

Substantial Change Information - REC SUH Standard Application Form, v8.7.24

Please find below information of substantial changes to the version REC SUH Standard Application Form, v26.6.23. Please note that from 1st of August 2024 only research ethics application form version 8th July 2024 will be accepted for review by the REC SUH.

Rationale

- Substantial change to add a new Sub-Section E4, Artificial Intelligence
- Substantial change to Section A to make it clearer when chief investigators / site principal investigators have joint appointments
- Minor changes to instructions and formatting

Document changed:

REC SUH Standard Application Form, v26.6.23 (RECSAF) 5.6

ADAPTED VERSION – REC SUH Standard Application Form, v8.7.24 © Beaumont Hospital

Substantial Change
Add text to A2 (b), A2 (d), A2 (e) and A2 (g) (ii) If yes, name the organisations: Answer (iii) If yes, specify which organisation the chief investigator will represent for entire duration of this research study: Answer
Add text to A2, A3 and A5 Accreditation Body: Answer Professional Registration No: Answer
A2 (e) (iii) change 'principal' to 'chief'
Contents Page Remove reference to Guidance Manual
Add text to C2.1 (c) Consent must be informed and participation voluntary.
Change
Add instruction before Question E2.2 Please obtain data protection advice before answering the next question.
Add highlighting to Table E2.2
Add new Sub-section E5 Artificial Intelligence
Add instruction before Question J3.1 Please obtain research governance advice before answering the next question.
Add highlighting to Table J3.1
Add footer (definition of a clinical trial) to Question J3.1
All changes to questions marked in coloured font All changes to instructions marked in coloured font

No changes have been made to the 'Instructions for Use'

Substantial Change #1

Date of Change: 8 July 2024