

FREQUENTLY MADE MISTAKES

RECSAF 5.6

MOST COMMON MISTAKE	CORRECT APPROACH
taking the questions at face value, and attempting to complete the application form without reference to the Guidance Manual	refer to the Guidance Manual – it provides 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 Guidance Manual – it will tell you when you can delete certain questions.
forgetting to delete sections which do not apply	refer to the Guidance Manual – it will tell you when you can delete certain sections.
forgetting the signatures	<p>refer to the <u>Local Checklist and Signatory Page</u>. And remember, this is not just a signing exercise!</p> <p>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.</p> <p>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.</p> <p>Signatures required by Beaumont Hospital Ethics (Medical Research) Committee include the Principal Investigator, the Co-Investigators, the Academic Supervisor; and in the case of multi-site studies, the Lead Co-investigator at the Beaumont Hospital site.</p>

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. Please take into account the nature of the study and the level of risk to participants, as well as who the participants are when making this decision. Individuals, as opposed to organisations, conducting research are advised to ensure that your choice of Principal Investigator corresponds appropriately with your response to Question J3.1 (legal responsibility)
failing to name a Beaumont Hospital consultant as either lead co-investigator (A2) or co-investigator (A3)	In studies involving patients for review by Beaumont Hospital Ethics (Medical Research) Committee it is essential to name at least one Beaumont Hospital consultant as a co-investigator

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 end in 2016, or the study will result in publication’ are incorrect. Answers which are ‘numbers’ which a statistician can measure 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 framing an excellent response to this question Expert members zone in on this question, and the golden rule 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
<i>The concepts which Section E deals with are difficult ones; both the questions asked and the accompanying guidance notes are imperfect attempts to deal with difficult concepts.</i>	
<p>Responding to Question E2.3 in a way which the committee <u>does not understand your intended meaning</u></p>	<p>Applicants variously find the guidance note to this question helpful / the opposite of helpful.</p> <p>Hence, be careful with your choice of term and make it clear in brackets what you mean when you use a particular term.</p> <p>It may help to refer to this document: - ‘Help with Question E3.2 (a)’ which gives an insight into how Beaumont Hospital Ethics (Medical Research) Committee uses these terms.....</p>
<p>Answering Questions E2.8 (a)(b)(c) and (d) incompletely or inconsistently</p>	<p>most researchers collect data, retain it for a period of time, and then destroy the data, hence, they are both retaining and destroying the data.</p>
<p>Answering Question E3.2 (a) incorrectly i.e. the wrong data controller!</p>	<p><u>This question only applies if you answered ‘no’ to Question E3.1 (d)</u> Where the question applies, the data controller for Beaumont Hospital healthcare records is ‘Beaumont Hospital Board’</p>
<p>answering Question E3.2 (b) in a way that causes concern.</p>	<p><u>This question only applies if you answered ‘no’ to Question E3.1 (d)</u> Where the question applies, please exercise care with your answer.</p> <p>It is legally difficult for ‘data controllers’ to permit access to healthcare records without consent, and this difficulty increases if the proposed access is by ‘third parties’ i.e. non-employees.</p> <p>Obtain advice from a data protection specialist when framing a response to this question.</p>

For an insight into which themes commonly recur during research ethics review, please refer to the document called “*Recurring Review Themes*”