FREQUENTLY MADE MISTAKES
RECSAF 5.6 (ADAPTED BEAUMONT, 26/6/23)
(UPDATED June 2023)

Most Common Mistake	**Correct Approach**
Taking each question at face value, and attempting to complete the application form without reference to the Instructions	**Refer to the Instructions 31.8.23 – they provide detailed explanations, and context for the questions posed in the application form**
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	Refer to the Instructions – they will tell you when you can delete certain questions
Forgetting to delete sections when they do not apply	Refer to the Instructions – they will tell you when you can delete certain sections
Forgetting the signatures	Refer to the Local Checklist and Local Signatory Page. And remember that this is not just a signing exercise! Signing the signatory page is evidence that all involved have proofread the ethics submission, and are happy for their names to be associated with its content.

	The signature page reflects the collaborative nature of all research and is designed to prevent poorly-completed ethics applications forms and ill-advised research studies being submitted for ethical review. Signatures required include that of the Principal Investigator & the academic supervisor
Mistake – Section A	**Correct Approach**
Naming a principal investigator at the study site who is not an employee of the study site.	Name an employee of the study site as the site principal investigator For clinical studies, this employee should be a healthcare professional. For clinical trials, this employee should be a medical practitioner. Difficulties can arise in obtaining confirmation of cover under the CIS / GIS Scheme where the named principal investigator is not an employee of the hospital.
Mistake – Section B	**Correct Approach**

Not pitching the answer to Question B3 to lay committee members (IMPORTANT)	this answer should be written in plain english. Lay committee members will use your response to question B3 as their window into understanding your ethics application.
Misunderstanding what an 'endpoint' is in response to Question B6	'endpoint' is a statistical term related to what is being measured in the study. Answers such as 'the study will finish in 2025' or 'the study will result in publication' are incorrect. Answers which are 'numbers' are more likely to be correct. Obtain advice from a statistician when answering this question.
Providing an incomplete answer to Question B8 (IMPORTANT)	Take your time in framing an excellent response to this question. Expert members zone in on this question, and the golden rule is that they shouldn't find out about key elements of your methodology later in the application, or in the participant information leaflet
Struggling with questions B9, B10 (a) and B10 (b)	Obtain advice from a statistician not only in responding to these questions, but in designing your study!
Mistake – Section E	**Correct Approach**
The concepts which Section E deals with are difficult ones: please obtain advice from your Data Protection Officer when completing this section	
Not cross-checking Section E with the Data Protection Impact Assessment (DPIA)	Do a final cross-check of Section E with your Data Protection Impact Assessment – some questions interconnect – a revised Data Protection Impact Assessment (DPIA) released in May 2023 allows you to paste your answers in to the DPIA
Not cross-checking Section E with the Patient	Do a final cross-check, and get advice from

Information Leaflet	the relevant data protection officer (DPO) if necessary e.g. dpo@beaumont.ie; ddpo.dne@hse.ie; dataprotection@rcsi.ie
Answering E4.2 incorrectly i.e. the wrong data controller	**This question only applies if you answered 'no' to Question E4.1 (d)** When the question applies, the data controller for Beaumont Hospital healthcare records is *'Beaumont Hospital Board.'*
Mistake – Section J	**Correct Approach**
Struggling with Questions J1 and J2	for studies taking place in Beaumont Hospital, see sample answers… Please supplement / adapt as appropriate. This particularly applies if your study involves investigators who are not employees of Beaumont, or other sites / organisations and collaborators etc.
Struggling with Questions J3.1	Please consider carefully your response to this question. Refer to the Instructions, and obtain advice if necessary. The HSE RGMS Framework requires all clinical trials regardless of level of risk to have a sponsor. The HSE RGMS Framework states that can be a number of legally responsible entities for a research study other than a clinical trial, and that these entities can be responsible for

	different aspects of the study.
Failing to complete J3.2	Please provide answer.
Failing to complete J3.3	State ‘none’ rather than leave blank
Mistake – Section K	**Correct Approach**
Failing to complete K2.1 (c)	Please complete the table for funded studies