**FREQUENTLY MADE MISTAKES**

**RECSAF 5.6 (ADAPTED BEAUMONT, 8/6/21)**

**(UPDATED SEPTEMBER 2021)**

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| **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 – they provide detailed explanations, and context for the questions posed in the application form** | |
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| **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? **Yes** / 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 Lead Co-Investigator & the academic supervisor | |
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| **Mistake – Section A** | **Correct Approach** | |
| Choosing an inappropriate Principal Investigator – Section 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.  Please take into account who / which organisation is legally responsible for the study (J3.1) and how the study is being funded (K2.1 (c))  Please also take into account who / which organisation(s) are the Data Controllers/Joint Data Controllers (- E2.2, and Template Information Leaflet) | |
| Failing to name a local consultant doctor as lead co-investigator (-A2) or co-investigator (-A3) | **In studies involving patients / service users, it is essential to name at least one local consultant doctor as co-investigator** | |
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| **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! | |
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| **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*** | | |
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| 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 August 2021 allows you to past your answers in to the DPIA |
| Not cross-checking Section E with the Patient Information Leaflet | | Do a final cross-check, and get advice from the relevant data protection officer (DPO) if necessary e.g. [dpo@beaumont.ie](mailto:dpo@beaumont.ie); [ddpo.dne@hse.ie](mailto:ddpo.dne@hse.ie); [dataprotection@rcsi.ie](mailto: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.’*  The data controller for Dublin North Mental Health Services health care records however is the *‘HSE’* |
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| **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.  if naming yourself as legally responsible, please do not list your home address |
| Failing to complete J3.2 | | Please complete where organisation applies |
| 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 |