

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 Section A to reflect the fact that the Chief Investigator with overall responsibility for the study may or may not be the same person as the Principal Investigator at the study site (principal investigator at the study site is an employee of the site)
- Minor changes to refer to release of updated HSE National Consent Policy for Health and Social Care Research, v1.1, June 2023

Document changed:

RESEARCH ETHICS STANDARD APPLICATION FORM (RECSAF) 5.6

ADAPTED VERSION – 16.5.23 © Beaumont Hospital

Substantial Change	
Change	Rationale
<p>Change word 'principal' to 'chief'</p> <p>A2 (e) If no, please name the chief investigator with overall responsibility for the conduct of this single-site study.</p>	<p>To allow space to name the Chief Investigator where the study is single-site.</p> <p>(Chief Investigator may or may not be the same person as the Principal Investigator at the study site)</p>
<p>Add question A2 (g)</p> <p>A2 (g) For single-site studies, please provide details of the principal investigator at the site.</p> <p>Title: <input type="text" value="Dr. / Ms. / Mr. / Prof."/> Name:</p> <p>Answer</p> <p>Qualifications: Answer</p> <p>Position: Answer</p> <p>Dept: Answer</p> <p>Organisation: Answer</p> <p>Address: Answer</p> <p>Tel: Answer E-mail: Answer</p>	<p>To collect details of Principal Investigator at the study site.</p> <p>(Principal Investigator at the study site is an employee of the site)</p>

<p>A2 (g) (i) Joint appointment / Dual affiliation applies: Yes / No</p> <p>A2 (g) (ii) If yes, name the organisation the principal investigator will represent for entire duration of this research study: Answer</p>	
<p>Edit instruction after Question A2 (a)</p> <p>If you chose 'yes' please delete questions A2 (e) (f) and (g);</p>	In line with the above
<p>Delete phrase at start of Subsection C3:</p> <p>The HSE National Consent Policy for Health and Social Care Research will be updated to reflect this development.</p>	no longer required
<p>Insert note at start of Subsection C3:</p> <p>Note: Refer to the HSE National Consent Policy for Health and Social Care Research – search "capacity" and / or "emergency"</p>	<p>Refer researchers to:</p> <p>HSE National Consent Policy for Health and Social Care Research, v1.1, June 2023</p> <p>Provide search keyword hint – – search "capacity" and / or "emergency"</p>
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: 26 June 2023