CONSIDERED** by the HRCDC

<sup>1</sup> <http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf>

<sup>2</sup> <http://www.irishstatutebook.ie/eli/2019/si/188/made/en/pdf>

<sup>3</sup> <https://www.dataprotection.ie/en/guidance-landing/anonymisation-and-pseudonymisation>

<sup>4</sup> [https://ec.europa.eu/newsroom/article29/item-detail.cfm?item\\_id=623051](https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051)