** Audio Recording 6 – Transcript:**

There are now only a small number of sections remaining in this ethics application form:

* Section G (Radiation);
* Section H (Medical Devices); and
* Section I (Medicinal Products, Cosmetics and Foodstuffs).

These sections may not apply to your research study.

Let’s begin with Section G. Section G applies only if this research study will involve exposure of research participants to medical ionising radiation. If the study does not involve such exposure, Section G can be deleted.

Section H relates to medical devices. In the event that you respond ‘yes’ to Question H1 (a), i.e. is the focus of this study to investigate or evaluate a medical device? - **it is strongly advised that you immediately contact the Medical Devices Section of the Health Products Regulatory Authority.** If the study proves to be a clinical investigation of a medical device, or a post-marketing follow up investigation of a medical device, Beaumont Hospital Ethics Committee is not permitted to review this study. Applications of this sort need to be re-directed to the National Research Ethics Committee for Medical Devices.

Section I deals with medicinal products, cosmetics, and foodstuffs.

If you answer ‘yes’ to question I 1.1 (a) – does this study involve a medicinal product? Or ‘yes’ to question I 2.1 (a) – does this study involve a cosmetic? Or ‘yes’ to question I 3.1 (a) does this study involve food or food supplements? - **it is strongly advised that you contact the relevant departments in the Health Products Regulatory Authority.** It is important to ensure that your study is not a clinical trial of a medicinal product. There can be circumstances where a cosmetic is being used as a medicinal product, or where a food or food supplement is being used as a medicinal product.

Beaumont Hospital Ethics Committee is not permitted to review clinical trials of medicinal products. These studies will need to be reviewed by the National Research Ethics Committee for Clinical Trials.

You have now completed the vast majority of sections in the application form. You should proofread the submission to ensure that all questions and sections which apply have been completed. As part of the final proofread, please ensure that you have listed the title to the research study on page 1 (cover sheet), along with the version number of this application (likely to be version 1), along with this date of the application (likely to be the date that you submit to the ethics committee).

When you have proofread all questions and sections in the application form, you should now proceed to Section L.

This is the last section, and the question which arises is does this project raise any additional ethical issues? Only when all other sections have been completed are you in a position to assess if any additional ethical issues arise.

It is recommended now that you go to the Data Protection Impact Assessment Form, and complete any answers which are blank or remain blank in this document. The vast majority of the answers can be pasted over from the application form. The questions highlighted in yellow are questions which do not appear in the ethics application form and hence, need to be responded, de novo, in the Data Protection Impact Assessment Form. You may have already completed some of these questions. You should be in a position to complete all questions in the Data Protection Impact Assessment Form with the exception of Section 6 and Section 7. You will be able to return to Section 6 and Section 7 and complete these sections once you have drafted your Information leaflet and Consent Form.