**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: -

1. to further align with requirements of the HSE National Framework for the Governance, Management and Support of Research (September 2021)
2. for research governance purposes - to assist researchers in ascertaining if contracts apply
3. for research ethics purposes - to assist research ethics committee in ascertaining when broad consent for future research applies.

**Document changed:**

RESEARCH ETHICS STANDARD APPLICATION FORM (RECSAF) 5.6

ADAPTED VERSION – 26.11.21 © Beaumont

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| **Substantial Changes** |
| **Change** | **Rationale** |
| Extend question A2 (b) **Joint appointment / Dual affiliation applies:** Yes / No**If yes, name the organisation the chief investigator will represent for entire duration of this research study:**  | Requirement of HSE RGMS Framework (Sept 2021) |
| Extend questions A2 (d)(e)**Joint appointment / Dual affiliation applies:** Yes / No**If yes, name the organisation the principal investigator will represent for entire duration of this research study:** | As above |
| **Change** | **Rationale** |
| E2.2 - Insert Table

|  |  |  |
| --- | --- | --- |
| **Name of Organisation which is the sole Data Controller for this research study** | **Name of Organisations which are the Joint Data Controllers for this research study (where applicable)** | **Name of Organisations which are data processors acting on behalf of / and under the instruction of the sole data controller or joint data controllers (if any)** |
| Answer | Answer | Answer |
|  | **Please note contracts will apply** |

 | Applicants having difficulty with this question – change to table format – and flag that contracts will apply in cases where- there are joint data controllers or data processors |
| Adjust question E2.4**E2.4 Please specify any person other than employees of the named data controller, joint controllers or processors with whom it is intended to share any of the personal data collected (including where it has been pseudonymised or anonymised) and the purpose of such sharing.** | To provide clarity in light of change to E2.2 -HSE RGMS framework (2021) states employees act on behalf of their employer |
| Adjust question E3.4 (a)**E3.4 (a) Will data collected be at any stage leaving the site (s) or organisation (s) of origin?** **Please note contracts may apply**Yes / No | To address situations where several different organisations operate on the same physical site / campusTo flag to applicants that contracts may apply |
| **Substantial Changes cont.** | **Rationale** |
| Adjust question E3.5**E3.5 Where will data analysis take place and who will perform data analysis (if known)? Please note contracts may apply** | To flag to applicants that contracts may apply |
| Adjust question E3.6 (b)**E3.6 (b) If yes, for how long, for what purpose, and where will it be retained? [Note – if retention for future research purposes applies, please specify]** | To assist REC in ascertaining if broad consent for future research applies |
| Adjust question F2.5 (d)**F2.5 (d) If yes, for what purpose will samples be retained? [Note – if retention for future research purposes applies, please specify]** | As above |
| Insert sub-heading before F2.5 (f)**FUTURE USE** | As above |
| Adjust question F2.5 (g)**F2.5 (g) If yes, please elaborate and comment on consent for future use of human biological material and/or data derived from it.**  | As above |
| Adjust question F4.1 (a)**F4.1 (a) Will human biological material at any stage leave the institution(s) of origin?** Yes / No **Please note contracts may apply.** | To flag to applicants that contracts may apply |
| Insert sub-headings in Section F5**INFORMATION PRIOR TO TESTING: RESULTS / FINDINGS:****THIRD PARTY DISLOSURE: PRIVACY AND CONFIDENTIALITY:** | For emphasis |
| Add note to Question E5.4**(The EDPB recommend that genetic data be treated as personal data stating that it remains unresolved as to whether genetic data can ever be fully anonymised)** | To highlight EDPB position on genetic data (Feb ‘2021) |
| All changes to questions formatted in **coloured font** | To distinguish changes |

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

**Substantial Changes**

**Date of Change: 31th July 2022**