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|  | **BEAUMONT HOSPITAL & RCSI****DATA PROTECTION IMPACT ASSESSMENT TEMPLATE****FOR RESEARCH AND CLINICAL TRIALS** |  |

**COMPLETING THIS FORM**

**This form has been divided in sections. Section 1-7 is mandatory and *must* be fully completed. Section 8 is only required if data/materials are being transferred outside of the EEA.**

**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** |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| --- | --- | --- | --- |
| **DOCUMENT HISTORY** |  | **ETHICS NUMBER** |  |
| **VERSION** | **DATE** | **REASON** |  |
| **1** | **March 2023** | **Joint DPIA template with RCSI** |  | **DPIA NUMBER** |  |
| **2** | **07/05/2023** | **Addition of Transfer Impact Assessment** |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| **DATA PROTECTION OFFICER(S) DETAILS** | **Beaumont Hospital:** | **Orla Carty** | **dpo@beaumont.ie** |  |
| **RCSI:** | **Dónall King** | **dataprotection@rcsi.ie** |  |
|  |  |  |  |  |  |

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**SECTION 1 – GENERAL DETAILS**

* 1. **- DETAILS OF PERSON COMPLETING THE FORM**

|  |  |  |  |
| --- | --- | --- | --- |
| **NAME** |  | **ORGANISATION** |  |
| **E-MAIL** |  | **PHONE** |  |

|  |  |
| --- | --- |
| **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?** |  |
| **1.4 - WHAT ETHICS COMMITTEE ARE YOU SUBMITTING TO?** |  |

***(LIAISE WITH YOUR LOCAL ETHICS COMMITTEE TO ENSURE THAT YOU ARE SUBMITTING TO THE CORRECT ONE)***

**1.5 - TITLE OF THE RESEARCH STUDY:**

|  |  |
| --- | --- |
| **A1** |  |

**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** |  |

**1.7 – LIST THE AIMS AND OBJECTIVES OF THE STUDY**

|  |  |
| --- | --- |
| **B5** |  |

**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]](#footnote-1)

**1.9 – DETAILS OF THE PRINCIPAL INVESTIGATOR IN BEAUMONT HOSPITAL**

|  |  |
| --- | --- |
| **A2** |  |
| **NAME** |  | **DEPARTMENT** |  |
| **TITLE** |  | **E-MAIL** |  |

**SECTION 2 – STAKEHOLDERS**

|  |  |
| --- | --- |
|  |  |
| **2.1 – IS THIS A MULTI-SITE STUDY?** |  |
| **A2(a)** |  |

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

|  |  |
| --- | --- |
| **A2(c)** |  |

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **2.4 – STUDY START DATE** |  |  | **2.5 – STUDY END DATE** |  |  |
| **B1** |  |  |  | **B2** |  |  |  |

|  |  |
| --- | --- |
| **2.6 – HOW MANY INDIVIDUALS ARE YOU RECRUITING FROM BEAUMONT HOSPITAL?** |  |
|  |
| **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]](#footnote-2)

|  |  |  |
| --- | --- | --- |
| **Organisation Name** | **Jurisdiction / Country** | **Role** |
|  |  |  |
|  |  |  |
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**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]](#footnote-3)

|  |  |  |
| --- | --- | --- |
| **Organisation Name** | **Jurisdiction / Country** | **Role** |
|  |  |  |
|  |  |  |
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**2.9 – LIST ANY ORGANISATION WHO IS PROVIDING FUNDING OR OTHERWISE SUPPORTS THE PROJECT.**

|  |  |
| --- | --- |
| **E2.3** |  |

**2.10 – WHAT AGREEMENTS EXIST / WILL BE IMPLEMENTED, BETWEEN THE ORGANISATIONS ABOVE?**

***(DATA SHARING AGREEMENT, DATA PROCESSING AGREEMENT, MATERIAL TRANSFER AGREEMENT ETC.)***

**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** |  |

**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]](#footnote-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***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **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)***

|  |  |  |
| --- | --- | --- |
| ***IN GENERAL THE MOST APPROPRIATE LEGAL BASIS FOR RCSI AND BEAUMONT HOSPITAL IS PROCESSING IS NECESSARY FOR THE PERFORMANCE OF A TASK CARRIED OUT IN THE PUBLIC INTEREST…6.1(E)******IF YOU ARE UNSURE OF THIS PLEASE GET ADVICE FROM THE DPO*** | 1. **the data subject has given consent to the processing of his or her personal data for one or more specific purposes;**
 | [ ]  |
| 1. **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;**
 | [ ]  |
| 1. **processing is necessary for compliance with a legal obligation to which the controller is subject;**
 | [ ]  |
| 1. **processing is necessary in order to protect the vital interests of the data subject or of another natural person;**
 | [ ]  |
| 1. **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;**
 | [ ]  |
| 1. **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?**

***(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]](#footnote-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]](#footnote-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]](#footnote-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]](#footnote-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]](#footnote-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]](#footnote-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***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **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)** |  |
|  |

**LEGAL BASIS FROM ARTICLE 9 OF GDPR*****(SELECT THE MOST APPROPRIATE LEGAL BASIS FROM THE LIST BELOW)***

|  |  |  |
| --- | --- | --- |
| ***IN GENERAL THE MOST APPROPRIATE LEGAL BASIS FOR RCSI AND BEAUMONT HOSPITAL IS PROCESSING IS NECESSARY FOR ARCHIVING PURPOSES IN THE PUBLIC INTEREST, SCIENTIFIC OR HISTORICAL RESEARCH…9.2.(J)******IF YOU ARE UNSURE OF THIS, PLEASE GET ADVICE FROM THE DPO*** | 1. **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;**
 | [ ]  |
| 1. **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;**
 | [ ]  |
| 1. **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**
 | [ ]  |
| 1. **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;**
 | [ ]  |
| 1. **processing relates to personal data which are manifestly made public by the data subject;**
 | [ ]  |
| 1. **processing is necessary for the establishment, exercise or defence of legal claims or whenever courts are acting in their judicial capacity;**
 | [ ]  |
| 1. **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;**
 | [ ]  |
| 1. **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;**
 | [ ]  |
| 1. **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;**
 | [ ]  |
| 1. **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** |  |

|  |  |
| --- | --- |
| **4.2 - WILL CONSENT BE OBTAINED FOR COLLECTING OR PROCESSING GENETIC/GENOMIC DATA?** |  |
| **F5.2(a)** |  |

Consent is mandatory under the Disability Act 2005[[11]](#footnote-11)

*(b) the consent of the person to the processing of any genetic data to be derived from the testing has been obtained in accordance with the Acts.*

|  |  |
| --- | --- |
| **4.3 - WILL INFORMED CONSENT TO TAKE PART IN THE RESEARCH BE OBTAINED?**  |  |
| **C2.1(a)** |  |

**4.4 - 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)** |  |

**4.5 IF YES, PLEASE OUTLINE THE CONSENT PROCESS IN FULL.**

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

|  |  |
| --- | --- |
| **C2.1(c)** |  |

|  |  |
| --- | --- |
| **4.6 - WILL ALL OF THE PARTICIPANTS HAVE THE CAPACITY TO GIVE INFORMED CONSENT?** |  |
| **C3.1(a)** |  |

**4.7 – 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** |  |

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

|  |  |
| --- | --- |
| **C3.6** |  |

|  |  |
| --- | --- |
| **4.9 - WILL PARTICIPANTS BE INFORMED OF THEIR RIGHT TO REFUSE TO PARTICIPATE AND THEIR RIGHT TO WITHDRAW FROM THIS RESEARCH STUDY?** |  |
| **C2.2(a)** |  |

**4.10 - IF NO, PLEASE JUSTIFY.**

|  |  |
| --- | --- |
| **C2.2(b)** |  |

|  |  |
| --- | --- |
| **4.11 - WILL THERE BE A TIME INTERVAL BETWEEN GIVING INFORMATION AND SEEKING CONSENT?** |  |
| **C2.3(a)** |  |

**4.12 - IF YES, PLEASE ELABORATE.**

|  |  |
| --- | --- |
| **C2.3(b)** |  |

**4.13 - 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)** |  |

|  |  |
| --- | --- |
| **4.14 - WILL EXPLICIT CONSENT BE SOUGHT FOR THE PROCESSING OF DATA?** |  |
| **E1.1(a)** |  |

**4.15 - 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)** |  |

**4.16 - 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)** |  |

**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** |  |

**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** |  |

**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** |  |

**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** |  |

**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** |  |

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

|  |  |
| --- | --- |
| **E2.10** |  |

**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** |  |

**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** |  |

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

|  |  |
| --- | --- |
| **E2.13** |  |

**5.10 - WHAT MEDIA OF DATA WILL BE COLLECTED?**

|  |  |
| --- | --- |
| **E3.1** |  |

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

|  |  |
| --- | --- |
| **E3.2(a)** |  |

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

|  |  |
| --- | --- |
| **E3.2(b)** |  |

**5.13 - WHERE WILL DATA WHICH IS COLLECTED BE STORED?**

|  |  |
| --- | --- |
| **E3.3** |  |

|  |  |
| --- | --- |
| **5.14 - WILL DATA COLLECTED BE AT ANY STAGE LEAVING THE SITE(S) OF ORIGIN?** |  |
| **E3.4(a)** |  |

**5.15 - IF YES, PLEASE ELABORATE.**

|  |  |
| --- | --- |
| **E3.4(b)** |  |

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

|  |  |
| --- | --- |
| **E3.5** |  |

|  |  |
| --- | --- |
| **5.17 - AFTER DATA ANALYSIS HAS TAKEN PLACE, WILL DATA BE RETAINED?** |  |
| **E3.6(a)** |  |

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

|  |  |
| --- | --- |
| **E3.6(b)** |  |

**5.19 - PLEASE COMMENT ON THE CONFIDENTIALITY OF COLLECTED DATA.**

|  |  |
| --- | --- |
| **E3.7** |  |

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

|  |  |
| --- | --- |
| **E3.8** |  |

 |  |
| **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)** |  |

|  |  |
| --- | --- |
| **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)** |  |

**5.25 - WHO WILL ACCESS THESE HEALTHCARE RECORDS?**

|  |  |
| --- | --- |
| **E4.1(c)** |  |

|  |  |
| --- | --- |
| **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)** |  |

**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)** |  |

**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.***

* ***THIS SHOULD BE COMPLETED BY THE RESEARCHER.***
* ***THIS DPIA WILL BE CONSIDERED INCOMPLETE IF THE RISK ASSESSMENT REMAINS BLANK.***
* ***IF YOU HAVE DETERMINED THAT THERE ARE NO RISKS WITHIN THIS RESEARCH PROJECT PLEASE INDICATE THAT FACT AT THE END OF THIS SECTION.***

|  |  |  |
| --- | --- | --- |
|  |  | **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** |

|  |  |  |
| --- | --- | --- |
| **6.1 – HAVING COMPLETED ALL OTHER SECTIONS OF THIS DPIA - I HAVE DETERMINED THAT THERE ARE NO DATA PROTECTION OR PRIVACY RISKS IN THIS PROJECT*****(ONLY TICK THIS BOX IF YOU HAVE DETERMINED THAT THERE ARE NO RISKS IN THE PROJECT. OTHERWISE COMPLETE THE RISK TABLES BELOW)*** | [ ]  | **6.2 – NAME OF PERSON MAKING THIS DETERMINATION** |
|  |
|  |

**TABLE 1 - IDENTIFY THE RISKS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Ref. No.** | **Privacy issue -** Element of the initiative that gives rise to the risk | 1. **Risk to individuals**

(complete if appropriate to issue or put not applicable) | 1. **Compliance risk**

(complete if appropriate to issue or put not applicable) | 1. **Associated organisation / corporate risk**

(complete if appropriate to issue or put not applicable) | **Risk Score** |
| **Likelihood** | **Impact** | **Risk Status** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

**TABLE 2 - IDENTIFY THE SOLUTIONS OR MITIGATING FACTORS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Ref. No.** | **Risk – taken from column (a), (b) and/or (c) above in table 1.** | **Proposed solution(s) / mitigating action(s)** | **Anticipated risk score following mitigation** | **Result: is the risk accepted, eliminated, or reduced?** | **Risk to individuals is now OK?****Signed off by?** |
| **Likelihood** | **Impact** | **Risk Status** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

**TABLE 3 – INTREGRATE THE DPIA OUTCOMES BACK INTO THE PROJECT PLAN**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Ref. No.** | **Action to be taken** | **Date for completion of actions** | **Responsibility for action** | **Current status / progress** |
|
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**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 6 has been completed and all known risks have been mitigated or reduced to an acceptable level** | [ ]  | [ ]  | [ ]  |

**SECTION 8 – TRANSFER IMPACT ASSESSMENT**

***A TRANSFER IMPACT ASSESSMENT (TIA) IS REQUIRED WHEN TRANSFERRING PERSONAL DATA TO A THIRD COUNTRY OUTSIDE OF THE EEA, NOT COVERED BY AN ADEQUACY DECISION (GDPR, ARTICLE 45)***

|  |
| --- |
| ***THE TABLE BELOW REPRESENTS COUNTRIES WITH GDPR ADEQUACY.***  |
| * Andorra
 | * Japan
 |
| * Argentina
 | * Jersey
 |
| * Canada (commercial organisations)
 | * New Zealand
 |
| * Faroe Islands
 | * Republic of Korea
 |
| * Guernsey
 | * Switzerland
 |
| * Israel
 | * United Kingdom (sunset clause 27 June 2025)
 |
| * Isle of Man
 | * Uruguay
 |

|  |
| --- |
| **8.1 – KNOW YOUR TRANSFER – MAP THE TRANSFERS*****WHAT DATA ARE YOU TRANSFERRING? WHERE IS IT GOING? ETC.*** |
|  |
|  |
| **8.2 – ARE THERE ANY LAWS IN THE THIRD COUNTRY THAT MIGHT IMPINGE ON THE IMPORTERS ABILITY TO COMPLY WITH APPROPRIATE SAFEGUARDS?****IS THE DATA IMPORTER SUBJECT TO THEIR ‘HOME’ COUNTRY’S SURVEILLANCE OR MANDATORY DISCLOSURE LAWS?*****IF YES, PLEASE SPECIFY THE LAW AND HOW MANY SUCH REQUESTS THE IMPORTER RECEIVED IN THE PAST 24 MONTHS*** |
|  |
|  |
| **8.3 – WHICH DATA PROTECTION MECHANISM IS BEING RELIED UPON FOR THE DATA TRANSFER?*****WITH REFERENCE TO GDPR ARTICLES 46-49******(I.E. SCCs, BCRs, DEROGATION)*** |
| **8.3.1 –** **Standard Contractual Clauses (SCCs)** | [ ]  | **8.3.2 –** **Binding Corporate Rules (BCRs)** | [ ]  | **8.3.3 –** **Derogation (Article 49 GDPR)** | [ ]  | **8.3.4 –** **Other** | [ ]  |
|

|  |  |  |
| --- | --- | --- |
| **8.3.1 – IF RELYING ON STANDARD CONTRACTUAL CLAUSES (SCCs): WHICH OF THE FOUR SCC MODELS IS APPROPRIATE?** | **Model I - EU Controller to TC Controller** | [ ]  |
| **Model II - EU Controller to TC Processor** | [ ]  |
| **Model III - EU Processor to TC Processor** | [ ]  |
| **Model IV - EU Processor to Non-EU Controller** | [ ]  |

|  |
| --- |
| **8.3.2 – IF RELYING ON BINDING CORPORATE RULES (BCRs): WHEN WAS IT GRANTED AND UNDER WHAT JURISDICTION / SUPERVISORY AUTHORITY?** |
|  |

|  |  |  |
| --- | --- | --- |
| **8.3.3 – IN THE ABSENCE OF AN ARTICLE 46 SAFEGUARD (SCC, BCR, etc.) AN ARTICLE 49 DEROGATION CAN BE RELIED-UPON FOR THE TRANSFER OF DATA.****WHICH ONE APPLIES?*****NOTE: ARTICLE 49 TRANSFERS RARELY APPLY FOR RESEARCH AND SHOULD ONLY BE A ONCE OFF. THEY ALSO HAVE TO HAVE A GROUNDING NATIONAL OR EU LEVEL LAW TO ALLOW FOR THE TRANSFER.*** | **Explicit Data Subject Consent;** | [ ]  |
| **Processing necessary for a contract;** | [ ]  |
| **Processing necessary in the Public Interest;** | [ ]  |
| **Necessary for defence of legal claims;**  | [ ]  |
| **Necessary in the vital interests of the Data Subject;**  | [ ]  |
| **Transfer based on a public register;**  | [ ]  |
| **Transfer is one-off or occasional, in compliance with Article 49.1.2** | [ ]  |
| **IF YOU ARE RELYING ON ONE OF THE ABOVE ARTICLE 49 DEROGATIONS – PLEASE SPECIFY WHY.** |
|  |

|  |
| --- |
| **8.3.4 – OTHER: PLEASE SPECIFY** |
|  |

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|  |
|  |
| **8.4 – IS THERE A LIKELIHOOD THAT THE DATA WILL BE FURTHER TRANSFERRED TO ANOTHER THIRD COUNTRY?*****IF YES, PLEASE GIVE DETAILS OF ONWARD TRANSFERS.*** |
|  |
|  |
| **8.5 – RE-EVALUATE AT APPROPRIATE INTERVALS THE LEVEL OF PROTECTION AFFORDED TO THE PERSONAL DATA YOU TRANSFER TO THIRD COUNTRIES.*****PLEASE INDICATE HOW OFTEN THE TRANSFER IMPACT ASSESSMENT WILL BE REVIEWED.*** |
|  |

1. European Convention on Human Rights, Article 8 [↑](#footnote-ref-1)
2. GDPR, Article 4(7) [↑](#footnote-ref-2)
3. GDPR, Article 4(8) [↑](#footnote-ref-3)
4. GDPR, Article 4(1) [↑](#footnote-ref-4)
5. GDPR, Article 4(15) [↑](#footnote-ref-5)
6. GDPR, Article 4(13) [↑](#footnote-ref-6)
7. GDPR, Article 4(14) [↑](#footnote-ref-7)
8. <https://www.phgfoundation.org/report/the-gdpr-and-genomic-data> (page 7, paragraph 3) [↑](#footnote-ref-8)
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 [↑](#footnote-ref-9)
10. https://www.who.int/genomics/geneticsVSgenomics/en/ [↑](#footnote-ref-10)
11. The Disability Act 2005, [*https://www.irishstatutebook.ie/eli/2005/act/14/section/42/enacted/en/html*](https://www.irishstatutebook.ie/eli/2005/act/14/section/42/enacted/en/html) [↑](#footnote-ref-11)