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

**Notification of Administrative Change**

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

**Context:**

* HSE National Consent Policy for Health and Social Care Research 20 December 2022
* Assisted Decision-Making Capacity (Amendment) Act 2022
* S.I. No. 29/2023 - European Union (Basic Safety Standards for Protection Against Dangers Arising From Medical Exposure To Ionising Radiation) (Amendment) Regulations 2023
* Notification from Department of Health 3 May 2023 to recognised research ethics committees re. S.I. No. 29/2023

**Document changed:**

RESEARCH ETHICS STANDARD APPLICATION FORM (RECSAF) 5.6

ADAPTED VERSION – 31.7.22 © Beaumont Hospital

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| **Administrative Change** | |
| **Change** | **Rationale** |
| Insert question numbers in Section A :  **A2 (b) (i)**, **A2 (b) (ii)**, **A2 (d) (i), A2 (d) (ii)**, **A2 (e) (i), A2 (e) (ii)** | For identification purposes only |
| Insert note at start of Subsection C2:  Note: The HSE first released a National Consent Policy for Health and Social Care Research in December 2022. This policy, which will be regularly updated, introduces a definition of consent which combines elements of informed consent to take part and explicit consent for data processing (see Sub-Section E1 for explicit consent for data processing) | To advise researchers of this development, definition as follows:  “For the purpose of this policy, the term ‘consent’ refers to the informed and explicit agreement of a prospective research participant to take part in a research study and, when relevant, to the use of their personal data for such research. The agreement for both must be ethically obtained, recorded, and retained; the proposed consent protocol must be approved by an appropriate Research Ethics Committee (REC) and, when applicable, comply with Irish data protection legislation” |
| Insert note at start of Subsection C3:  Note: The Assisted Decision-Making Capacity (Amendment) Act 2022 took effect on the 26th April 2023. The HSE National Consent Policy for Health and Social Care Research will be updated to reflect this development. | To advise researchers of this development |
| Delete phrase in C5.1  **Please refer to the HSE’s National Consent Policy, particularly Part 3, Section 5.** | no longer applies |
| Insert note at intervals throughout the form:  Note: refer to the HSE National Consent Policy for Health and Social Care Research  Insert ‘keyword’ search hint at intervals:   * search ‘findings’ * search ‘broad’ and ‘secondary’ * search ‘biobank’ * search ‘genetic’ and ‘genomic’ * search ‘commercial’ * search ‘findings’ and ‘genetic’ | To refer researchers to the HSE National Policy for Health and Social Care Research esp. in relation to:   * secondary findings (-Questions D7, F5.3 (a)) - search ‘findings’ and ‘genetic’ * incidental findings (-Questions D7, F5.3 (a)) - search ‘findings’ and ‘genetic’ * broad consent (-Questions E3.6 (b), F2.5 (d), F2.5 (g)) - search ‘broad’ and ‘secondary’ * biobanks (-Question F2.6 (a)) - search biobank * genetic research (-Question F5.1 (a)) - search ‘genetic’ and ‘genomic’ * commercial research (-Question F6.1 (a)) - search ‘commercial’ |
| Insert note at start of Subsection E1:  Note: The HSE first released a National Consent Policy for Health and Social Care Research in December 2022. This policy, which will be regularly updated, introduces a definition of consent which combines elements of informed consent to take part and explicit consent for data processing (see Sub-Section C2 for informed consent to take part) | To advise researchers of this development |
| Adjust note at start of Subsection G1 :  Change phrase ‘recognised research ethics committee’  to “research ethics committee which has been recognised to give a single national opinion under S.I. No. 29/2023” | To refer to S.I. No. 29/2023  Section 40 (2) names the following research ethics committees as currently recognised for the purposes of these Regulations: -   1. Tallaght University Hospital / St. James’s University Hospital REC 2. Clinical Research Ethics Committee of the Cork Teaching Hospitals 3. Galway University Hospitals 4. Mater Misericordiae University Hospital / Mater Private Hospital 5. St. Vincent’s Healthcare Group 6. University of Limerick Hospitals 7. Beaumont Hospital REC 8. HSE South Eastern Area 9. HSE North East 10. National Maternity Hospital (Holles Street) 11. Irish College of General Practitioners 12. St. Luke’s Radiation Oncology REC   The above committees were notified by the Department of Health on the 3rd May 2023 that they can give a single national opinion for studies which involve exposure to medical ionising radiation. |
| All changes to questions numbers marked in coloured font | To distinguish changes |
| All changes to instructions marked in coloured font | To distinguish changes |
| Changes related to last substantial change in July 2022 remain in coloured font | No change |

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

**Admin Change #1**

**Date of Change: 16 May 2023**