**Instruction Sheet 1**

**Number One:**  Log on the Ethics website, Application Form and Templates Section. Download all the documents you will need.

**Two:** Familiarise yourself with the documents that will need to be submitted:

1. The application form;
2. The Data Protection Impact Assessment Form;
3. The Information Leaflet and Consent Form (if applicable)

**Three:** Attempt to complete the application form. On your first attempt, please focus on Section A of the application form. Ensure at a minimum that the Principal Investigator is an employee of the study site.

By reviewing the information that you input into Section A of the application form, the committee can assess the title of your research study; whether it is multi-site or single site; the name of the Chief Investigator; the name of the Principal Investigator at each study site; the names of the co-investigators involved in the study; and finally, if this research study is being conducted for the purposes of obtaining an academic qualification.

Once you have completed Section A, please PAUSE. Check with all of the investigators named that their details are correctly listed in Section A.

Then proceed to complete Section J. For studies taking place in Beaumont Hospital involving Beaumont Hospital employees as investigators, there are standard answers available for Questions J1 and J2. These can be found on the ethics committee website (Application and Templates Section.)

Proceed to complete Question J3.1. If your study is a **clinical trial** meaning a study which seeks to assign participants to one or more interventions, please state the name of the organisation which is the **sponsor of this clinical trial** in response to Question J3.1.  For all other studies, please name *each* of the organisations which are involved in this research study. **Please do not name individual persons in response to Question J3.1**. Please state the *role* of each of the organisations you have named. Please state what type of organisation each of these organisations is in Question J3.2. The final question is Section J, Section J3.3, asks if any of the organisations which you have named have provided for any additional insurance or indemnity arrangements in respect of this study. Where no additional insurance or indemnity arrangements apply, please state ‘none’ in respect of the final question.

You have now completed Section A and Section J. Please proceed to Section K.

Section K relates to funding for the research study. By reviewing your responses to Section K in conjunction with your responses to Section A and Section J, the committee will be able to assess which organisation is responsible for this research study; and where this research study is taking place; and how this research study is being funded.

When you have completed all three sections, A, J and K, it is recommended that you SEND these to your co-investigators and collaborators to check that these have been completed correctly.

At this point, please go to Sub-section E2 of the application form. Bearing in mind all of the organisations which you have listed in response to Section J as having a role to play in this research study, and the organisations that you have listed as funding this research study in response to Section K; and the investigators which you have listed in response to Section A, please now look at Question E2.2.

Question E2.2 asks you to specify what is the organisation or organisations which is the data controller or joint data controllers in respect of this research study. If you have stated in Question J3.1 that this study is a clinical trial and you have named an organisation as the sponsor of this clinical trial, then the sponsor organisation will most likely be the data controller which you list in response to Question E2.2. **The sponsor for a clinical trial is usually the data controller for a clinical trial.**

**Do not name an individual as the data controller in response to Question E2.2 of the application form. Always name an organisation.**

The single most important decision in respect of your research study is the correct naming of the organisation which is the data controller for the research study. The data controller is usually the organisation which decided to conduct this research study; the organisation which devised and designed this research study; the organisation which decided what data needed to be collected in order to conduct this research study; the organisation which decided how data should be collected; and the organisation which decided where this data should be sent.

If two or more organisations made these decisions in a joint fashion, these are called joint data controllers.

Please always ensure that the organisation that you are naming as the data controller or joint data controllers has / have agreed to be named as data controller.

If you are the person who is responsible for designing this research study; devising this research study; deciding what data needs to be collected in order to answer the research question; how data will be analysed; and where data will be sent, then you need to assess which organisation you are representing in this research study. If you are employed by two organisations or have a joint appointment, you need to choose one organisation and state that this organisation, with their permission, is the data controller.

It can be very difficult for researchers to assess which organisation is the data controller. Only when you have made this assessment can you proceed to make the assessment as to which organisation or organisations are data processors. Question E2.2 asks you to name the organisational data controllers and organisational data processors.

If you are conducting your research study in Beaumont Hospital and RCSI is involved in the study, you will be already know, as an outcome of the RCSI Sponsorship Office process, the identity of the data controller(s) and data processor(s): https://www.beaumontethics.ie/home/sponsorship\_office.htm

Once you have completed Question E2.2 and If you are satisfied that you have named correctly the organisation which is the data controller, the organisations which are the joint data controllers, and any organisations which are data processors, please now go back to Question J3.1 , and assess if any adjustments need to be made in respect of the roles of the organisations which you have stated as having a role to play in respect of this research study.

Then proceed to Question E2.3. Here you will be asked to state which organisation or organisations provides funds or supports this project. When responding to Question E2.3, always cross-check your answer with your responses to Section K which deals with funding and resources.

It is recommended that you now PAUSE completing the ethics application form, and move to the Data Protection Impact Assessment Form.

Answer Questions 2.7, 2.8, 2.9 and 2.10 in the Data Protection Impact Assessment Form. Answer these questions in a way that is consistent with the answers that you have provided in the ethics application form. Please pay *special* attention to Question 2.10 in the Data Protection Impact Assessment Form. This question asks you if there will be any contracts or agreements between the organisations which you have identified as having a role to play in respect of this research study.

Please now RETURN to the Ethics Application Form.

Please note but do not respond to the following questions at this time:

* Question E2.4;
* Question E3.5 (a); and
* Question E4.1 (a)

Please be aware only that these questions ask you who you will be sharing data (or samples) with, and if data (or samples) are leaving Beaumont Hospital.

You must be aware that if you are sending data (or samples) to the Royal College of Surgeons in Ireland, this means that data (or samples) will be leaving Beaumont Hospital.

With this awareness in mind, you may now go to Section B, and complete the questions in Sections B, C and D in the order in which the questions appear.

If at any stage when you are completing the ethics application form in its entirety, if you mention at any time another organisation which has not yet been mentioned; or if mention that data or samples will be sent to another party, please always pause and cross-check your responses to Question J3.1, Question E2.2, and the relevant questions in the Data Protection Impact Assessment Form. Always ensure that these questions remain consistent at all times.