

FREQUENTLY MADE MISTAKES

(RECSAF 5.5)

GENERAL MISTAKES	CORRECT APPROACH
hand-writing the application	application should be typed
underlining or bolding the chosen answer to a given question e.g. Is this a multi-site study? <u>Yes</u> / No	delete the answer which does not apply e.g. Is this a multi-site study? Yes
forgetting to delete questions when they don't apply e.g. A7 (b) e.g. C2.1 (b)(c)(d)(e)(f)(g)(h) e.g. C3.1 (b)(c)(d) e.g. C4.1 (b), C4.2, C4.3, C4.5, C4.6, C4.7 e.g. D4 (b) (c) e.g. D6 (b) e.g. E3.2 (a) (b) e.g. J1 (b) J2 (b) e.g. K2 (c) (d) (e) (f) (g)	refer to the Guidance Manual – it will tell you when you can delete certain questions.
forgetting to delete sections which do not apply e.g. Section F e.g. Section G e.g. Section H e.g. Section I	refer to the Guidance Manual – it will tell you when you can delete certain sections.
forgetting the signatures	refer to the Beaumont Hospital Checklist and Signatory Page. Signatures required include the Principal Investigator, the Co-Investigators and the Academic Supervisor. And remember, this is not just a signing exercise! Signing the signature page is evidence that all involved have proofread the ethics application form, and are willing to have their names associated with its content. The signature page reflects the collaborative nature of all research and is designed to prevent poorly-completed ethics application forms and ill-advised research studies being submitted for ethical review.

MISTAKE – SECTION A	CORRECT APPROACH
choosing an inappropriate Principal Investigator – Question A2	give careful thought as to whom is given the role of Principal Investigator. In studies without an external sponsor, the principal investigator is also the study sponsor (J3 (a))
failing to name a Beaumont Hospital consultant as a co-investigator – Question A4	in studies involving patients it is essential to name at least one Beaumont Hospital consultant as a co-investigator
failing to name the academic supervisor as a co-investigator – Question A4	in studies being undertaken as part of an academic qualification it is essential to name the academic supervisor as a co-investigator
not pitching the answer to Question A6 to lay committee members (IMPORTANT)	this answer should be written in plain english. Lay committee members will use your response to question A6 as their window into understanding your ethics application.

MISTAKE – SECTION B	CORRECT APPROACH
struggling with questions B8 (c) (d) (e)	obtain advice from a statistician not only in responding to these questions, but in designing your study!

MISTAKE – SECTION C	CORRECT APPROACH
forgetting to fill in question C1.1	type in the name of the site; type in the name of the group; type in the number of study participants;

MISTAKE – SECTION D	CORRECT APPROACH
stating ‘none’ in response to Question D1	refer to the Guidance Manual and read thoroughly the guidance note in relation to this question. The phrase ‘procedures and interventions’ is misleading, and is defined in a broad sense in the Guidance Manual

MISTAKE – SECTION E	CORRECT APPROACH
misunderstanding Question E2.3	refer to the Guidance Manual and read thoroughly the guidance note <u>several times</u> . Obtain advice from the Data Protection Commission if necessary
answering Question E3.2 (a) incorrectly.	the data controller for Beaumont Hospital healthcare records is ‘Beaumont Hospital Board’ and remember this question only applies if you answered ‘no’ to Question E3.1 (d).
answering Question E3.2 (b) incorrectly	read the Guidance Note carefully and remember this question only applies if you answered ‘no’ to Question E3.1 (d)

MISTAKE – SECTION J	CORRECT APPROACH
forgetting to answer Question J1 (b) where it applies	where it applies, it is an important question. Refer to the Guidance Manual. And <u>IF THERE ARE SITES WHICH ARE NOT COVERED BY THE CLINICAL INDEMNITY SCHEME</u> don't forget the Certs of Insurance for the committee's review....
Forgetting to answer Question J2 (b)	where it applies, it is an important question. Refer to the Guidance Manual. And <u>IF THERE ARE INVESTIGATORS WHICH ARE NOT COVERED BY THE CLINICAL INDEMNITY SCHEME</u> don't forget the Certs of Insurance for the committee's review...
forgetting to answer Question J3 (a)	Always answer Question J3 (a). The term 'sponsor' is misleading. Refer to the definition in the Guidance Manual. And remember if the study doesn't have an <u>external</u> sponsor, the Principal Investigator is the sponsor!
Misunderstanding Question J3 (a) by stating that the 'HRB' is the sponsor of the research study.	the HRB is a funding agency and if the HRB is funding your study, please state this in response to Question K2 (c) The HRB is <u>never</u> the sponsor of the study. Please refer to the Guidance Manual for a definition of the term 'sponsor'

MISTAKE – SECTION K	CORRECT APPROACH
answering Question K2 (c) with a single word: industry, grant, or other	name the source of funding in your answer e.g. Science Foundation Ireland state the amount of funding in your answer e.g. €150, 000
getting lost within Section K and failing to delete questions which do not apply e.g. K2 (c) (d) (e) (f) (g)	refer to the Guidance Manual – it will tell you when you can delete certain questions.