BEAUMONT HOSPITAL

DATA PROTECTION IMPACT ASSESSMENT TEMPLATE FOR RESEARCH AND CLINICAL TRIALS

COMPLETING THIS FORM

This form has been divided in sections. Each section is mandatory and *must* be fully completed.

You may have already answered some of the questions from this assessment on another form; however, you are required to provide those answers again, in full.

Referring to answers/information from other forms/documents is insufficient; you must provide full answers for all questions asked. Incomplete forms will be returned to the applicant.

PURPLE TEXT	*USED TO FURTHER EXPLAIN QUESTIONS*
Red Text	Definitions or Reference
GREEN HIGHLIGHTS	INDICATES WHERE SIMILAR QUESTIONS ARE LOCATED ON THE BEAUMONT HOSPITAL RESEARCH ETHICS APPLICATION FORM
HIGHLIGHTED TEXT	INDICATES NEW QUESTIONS THAT YOU HAVE NOT ANSWERED ON THE BEAUMONT HOSPITAL RESEARCH ETHICS APPLICATION FORM

DOCUMENT HISTORY	
VERSION NUMBER	DATE
1	03/04/2023
2	18/05/2023

ETHICS NUMBER	1
DPIA NUMBER	1

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IF YOU REQUIRE DPO ASSISTANCE PLEASE CONTACT DPO@BEAUMONT.IE

SECTION 1 – GENERAL DETAILS

1.1 - DETAILS OF PERSON COMPLETING THE FORM

NAME	Professor Norman Delanty	**ORGANISATION**	Beaumont Hospital
E-MAIL	normandelanty@beaumont.ie	**PHONE**	01 8092210

1.2 - THIS PROJECT REQUESTS THE USE OF PERSONAL DATA CURRENTLY HELD BY BEAUMONT HOSPITAL. ☑
(PLEASE TICK THIS BOX IF YOU WILL BE USING BEAUMONT HOSPITAL DATA WHETHER IT IS IDENTIFIABLE, PSEUDONYMISED OR ANONYMISED.)

1.3 - ARE YOU SEEKING ETHICAL APPROVAL FOR THIS STUDY?	yes
1.4 - WHAT ETHICS COMMITTEE ARE YOU SUBMITTING TO?	Beaumont Hospital

1.5 - TITLE OF THE RESEARCH STUDY:

A1

Research Use of Diagnostic Genomic Testing Data for Epilepsy

1.6 - PLEASE PROVIDE A BRIEF LAY (PLAIN ENGLISH) DESCRIPTION OF THE STUDY. PLEASE ENSURE THE LANGUAGE USED IN YOUR ANSWER IS AT A LEVEL SUITABLE FOR USE IN A RESEARCH PARTICIPANT INFORMATION LEAFLET.

B3

This study involves secondary use of diagnostic genomic testing data for use in research studies for epilepsy. Diagnostic testing in Irish hospitals is increasingly producing genomic data related to epilepsy. This study seeks to use that data (with consent) to better understand genetic factors in the development and treatment of epilepsy.

1.7 – LIST THE AIMS AND OBJECTIVES OF THE STUDY

B5

To identify monogenic genetic causes of epilepsy

To identify genetic modifiers of epilepsy

To identify genetic risk factors of epilepsy

To identify genetic factors that influence treatment of the epilepsy (e.g. predictors of adverse reactions)

1.8 – IS THE PROCESSING OF DATA LIKELY TO INTERFERE WITH THE 'RIGHT TO PRIVACY' UNDER ARTICLE 8 OF THE EUROPEAN CONVENTION ON HUMAN RIGHTS?

Right to respect for private and family life
1. Everyone has the right to respect for his private and family life, his home and his correspondence.
2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the

country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.[1]

No

1.9 – DETAILS OF THE PRINCIPAL INVESTIGATOR IN BEAUMONT HOSPITAL

A2

NAME	Professor Norma Delanty	**DEPARTMENT**	Neurology
TITLE	Professor of Neurology	**E-MAIL**	normandelanty@beaumont.ie

SECTION 2 – STAKEHOLDERS

2.1 – IS THIS A MULTI-SITE STUDY? No

A2(a)

2.2 – IF YES, PLEASE SUBMIT A LIST OF ALL SITES PARTICIPATING IN THE STUDY.

A2(c)

ANSWER

2.3 – TYPE OF RESEARCH? (E.G. RESEARCH, CLINICAL TRIAL, RETROSPECTIVE CHART REVIEW ETC.)

Observational study

2.4 – STUDY START DATE	01/06/23	**2.5 – STUDY END DATE**	Until the study is deemed complete
B1		**B2**	

2.6 – HOW MANY INDIVIDUALS ARE YOU RECRUITING FROM BEAUMONT HOSPITAL? All suitable individuals

B12

2.7 – LIST ALL DATA CONTROLLERS OR JOINT CONTROLLERS INVOLVED IN THIS PROJECT; THEIR ROLES AND RESPONSIBILITIES.

(THIS SHOULD INCLUDE IF THE ORGANISATION IS COMMERCIAL, NOT-FOR-PROFIT, ACADEMIC ETC.)

'Controller' means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law;[2]

Organisation Name	Jurisdiction / Country	Role
Beaumont Hospital	Ireland	Joint Controller Joint Controller for the original

[1] European Convention on Human Rights, Article 8

[2] GDPR, Article 4(7)

		clinical information gathered through front-line clinical encounters for this research and belonging to this HSE hospital organisation.
RCSI	Ireland	Joint Controller This is the academic organisation who is funded to carry out this research. RCSI will act as controller for the information generated. In addition to a data controller role, RCSI will process data, but as a Controller.

2.8 – LIST ALL THE DATA PROCESSORS INVOLVED IN THIS PROJECT; THEIR ROLES AND RESPONSIBILITIES. (THIS SHOULD INCLUDE IF THE ORGANISATION IS COMMERCIAL, NOT-FOR-PROFIT, ACADEMIC ETC.)

'Processor' means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller;[3]

Organisation Name	Jurisdiction / Country	Role
CeGat	Germany	Processor CeGaT is a provider of genetic diagnostics and NGS services. This company will be used as a genetic sequencing provider in this project.
ANSWER	ANSWER	ANSWER
ANSWER	ANSWER	ANSWER
ANSWER	ANSWER	ANSWER
ANSWER	ANSWER	ANSWER
ANSWER	ANSWER	ANSWER

2.9 – LIST ANY ORGANISATION WHO IS PROVIDING FUNDING OR OTHERWISE SUPPORTS THE PROJECT.

E2.3

SFI through FutureNeuro

2.10 – WHAT AGREEMENTS EXIST BETWEEN THE ORGANISATIONS ABOVE?
(DATA SHARING AGREEMENT, DATA PROCESSING AGREEMENT, MATERIAL TRANSFER AGREEMENT ETC.)

Material transfer agreement will be put in place between RCSI and CeGAT. Additional data sharing agreements between the data controllers and data processors will be put in place before study commences.

2.11 – HAS EVERYONE INVOLVED IN THE HEALTH RESEARCH STUDY RECEIVED TRAINING IN DATA PROTECTION AND ARE THEY AWARE OF THEIR DATA PROTECTION OBLIGATIONS? *(PLEASE EXPLAIN)*

E2.5

[3] GDPR, Article 4(8)

All involved in the research study have received data protection training. This course is delivered every year as an online module by the RCSI and included self-assessment.
2. Good clinical practice (GCP) training. GCP is the international ethical, scientific and practical standard to which all clinical research is conducted. Compliance with GCP provides public assurance that the rights, safety and wellbeing of research participants are protected and that research data are reliable

SECTION 3 – INFORMATION AUDIT AND LEGAL BASIS FOR PROCESSING

3.1 – WHAT CATEGORIES OF BASIC PERSONAL DATA ARE YOU PROCESSING? *(PRIOR TO PSEUDONYMISING OR ANONYMISING THE DATA)*

'Personal data' means any information relating to an identified or identifiable natural person ('data subject');[4]

DPO NOTE FOR SELECTING THE LEGAL BASIS UNDER ARTICLE 6 OF GDPR:
Although consent is mandatory for the processing of data under the Data Protection Act 2018 (Section 36(2))(Health Research) – it is not necessarily the correct legal basis to collect and process the data.

ENSURE THAT YOUR LEGAL BASIS BELOW MATCHES THE LEGAL BASIS ON THE PATIENT INFORMATION LEAFLET

BASIC PERSONAL DATA
(SELECT ALL THAT APPLY)

NAME	☑	YEAR OF BIRTH	☑	LOCATION DATA (IP ADDRESS)	☐
ADDRESS	☑	GENDER	☑	FINANCIAL	☐
POSTCODE	☑	EMAIL	☑	GOVERNMENT IDENTIFIERS e.g. PPSN	☐
DATE OF BIRTH	☑	PHONE	☑		
OTHER (SPECIFY)	☐				

LEGAL BASIS FROM ARTICLE 6 OF GDPR
(SELECT THE MOST APPROPRIATE LEGAL BASIS FROM THE LIST BELOW)

(a)	the data subject has given consent to the processing of his or her personal data for one or more specific purposes;	☐
(b)	processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract;	☐
(c)	processing is necessary for compliance with a legal obligation to which the controller is subject;	☐
(d)	processing is necessary in order to protect the vital interests of the data subject or of another natural person;	☐
(e)	processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;	☑
(f)	processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.	☐

3.2 – WHAT SPECIAL CATEGORIES OF PERSONAL DATA ARE YOU PROCESSING?

[4] GDPR, Article 4(1)

(PRIOR TO PSEUDONYMISING OR ANONYMISING THE DATA)

'Data concerning health' means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status;[5]

'genetic data' means personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question;[6]

'biometric data' means personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images or dactyloscopic data[7]

Genomics is the study of the genome. It can be defined as the examination of genes and how they function, but it can also encompass structure, function, sequencing, mapping and evolution of DNA sequences and chromosomes. In healthcare and medical research, the term genomics generally indicates the examination of, part or all of, an individual's DNA sequence to gain information related to their current or future health, or the investigation of pathogens (and their genomes) that they may be hosting.[8]

The World Health Organisation defines genetics as the study of heredity and genomics is defined as the study of genes and their functions, and related techniques.[9]
The main difference between genomics and genetics is that genetics scrutinises the functioning and composition of the single gene whereas genomics addresses all genes and their inter-relationship in order to identify their combined influence on the growth and development of the organism.[10]

DPO NOTE FOR SELECTING THE LEGAL BASIS UNDER ARTICLE 9 OF GDPR:
Although consent is mandatory for the processing of data under the Data Protection Act 2018 (Section 36(2))(Health Research) – it is not necessarily the correct legal basis to collect and process the data.

ENSURE THAT YOUR LEGAL BASIS BELOW MATCHES THE LEGAL BASIS ON THE PATIENT INFORMATION LEAFLET

SPECIAL CATEGORY DATA
(SELECT ALL THAT APPLY)

RACIAL OR ETHNIC ORIGIN	☑	DATA CONCERNING HEALTH	☑
POLITICAL OPINIONS	☐	DATA CONCERNING A NATURAL PERSON'S SEX LIFE OR SEXUAL ORIENTATION	☐
RELIGIOUS OR PHILOSOPHICAL BELIEFS	☐	GENETIC DATA	☑
TRADE UNION MEMBERSHIP	☐	GENOMIC DATA	☑
BIOMETRIC DATA FOR THE PURPOSE OF UNIQUELY IDENTIFYING A NATURAL PERSON	☐		

3.3 - IF YOU SELECTED GENETIC DATA OR GENOMIC DATA, PLEASE SPECIFY THE NATURE AND PURPOSE OF THE TESTING.

F5.1(b)

Genetic testing will be performed as part of this study to determine if a genetic component is influencing a

[5] GDPR, Article 4(15)
[6] GDPR, Article 4(13)
[7] GDPR, Article 4(14)
[8] https://www.phgfoundation.org/report/the-gdpr-and-genomic-data (page 7, paragraph 3)
[9] Reference- Genomics and World Health:Report of the Advisory Committee on Health research, Geneva, WHO 2002 & WHA 57.13:Genomics and World Health, Fifty Seventh World Health Assembly Resolution;22nd May 2004
[10] https://www.who.int/genomics/geneticsVSgenomics/en/

participant's epilepsy and their response to treatment.

3.4 - WILL CONSENT BE OBTAINED FOR COLLECTING OR PROCESSING GENETIC/GENOMIC DATA?

yes

Consent is mandatory.

F5.2(a)

LEGAL BASIS FROM ARTICLE 9 OF GDPR

(SELECT THE MOST APPROPRIATE LEGAL BASIS FROM THE LIST BELOW)

(a)	**the data subject has given explicit consent to the processing of those personal data for one or more specified purposes, except where Union or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject;**	☐
(b)	**processing is necessary for the purposes of carrying out the obligations and exercising specific rights of the controller or of the data subject in the field of employment and social security and social protection law in so far as it is authorised by Union or Member State law or a collective agreement pursuant to Member State law providing for appropriate safeguards for the fundamental rights and the interests of the data subject;**	☐
(c)	**processing is necessary to protect the vital interests of the data subject or of another natural person where the data subject is physically or legally incapable of giving consent**	☐
(d)	**processing is carried out in the course of its legitimate activities with appropriate safeguards by a foundation, association or any other not-for-profit body with a political, philosophical, religious or trade union aim and on condition that the processing relates solely to the members or to former members of the body or to persons who have regular contact with it in connection with its purposes and that the personal data are not disclosed outside that body without the consent of the data subjects;**	☐
(e)	**processing relates to personal data which are manifestly made public by the data subject;**	☐
(f)	**processing is necessary for the establishment, exercise or defence of legal claims or whenever courts are acting in their judicial capacity;**	☐
(g)	**processing is necessary for reasons of substantial public interest, on the basis of Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject;**	☐
(h)	**processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3;**	☐
(i)	**processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy;**	☐
(j)	**processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.**	☑

SECTION 4 – SELECTION, RECRUITMENT AND CONSENT

4.1 – HOW ARE YOU SELECTING AND RECRUITING PARTICIPANTS IN BEAUMONT HOSPITAL?

C1.1 AND C1.2

Suitable adult candidates will be selected based on their medical presentation at clinic. If it is recommended that they have a blood sample taken for genetic analysis as part of their routine medical care, their participation will be requested. Healthcare providers in the Beaumont Epilepsy Clinic, in the Epilepsy Monitoring Unit or in Neurology Ward will assist with identifying patients who may be interested in participating in the project. They will secure agreement from participants to share their contact information with the research team or consent to have contact details shared with research team.

4.2 - WILL INFORMED CONSENT TO TAKE PART IN THE RESEARCH BE OBTAINED? yes

C2.1(a)

4.3 - IF NO, PLEASE JUSTIFY.

YOU MUST PROVIDE A FULL AND DETAILED EXPLANATION AS TO WHY INFORMED CONSENT WILL NOT BE OBTAINED. PLEASE NOTE EXPLICIT CONSENT TO PROCESS PERSONAL DATA FOR RESEARCH PURPOSES IS MANDATORY UNDER THE DATA PROTECTION ACT 2018 (SECTION 36 (2)) (HEALTH RESEARCH) REGULATIONS UNLESS THE DATA IS ANONYMOUS OR A 'CONSENT DECLARATION' HAS BEEN OBTAINED OR AN EXEMPTION UNDER THE DATA PROTECTION ACT 2018 (SECTION 36 (2)) (HEALTH RESEARCH) (AMENDMENT) REGULATIONS 2021 APPLIES.

C2.1(b)

ANSWER

4.4 IF YES, PLEASE OUTLINE THE CONSENT PROCESS IN FULL.

(HOW WILL CONSENT BE OBTAINED, WHEN AND BY WHOM ETC.)

C2.1(c)

Potential participants will have the study explained to them during a routine clinic visit or while an inpatient. They will be given a Patient Information Leaflet and an opportunity for discussion where any questions they have will be answered. It will be emphasised from this initial approach that no extra procedures or activities are required of them to participate in the study and that there are no implications for their treatment if they have no interest in either receiving an information leaflet or giving consent. Potential participants will be given the opportunity to take as much time as they like to consider their participation and all questions and queries will be answered. If they decide to participate their consent will be sought and a consent form will be completed. Every effort in so far as is practicable will be made to support and assist potential participants in their decision-making. Additionally, a simplified information leaflet has been prepared to help support individuals who may have a difficulties with the more detailed information leaflet.

4.5 - WILL ALL OF THE PARTICIPANTS HAVE THE CAPACITY TO GIVE INFORMED CONSENT? **No**

C3.1(a)

4.6 – IF YOU ANSWERED NO PLEASE STATE WHETHER:

- **A CONSENT DECLARATION HAS BEEN OBTAINED IN ADVANCE OF COMMENCING THE RESEARCH;**
- **THE INDIVIDUAL'S "LEGAL REPRESENTATIVE" CONSENTED;**
  (APPLICABLE TO ADULTS WITH A POWER OF ATTORNEY, OR WHO ARE WARDS OF COURT ONLY)
- **THE DATA HAS BEEN ANONYMISED.**

Or

- **AN EXEMPTION UNDER THE DATA PROTECTION ACT 2018 (SECTION 36 (2)) (HEALTH RESEARCH) (AMENDMENT) REGULATIONS 2021 APPLIES.**

C3.5

A consent declaration will be sought from the HRCDC prior to commencement of the research once provisional ethical approval has been granted.

4.7 – WHAT ARRANGEMENTS ARE IN PLACE FOR RESEARCH PARTICIPANTS WHO REGAIN THEIR CAPACITY DURING THE STUDY?

C3.6

It is not anticipated that any vulnerable participants will regain capacity but if that were to occur their consent would be sought and supportive decision-making measures would be taken.

4.8 - WILL PARTICIPANTS BE INFORMED OF THEIR RIGHT TO REFUSE TO PARTICIPATE AND THEIR RIGHT TO WITHDRAW FROM THIS RESEARCH STUDY?

Yes

C2.2(a)

4.9 - IF NO, PLEASE JUSTIFY.

C2.2(b)

ANSWER

4.10 - WILL THERE BE A TIME INTERVAL BETWEEN GIVING INFORMATION AND SEEKING CONSENT?

Yes

C2.3(a)

4.11 - IF YES, PLEASE ELABORATE.

C2.3(b)

Potential participants can take as much time as they need, there is no time limit.

4.12 - IF NO, PLEASE JUSTIFY AND EXPLAIN WHY AN INSTANTANEOUS DECISION IS REASONABLE HAVING REGARD TO THE RIGHTS OF THE PROSPECTIVE RESEARCH PARTICIPANTS AND THE RISKS OF THE STUDY.

C2.3(c)

ANSWER

4.13 - WILL EXPLICIT CONSENT BE SOUGHT FOR THE PROCESSING OF DATA?

Yes

E1.1(a)

4.14 - IF NO, PLEASE ELABORATE.

(PLEASE NOTE EXPLICIT CONSENT IS MANDATORY UNDER THE DATA PROTECTION ACT 2018 (SECTION 36 (2)) (HEALTH RESEARCH) REGULATIONS 2018 UNLESS THE DATA IS ANONYMOUS OR A 'CONSENT DECLARATION HAS BEEN OBTAINED' OR AN EXEMPTION UNDER THE DATA PROTECTION ACT 2018 (SECTION 36 (2)) (HEALTH RESEARCH) (AMENDMENT) REGULATIONS 2021 APPLIES.)

E1.1(b)

ANSWER

4.15 - IF YES, PLEASE CONFIRM THAT A COPY OF THE 'EXPLICIT CONSENT' WILL BE PROVIDED TO THE DATA SUBJECT PRIOR TO THE COMMENCEMENT OF THE HEALTH RESEARCH. ***(THIS IS MANDATORY REQUIREMENT UNDER THE DATA PROTECTION ACT 2018 (SECTION 36 (2)) (HEALTH RESEARCH) (AMENDMENT) REGULATIONS 2021.)***

E1.1(c)

Yes. A copy of their consent form will be given to each participant.

SECTION 5 – DATA PROCESSING AND INFORMATION FLOWS

5.1 - PLEASE SPECIFY WHICH ARRANGEMENTS ARE IN PLACE TO ENSURE THAT PERSONAL DATA WILL BE PROCESSED AS IS NECESSARY;

- **TO ACHIEVE THE OBJECTIVE OF THE HEALTH RESEARCH AND;**
- **TO ENSURE THAT SHALL NOT BE PROCESSED IN SUCH A WAY THAT DAMAGE OR DISTRESS TO THE DATA SUBJECT?**

E2.1

This project will follow the principle of Privacy by Design and Data Minimisation in its execution so that processing of participant data is done with data protection and confidentiality in mind at every step. In all cases, only data relevant to the attainment of the study objective(s) and to which the participants have consented to, will be collected and will go no further than is necessary. All consideration has been given to the transfer, storage, and eventual destruction of the data to ensure there is minimal risk of breach or loss of data.

Following receipt of explicit consent, data will be collected directly from the patient and their medical notes and epilepsy electronic records. This data will initially be collected by Professor Norman Delanty or by suitably qualified persons acting on his behalf and under his supervision. Data will then be pseudonymised and inputted into a secure server. Patients will be assigned a unique patient identifier. The patient will be identifiable to local clinicians but not to individuals or parties outside Beaumont. The key will be maintained by the Beaumont data controllers and only the Beaumont data controllers will have access to this key. The key will be stored in an encrypted, password protected file. This file will be stored on a designated secure folder on a RCSI drive. The collected patient data and consent forms will be stored in a locked filing cabinet in the RCSI research centre.

The data to be collected has been discussed between the data controllers and the data processors as part of the DPIA. The quantity of data collected on each individual will be kept to a minimum. The data collected will include demographic information, blood results, family history, current medications, BMI, imaging results.

The data will NOT be shared with any other research team of any other third party.

The pseudonymised dataset will be retained.

Data subjects who consent to participate in the study will be given a contact number of a staff member of the data controller to raise any concerns they may have with the handling of their data.

5.2 - 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 OR SAMPLES COLLECTED (INCLUDING WHERE IT HAS BEEN PSEUDONYMISED OR ANONYMISED) AND THE PURPOSE OF SUCH SHARING.

E2.4

No personal data will be shared beyond the project team.

5.3 - PLEASE SPECIFY THE MEASURES IN PLACE THAT DEMONSTRATE COMPLIANCE WITH THE DATA MINIMISATION PRINCIPLE (IS IT ADEQUATE, RELEVANT AND LIMITED TO WHAT IS NECESSARY?)

E2.7

The collection and use of personal data will go no further than is necessary for the attainment of the research objective(s) of this project. Rationale for the collection of special categories of personal data:

Special Categories of personal data collected includes:

Gender: this is important for the purpose of determining inheritance patterns and is relevant information for many research studies. Specifically, we will ask for sex at birth because chromosome differences may have an impact on disease development.

Ethnicity: this category is relevant in aiding to identify relationships between ethnicity and other factors such as disease symptoms or occurrence. This is also relevant from the context of genetic sequencing and analysis.

Genetic Data: We will collect, analyse and store genetic information because finding the genetic indicators of epilepsy is a core objective of the research study.

5.4 - 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.

E2.8

This research study will involve the collection and processing of patient data. This will include data relating to the patient's health status and detailed family history. The data to be obtained is: genetic information generated from the processing of patient blood samples and existing information from an individual's medical notes and epilepsy electronic patient record, including radiological imaging and pathology. Study data will be stored at a site separate to the patient's medical notes. Stored data will be pseudonymised. The key to the pseudonymised data will be stored on an encrypted and password-protected file. The password will be held by the Prof Delanty. An access log for the file will be kept. All computer software is encrypted and password protected.

The room in which the paper consent forms are kept will be locked outside of normal working hours and access to this area is restricted to RCSI staff and requires swipe card access. An access log will be kept.

5.5 - PLEASE SPECIFY THE CONTROLS IN PLACE TO LOG WHETHER AND BY WHOM PERSONAL DATA HAS BEEN CONSULTED, ALTERED, DISCLOSED OR ERASED.

E2.9

A data log for all software will be put in place to record all access made to the log.

5.6 - PLEASE SPECIFY MEASURES TO PROTECT THE SECURITY OF THE PERSONAL DATA CONCERNED.

E2.10

Identifiable blood samples will be transferred off site to CeGaT laboratories in Germany for DNA extraction. Returned sequencing data will be pseudonymised with a unique identifier before access is given to the RCSI research team under the supervision of Prof Cavalleri.

5.7 - PLEASE SPECIFY THE ARRANGEMENTS TO ANONYMISE, ARCHIVE OR DESTROY PERSONAL DATA AND/OR SAMPLES ONCE THE HEALTH RESEARCH HAS BEEN COMPLETED.

E2.11

There will be no long-term retention of blood samples.

Samples will be coded in Beaumont and pseudonymised before being sent to CeGaT (or other contracted data processors) for DNA extraction and sequencing. Samples will be retained only long enough to ensure that adequate genetic information has been extracted. The key will be retained in Beaumont and will not be made available to anyone not an employee of Beaumont Hospital

5.8 - 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.

E2.12

The data collected will be stored on a dedicated EXCEL Database Spreadsheet on an encrypted server in RCSI that principle investigator (or authorised person on his behalf) assigned to the register will have access to. We will comply with the organizational policies to ensure the confidentiality, integrity and availability of the system and the personal data processed within them.

5.9 - PLEASE SPECIFY WHICH ARRANGEMENTS ARE IN PLACE TO ENSURE THAT PERSONAL DATA IS PROCESSED IN A TRANSPARENT MANNER.

E2.13

The Data Controller of the site participating in this project (Beaumont Hospital), provide Fair Processing Notices to patients (data subjects) attending their organisation for healthcare and services. These Fair Processing Notices let patients (data subjects) know how personal and confidential information about them is collected and shared in order to fulfil their role as provider of healthcare services. Within the Fair Processing Notice, reference is made to the use of personal data to drive continuous improvement in healthcare and service delivery. Patient information leaflets are also provided in the epilepsy outpatient clinics advising of the use of the collection and use of electronic health data for research purposes.

5.10 - WHAT MEDIA OF DATA WILL BE COLLECTED?

E3.1

Paper and Electronic Data

5.11 - WOULD YOU CLASS THE DATA COLLECTED IN THIS STUDY AS ANONYMOUS, PSEUDONYMISED OR IDENTIFIABLE DATA?

E3.2(a)

Identifiable data

5.12 - IF 'PSEUDONYMISED', PLEASE CONFIRM WHO WILL RETAIN THE 'KEY' TO RE-IDENTIFY THE DATA?

E3.2(b)

Prof Delanty

5.13 - WHERE WILL DATA WHICH IS COLLECTED BE STORED?

E3.3

The pseudonymised research dataset generated for the purposes of this project will be stored within a password protected folder on a secure drive on a RCSI server which is only accessible to selected members of the research

team involved in this project. Only those authorised will be provided with a password to access the secure folder containing the dataset.

5.14 - WILL DATA COLLECTED BE AT ANY STAGE LEAVING THE SITE(S) OF ORIGIN?

YES

E3.4(a)

5.15 - IF YES, PLEASE ELABORATE.

E3.4(b)

- For the purposes of this project, a pseudonymised dataset will be generated at the request of the joint data controllers (Beaumont, RCSI).
- The pseudonymised dataset will be sent to the RCSI-based research team via a secure file sharing .
- The pseudonymised dataset will be stored in a password protected folder on a secure server within RCSI Research IT system and will only be accessible to authenticated and authorized researchers involved in this project.

5.16 - WHERE WILL DATA ANALYSIS TAKE PLACE AND WHO WILL PERFORM DATA ANALYSIS (IF KNOWN)?

E3.5

The research will be conducted by the research team (clinician and senior researchers) employed by the SFI funded FutureNeuro Research Centre at RCSI, 123 St. Stephens Green, Dublin, Ireland.

5.17 - AFTER DATA ANALYSIS HAS TAKEN PLACE, WILL DATA BE RETAINED?

YES

E3.6(a)

5.18 - IF YES, FOR HOW LONG, FOR WHAT PURPOSE, AND WHERE WILL IT BE RETAINED?

E3.6(b)

As this is a long term study the data will be retained indefinitely. The purpose for such retention is to maximise the potential for genetic diagnosis to be successfully achieved for participants. It has been our experience in other research that a genetic diagnosis can be made many years after a sample is given for analysis as more data is gathered and knowledge expands. The data will be retained on the RCSI secure file network in the research IT infrastructure..

We are also committed to data based research that adheres to FAIR principles (Findable, Accessible, Interoperable, Reusable). We therefore plan to deploy at the end of the project an anonymized file (with all pseudonyms removed) will be deposited in an appropriate, as yet unidentified cost-free data repository, whose security policy has been written according to best practices, for indefinite data retention and to ensure that the research community has long-term access to the data.

5.19 - PLEASE COMMENT ON THE CONFIDENTIALITY OF COLLECTED DATA.

E3.7

For the purposes of this project no identifiable personal data will be processed by members of the research team. With their agreement and approval of this project, the Data Controller of the participating site (Beaumont Hospital) will arrange for a pseudonymised dataset of the required datafields to be generated. The research team will only have access to the pseudonymised dataset (without access to the key) and with no reasonable means of re-identifying individuals from the data

5.20 - WILL ANY OF THE INTERVIEW DATA COLLECTED CONSIST OF AUDIO RECORDINGS / VIDEO RECORDINGS?

NO

E3.8

NO

5.21 - WILL ANY OF THE STUDY DATA COLLECTED CONSIST OF PHOTOGRAPHS/ VIDEO RECORDINGS?

E3.9(a)

5.22 - IF YES, PLEASE ELABORATE.

E3.9(b)

ANSWER

YES

5.23 - DOES THE STUDY INVOLVE ACCESS TO HEALTHCARE RECORDS (HARD COPY / ELECTRONIC)?

E4.1(a)

IF ANSWER IS NO, PLEASE SKIP REMAINING QUESTIONS IN SECTION 5

5.24 - IF YES, PLEASE ELABORATE.

E4.1(b)

There will not be any direct access to epilepsy electronic records or other healthcare records granted to any researchers who are not directly involved in the patient's clinical care. Professor Delanty or authorised persons acting on his behalf and under his supervision will have access to the records. A pseudonymised minimised dataset will be created for analysis by the RCSI research team.

5.25 - WHO WILL ACCESS THESE HEALTHCARE RECORDS?

E4.1(c)

Prof Delanty and the clinical care team.

NO

5.26 - WILL CONSENT BE SOUGHT FROM PATIENTS FOR RESEARCH TEAM MEMBERS TO ACCESS THEIR HEALTHCARE RECORDS?

(CONSENT IS REQUIRED FROM THE PATIENT TO ACCESS HEALTHCARE RECORDS FOR RESEARCH PURPOSES UNLESS A 'CONSENT DECLARATION' HAS BEEN GRANTED OR THE RECORDS ARE ANONYMOUS OR AN EXEXMPTION UNDER THE DATA PROTECTION ACT 2018 (SECTION 36(2)) (HEALTH RESEARCH)(AMENDMENT) REGUALTIONS 2021 APPLIES).

E4.1(d)

IF ANSWER IS YES, PLEASE SKIP REMAINING QUESTIONS IN SECTION 5

5.27 - WHO OR WHAT LEGAL ENTITY IS THE DATA CONTROLLER IN RESPECT OF THE HEALTHCARE RECORDS?

E4.2(a)

Beaumont Hospital Board

5.28 - WHAT MEASURES HAVE BEEN PUT IN PLACE BY THE DATA CONTROLLER WHICH MAY MAKE ACCESS TO HEALTHCARE RECORDS PERMISSIBLE WITHOUT CONSENT?

(A 'CONSENT DECLARATION' OR ANONYMISED RECORDS OR AN EXEMPTION UNDER THE DATA PROTECTION ACT 2018 (SECTION 36 (2)) (HEALTH RESEARCH) (AMENDMENT) REGULATIONS 2021 ARE THE ONLY OPTIONS HERE.)

E4.2(b)

A Consent Declaration from the HRCDC will be sought before commencement of this study.

SECTION 6 – RISK ASSESSMENT

RISK ASSESSMENTS ARE ESSENTIAL TO DPIA's. IT IS IMPORTANT TO CAPTURE ALL OF THE RISKS ASSOCIATED WITH THE PROCESS AND ENSURE THAT SUITABLE MEASURE ARE IN PLACE TO REDUCE OR ELIMINATE THOSE RISKS.

		IMPACT				
		1 - Negligible	2 - Minor	3 - Moderate	4 - Major	5 - Critical
LIKELIHOOD	1 - Rare	1	2	3	4	5
	2 – Unlikely	2	4	6	8	10
	3 – Possible	3	6	9	12	15
	4 – Likely	4	8	12	16	20
	5 – Almost Certain	5	10	15	20	25

TABLE 1 IDENTIFIES THE RISK

REF NO.	RISK	LIKELIHOOD	IMPACT	SCORE
1	Data breaches. The storage of data may be breached.	1	3	3
2	Data may be transferred outside the EEA and not subject to GDPR.	1	3	3

TABLE 2 IMPLEMENTS THE SOLUTIONS OR MITIGATING FACTORS

REF NO.	SOLUTION / MITIGATING FACTORS	NEW LIKELIHOOD	NEW IMPACT	NEW SCORE
1	the data extract is minimised, de-identified and pseudonymised to an extent that even when breeched no personal data is expected to become available. Even if the data is breeched, the effort required to re-identify persons with epilepsy is prohibitive since the pseudonym key will be separately stored	1	1	1
2	Data processing agreements to be put in place with all data processors involved in the research which restricts data transfers and storage to non-EEA locations or if data is being sent outside of the EEA the data subject has agreed to allow this and suitable safeguards will be put in place to protect the data e.g. anonymization etc.	1	1	1

SECTION 7 – DATA SUBJECT RIGHTS (CHECKLIST)

DATA SUBJECT RIGHTS	YES	PARTIAL OR LIMITED RIGHTS	NO
7.1 - Data subjects' know the purpose or reason for processing their personal data	☑	☐	☐
7.2 - Data subjects' know the legal basis under which you are processing their data	☑	☐	☐
7.3 - Data subjects' know who are the recipients of their data	☑	☐	☐
7.4 - Data subjects' know how long their data will be stored for	☑	☐	☐
7.5 - Data controller has a mechanism to deal with data protection breaches	☑	☐	☐
7.6 - Data subjects' have the right to withdraw consent and how to go about this	☑	☐	☐
7.7 - Data subjects' have the right to lodge a complaint with the data protection 8.1 - commission	☑	☐	☐
7.8 - Data subjects' have a right to request access to their data and a copy of it	☑	☐	☐
7.9 - Data subjects' have a right to restrict or object to processing	☑	☐	☐
7.10 - Data subjects' have a right to have any inaccurate information about them corrected or deleted	☑	☐	☐
7.11 - Data subjects' have a right to have their personal data deleted	☑	☐	☐
7.12 - Data subjects' have a right to data portability, meaning they have a right to move their data from one controller to another in a readable format	☑	☐	☐
7.13 - Data subjects' have the right to know if there will be any automated decision making, including profiling and have a right to object to automated processing including profiling	☑	☐	☐
7.14 - There will be no disclosure of the personal data unless that disclosure is required by law or the data subject have given explicit consent to the disclosure	☑	☐	☐
7.15 - Data subjects will be informed if you wish to transfer their data to a country outside of the EEA and suitable safeguards will be put in place to protect their data	☑	☐	☐
7.16 - The risk assessment in Section 7 has been completed and all known risks have been mitigated or reduced to an acceptable level	☑	☐	☐