Recurring Review Themes: A Checklist for Applicants

An audit of comments made by Beaumont Hospital Ethics (Medical Research) Committee was conducted in 2011. The results indicated that there are a number of common recurring themes during review. We would like to share with you the most common themes and hope that these will be helpful to you as your prepare your ethics submission.

Themes which recur during review, and comments you can anticipate are: -

General Study Details /Administration	Study Investigators	Is a Beaumont Hospital consultant involved?
		Ensure the principal investigator (PI) is consistent throughout the application
		Include an expert co-investigator if necessary
	Queries about Irish Medicines Board (IMB) issues	Is the application for a clinical trial? (If so, a different application applies)
Study Descriptors	Statistical Analysis	Provide details of sample size
		Provide a power calculation
	Justification for elements of the study	Justify the outcome measures
		Is the timeframe practical?
Study Participants (Recruitment & Selection)	Inclusion / Exclusion Criteria	Ensure consistency throughout the application
		Are all the criteria justified?
	Recruitment	Comment on the feasibility of recruiting adequate numbers
		How will participants be recruited?
Research Procedures	Provide more details	What procedures will participants undergo?
		Justify use of procedures
	Clarify what is part of routine care and what is not	What exactly does the study involve, and how is it separate from the treatment patients already receive?
	Queries regarding aspects of treatment	Provide specifics of what is involved if the research study is also part of the participant's treatment
Data Protection	Data Access	Will medical records be accessed?
		Who will be accessing the data?
	Confidentiality	Will identifiable data be collected?
		Will data be anonymised or coded?
	Data Storage	Where will data be stored?
		Will data leave the hospital?
		Will data be sent abroad?
Patient Documentation *(includes patient information leaflets, consent forms, questionnaires, and any other documentation provided to the patient themselves*	Clarify information in patient documentation	State if a procedure is part of the participant's standard care or if it is separate
		State who has access to data collected
	Additional information required	Include contact details
		State risks of participating
		State what will happen to data collected
	Grammar / Formatting	Correct typos
		Correct inappropriate use of headings
		Adjust font size
		Adjust layout
	Missing documents	Provide information leaflets specific to next-of-kin, parents etc.

The audit findings were that the highest volume of committee comments relate to patient documentation.

Kelleher, E., Vale, G., Smith, D, Stanton, A. (2011)
An audit of comments made by Beaumont Hospital Ethics (Medical Research) Committee before and after the adoption of a new application form.