**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.

**Rationale**

* Substantial change to add a new Sub-Section E4, Artificial Intelligence
* Substantial change to Section A to make it clearer when chief investigators / site principal investigators have joint appointments
* Additional changes at request of local RECs
* Minor changes to instructions and formatting

**Document changed:**

RESEARCH ETHICS STANDARD APPLICATION FORM (RECSAF) 5.6

ADAPTED VERSION – 8.7.24 © Beaumont Hospital

| **Substantial Change** | |
| --- | --- |
| **Change** | **Rationale** |
| Add text to A2 (b), A2 (d), A2 (e) and A2 (g)  **(ii) If yes, name the organisations:** Answer  **(iii) If yes, specify which organisation the chief investigator will represent for entire duration of this research study:** Answer | to make it clearer when chief investigators / site principal investigators have joint appointments and bring further in line with the HSE RGMS Framework Sept ‘21 |
| Add text to A2 (d), and A2 (g)  **Accreditation Body**: Answer  **Professional Registration No:** Answer | Text added at request of local REC |
| A2 (e) (iii) change ‘principal’ to ‘chief’ | Correct typo |
| Contents Page  Remove reference to Guidance Manual | Text removed at request of local REC |
| Add text to C2.1 (c) **Consent must be informed and participation voluntary.** | Text added at request of local REC |
| **Change** | **Rationale** |
| Add instruction before Question E2.2 Please obtain data protection advice before answering the next question. | Applicants experiencing difficulty with this question |
| Add highlighting to Table E2.2 | As above |
| Add new Sub-section E5 Artificial Intelligence | to capture studies which involve AI |
| Add instruction before Question J3.1 Please obtain research governance advice before answering the next question. | Applicants experiencing difficulty with this question |
| Add highlighting to Table J3.1 | As above |
| Add footer (definition of a clinical trial) to Question J3.1 | As above |
|  |  |
| All changes to questions marked in coloured font | To distinguish changes |
| All changes to instructions marked in coloured font | To distinguish changes |

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

**Substantial Change #1**

**Date of Change: 8 July 2024**