**Instruction Sheet 5:**

This instruction sheet relates to Section F of the ethics application form. Section F applies only in respect of research studies which involve collection of, analysis of, or access to human biological material. It can be deleted for studies which do not involve biological material.

By the time the committee members review Section F of the application form, they will have a good picture of what your research study entails. This will include a strong understanding of the design and methodology of the study; the methods of approach and recruitment and consent of participants; what participation will involve for research participants; and what data will be collected including how this data will be managed and where it will be sent.

You will have already mentioned earlier in the ethics submission, in particular, in Section B8 (the study methodology) and in Question D1 (a) (research participation) and in Question D1 (b) (research activities) that this study will involve human biological material or samples.

There are a number of sub-sections in Section F.

Sub-section F2 relates to samples which have yet to be collected.

Sub-section F3 relates to samples which have already been collected.

Sub-section F4 relates to the movement of samples outside of Beaumont Hospital, for example, for analysis purposes.

Sub-section F5 relates to genetic testing of samples, while the final section, Sub-section F6, relates to the commercial value of samples or the commercial value of data derived from the analysis of the samples.

When you have completed all of Section F, the committee will have a strong understanding of what human biological material will be collected or accessed in this research study.

You will see many similarities between the questions in Section F, and the questions which are asked in Section E3 of the application form. This is because the committee is also trying to establish, in particular, where human biological samples will be sent; if they will be sent outside Beaumont Hospital; if they will be sent outside of the country; if these samples will be anonymous, pseudonymised, or identifiable; how long samples will be retained for; for what purpose will samples be retained, and where will samples be retained.

The same issues arise as arose in Sub-section E3 i.e. some samples will be retained for a short period of time to allow for sample analysis, and for the results from sample analysis to be used in the research study. Samples will usually be destroyed at the end of the study. In other cases, researchers request permission to retain any samples which remain for a longer period, perhaps for use in future studies as yet unknown. Longer term retention of samples is common in respect of long-term projects such as, in particular, biobanks.

Section F is also similar to Section E in another key respect. It is usual for contracts and agreements to be put in place between organisations when samples are being sent from one organisation to another organisation. As with Sub-section E3, you are reminded that the Royal College of Surgeons in Ireland is a different organisation to Beaumont Hospital. Please ensure to state if you are sending samples outside the organisation which is Beaumont Hospital.

The main issues which arise in Section F are at the intersection between Section F and the Participant Information Leaflet. It can sometimes be difficult to explain clearly in cases where a research study involves:

* collection of data;
* analysis of data;
* collection of samples;
* analysis of samples;

in particular, where data and samples are being managed differently.

This could mean that they are being stored for different periods of time, or sent to different organisations, or it could mean that different members of the research team hold the code to re-identify participants, depending on whether one is referring to coded, pseudonymised data or coded, pseudonymised samples.

As this area can get very complicated very quickly, it is recommended that where you have a study that involves both data and samples that you develop a simple flow chart where you are able to see where samples are being sent and where data is being sent.

Studies which involve human biological material require longer Participant Information Leaflets. Certain complexities arise especially where human biological material is being retained for future research as yet unknown, and, in particular, where human biological material is being used for the purposes of genetic testing, including genomic or genetic sequencing.

When you have finished completing Section F of the application form, please OPEN the Data Protection Impact Assessment Form. You are now ready to complete Question 3.2 of the Data Protection Impact Assessment Form.