

## STATUTORY INSTRUMENTS.

S.I. No. 188 of 2019

\_\_\_\_\_

DATA PROTECTION ACT 2018 (SECTION 36(2)) (HEALTH RESEARCH) (AMENDMENT) REGULATIONS 2019

## S.I. No. 188 of 2019

Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2019

- I, SIMON HARRIS, Minister for Health, in exercise of the powers conferred on me by section 36(2) of the Data Protection Act 2018 (No. 7 of 2018), and having duly complied with subsections (5)(b) and (6) of section 36 of the Data Protection Act 2018, hereby make the following regulations:
- 1. These Regulations may be cited as the Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2019.
- 2. The Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (S.I. No. 314 of 2018) are amended, in Regulation 6 -
  - (a) by the substitution of the following paragraph for paragraph (1):
    - "(1) Subject to paragraph (9), a 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 shall, as soon as practicable and no later than 7 August 2019, have explicit consent of the data subject for the processing of his or her personal data for the purpose of specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof.", and
  - (b) by the insertion of the following paragraph after paragraph (8):
    - "(9) Where a data controller has made an application under paragraph (4) on or before 7 July 2019, the date for the purposes of explicit consent under paragraph (1) shall be the date of the notice in writing given by the Committee under Regulation 8(5).".



GIVEN under my Official Seal, 29 April 2019

> SIMON HARRIS, Minister for Health.

## EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation)

These Regulations are made by the Minister for Health under section 36 of the Data Protection Act 2018 and amend Regulation 6 of the Health Research Regulations made by the Minister on 7 August 2018.

## BAILE ÁTHA CLIATH ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR Le ceannach díreach ó FOILSEACHÁIN RIALTAIS, 52 FAICHE STIABHNA, BAILE ÁTHA CLIATH 2 (Teil: 01 - 6476834 nó 1890 213434)

DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased from
GOVERNMENT PUBLICATIONS,
52 ST. STEPHEN'S GREEN, DUBLIN 2.
(Tel: 01 - 6476834 or 1890 213434)

9 "781446" 892053

€ 1.50

(DH-15) 75. 4/19. Propylon.