**To: Research Ethics Committees using the Research Ethics Committee Standard Application Form (RECSAF)**

**Notification of Substantial Change**

Please find below notification of **substantial changes** to one of the versions of the Research Ethics Committee Standard Application currently in circulation.

**Context:**

Substantial Changes necessitated as a result of Data Protection Act 2018 (Section 36 (2)) (Health Research) (Amendment) Regulations 2021

**Document changed:**

RESEARCH ETHICS STANDARD APPLICATION FORM (RECSAF) 5.6

ADAPTED VERSION – Aug 2018, Edited 31.8.18 © RCSI/Beaumont

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| **Change** | **Rationale** |
| Add new question:  “E1.1 (c) If yes, please confirm that a copy of the ‘explicit consent’ will be provided to the data subject prior to the commencement of the health research. This is mandatory requirement under the Data Protection Act 2018 (Section 36 (2)) (Health Research) (Amendment) Regulations 2021” | To reflect new requirement introduced under the Data Protection Act 2019 (Section 36 (2)) (Health Research) (Amendment) Regulations 2021” |
| Add reference to  “an exemption under the Data Protection Act 2018 (Section 36 (2)) (Health Research) (Amendment) Regulations 2021”  (-various questions, Section C and E) | To reference exemptions to the requirement for explicit consent prior to the commencement of the health research or a Health Research Consent Declaration Committee as provided for under the Data Protection Act 2018 (Section 36 (2)) (Health Research) (Amendment) Regulations 2021  Note: the four Key exemptions relate to:   1. Pre-screening (subject to conditions) 2. Low Risk Retrospective chart reviews (subject to conditions) 3. Deferred Consent in exceptional circumstances (subject to conditions) 4. Consent previously obtained under the ’95 Directive (subject to conditions) |
| Add phrase to C3.5 (b)  (applicable to adults with a power of attorney, or who are wards of court only) | Explanatory purposes only |
| All changes formatted in **coloured font** | To distinguish changes |

No changes have been made to the ‘Instructions for Use’

**Substantial Changes**

**Date of Change: 8th June 2021**