

**IN DEPTH INSTRUCTIONS ON HOW TO COMPLETE EACH QUESTION
IN THE STANDARD APPLICATION FORM**

ADAPTED VERSION (AUGUST 2018)

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**Royal College of Surgeons in Ireland (RCSI)
& Beaumont Hospital**

SECTION E2 ONLY

E2 DATA PROCESSING – GOVERNANCE AND PROCEDURE

YOU MUST ANSWER ALL QUESTIONS IN THIS SECTION AS THEIR FULFILLMENT IS A MANDATORY REQUIREMENT UNDER THE DATA PROTECTION ACT 2018 (SECTION 36(2)) (HEALTH RESEARCH) REGULATIONS 2018

E2.1 Please specify which arrangements are in place to ensure that personal data will be processed as is necessary; a) to achieve the objective of the health research and; b) and shall not be processed in such a way that damage or distress to the data subject?

[TYPE ANSWER]

E2.2 Please specify the data controller; joint data controllers if applicable and any data processors involved in the research.

“DATA CONTROLLER

- *Data controllers can be either individuals or “legal persons” such as companies, government departments and voluntary organisations.*
- *Data controllers also include sections or units of the organisation (e.g. academic departments, research centre etc.) and employees (including research students) that control and are responsible for the data processing.*

The Data Controller determines the purpose and the means of processing. To find out who the data controller is you should ask who determines the following:

- *Why are we processing this data?(e.g. To investigate inhaler compliance)*
- *How will we process the data in order to conduct this research?*
- *You are a data controller if you are the person or organization who determines the “why” and the “how” of the data processing.*
- *The data controller exercises overall control over the ‘why’ and the ‘how’ of a data processing activity*

DATA PROCESSOR

- *A data processor processes personal data on behalf of the data controller.*
- *Examples of data processors include:*
 - *payroll companies or accountants or similar who hold and process personal information on behalf of someone else;*
 - *“cloud” providers are also generally data processors;*
 - *if you hire a 3rd party to process data for your research (e.g. a transcription service to transcribe audio tapes of interviews) - the third party will be a data processor.*
 - *A data processor does not include the employees of a Data Controller (e.g. researchers employed on research projects in which personal data is collected, processed and stored)*
 - *If you are a researcher, you might be a data processor if you are employed on a service contract that collects, stores or processes personal data.*
 - *Data processing includes for example: collection, recording, organising, structuring, storage, retrieval, alteration, erasure, destruction.” HEALTH RESEARCH BOARD GDPR GUIDANCE FOR RESEARCHERS 2018*

[TYPE ANSWER]

E2.3 Please specify any person or organisation who provides funding for, or otherwise supports, the project.

e.g. SFI, pharmaceutical company, H2020 etc. See Section K

[TYPE ANSWER]

E2.4 Please specify any person other than the named data controller, joint controllers or processors with whom it is intended to share any of the personal data collected (including where it has been pseudonymised or anonymised) and the purpose of such sharing.

e.g. will personal data be shared with the data subject's doctor?

[TYPE ANSWER]

E2.5 The provision of training in data protection law and practice to anyone involved in carrying out the health research is a mandatory legal requirement. Please specify the provision of training.

You must show that everyone involved in the research have had training in data protection law and practice.

[TYPE ANSWER]

E2.6 Has a "risk" assessment and/or "data protection impact assessment" been carried out, taking in to account local policy and/or legal requirements?

A risk assessment must be carried out for all health research. If the risk assessment indicates a high risk you must conduct a data protection impact assessment (DPIA).

DATA PROTECTION ACT 2018 (SECTION 36(2)) (HEALTH RESEARCH) REGULATIONS 2018

"Regulation 3 (c)(i) the carrying out of an assessment of the data protection implications of the health research;

(ii) where the assessment carried out under clause (i) indicates a high risk to the rights and freedoms of individuals, the carrying out of a data protection impact assessment;"

Please note completion of a DPIA may be a mandatory requirement under local policy regardless of the outcome of the risk assessment. Please check local policy requirements.

[TYPE ANSWER]

E2.7 Please specify the measures in place that demonstrate compliance with the data minimisation principle. (Is it adequate, relevant and limited to what is necessary?)

Data minimisation means you must ensure the personal data you are processing is:

- adequate – sufficient to properly fulfil your stated purpose;
- relevant – has a rational link to that purpose; and
- limited to what is necessary – you do not hold more than you need for that purpose.

[TYPE ANSWER]

E2.8 Please specify the controls in place to limit access to the personal data undergoing processing in order to prevent unauthorised consultation, alteration, disclosure or erasure of personal data.

(For example, access logs...)

[TYPE ANSWER]

E2.9 Please specify the controls in place to log whether and by whom personal data has been consulted, altered, disclosed or erased.

(For example, review access logs at regular intervals...)

[TYPE ANSWER]

E2.10 Please specify measures to protect the security of the personal data concerned.

What security measures will be in place during processing? e.g. double encryption, password protection, encryption of desktop computers and portable devices and encryption of individual files. It is strongly advised that 'personal' data is not stored on portable devices or home-based desktops. However, where this is absolutely necessary, encryption software should be installed. Researchers should be aware of their responsibilities under the data protection legislation to keep electronic and hard copy 'personal data' safe and secure.

[TYPE ANSWER]

E2.11 Please specify the arrangements to anonymise, archive or destroy personal data once the health research has been completed.

Please specify who will anonymise, archive or destroy the personal data once the research is completed and how they will do it.

[TYPE ANSWER]

E.2.12 Please specify other technical and organisational measures designed to ensure that processing is carried out in accordance with the Data Protection Regulation, together with processes for testing and evaluating the effectiveness of such measures.

Please specify any other measures in place to ensure the protection of data subject's personal data.

[TYPE ANSWER]

E2.13 Please specify which arrangements are in place to ensure that personal data is processed in a transparent manner.

Transparency is about better informing patients, public and participants about research; it is not about getting permission. Making transparency information understandable and drawing people's attention to it is key:

- Individuals have the right to be informed about the collection and use of their personal data. This is a key transparency requirement under the GDPR.
- You must provide individuals with information including: your purposes for processing their personal data, your retention periods for that personal data, and who it will be shared with. This is 'privacy information'.
- You must provide privacy information to individuals at the time you collect their personal data.
- The information you provide must be concise, transparent, intelligible, easily accessible, and it must use clear and plain language.
- It is often most effective to provide privacy information to people using a combination of different techniques including layering, dashboards, and just-in-time notices.
- User testing is a good way to get feedback on how effective the delivery of your privacy information is.
- You must regularly review, and where necessary, update your privacy information. You must bring any new uses of an individual's personal data to their attention before you start the processing.

[TYPE ANSWER]