**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 to align with terminology and definitions in the HSE National Framework for the Governance, Management and Support of Research (September 2021)

Minor changes made to reference post-marketing follow up investigations of medical devices, and direct applicants to National Research Ethics Committee for Medical Devices (NREC-MD) etc.

**Document changed:**

RESEARCH ETHICS STANDARD APPLICATION FORM (RECSAF) 5.6

ADAPTED VERSION – 8.6.21 © Beaumont

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| **Minor Changes** |
| **Change** | **Rationale** |
| Add phrase (cover sheet, page 1; contents page, page 2) or a post-marketing follow-up investigation of a medical device  | To advise applicants to direct post-marketing follow up investigations of medical devices to National Research Ethics Committee |
| Add instructions (contents page, page 2) Please contact the Health Products Regulatory Authority, the National Research Ethics Committee for Clinical Trials (NREC-CT) or the National Research Ethics Committee for Medical Devices (NREC-MD) if in doubt. | Advice purposes only |
| J3.2 - Change question from: -**H3 (a) Is this an application to conduct a clinical investigation of a medical device?**To: - **H3 Is this an application to conduct a clinical investigation of a medical device or a post-marketing follow-up investigation of a medical device?** | To advise applicants to direct post-marketing follow up investigations of medical devices to National Research Ethics Committee |
| End of Section H – add instruction - If answer is Yes, please redirect your submission to the NREC-MD | As above |
| End of Section H - delete question H3 (b) | No longer required |
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| **Substantial Changes** |
| **Change** | **Rationale** |
| A2 (b) – change terminology as follows: ‘principal investigator’ to ‘**chief** investigator’ | To move to terminology in HSE RGMS Framework (Sept 2021) |
| A2 (c) – change terminology as follows: ‘lead co-investigator’ to  **‘principal** Investigator’ | As above |
| E2.2 Add footnotes: ‘The data controller for a research study is the organisation that determines the purpose and the manner by which personal data are processed for the research study (i.e. ‘Whom’, ‘Why’, ‘How’).’ **– HSE RGMS Framework, Sept ‘21** ‘A data processor is defined as the organisation that processes personal data on behalf of, and under the instruction of, the data controller (i.e. two distinct organisations).’ **– HSE RGMS Framework, Sept ‘21** | To direct applicants to definitions in the HSE RGMS Framework |
| J3.1 – Change terminology as follows: ‘organisation / or individual legally responsible for this research study’ to ‘**sponsor for this clinical trial (or the legally responsible entity /entities for research other than clinical trials)’** | To move to terminology in HSE RGMS Framework |
| J3.1 – Insert Table | For ease of response |
| **Substantial Changes cont.** |
| **Change** | **Rationale** |
| J3.1 - Add footnote: Refer to **HSE RGMS Framework, Sept ’21** for more information **-** [**https://hseresearch.ie/governance-framework/**](https://hseresearch.ie/governance-framework/) | To direct applicants to definitions in the HSE RGMS Framework. i.e. sponsor; clinical trial; legally responsible entity/entities; research other than clinical trials. |
| J3.2 - Change question from: -**J3.2 Where an organisation is legally responsible, please specify if this organisation is:****A pharmaceutical company** Yes / No**A medical device company** Yes / No**A university** Yes / No**A registered charity** Yes / No**Other** Yes / No **If yes, please specify:** AnswerTo: - **J3.2 Please specify if the sponsor or legally responsible entity / entities is/are pharmaceutical companies, medical device companies, academic institutions, registered charities or other.** | Rephrase in light of previous question |
| J3.2 - Change question from: -**J3.3 Please confirm and provide evidence of any specific additional insurance / indemnity arrangements which have been put in place, if any, by this organisation / or individual for this research study?**To: -**J3.3 Please confirm and provide evidence of any specific additional insurance / indemnity arrangements which have been put in place, if any, by the above-named sponsor, legally responsible entity or entities in respect of this research study.** | As above |
| All changes to instructions formatted in coloured font | To distinguish changes |
| All changes to questions formatted in **coloured font** | As above |
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No changes have been made to the ‘Instructions for Use’

**Substantial Changes**

**Date of Change: 26th November 2021**