



**Authorised Person
for Pre-Screening Actions Agreement**



HSE Reference:

R&D PSAP-Agreement LMP [HSE/HSE Entity' Acronym] [ddmmyy]

Pre-screening template introduction

A key publicly stated objective of the Health Research Regulations and the Amendments is to strengthen governance in organisations that facilitate or carry out health research involving the processing of personal data.

In an organisation that provides healthcare services to patients, effective governance recognises the inter-dependencies between corporate and clinical governance across services and integrates them.

The amendment on pre-screening which is designed to facilitate health research is necessarily built around that governance principle because it facilitates a purpose specific and controlled exception to the general rule on third party access to personal data by an “authorised person” (who is not an employee of the data controller).

It means that a data controller (most likely a hospital but any healthcare provider) that envisages the use of the amendment must put formal and documented governance arrangements in place regulating the appointment and data processing activities of an “authorised person” and the relationship between the data controller and the employer of the “authorised person”.

Those formal governance arrangements also involve appropriate transparency arrangements.

THIS AGREEMENT is dated and effective this and made between:

- (1) **The Health Service Executive**, a body corporate with perpetual succession established by the Health Act 2004 (Hereinafter “the **HSE**”), and
- (2) **[Organisation/Legal Person]** (Hereinafter “**acronym**”) having its principal place of business at [...]

Hereinafter referred to individually as a “**Party**” or collectively referred as “**the Parties**”.

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WHEREAS

- A. Health Research, as defined under the Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021 (S.I. No 18 of 2021) (the “**HRR Amendment 2021**”), shall include Pre-Screening Actions which are actions that subject to certain Specific Requirements shall not require explicit consent or ethical approval by a research ethics committee;
- B. In this Agreement Pre-Screening Actions should solely be understood as defined in Regulation 4. (b) of the HRR Amendment 2021, meaning an “[...] **Action taken to establish whether an individual may be suitable or eligible for inclusion in the research**”; for the avoidance of doubt it does not include the recruitment of research participants;
- C. The General Data Protection Regulation (“**GDPR**”), the Data Protection Acts 1999-2018 (“**DP Acts**”) and the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (“**HRR**”) all directly impact on the processing of Personal Data for the purpose of Health Research and Explicit Consent is deemed a suitable and specific safeguard under the HRR Amendment 2021 for the processing of Personal Data for such purpose;
- D. Subject to complying with certain Specific Requirements (See Section 4 of this Agreement), Regulation 4 of the HRR Amendment 2021 (the “**HRR Amendment**”) allows for an Authorised Person who is an employee of [**acronym**] to conduct such Pre-Screening Actions”;
- E. The HSE, as Controller of the Personal Data held by it for the purpose of providing healthcare to individual, may appoint an “**Authorised Person**” to conduct Pre-Screening Actions where such Authorised Person is “**[...] Under the direction and control of a health practitioner who is employee of the HSE**”;
- F. This Agreement does not regulate the substantial part of any specific research study for which Pre-Screening Actions may be undertaken under this Agreement. Nevertheless, the Parties may consider to evidence their compliance to the HRR Amendment 2021 in any subsequent ethics applications they will need to submit for the conduct of such specific research study by incorporating electronic or hard copies of the signed and stamped appointment and activation forms approving the conduct of Pre-Screening Actions by the Authorised Person for a specific research study for which ethics approval is sought;
- G. The Parties hereby confirm their intention to set up their respective rights and obligations in relation to such Specific Requirements and the appointment and activation of an Authorised Person;
- H. Annex 1A: Pre-Screening Authorised Person Appointment Vetting Form (“**PSAP-Vetting Form**”)
- I. Annex 1B: Pre-Screening Authorised Person Appointment Activation Form for specific projects (“**PSAP-Activation form**”);
- J. Annex 2: Pre-Screening Authorised Person Local HSE Management and Signatories Form
- K. Annex 3A: General Notice on Pre-screening for eligibility or suitability for inclusion in health research
- L. Annex 3B: HSE Website Privacy Statement Notification
- M. Annex 4: List of HSE Entities
- N. Annex 5: List of HSE Deputy Data Protection Officers by HSE Entity
- O. Annex 6: HSE Data Breach Incident Form
- P. Annex 7. Authorised Person appointment and Activation Mechanism Summary Flow Chart

NOW IT IS HEREBY AGREED by and between the parties hereto as follows: -

1. Definitions

In this Agreement, and unless the context otherwise requires, capitalised terms and expressions used in this Agreement shall have the following meaning: -

Agreement shall mean the Appointment of an Authorised Person for Pre-Screening Actions Agreement;

Authorised Person has the meaning given to that term in Regulation 4. (c) (iii) (I-III) of the Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2020;

Data Controller or **Controller** has the meaning given to that term in Article 4(7) of the GDPR;

Data Processor or **Processor** has the meaning given to that term in Article 4(8) of the GDPR;

Data Protection Commission shall mean the Irish Data Protection Commission which is the Irish data protection supervisory authority;

Data Protection Legislation shall mean all applicable laws and regulations relating to the processing of Personal Data and privacy including the Data Protection Act 2018, the General Data Protection Regulation 2016/679 (the "GDPR") and the European Communities (Electronic Communications, Networks and Services) (Privacy and Electronic Communications) Regulations 2011 (S.I. 336/2011) and any statutory instrument, order, rule or regulation made thereunder, as from time to time amended, extended, re-enacted or consolidated;

Data Subject has the meaning given to that term in Article 4(1) of the GDPR;

Explicit Consent has the meaning given to that term in Article 4(11) of the GDPR;

GDPR means the EU General Data Protection Regulation, Regulation (EU) 2016/679, the effective date of which is 25th May 2018;

Health Research means health research as defined in Regulation 3 of the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018;

HRR Amendment 2021 means the Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021 (S.I. No 18 of 2021)

HSE Personal Data shall mean the Personal Data and Special Categories of Personal Data Processed by or on behalf of the HSE for which the HSE is the Data Controller;

Health Practitioner has the same meaning as it has in Section 2 of the Health Identifiers Act 2014 (No.15 of 2014);

Joint-Controller has the meaning given to that term in Article 26 of the GDPR;

Personal Data has the meaning given to that term in Article 4³ of the GDPR, and for the purpose of this Agreement includes Special Categories of Personal Data;

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Personal Data Breach means a breach of security leading to the accidental or unlawful; destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed;

Pre-screening Actions has the meaning of specific actions defined in Regulation 4.(b) of the HRR Amendment 2021, meaning "[...] *action taken [by the Authorised Person] to establish whether an individual may be suitable or eligible for inclusion in the research*". It does not include the recruitment of research participants;

Processing and like words, have the meaning given to those terms in Article 4 (2) of the GDPR;

Purpose: has the meaning provided by the EDPB in its 'Guidelines 07/2020 on the concepts of controller and processor in the GDPR version 1.0', meaning '*of anticipated outcomes that is intended or that guides the actions, meaning how a result is obtained or an end is achieved*';

Research ethics committee has the same meaning as in Regulation 4.(3) of the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulation 2018 (S.I. No. 314 of 2018) (as amended);

Specific Requirements shall mean all the requirements set up in regulation 4. (d) of the HRR Amendment 2021 and detailed in Section 4 of this Agreement.

2. Scope of this Agreement

- 2.1. The Health Research Regulations and the HRR Amendment are one element of the ethical and legislative framework that applies to the processing of personal data for health research purposes;
- 2.1. The HRR Amendment 2021 sets out circumstances where, subject to certain Specific Requirements defined under Regulation 4 of the HRR Amendment 2021, the HSE as Controller of the Personal Data held by it for the purpose of providing healthcare to individuals, may appoint an Authorised Person to conduct specific Pre-Screening Actions (See Section 3. hereinafter) for specific Health Research;
- 2.2. This Agreement is limited to the Appointment of such Authorised Person and the processing of Personal Data by such Authorised Person for the sole purpose of conducting Pre-Screening Actions as defined under this Agreement, and is to set out the roles, responsibilities and accountability of the Parties in relation to such Appointment;
- 2.3. Any processing of Personal Data without explicit consent that is not for the sole purpose of carrying out Pre-screening actions HRR Amendment 2021 shall be : -
 - (a) A breach of the terms and conditions of this Agreement; and
 - (b) Under Regulation 4 (d) (iii) of the HRR Amendment 2021 a breach of the Authorised Person's employment; and
 - (c) Carry sanctions as specified by the Parties in Section 9 of this Agreement;
- 2.4. The HRR Amendment 2021 is an option and this Agreement shall not prevent or hinder the Parties to rely on the Explicit Consent of the Data Subject when undertaking Pre-Screening Actions, or to apply for a Declaration from the Health Research Consent Declaration Committee (HRCDC) (<https://hrcdc.ie/apply>);
- 2.5. Where the Parties rely on the HRR Amendment 2021 to conduct Pre-Screening Actions as defined under this Agreement, they should comply with their obligations under the terms of this Agreement and any obligations they may have under Data Protection legislation;
- 2.6. This Agreement does not regulate the substantial part of any specific research study for which Pre-Screening Actions may be undertaken under this Agreement. Nevertheless, the Parties may consider to evidence their compliance to the HRR Amendment 2021 in any subsequent ethics applications they will need to submit for the conduct of such specific research study by incorporating electronic or hard copies of the signed and stamped appointment and activation Forms approving the conduct of Pre-Screening Actions by the Authorised Person for a specific research study for which ethics approval is sought. Unless otherwise specified in writing by the Parties, such completed, signed and stamped Forms shall be retained by the Parties for no less than 7 (seven) years.

3. Pre-Screening Actions

- 3.1. For the purpose of this Agreement Pre-Screening Actions solely includes actions taken by an Authorised Person who is an employee of [acronym] to establish whether an individual may be suitable or eligible for inclusion in the substantive part of a Health Research. **It does not include the recruitment of research participants;**
- 3.1. Whilst not detailed in the Regulations, the following actions are envisaged as authorised Pre-Screening Actions for the purposes of this Agreement: -
 - (a) Reviewing the personal data of a data subject in order to assess whether he or she might be suitable or eligible for inclusion in a health research study;
 - (b) Analysing the pre-screening data and documenting the findings;
 - (c) Approaching an individual found to be eligible or suitable **to determine their interest in participation in the specified study for which Pre-Screening Actions are conducted, but without enrolling the individual into the research.** For the avoidance of doubt, Pre-Screening Actions conducted under this Amendment are without ethical approval, whilst the substantial part

of the research study, including consenting research participants, must solely be undertaken with prior ethics approval;

- (d) Sharing the identity of the individual with the research team on a confidential basis where the individual has consented to be contacted by the research team;
- (e) Sharing the findings (in a non-identifiable way) with others involved in the research team for the sole purpose of further confirming eligibility and suitability criteria. However, only [acronym] employees with relevant qualification(s) or expertise or experience will be appointed to conduct Pre-Screening Actions, it is therefore anticipated that such sharing will only be required in exceptional circumstances and: - the Parties will need to enter into the necessary additional legally binding instruments, and sharing of non-identifiable data will be restricted in purpose and retention to the sole requirement of confirming eligibility and suitability.

4. Specific Requirements

4.1. An Authorised Person who is an employee of [acronym] may only undertake Pre-screening Actions defined under this Agreement where: -

- (a) [Acronym] satisfies any of the conditions set up in Regulation 4. (c) (iii) of the HRR Amendment 2021 and complies with Regulation 4. of the HRR Amendment 2021;
- (b) The Authorised Person is under the direction and control of a Health Practitioner who is an employee of the HSE;
- (c) The HSE has put in place and made public, including on its website, a process for authorising a person as an Authorised Person for the purposes of conducting such Pre-Screening Actions;
- (d) The HSE ensures that Personal Data are processed in a transparent manner under Regulation 3 (1) (d) of the HRR Amendment 2021, and where it has appointed an Authorised Person that notices and posters are displayed in HSE public areas where individuals attend for the provision of health care stating that : -
 - (i) "The HSE has appointed an Authorised Person who may, without explicit consent, access and use the Personal Data held by it for the sole purpose of establishing whether an individual who has been provided with health care from the HSE may be suitable or eligible for inclusion in specified health research"; And
 - (ii) Any Personal Data accessed and used by an Authorised Person without explicit consent shall be only such data that is required to assist in determining the suitability or eligibility of an individual for the inclusion in the Health Research concerned; And
 - (iii) The HSE and [acronym] have entered into this Agreement providing that any processing of Personal Data, without explicit consent, that is not for the purpose of establishing whether an individual may be suitable or eligible for inclusion in specified Health Research shall be a breach of the terms and conditions of the Authorised Person's employment carrying such sanctions as may be specified in the Agreement;

5. Appointment of an Authorised Person and Appointment Activation

5.1. Only applications of employees of [acronym] with qualifications and/or expertise relevant to the conduct of pre-screening actions in Health Research will be considered by the HSE when appointing Authorised Persons;

5.1. The Appointment of an Authorised Person will be for a period of up to a maximum of 2 (two years), and subject to the terms of his/her employment with [acronym], and the terms of this Agreement; and in addition will be subject to review every five years, starting November 2025;

5.2. Arrangements for appointing an Authorised Person: -

- (a) A duly completed, signed and stamped Pre-Screening Authorised Person Appointment Vetting Form ("PSAP-Vetting Form") (See Annex 1A) shall be submitted by email to a HSE signatory for decision regarding the appointment of an Authorised Person (See Annex 2 of this Agreement) by the employee of [acronym] seeking to be appointed as an Authorised Person;
- (b) A decision on the appointment of the applicant as an Authorised Person will be confirmed by the HSE to [acronym] within 15 (fifteen) days of reception of a PSAP-Vetting Form. Confirmation of approval or rejection of the appointment will be in writing under Section B of the PSAP-Vetting Form and will be sent by email to [acronym] as indicated by the applicant in Section A of the PSAP-Vetting Form. Incomplete Forms will automatically be rejected;
- (c) An employee of [acronym] is deemed an appointed Authorised Person when a fully executed and

stamped PSAP-Vetting Form confirming the appointment, including a unique PSA-Vetting Reference, has been returned by email to [acronym] recipients listed in the form;

- (d) Approval of an appointment as an Authorised Person by a HSE signatory for decision regarding the Appointment of an Authorised Person (See Annex 2 of this Agreement) will be valid in any of the HSE Entities listed in Annex 4;
- (e) Approved PSAP-Vetting Form confirming the appointment of an Authorised Person shall be stored and retained by each of the Parties for no less than 7 (seven) years after the date of the appointment and shall be made available as required to the HSE to (1) activate the appointment (see clause 5.7 hereinafter), and (2) during Quinquenal or other reviews the Parties may need to conduct in relation to the management of this Agreement;

5.3. Activation of the Appointment of an Authorised Person

- (a) In compliance with the HRR Amendment 2021, the appointment of an Authorised Person must be activated for each specific Health Research requiring the conduct of Pre-Screening Actions by the Authorised Person;
- (b) An appointed Authorised Person must submit a Pre-Screening Authorised Person Activation Form ("PSAP-Activation Form") to the relevant HSE signatory for decision regarding the activation of an appointment of an Authorised Person (See Annex 2 of this Agreement) for each Health Research or group of Health Research for which he/she needs to undertake Pre-Screening Actions. PSAP-Activation Form submissions must include all documentation and signatures required in the form, including from the HSE health Practitioner who will control and supervise the Authorised Person when conducting Pre-Screening Actions. Incomplete application will be rejected;
- (c) Applications to activate an appointment must be reviewed and approved by the relevant HSE signatories (See Annex 2) of the HSE Entity where the Pre-Screening Actions will be conducted;
- (d) Where Pre-Screening Actions by an Authorised Person are to take place in more than one HSE Entity (See Annex 4) for a same Health Research study, the decision of activation by one of the HSE signatories for decision and signature regarding the activation of an Appointed Authorised Person for specific Health Research in any of these HSE Entities will be recognised by all other HSE Premises for this specific Health Research;
- (e) A decision on the activation of the appointment of the Authorised Person will be confirmed by the HSE to [acronym] within 15 (fifteen) days of reception of a PSAP-Activation Form. Confirmation on the decision of activation by the HSE will be in writing under Section B of the PSAP-Activation Form and will be sent by email to [acronym] as indicated by the applicant in Section A of the PSAP-Activation Form;
- (f) An Authorised Person shall not start to conduct any Pre-Screening Action as an Authorised Person for any Health Research unless his/her appointment has been activated for such Health Research by an authorised HSE signatory (See Annex 2);
- (g) Approved PSAP-Activation Form confirming the activation of an Authorised Person shall be stored and retained by each of the Parties for no less than 7 (seven) years after the date of the activation and shall be made available as required to the HSE during Quinquenal or other reviews the Parties may need to conduct in relation to the management of this Agreement;

6. Termination

6.1. The appointment of an Authorised Person shall cease immediately when either of the following does apply:

- (a) This Agreement has expired, lapsed or terminated;
- (b) The Authorised Person advises [acronym] and the HSE that he or she no longer wishes to act as an Authorised Person;
- (c) The contract of employment of the Authorised Person with [acronym] has terminated;
- (d) Due to a breach of the Terms of this Agreement by the Authorised Person or [acronym];

6.1. For the purpose of this Agreement the processing of Personal Data by an Authorised Person, without Explicit Consent from the data subject and without Ethics Approval by A Research Ethics Committee, is always subject to the terms of this Agreement. A breach to these terms will result in sanctions as described in Section 7 of this Agreement;

6.2. Shall a Party to this Agreement wish to terminate this Agreement it must notify by e-mail the contact points of the other Party listed in Section 10 of this Agreement at least 30 (thirty) days prior to the proposed termination date specifying the date of termination;

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- 6.3. Should [acronym] repeatedly breach any of the terms of this Agreement in such a manner as to reasonably justify the opinion that its conduct is inconsistent with it having the intention or ability to give effect to the terms of this Agreement
- 6.4. Notwithstanding the termination of this Agreement for any reason the provisions of Section 9.3 of this Agreement shall continue to bind the parties;

7. Incidents and Breaches

- 7.1. A Breach by an Authorised Person or [acronym] to the terms of this Agreement, or of any instrument agreed by the Parties in relation to this Agreement, shall be notified without delay to the relevant HSE signatory (See Annex 2);
- 7.2. Any processing of Personal Data by an Authorised Person, without the explicit consent of data subject, that is not for the purpose of establishing whether an individual may be suitable or eligible for inclusion in specified Health Research shall be a breach of the terms and conditions of this Agreement and of the Authorised Person's employment and carry the following sanctions: -
- (a) The immediate revocation by the HSE of the appointment of the Authorised Person; and
 - (b) [for acronym] – detail disciplinary actions
- 7.3. Where a Personal Data Breach has occurred, the Authorised Person must, as soon as possible when the incident is verified (meaning within 24 hours maximum), complete a [HSE Data Breach Incident Form](#) (see Annex 6). All sections of the form must be completed by the Authorised Person and the HSE Health Practitioner who controls and directs the Authorised Person in the HSE Entity where the breach has occurred. A duly completed [and signed] HSE Data Breach Incident Form should be submitted by such HSE Health Practitioner to the HSE DDPO for the HSE Entity where the breach has occurred (See Annex 5) and the HSE Health Practitioner who controls and directs the Authorised Person shall contact the HSE National Service Desk in the event of an information systems security breach. The Authorised Person shall additionally contact their employer as required by [acronym];
- 7.4. Severity of the incident shall be assessed by the HSE DDPO using the HSE Data Breach Incident Form. Where an incident constitutes a breach which is likely to represent a risk to the affected individuals, such breach shall additionally be reported by the HSE DPO within 72 (seventy two) hours of becoming aware of the breach to the affected individuals and to the Data Protection Commission;
- 7.5. Each Party shall support, as required, the other Party in identifying and qualifying data incident resulting from Pre-Screening Actions taken by an Authorised Person who is an employee of [acronym] whilst using Personal Data held by the HSE;
- 7.6. Qualification and gravity of the incident, and allocation of responsibilities in the incident, will determine the consequences of such incident on the appointment of the Authorised Person. A Personal Data Breach caused by the Authorised Person shall always result in the revocation by the HSE of the appointment of the Authorised Person;
- 7.7. The HSE reserves the right to take such action as it deems appropriate against the Authorised Person and [acronym].

8. Access Rights

- 8.1. Access Rights to Personal Data or individuals provided with health care from the HSE will be granted to the Authorised Person for specific Health Research based on the activation of their Appointment and will always be subject to the terms of this Agreement;
- 8.2. Access to Personal Data will solely be under the direction and control of the Health Practitioners employed by the HSE who are named in the PSAP-Activation Form;
- 8.3. Access rights granted to the Authorised Person will:-
- (a) Be temporary, and for the sole purpose of performing Pre-Screening Actions as defined under this Agreement;
 - (b) Always be subject to the Authorised Person fulfilling their Obligations under this Agreement.

9. Responsibilities of the Parties

- 9.1. The HSE is the Controller of Personal Data it holds for the purpose of providing health care to individuals and the Parties shall ensure that the essence of their arrangements on the processing of Personal Data held by the HSE for the purpose of Pre-Screening Actions conducted by an Authorised Person who is an employee of [acronym] and acting under the supervision and direction of a health practitioner who is an employee of the HSE are appropriately recorded are transparent;
- 9.2. Stemming from legal provision 4 (c) of the HRR Amendment 2021 the HSE will act either as a Controller or Joint-Controller with [acronym] for key element of the processing of the Personal Data used by the Appointed Authorized Person to conduct the Pre-Screening actions under the direction and control of a health practitioner who is an employee of the HSE do apply;
- 9.3. The Parties must comply with Data Protection Legislation that applies to it in relation to Personal Data processed in connection with the conduct of Pre-Screening Actions by an Authorised Person and the performance of this Agreement. Neither Party shall assign, sub-licence, delegate or otherwise transfer all or any of its rights or obligations under this Agreement;
- 9.4. The Parties should undertake for each Health Research requiring Pre-Screening Actions by the Appointed Authorised Person, a functional analysis of processing required. A qualification of the Parties as Controller or Joint-Controller must be established on the basis of an assessment of the factual circumstances surrounding the processing of the Personal Data for the sole Purpose of Pre-screening Actions conducted by the person seeking to be appointed as an Authorised Person, meaning concrete activities required in the context of Pre-screening Actions for a specific project for which the person has applied for an activation of their appointment;
- 9.5. The existence of joint responsibilities does not necessarily implies equal responsibilities of the Parties involved in different stages of the process of Personal Data and to different degrees and the level of responsibilities of each of the Parties must be assessed with regards to all the relevant circumstances prior to the Pre-Screening Actions are taking place;
- 9.6. The Parties will issue all required instruments in relation to the control, processing and sharing of the Personal Data required to comply with Data Protection Legislation and confidentiality requirements. Such instruments shall include all necessary technical and organisational measures and security requirements;
- 9.7. The HSE cannot activate the appointment of an Authorised Person for a specific Health Research project unless all of the terms of this Agreement are fully met. An appointment as an Authorised Person may be for one or more Health Research and cover one or more HSE Entities and will always be subject to the terms and conditions of this Agreement;
- 9.8. Each Party shall ensure that it has well defined arrangements for investigating and resolving allegations of misconduct from the Authorised Person.
- 9.9. Other Specific Responsibilities of the Parties
- 9.9.1. [Acronym] shall: -
- (a) Ensure that all its employees applying to be appointed as an Authorised Person to conduct Pre-Screening Actions under this Agreement : -
 - (i) Are bound by a professional, organisational or contractual confidentiality obligations;
 - (ii) Have been subject to appropriate successful Garda Vetting from the National Vetting Bureau;
 - (iii) Have successfully undertaken relevant Data Protection Legislation in-house training prior to submitting their application for an appointment;
 - (iv) Where appropriate, have taken the necessary steps to comply with HSE occupational health guidelines.
 - (b) Effect and maintain in force at all times during the continuance of this Agreement : -
 - (i) Public liability insurance with a minimum limit of indemnity of €6,500,000.00 (Six million and five hundred thousand Euros);

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- (ii) Professional indemnity policy in relation to professional services with a minimum limit of €6,500,000.00 (Six million and five hundred thousand Euros) for any one claim. The policy must be maintained in force during the terms of this Contract and for a further period of six years after termination;
 - (iii) Employer's liability insurance in relation to employees of the Service Provider supplying the Services. The minimum limit of indemnity under this policy should be €12,700,00.00 (Twelve million and seven hundred thousand Euros) for any one occurrence.
- (c) Ensure that any and all Authorised Person it employs comply fully and at all times with the terms of this Agreement and Data Protection Legislation. In particular, the Authorised Person will only process personal data for the sole purpose of conducting Pre-Screening Actions in compliance with Section 3 of this Agreement and the HRA Amendment 2020;
 - (d) Accept full responsibility for the actions of its employee appointed by the HSE as an Authorised Person and agrees to indemnify the HSE against any and all losses or damages suffered by the HSE as a result of the actions by the Authorised person;
 - (e) Ensure it will assist the HSE in relation to any enquiry or notice received by the HSE from the Data Protection Commission or investigation by the Data Protection Commission into the HSE;
 - (f) Informs the HSE when the contract of employment of an Authorised Person it employs has terminated. Such notification may be done by email to [the relevant HSE signatory (See Annex 2) of the HSE Entity which had originally vetted the appointment of such Authorised Person];
 - (g) Ensure that where the Authorised Person is legally required to disclose any Personal Data held by the HSE to a third party, he or she must inform without delay the HSE Health Practitioner who provides her with Control and direction and the relevant HSE DDPO based on the HSE Entity which has validated their appointment (See Annex 4).

9.9.2 The HSE shall: -

- (a) Comply with, and implement, Specific Requirements 4. (b) (c) (d) of this Agreement;
- (b) Ensure a Health Practitioner who is an employee of the HSE provides the necessary control and supervision to the appointed Authorised Person; such arrangement shall exist for each of the HSE Entities where the Authorised Person is to conduct Pre-Screening Actions under this Agreement;
- (c) Ensures it maintains appropriate records in relation to the management of this Agreement, in particular appointments of Authorised Persons, and their activation or revocation;
- (c) Ensure that all HSE Entities listed in Annex 4 of this Agreement have completed Annex 2 of this Agreement and that information recorded in such Annexes are up-to-date;
- (d) Conduct Quinquenal reviews of this Agreement and its implementation.

10. General Provisions

- 10.1. This Agreement represents the entire agreement between the Parties with respect to the subject matter therein and supersede all prior representations, agreements, arrangements and undertakings with respect thereto whether written or oral. This Agreement may only be amended in writing signed by duly authorised representatives of the Parties;
- 10.2. No Party shall be in breach of this Agreement nor liable for delay in performing, or failure to perform, any of its obligations under this Agreement if such delay or failure results from events, circumstances or causes beyond its reasonable control;
- 10.3. This Contract may not be released, discharged, supplemented, amended, varied or modified in any manner except by a writing amendment signed by a duly authorised officer or representative of each of the Parties hereto;

10.4. The Parties representatives for the purpose of receiving written notices or other communications under or in connection with the management of this Agreement shall until further notice be:

For the HSE	For [acronym]
Individuals listed under function 6 of Annex 2 of this Agreement	

10.7. If any provision of this agreement is found by any court or administrative body of competent jurisdiction to be invalid, unenforceable or illegal, the other provisions of this agreement will remain in force. If any invalid, unenforceable or illegal provision would be valid, enforceable or legal if some part of it were deleted, the provision will apply with whatever modification is necessary to make it valid, enforceable or legal;

11. Governing Law

This Agreement shall be governed by and construed in accordance with the laws of Ireland and the Parties submit to the exclusive jurisdiction of the Irish courts as regards any claim or matter arising under this Agreement.

EXECUTION PAGE

<i>Certified on behalf of the HSE by</i>	
<i>Signature of Authorised Representative:</i>	
<i>Printed Name:</i>	
<i>Position:</i>	
<i>Date:</i>	

<i>Certified on behalf of [acronym]</i>	
<i>Signature of Authorised Representative:</i>	
<i>Printed Name:</i>	
<i>Position:</i>	
<i>Date:</i>	

Annex 1A Pre-Screening Authorised Person Appointment Vetting Form



HEALTH SERVICE EXECUTIVE PRE-SCREENING ACTIONS AUTHORISED PERSON APPOINTMENT VETTING APPLICATION FORM "PSAP-VETTING FORM"

The HSE and your employer [acronym] have entered into an **Appointment of an Authorised Person for Pre-Screening Actions Agreement** ("the Agreement") to define the terms and conditions under which an employee of [acronym] can be appointed by the HSE under the Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2020 (the HRR Amendment 2021) as an Authorised Person to process personal data held by the HSE, without explicit consent and without ethics approval, for the sole purpose of establishing whether an individual may be suitable or eligible for inclusion **in specified health research** conducted by [acronym].

It is very important that this Application Form is duly completed and signed by all signatories before you submit it to the HSE. Submission should be by email to the relevant HSE signatory as per Section 5 of the Agreement. You must complete all relevant information in **Section A** before submitting your application. **Incomplete Form will be rejected.**

If approved, your vetted Appointment will be for a duration of up to a maximum of 2 (Two) years AND:

Subject to your terms of employment with [acronym],

Subject always to your compliance with the terms of your appointment as an Authorised Person,

Subject always to your employer compliance with the terms of the Agreement,

Subject to a Quinquenal review of appointment for [acronym] by the HSE, such reviews to start in November 2026

The HRR Amendment 2021

All signatories to this Application Form understand that they are bound by the terms and conditions of the **HSE-[acronym] HRR Amendment 2021 Authorised Person Agreement** and all relevant contracts, policies and terms applied by the HSE and [acronym] in relation to the processing of data for the purpose of this Agreement. Signatories shall contact their employer for further details if required.

To comply with the Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2020 (the HRR Amendment 2021) **the activation of your appointment will need to be confirmed for each health research project you will undertake pre-screening actions using a PSA-ACTIVATION Form**

SECTION A: TO BE COMPLETED BY THE APPLICANT

First Appointment Previous Appointment	<ul style="list-style-type: none">• Period: [dd/mm/yyyy] to [dd/mm/yyyy]
Title	Appointment Reference
Full Name	
Telephone Number	
Email address	
Position/Role [employment contract with [acronym]]	
CRITERIA 1	
Qualifications	
Health research areas of expertise / experience (10 keywords max)	
CRITERIA 2	
Appointment start date requested Appointment end date	Appointment will be for up to two years maximum and you must be employed by [acronym] for the full duration of your appointment dd/mm/yyyy dd/mm/yyyy
Employee ID at [acronym]	
Your employer Manager/Supervisor	
Your supervisor/Manager email address	

As a Pre-Screening Appointed Authorised Person I [TITLE] [FIRST NAME] [SURNAME] confirm that I understand and will comply with all the conditions of this appointment, including but not limited to the below requirements (please tick to confirm your acceptance): -

- ☐ I confirm the information contained in this form are correct and up-to-date
- ☐ I will inform the HSE of any changes that may apply to the above recorded information
- ☐ I will only undertake pre-screening actions for the sole purpose of establishing whether an individual may be suitable or eligible for inclusion in a health research project conducted by my employer and
- ☐ I will not use information collected for any another purpose which are all forbidden under this appointment;
- ☐ I will not recruit research participants
- ☐ I will obtain PSA-ACTIVATION approval prior to conducting any pre-screening actions for my employer
- ☐ I understand a breach to the terms of this Appointment shall be immediately reported [DDPO & Annex 2] and will result in the revocation of my Appointment by the HSE and will possibly result in further consequences for me and my employer, including the termination the HSE-[acronym] Agreement by the HSE and may be subject to other consequences may apply to the Authorised Person and [acronym] under Data Protection Legislation
- ☐ I understand that where required, the Appointment of an Authorised Person may be revoked by the HSE before the end of the appointment
- ☐ I confirm the information contained therein are up-t-date and I will advise the HSE of any changes to the data
- ☐ I consent to the HSE holding the data contained within this PSA-Vetting Form
- ☐ I understand I will need to activate my appointment for each health research project using a PSAP-Activation Form

Print Name: _____

Signature: _____ Date: _____

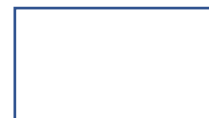
ON BEHALF OF [ACRONYM]

I, [TITLE] [FIRST NAME] [SURNAME] [POSITION] confirm that

- ☐ [TITLE] [FIRST NAME] [SURNAME] holds a post (permanent or a contract) that covers the full duration of the requested appointment as an Authorised Person, and that the information contained in Section A of this form are correct and up-to-date, and that the terms of this appointment have been fully explained to and understood by her/him;
- ☐ Records of this Appointment will be kept by [acronym] for not less than 7 (seven) years from the date of the Appointment.

Signed: _____
Authorised Signatory for [acronym]

Date: _____ Stamp




Decision to be returned to:

	Name:	Name:
	Email:	Email:

Section B: FOR THE HSE – DECISION ON THE APPOINTMENT

HSE Representative	Name: Position: Email address: HSE Entity:
Decision	Set Criteria 1: Must hold qualifications and/or expertise or experience relevant to the conduct of pre-screening actions in Health Research <ul style="list-style-type: none"> • Appointment as an Authorised Person accepted • Appointment as an Authorised Person rejected Reason for rejection/Comment:
Duration of the Appointment	Set criteria 2: Max up to two (2) years and applicant MUST be an employee of [acronym] during the whole period of the appointment Decision on duration of appointment: From : dd/mm/yyyy to dd/ mm/ yyyy
Data Retention Compliance for this Form:	7 (seven) years from appointment start date
PSA-VETTING approval Reference	PSA-Vetting [Applicant initials] [acronym] [DDMMYYYY] [HSE Signatory Initials] [HSE Entity acronym]

I, **TITLE** [FIRST NAME] [SURNAME], hereby approve the appointment of [...] an employee of [acronym] as an Authorised Person to conduct Pre-Screening Actions under the terms and conditions of the **Appointment of an Authorised Person for Pre-Screening Actions Agreement**.

Signed: _____ Date: _____ Stamp 

On behalf of the HSE
[TITLE] [FIRST NAME] [SURNAME]
[POSITION]

To be returned to applicant as indicated by applicant page 2

Section C: FOR THE HSE – TERMINATION OF THE APPOINTMENT

HSE Representative	Name: Position: Email address:
Reason for termination	<ul style="list-style-type: none"> • Appointment of an Authorised Person for Pre-Screening Actions Agreement • Authorised Person or [acronym] request for end of contract or other • Breach : Details:

Signed: _____ Date: _____ Stamp

On behalf of the HSE
[TITLE] [FIRST NAME] [SURNAME]
[POSITION]



**PRE-SCREENING AUTHORISED PERSON APPOINTMENT ACTIVATION FORM
FOR SPECIFIC PROJECTS
PSAP-ACTIVATION FORM**

Please **attach the electronic copy of your approved (signed & stamped) PSA-VETTING FORM** to your request when submitting this request of activation.

The HSE and your employer [acronym] have entered into an **Appointment of an Authorised Person for Pre-Screening Actions Agreement** ("the Agreement") to define the terms and conditions under which an employee of [acronym] can be appointed by the HSE under the Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2020 (the HRR Amendment 2021) as an Authorised Person to process personal data held by the HSE, without explicit consent and without ethics approval, for the sole purpose of establishing whether an individual may be suitable or eligible for inclusion **in specified health research** conducted by [acronym]. Information can be found at <https://hseresearch.ie/data-protection-and-research/>.

The purpose of this PSAP-Activation Form is

- to activate for a specific health research project your appointment as an Authorised Person; and
- to confirm the details and acceptance of the HSE health practitioner who, within one or more specified HSE Entity, will control and direct you when conducting Pre-Screening Actions without the explicit consent of the data subject and without ethics approval.

SECTION A: TO BE COMPLETED BY THE APPLICANT [one form per project]

A1. VETTING REFERENCE AUTHORISED PERSON:

Title	
Full Name	
Telephone Number	
Email address	
Vetted Authorised Person as an employee of	[acronym]
PSAP-VETTING Reference	Ref: Please <u>also insert in the Activation Card at the end of this Form</u>

A2. SPECIFIC HEALTH RESEARCH FOR WHICH ACTIVATION IS REQUIRED

PROJECT	
Title /Acronym	
Project contract reference & sponsor (EC,HRB, SFI,...) or [acronym] internal reference if not funded	(Mandatory)
Mandatory data retention in the research contract	
Project Data Controller or joint controllers	
Project Start & End Date	Start Date: [dd/mm/yyyy] - End Date: [dd/mm/yyyy]
Project Principal Investigator (PI)	
PI email	
Additional Data Protection legal instruments as relevant	Exceptional circumstances where research team may need to confirm eligibility & suitability Specify:

A3. HSE ENTITIES, ACCESS, HEALTH PRACTITIONER REQUIRED, & ACCEPTANCE & SIGNATURE

- Please, add tables as required for multi-sites Pre-Screening Actions; And
- Where the same HSE Health Practitioner will control and direct you in more than one HSE Entity for a same project (activation), and both access required and intended period for Pre-screening Actions are the same for all these HSE Entities, then you may use one single A3 table and list all relevant HSE Entities.

HSE ENTITY 1

HSE Entity where Pre-Screening Actions is required		
Access Required	Data:	Location
Intended period for conducting Pre-Screening Actions	Start Date:	End Date:
HSE Health practitioner who will control & direct you in this HSE Entity	Title: Name:	Position:

Applicant and HSE Health Professional Acceptance and Signature

FOR THE APPLICANT	FOR THE HSE HEALTH PRACTITIONER HSE ENTITY 1
	<p>I hold a dual affiliation with an academic organisation or other organisation Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>I understand that I must solely act as a HSE employee for the purpose of this activation Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>I agree to solely act as an employee of the HSE when providing control and direction to the Authorised Person (Applicant) under the terms of this activation Yes <input type="checkbox"/> No <input type="checkbox"/></p>
	I have ordinarily access to the personal data required Yes <input type="checkbox"/> No <input type="checkbox"/>
I have fully discussed the Pre-Screening Actions I am to undertake for the project herein listed, and the terms of this activation with the HSE Health Practitioner who will control and direct me Yes <input type="checkbox"/> No <input type="checkbox"/>	I understand the Authorised Person (Applicant) must only undertake Pre-Screening Actions for the <u>sole purpose</u> of establishing whether an individual may be suitable or eligible for inclusion in the health research for which activation is required. It must not include any other purpose or the recruitment of research participants. Yes <input type="checkbox"/> No <input type="checkbox"/>
I accept to control and direct the Authorised Person (Applicant) conducting the Pre-Screening Actions and I will ensure that he/she fully complies with the terms of this activation and all relevant HSE policies Yes <input type="checkbox"/> No <input type="checkbox"/>	I confirm that roles and responsibilities of the HSE and the employer of the Authorised Person (Applicant) in relation to the control, processing and sharing of the Personal Data required for the Pre-Screening Actions required under this activation have been clearly defined and all instruments required to comply with Data Protection Legislation and confidentiality have been issued Yes <input type="checkbox"/> No <input type="checkbox"/>
I understand that I should, at all times when conducting Pre-Screening Actions, be able to show a signed and stamped copy of an approved PSPA-Activation Card (bottom) Yes <input type="checkbox"/> No <input type="checkbox"/>	I accept to control and direct the Authorised Person (Applicant) conducting the Pre-Screening Actions and I will ensure that he/she fully complies with the terms of this activation and all relevant HSE policies Yes <input type="checkbox"/> No <input type="checkbox"/>
I understand that, if necessary, I will be responsible for completing HSE Data Breach Incident Form with the HSE Health Practitioner Yes <input type="checkbox"/> No <input type="checkbox"/>	I understand that, if necessary, I will be responsible for reporting data incident to the relevant HSE DDPO Yes <input type="checkbox"/> No <input type="checkbox"/>
I [TITLE] [FIRST NAME] [SURNAME] confirm that I fully understand the terms of this activation, of the Agreement, and my role and responsibilities in relation to this activation	I [TITLE] [FIRST NAME] [SURNAME] confirm that I fully understand the terms of this activation, of the Agreement, and my role and responsibilities in relation to the control and direction of the Authorised Person conducting Pre-Screening Actions under this activation
Signed: _____ Date _____	Signed: _____ Date _____

HSE ENTITY 2 (add HSE Entities as required if multi-sites Pre-Screening Actions applies)

HSE Entity where Pre-Screening Actions is required		
Access Required	Data:	Location
Intended period for conducting Pre-Screening Actions	Start Date:	End Date:
HSE Health practitioner who will control & direct you in this HSE Entity	Title: Name:	Position:

Applicant and HSE Health Professional Acceptance and Signature

FOR THE APPLICANT	FOR THE HSE HEALTH PRACTITIONER HSE ENTITY 2
	<p>I hold a dual affiliation with an academic organisation or other organisation Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>I understand that I must solely act as a HSE employee for the purpose of this activation Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>I agree to solely act as an employee of the HSE when providing control and direction to the Authorised Person (Applicant) under the terms of this activation Yes <input type="checkbox"/> No <input type="checkbox"/></p>
	I have ordinarily access to the personal data required Yes <input type="checkbox"/> No <input type="checkbox"/>
I have fully discussed the Pre-Screening Actions I am to undertake for the project herein listed, and the terms of this activation with the HSE Health Practitioner who will control and direct me Yes <input type="checkbox"/> No <input type="checkbox"/>	I understand the Authorised Person (Applicant) must only undertake Pre-Screening Actions for the <u>sole purpose</u> of establishing whether an individual may be suitable or eligible for inclusion in the health research for which activation is required. It must not include any other purpose or the recruitment of research participants. Yes <input type="checkbox"/> No <input type="checkbox"/>
I accept to control and direct the Authorised Person (Applicant) conducting the Pre-Screening Actions and I will ensure that he/she fully complies with the terms of this activation and all relevant HSE policies Yes <input type="checkbox"/> No <input type="checkbox"/>	I confirm that roles and responsibilities of the HSE and the employer of the Authorised Person (Applicant) in relation to the control, processing and sharing of the Personal Data required for the Pre-Screening Actions required under this activation have been clearly defined and all instruments required to comply with Data Protection Legislation and confidentiality have been issued Yes <input type="checkbox"/> No <input type="checkbox"/>
I understand that I should, at all times when conducting Pre-Screening Actions, be able to show a signed and stamped copy of an approved PSPA-Activation Form Yes <input type="checkbox"/> No <input type="checkbox"/>	I accept to control and direct the Authorised Person (Applicant) conducting the Pre-Screening Actions and I will ensure that he/she fully complies with the terms of this activation and all relevant HSE policies Yes <input type="checkbox"/> No <input type="checkbox"/>
I understand that, if necessary, I will be responsible for completing HSE Data Breach Incident Form with the HSE Health Practitioner Yes <input type="checkbox"/> No <input type="checkbox"/>	I understand that, if necessary, I will be responsible for reporting data incident to the relevant HSE DDPO Yes <input type="checkbox"/> No <input type="checkbox"/>
I [TITLE] [FIRST NAME] [SURNAME] confirm that I fully understand the terms of this activation, of the Agreement, and my role and responsibilities in relation to this activation Signed: _____ Date _____	I [TITLE] [FIRST NAME] [SURNAME] confirm that I fully understand the terms of this activation, of the Agreement, and my role and responsibilities in relation to the control and direction of the Authorised Person conducting Pre-Screening Actions under this activation Signed: _____ Date _____

FOR THE HSE – DECISION ON ACTIVATION


HSE Representative	Name: Position: Email address: HSE Entity:
Decision	You must be satisfied that all required safeguards are in place <ul style="list-style-type: none">• Activation Appointment as an Authorised Person accepted• Activation Appointment as an Authorised Person rejected Reason for rejection/Comment:
Duration of the Activation	For the intended Period for conducting Pre-Screening Actions only dd/mm/yyyy to dd/mm/yyyy (see section x)
PSAP-Activation approval Reference	PSAP-Activation [Applicant initials] [acronym] [project acronym] [DDMMYYYY] [HSE Entity of the HSE Signatory & signatory Initials][HSE Entities acronym]

I, **TITLE** **FIRST NAME** **SURNAME**, hereby approve the appointment of [...] an employee of [acronym] as an Authorised Person to conduct Pre-Screening Actions under the terms and conditions of the **Appointment of an Authorised Person for Pre-Screening Actions Agreement**.

Signed: _____
On behalf of the HSE
[TITLE] [FIRST NAME] [SURNAME]
[POSITION]

Date: _____ Stamp

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	PRE-SCREENING ACTIVATION CARD	To Be Kept At All Times By The Authorised Person When In HSE Premises
	PSAP-Vetting (Appointment) Reference	
	HSE Site which activated the Appointment	
	Contact reference for control	
	PSAP-Activation Reference contact	
	Activation End Date	
		Signed
		Stamp

Annex 2 Pre-Screening Authorised Person Local HSE Management and Signatories Form



Health Service Executive Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2020 Pre-Screening Authorised Person Local HSE Management and Signatories Form [HSE Entity X]

The HSE and [acronym] have entered into an "HSE-[acronym] HRR Amendment 2021 Authorised Person Agreement"/("the Agreement") to defined the terms and conditions under which an employee of [acronym] can be appointed by the HSE under the Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2020 (the HRR Amendment 2021) as an Authorised Person to process personal data held and controlled by the HSE without explicit consent and without Ethics Approval for the sole purpose of establishing whether an individual may be suitable or eligible for inclusion in specified health research conducted by [acronym].

In accordance with Regulation 4. (c) (III) of the Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2020, I [TITLE] [FIRST NAME] [SURNAME] [POSITION], hereby confirm the following authorised functions (which may be amended, revoked or substituted from time to time) as listed in Column 1 below and relating to the Regulation, to the employee of the Health Service Executive, and whoever is officially acting for him/her in his/her absence, listed in Column 2 below, save where otherwise provided.

Column 1	Column 2	Column 3
Function	Name	Notification
1. Decision and signature regarding the Appointment [Vetting] or termination of an Authorised Person	e.g. CEO /Dir Research/GM - TBC [TITLE] [FIRST NAME] [SURNAME] [POSITION] [Work address]	[email named staff] AND Copied to R&D or local Research Office email
2. Decision and signature regarding the Activation of an Appointed Person for specific projects (other than HP always a signatory)	e.g. Research Manager, local Manager - TBC [TITLE] [FIRST NAME] [SURNAME] [POSITION] [Work address] Can be allocated to a position, eg. 'Onsite Health Professional who controls and direct the AP'	[email named staff] If so, then 'As per Form'
3. Record keeping incl. notification appointment of Authorised Person, Activation, HP Controlling & Directing Authorised Persons, breach., 2B internal table	e.g. local admin/clerk [TITLE] [FIRST NAME] [SURNAME] [POSITION] [Work address]	[email named staff]
4. Decision and signature regarding a breach of the terms of this appointment by the appointed Authorised Person	e.g. DDPO, & as function 1 [TITLE] [FIRST NAME] [SURNAME] [POSITION] [Work address]	[email] [email named staff]
5. Decision and signature regarding a variation to Annex 2 of this Agreement	e.g. same as signatory to this Form [TITLE] [FIRST NAME] [SURNAME] [POSITION] [Work address]	R&D email] [email named staff]
6. Decision and signature regarding a variation to the terms of the Agreement at the exception of Annex 2	Dr Ana M. Terrés Room 221, Dr Steevens Hospital, Dublin 8 D08 W2A8	Local notification to confirm [Local Function 1 Person] TBC

In exercising the functions hereby listed the above-named employee shall have regard to the provisions of HSE-[acronym] HRR Amendment 2021 Authorised Person Agreement", Data Protection Legislation and are obliged to comply with the policies of the HSE in relation thereto.

The functions are effective until formally revoked in whole or part. If these functions are amended it shall continue in force as amended from the effective date of such amendment.

I reserve the right to personally, at my discretion, exercise functions 1 and 2 in any particular instance.

These functions are effective from [the enactment of the Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2020 [or [Day] [Month]

Signed: _____
[TITLE] [FIRST NAME] [SURNAME]
[POSITION]

Date: _____



HEALTH RESEARCH in the HSE

The HSE supports and carries out health research to the highest ethical standards to benefit patients, improve patient care and the health system. The HSE is not required under the Law to seek your consent to access your personal data to conduct Pre-Screening or Retrospective Chart Review. However, we will at all times operate to the highest standards of privacy and data protection and will respect your wishes in relation to the use of your personal data.

PRE-SCREENING

What is Pre-Screening

Activities used by research active persons (e.g. *research nurse*) to establish if you might be a suitable candidate for inclusion in a particular health research study. It involves reviewing medical records of patients who have received health services in the HSE.

Only personal data necessary to establish if you are a suitable candidate will be accessed. It does not mean that you will be recruited into the health research study, but simply that you may be eligible.

How Pre-Screening works

Your personal data can only be accessed by:

- a health practitioner employed by the HSE (e.g. a *registered doctor or a registered nurse*)
- a health student supervised by a health practitioners employed by the HSE
- a HSE employee who would ordinarily have access your data (e.g. *medical records clerk*)
- A limited number of research active persons called 'Authorised Person' who are appointed by the HSE (e.g. a *research nurse*)

An Authorised Person must

- be an employee of either: a university, a registered charity which supports research and education, a practice which provides, manages or develop healthcare practitioners
- be Garda vetted
- be under the control and direction of a healthcare practitioner employed by the HSE

The appointment of an Authorised Person

A legal agreement between the HSE and the employer of the Authorised Person regulates:

- the appointment of the Authorised Person
- access only to personal data necessary to identify suitable candidates for a specified study

Suitable candidates may be contacted by the HSE or a health professional who is an Authorised Person to establish their interest in taking part in the health research study or being contacted by the research team.

Your participation in health research is voluntary and will not affect the care and treatment you receive from the HSE.

RETROSPECTIVE CHART REVIEW

What is Retrospective Chart Review

Also called medical records review, is a type of health research study where researchers review and examine existing patient records, which were collected for the provision of health care, to answer one or more health research questions.

When is this type of health research allowed

- for retrospective health research study only (i.e. *looking at existing medical records*)
- when the study has been approved by a Research Ethics Committee
- where the study does not put your privacy at risk

How Retrospective Chart Review works

Your personal data can only be accessed by:

- a health practitioner employed by the HSE (e.g. a *registered doctor or a registered nurse*)
- a health student supervised by a health practitioners employed by the HSE
- a HSE employee who would ordinarily have access your data (e.g. *medical records clerk*)

Your personal data can only be accessed and used for Retrospective Chart Review by the above authorised individuals and they cannot be shared. If results are published they will not identify you, any patient or former patient.

What is a Research Ethics Committee

A Research Ethics Committee is an independent group of people appointed to formally assess if health research conforms with recognised international ethical standards. It is responsible for protecting the rights of those who take part in the research and the usage of their personal data for health research.

If you have any questions regarding the use of your personal data, please contact dpo@hse

For more information on Research in the HSE, Pre-Screening Privacy Statement or Data Protection and Research, please consult: <https://hseresearch.ie>



HEALTH RESEARCH IN THE HSE PRIVACY STATEMENT ON PRE-SCREENING ACTIVITIES AND THE APPOINTMENT OF AN AUTHORISED PERSON

Document Information

<i>Title</i>	<i>Health research in the HSE, Privacy statement on pre-screening activities and the appointment of an Authorised Person</i>
<i>Version</i>	<i>1.0</i>
<i>Author</i>	<i>Laura Méchineau-Phelan</i>
<i>Approval</i>	<i>Jim O'Sullivan, Orlaith Magee</i>
<i>Publication</i>	<i>TBC</i>
<i>Review Date</i>	<i>2024 or as required</i>

Document History

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<i>1.0</i>	<i>HSE</i>	<i>Laura Méchineau-Phelan</i>	<i>TBC</i>

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The HSE supports and carry out health research to high ethical standards to benefit patients, improve patient care and the health system.

Your participation in health research is voluntary and will not affect the care and treatment you receive from the HSE.

1. Patients Personal Data

The HSE holds the personal data of patients who have received healthcare services in the HSE.

The management of your personal data is the responsibility of the HSE as a Data Controller. The HSE has appointed a Data Protection Officer (Head DPO) and Data Protection Officers to make sure your personal data are accessed and processed in the right manner.

If you have any questions regarding the usage of your personal data, please contact dpo@hse.ie

For more information on how your personal data are processed in the HSE: www.hse.ie/eng/gdpr

For more information on health research and data protection: <https://hseresearch.ie/data-protection-and-research/>

2. Pre-Screening Of Patients Personal Data and the Law

The law permits in certain circumstances to use your personal data without your consent to establish if you might be a suitable candidate for inclusion in a particular health research study. This is called pre-screening.



- **Legal basis for processing personal data for Pre-Screening without Explicit Consent: GDPR 9(2)(i) & Regulation 4 (c) of the Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021 (S.I. No. 18 of 2021)**

7. What is Pre-Screening

Pre-Screening are activities used by a research active person (e.g. a research nurse) to establish if you might be a suitable candidate for inclusion in a particular health research study.

It involves reviewing medical records of patients who have received health services in the HSE. Only personal data necessary to establish if you are a suitable candidate will be accessed.

It does not mean that you will be recruited into the health research study, but simply that you may be eligible.

Suitable candidates may subsequently be contacted by the HSE or an Authorised Person who is a health professional to establish:

- their interest in taking part in the health research study,
- if they want and consent to be contacted by the research team.

8. Who Can Conduct Pre-Screening

Your personal data can only be accessed by:

- a **health practitioner employed by the HSE** (e.g. a registered doctor or a registered nurse)
- a **health student supervised by a health practitioners employed by the HSE**
- a **HSE employee who ordinarily access your data** (e.g. medical records clerk)
- a limited number of research active persons called '**Authorised Person**' who are appointed by the HSE' (e.g. a research nurse)

9. The Authorised Person

Sometimes the HSE may appoint a research active person (e.g. a research nurse) who is not an employee of the HSE to conduct pre-screening activities. This person is called an Authorised Person.

A limited number of research active persons may be appointed as an Authorised Person.
An Authorised Person must be an employee of:

- a Higher Education Institution (a University)
- a registered charity which supports research and education (e.g. Irish Heart Foundation)
- a practice which provides, manages or develop healthcare practitioners (e.g. ICGP)

10. The Appointment of an Authorised Person

A legal Agreement between the HSE and the employer of the Authorised Person regulates the appointment and pre-screening activities of an Authorised Person.

Under this Agreement an Authorised Person must:

- be appropriately Garda vetted before they can be appointed
- only access, process and use your records to establish if you are a suitable candidate for inclusion in a specific research study (the pre-screening activities)
- be under the control and direction (supervised) of a health practitioner employed by the HSE when they conduct the pre-screening activities
- be granted permission for each specific health research study, rather than a blanket permission (i.e. which would not involve any restriction).

Any access or use of your personal data outside the purpose of establishing your suitability or eligibility for inclusion of a health research study will be a breach to this Agreement and result in sanctions.

11. How long do you hold onto my personal data?

Provision of healthcare services by the HSE:

The HSE will retain your information for as long as necessary to provide you with services, and to comply with our legal and regulatory obligations. We are committed to protecting your personal data to the very best of our ability and take the appropriate steps to do in collecting, storing and destroying your data.

Pre-Screening activities:

Records from Pre-Screening activities will never be kept for longer than required for the purpose of conducting the pre-screening activities

12. What are my rights relating to personal data?

Provision of healthcare services by the HSE:

You have the following rights under the GDPR in relation to your personal data.

- **Right to access the data** – you have the right to request a copy of the personal data that we hold about you, together with other information about our processing of that personal data.
- **Right to rectification**- you have the right to request that any inaccurate data that is held about you is corrected, or if we have incomplete information you may request that we update the information such that it is complete.

- **Right to erasure** – you have the right to request us to delete personal data that we hold about you. This is sometimes referred to as the right to be forgotten.
- **Right to restriction of processing or to object to processing** – you have the right to request that we no longer process your personal data for particular purposes, or to object to our processing of your personal data for particular purposes.
- **Right to data portability** – you have the right to request us to provide you, or a third party, with a copy of your personal data in a structured, commonly used machine readable format

Some of these rights only apply in certain circumstances; they are not guaranteed or an absolute right. Please contact our Data Protection Officer if you have any questions or concerns about your rights. If you make a request, we have one month to respond to you.

Pre-Screening activities applicable rights:

Right to access the data: you have the right to request a copy of your personal data that were accessed for pre-screening activities.

Right to restriction of processing or to object to processing – you have the right to request that we no longer process your personal data for pre-screening activities, or to object to our processing of your personal data for that particular purpose.

13. How to make a complaint?



You have the right to make a complaint if you feel unhappy about how we hold, use or share your information.

To make a complaint directly to the hospital see the contact information for the Data Protection Officer below.

Data Protection Officer HSE	Email: dpo@hse.ie Phone: 087-9082160
Deputy Data Protection Officer West, (excluding voluntary agencies) Consumer Affairs, Merlin Park University Hospital, Galway. <ul style="list-style-type: none"> • CHO 1 – Cavan, Donegal, Leitrim, Monaghan, Sligo • Community Healthcare West – Galway, Mayo, Roscommon • Mid-West Community Healthcare – Clare, Limerick, North Tipperary. • Saolta Hospital Group 	Email: ddpo.west@hse.ie Phone: 091-775 373
Deputy Data Protection Officer Dublin North-East (excluding voluntary hospitals and agencies) Consumer Affairs, HSE Dublin North East, Bective St., Kells, Co Meath. <ul style="list-style-type: none"> • Midlands, Louth, Meath Community Health Organisation • Community Health Organisation Dublin North City & County • CHO 6 – Dublin South East, Dublin South & Wicklow • RCSI Hospital Group • National Children's Hospital 	Email: ddpo.dne@hse.ie Phone: Kells Office: 046-9251265 Cavan Office: 049-4377343

<p>Deputy Data Protection Officer Dublin mid-Leinster (excluding voluntary hospitals and agencies) Consumer Affairs, HSE, Third Floor Scott Building, Midland Regional Hospital Campus, Arden Road, Tullamore, Co. Offaly.</p> <ul style="list-style-type: none"> • Dublin Midlands Hospital Group • Ireland East Hospital Group • Community Healthcare Dublin South, Kildare & West Wicklow 	<p>Email: ddpo.dml@hse.ie Phone:</p> <p>Tullamore Office: 057-9357876</p> <p>Naas Office: 045-920105</p>
<p>Deputy Data Protection Officer South (excluding voluntary hospitals and agencies) Consumer Affairs, HSE South, Ground Floor East, Model Business Park, Model Farm Road, Cork. Eircode: T12 HT02</p> <ul style="list-style-type: none"> • Cork & Kerry Community Healthcare • CHO 5 – Carlow, Kilkenny, South Tipperary, Waterford & Wexford • UL Hospital Group • South South-West Hospital Group 	<p>Email: ddpo.south@hse.ie</p> <p>Phone:</p> <p>Cork Office: 021-4928538</p> <p>Kilkenny Office: 056-7785598</p>

If you are dissatisfied with how we are using your personal data you can contact the DPC.
Phone: 0761 104 800 – Lo-Call: 1890 252 231 - Email: info@dataprotection.ie

Annex 4: List of HSE Entities

Where the HSE acts as controller for the data it holds for the provision of healthcare, and which may appoint and activate a Pre-Screening Authorised Person under Regulation 4. of the HRR Amendment 2021

Bantry General Hospital
Cavan Monaghan Hospital
Connolly Hospital Blanchardstown
Cork University Hospital
Cork University Maternity Hospital
Croom Hospital: UL Hospitals
Ennis Hospital: UL Hospitals
Galway University Hospitals
Kerry General Hospital
Letterkenny University Hospital
Lourdes Orthopaedic Hospital, Kilcreene
Louth County Hospital, Dundalk
Mallow General Hospital
Mayo General Hospital
Midland Regional Hospital Mullingar
Midland Regional Hospital Portlaoise
Midland Regional Hospital Tullamore
Naas General Hospital
Nenagh Hospital: UL Hospitals
Our Lady Of Lourdes Hospital, Drogheda
Our Lady's Hospital, Navan
Portiuncula Hospital, Ballinasloe
Roscommon County Hospital
Sligo General Hospital
South Tipperary General Hospital
St Colmcille's Hospital, Loughlinstown
St Luke's General Hospital Carlow / Kilkenny
University Hospital Limerick
University Maternity Hospital: UL Hospitals
University Hospital Waterford
Wexford General Hospital

CHO 1 : Donegal - Sligo/Leitrim/West Cavan - Cavan/Monaghan
CHO 2 : Galway – Roscommon - Mayo
CHO 3: Clare – Limerick - North Tipperary/East Limerick
CHO 4: Kerry - Cork
CHO 5: South Tipperary - Carlow/Kilkenny – Waterford - Wexford
CHO 6 : Wicklow - Dun Laoghaire - Dublin South East
CHO 7: Kildare/West Wicklow - Dublin West - Dublin South City - Dublin South West
CHO 8: Laois/Offaly - Longford/Westmeath - Louth/Meath
CHO 9: Dublin North - Dublin North Central - Dublin North West

Annex 5: List of HSE Data Protection Officer by HSE Entity

Bantry General Hospital	ddpo.south@hse.ie
Cavan General Hospital	ddpo.dne@hse.ie
Connolly Hospital	ddpo.dne@hse.ie
Cork University Hospital/CUMH	ddpo.south@hse.ie
Croom Orthopaedic Hospital	ddpo.south@hse.ie
Ennis Hospital	ddpo.south@hse.ie
Kerry General Hospital	ddpo.south@hse.ie
Letterkenny University Hospital	ddpo.west@hse.ie
Lourdes Orthopaedic Hospital, Kilcreene	ddpo.south@hse.ie
Louth County Hospital	ddpo.dne@hse.ie
Mallow General Hospital	ddpo.south@hse.ie
Mayo University Hospital	ddpo.west@hse.ie
Midland Regional Hospital Mullingar	ddpo.dml@hse.ie
Midlands Regional Hospital Portlaoise	ddpo.dml@hse.ie
Midlands Regional Hospital, Tullamore	ddpo.dml@hse.ie
Monaghan Hospital	ddpo.dne@hse.ie
Naas General Hospital	ddpo.dml@hse.ie
Nenagh Hospital	ddpo.south@hse.ie
Our Lady of Lourdes Hospital, Drogheda	ddpo.dne@hse.ie
Our Lady's Hospital, Navan	ddpo.dml@hse.ie
Portiuncula University Hospital	ddpo.west@hse.ie
Roscommon University Hospital	ddpo.west@hse.ie
Sligo University Hospital	ddpo.west@hse.ie
South Tipperary General Hospital	ddpo.south@hse.ie
St Columcille's Hospital	ddpo.dml@hse.ie
St Luke's General Hospital, Kilkenny	ddpo.dml@hse.ie
St. Luke's Radiation Oncology Network	ddpo.dml@hse.ie
University Hospital Galway and Merlin Park University Hospital	ddpo.west@hse.ie
University Hospital Limerick	ddpo.south@hse.ie
University Hospital Waterford	ddpo.south@hse.ie
University Maternity Hospital Limerick	ddpo.south@hse.ie
Wexford General Hospital	ddpo.dml@hse.ie

CHO 1

<i>Donegal</i>	<i>ddpo.west@hse.ie</i>
<i>Sligo/Leitrim/West Cavan</i>	<i>ddpo.west@hse.ie</i>
<i>Cavan/Monaghan</i>	<i>ddpo.west@hse.ie</i>

CHO 2

<i>Galway</i>	<i>ddpo.west@hse.ie</i>
<i>Roscommon</i>	<i>ddpo.west@hse.ie</i>
<i>Mayo</i>	<i>ddpo.west@hse.ie</i>

CHO 3

<i>Clare</i>	<i>ddpo.west@hse.ie</i>
<i>Limerick</i>	<i>ddpo.west@hse.ie</i>
<i>North Tipperary/East Limerick</i>	<i>ddpo.west@hse.ie</i>

CHO 4

Kerry

Cork

CHO 5

South Tipperary

Carlow/Kilkenny

Waterford

Wexford

CHO 6

Wicklow

Dun Laoghaire

Dublin South East

CHO 7

Kildare/West Wicklow

Dublin West

Dublin South City

Dublin South West

CHO 8

Laois/Offaly

Longford/Westmeath

Louth/Meath

CHO 9

Dublin North

Dublin North Central

Dublin North West

ddpo.south@hse.ie

ddpo.south@hse.ie

ddpo.south@hse.ie

ddpo.south@hse.ie

ddpo.south@hse.ie

ddpo.south@hse.ie

ddpo.dne@hse.ie

ddpo.dne@hse.ie

ddpo.dne@hse.ie

ddpo.dml@hse.ie

ddpo.dml@hse.ie

ddpo.dml@hse.ie

ddpo.dml@hse.ie

ddpo.dne@hse.ie

ddpo.dne@hse.ie

ddpo.dne@hse.ie

ddpo.dne@hse.ie

ddpo.dne@hse.ie

ddpo.dne@hse.ie

Annex 6: HSE Data Breach Incident Form

Link to the HSE Data Breach Incident Form:

<https://healthservice.hse.ie/filelibrary/staff/data-breach-incident-report-form.pdf>

Link to HSE Dealing with Data Breaches:

<https://healthservice.hse.ie/staff/procedures-guidelines/data-protection/updated-information-on-dealing-with-data-breaches/>

Link to the HSE Data Breach Process Guidance

<https://www.hse.ie/eng/services/publications/pp/ict/data-protection-breach-management-policy.pdf>

Annex 7. Authorised Person appointment and Activation Mechanism Summary Flow Chart

HSE | R&D – HSE Pre-Screening Agreement HRR Amendment 2021

