**Instruction Sheet 4:**

Here follows some general points when completing Section E of the ethics application form.

Point 1: Sub-section E1 deals with explicit consent for processing of data. Questions E1.1 (a) and E1.1 (b) will look very similar to Questions C2.1 (a) and C2.1 (b). Please note that the focus of Question E1.1 (a) and E1.1 (b) is on **explicit consent for processing of data in this research study.**  Section C2 i.e. Questions C2.1 (a) and C2.1 (b) related to informed consent for participation in this research study.

The second point of note is that the questions in Sub-section E2 come from the Irish data protection legislation called the Health Research Regulations. **You must complete all the questions in Section E2** as these are mandatory requirements in Irish data protection law.

The most important questions are Question E2.2, Question E2.3 and Question E2.4.

You have already completed Question E2.2 and Question E2.3.

Please exercise care when completing Question E2.4 and note you will be required to inform participants of the *recipients* of data in the Information Leaflet. Question E2.4 asks you who the recipients of data are.

The questions in Sub-section E2 in general are complex and technical in nature and can be difficult for researchers to answer. Please take as much time as you need to provide comprehensive answers in response to Sub-section E2.

When you have completed Sub-sections E1 and E2, it is recommended that you PAUSE at this point and review your answers.

The next step is to go to Sub-section E3.

Question E3.1 asks you what media of data will be collected. This refers to paper format, electronic format, audio format or visual format. It could relate to video recordings, photographs, images or scans. The media of data that you collect is very important as it helps the committee understand how data will be stored, in particular. Paper data, for example, tends to be stored in files and filing cabinets. Electronic data, including audio recordings and video, tends to be stored on computers, and computer systems and sometimes on cloud storage systems. The media of data you collect will help the committee to assess if it might be possible to identify a participant from this media type. For example, it can sometimes be difficult to de-identify participants if the data is being collected in the form of video recordings of these participants, or indeed audio recordings of these participants.

Before you proceed to answer Question E3.2, it is recommended that you pause and think about what data you will be collecting as part of this research study. If you have a Data Collection Sheet, for example, please keep this to hand.

It is advisable to now pause and MOVE to the Data Protection Impact Assessment Form.

Go to Question 3.1 in the Data Protection Impact Assessment Form. You have already specified the legal basis under Article 6 of GDPR. Now look at the columns to the left hand side and specify the basic personal data you will be collecting in respect of this research study. Tick all that apply. Please refer to your Data Collection Sheet as necessary.

Once you have completed Question E3.1 of the Data Protection Impact Assessment Form, you may now RETURN to the Ethics Application Form, and respond to Question E3.2 (a).

Please state whether the data you are collecting is anonymous, pseudonymised, or identifiable data.

The questions is Section E3 which can cause difficulty are questions are Questions E3.2 (a) and E3.2 (b). Researchers sometimes incorrectly class the data they are collecting; it is very common for researchers to mix up the terms pseudonymised and anonymised. If there is a code to re-identify the research participant, the data is pseudonymised.

The next question researchers sometimes have difficulty with is Question E3.4 (a). Sometimes it is clear from other answers within the body of the ethics submission that data is leaving Beaumont Hospital to go to the Royal College of Surgeons in Ireland. However, researchers would tend to write ‘no’ in response to this question when a ‘yes’ response is more accurate. In terms of data protection law, even though there are buildings owned by the Royal College of Surgeons on the campus of Beaumont Hospital, Beaumont Hospital and the Royal College of Surgeons are separate legal organisations and, although it is counter-intuitive, data is leaving the hospital.

Many of the questions in Sub-section E3 are trying to assess if data is leaving Beaumont Hospital. The questions are asked in different ways, including, where will data analysis take place. Issues which arise are which organisations data will be sent to and in which countries these organisations are.

E3.6 (b) can sometimes cause difficulty for researchers also. You need to specify how long data will be stored for, for what purpose the data will be stored, and where will it be retained. Hence, there are three parts to this question.

While data is retained for a period of time for many reasons, including preparation for publication, data analysis and write up of results, there is usually a time limit after which the data will be destroyed. In some cases the researcher will specify that they would like to retain data for a longer period for the purposes of future research as yet unknown. In some cases researchers will state that they would like to retain data for a considerable length of time – this may be the case in respect of long-term studies such as biobanks and registries.

Further questions follow in this section which seek to further assess if the study will involve the collection of recordings, either audio recordings, video recordings or photographs. The reason for these questions is that it can be difficult to de-identify this type of material.

The final point in respect of this section is that this section bears direct relevance to the content of the Participant Information Leaflet, and much of the information in this section must be conveyed to the research participant.

Subsection E4 relates to access to healthcare records. You may have indicated earlier in the ethics submission, for example, in Question C1.1 or in Question B8 or in Question D1 (b) that you are planning to access healthcare records as part of this research study. Section E4 gives you the opportunity to expand on this access, including the reasons for this access, who will be accessing records, and whether the access will be with patient consent or without. The committee will aiming to ensure compliance with the Irish data protection legislation in this regard.

Subsection E5 is a new section and relates to artificial intelligence. You may have indicated earlier in the ethics submission in Question B8 that the study involves artificial intelligence, for example, AI healthcare software or machine learning models. This section allows you to expand on this.