**Instruction Sheet 2:**

You may now proceed to complete Section B of the ethics application form.

The first question asks when the study will start. The usual answer to this question is when research ethics committee approval is in place, and any relevant contracts with the site have been entered in to.

The second question is the anticipated duration of the research study. This answer is usually given in days, months or years.

The remaining questions in Section B are self-explanatory. By reading the answers to the questions you provide, the committee will understand the aim and background of this research study; the design and methodology of this research study; how many participants will be taking part in this research study; the rationale for the decision to choose this number of participants; the statistical analysis plan; and any plan in respect of randomisation for this research study.

**If you are conducting this study for the purposes of obtaining an academic qualification, it is very important that your academic supervisor has input into each of the responses in Section B.**

If the research study cannot answer the question it seeks to ask based on the proposed design, methodology and statistical analysis plan, this research study should not proceed.

You may now proceed to Sub-section C1.

If you start by completing Question C1.5 which asks if any of your proposed participants will be taking part in another research study. The answers are: yes; no; and, not to my knowledge.

Before responding to the other questions in Sub-section C1, the first point of note is how many participant groups are in your research study. If there is only one group, for example, patients with high blood pressure, then the questions can be answered in relation to this group only. If there are several groups taking part in your research study, each of the questions in Section C1 will need to be answered in respect of *each* of these participant groups. The questions are: How will participants be selected? How will participants be recruited? What are the inclusion criteria for participants? What are the exclusion criteria for participants? To reiterate, please be very careful if you have several participant groups, especially if each of these groups have different inclusion and exclusion criteria, and if these groups will be selected in different manners, and recruited via different forms of approach.

You may now proceed to Sub-section C2.

The first question asks if you will be obtaining informed consent from your participants. If the answer is no, please proceed to Question C2.1 (b) where you will be asked to elaborate on the reasons why you are not obtaining informed consent from your participants. In Question C2.1 (c), you will be asked to expand on how informed consent will be obtained from participants. Please be as specific as possible when responding to this question. All of the aspects to this question apply: how will informed consent be obtained? Where will informed consent be obtained? By whom will informed consent be obtained? From whom will informed consent be obtained? Please exercise care if your research study involves more than one participant group, and if different methods or approaches to consent apply for each of these groups.

The remaining questions in Sub-section C2 are self-explanatory. Please note that it is normal practice where consent is being obtained from participants, to inform participants that they have the right to withdraw their consent. In addition it is normal practice to give participants as much time as they need to make a decision as to whether they would like to participate in this research study (or not).

Sub-section C3 applies to participation in your research study of adults over the age of eighteen years who lack capacity to give consent for themselves to take part in the study.

Sub-section C4 relates to the recruitment of children under the age of 18 to this research study. Please note that Beaumont Hospital is an adult hospital, and, as such, it is rare to recruit children under the age of 18 to a research study taking place in Beaumont Hospital.

Please proceed to Sub-section C5. The ethics committee is interested to know if any of the groups listed in Sub-section C5 will be targeted for inclusion in this research study as per the inclusion criteria in Sub-section C1. This sub-section can sometimes cause confusion to applicants. Please note that you should exercise care in saying yes to any of the groups in this section. If you have not previously used the term ‘healthy volunteers’ in Section B, or Section C1, Section C2, Section C3 or Section C4, the committee will not understand why you are stating that you are recruiting healthy volunteers to this study. This also applies if you stated for the first time in response to Section C5 that you are planning on recruiting relatives and carers to this research study. Please exercise care if you are choosing the options of patients with an acquired brain injury, or patients with an intellectual disability. If this is the case, you should cross-check with the inclusion and exclusion criteria in response to Sub-section C1, and also look at your responses in respect of patients who lack capacity in Sub-section C3.

Sub-section C5 was designed to help applicants to focus on the concepts of dependence and vulnerability in research participants. With this in mind, please be aware that many participants are in a dependent relationship on their employer, on their healthcare provider, on the healthcare provider of their relative, and on their academic institution. The application form seeks to ask what steps you have put in place in this research study in recognition of any vulnerability or dependence of your research participants.

With respect to the final question in Sub-section C5, please exercise caution in excluding female patients from participation in your research study. There are very few study types where it may not be appropriate for a pregnant patient or female patient of child bearing potential to take part in.

Please proceed to Section D.

The first two questions in Section D are important questions to answer. This is your opportunity to summarise what will happen to participants in this research study. Again, please exercise caution in answering these questions, in cases where there is more than one participant group in your research study.

The second question supplements the answer to Question D1 (a) and assesses all activities which are taking place as part of this research study.

The remaining questions in Section D are important as they help the committee to assess:

* what are the benefits of the research study;
* what are the risks of this research study.

**It is the role of the ethics committee to assess the benefits and risks of a research study, and to ensure the benefits outweigh any risks of participation.**

The questions seek to focus on the perspective of the research participant. They will match to a large extent the content of any included information leaflet for participants.

Information Leaflets for participants tell participants how a research study will be carried out, what will happen to them if they take part in a research study, what activities will take place as part of the research study, what are the risks and benefits of taking part in a research study.

The questions posed in Section D aim to assess what are the risks of participation in the research study, and if any treatments will be withheld from patients as a result of participation in the study, and if patients’ health will be monitored during and after participation in this study. Hence, there is a large focus on risks and harms to patients, and overall patient safety. In this context, researchers are also asked to provide information as to whether a patient’s GP or consultant will be informed that they are taking part in this research study.

As part of this emphasis on patient safety, there is also an emphasis on what results will be provided to patients, in particular, if they will receive individual results as a result of their participation in this study or if they will receive aggregated results of the study findings.

Section D is an excellent starting point for researchers who are designing information leaflets for their participants.