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

**Notification of Administrative Changes**

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

**Document changed:**

RESEARCH ETHICS STANDARD APPLICATION FORM (RECSAF) 5.6

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

|  |  |
| --- | --- |
| **Change** | **Rationale** |
| Adjust font colours, remove highlights throughout | Significant changes to the application form made by RCSI/Beaumont in Aug 2018 and 31 Aug 2018 as a result of the Health Research Regulations 8 August 2018 were delineated in green font or via yellow highlighted text at that time.Following passage of time, it is no longer necessary to highlight these changes. |
| Adjust instruction on table of contents page as follows: - “Please refer to **Sections H and I** within the form before any attempt to complete the Standard Application Form. **Section H** is designed to assist applicants in ascertaining if their research study is in fact a clinical investigation of a medical device. **Section I** is designed to assist applicants in ascertaining if their research study is in fact a clinical trial of a medicinal product.”  | To direct applicants to Section H (in addition to Section I) |
| Insert Note, Section H“Note: A National Research Ethics Committee to review clinical investigations of medical devices was set up in May 2021” | To advise applicants of this development |
| Insert Note, Section I“Note: A National Research Ethics Committee to review clinical trials of medicines was set up May 2021” | To advise applicants of this development |

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

**Administrative Change No. 3**

**Date of Change: 31st May 2021**