



**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: <i>Please <u>also insert in the Activation Card</u> at the end of this Form</i>

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		
<i>Access Required</i>	Data:	Location
<i>Intended period for conducting Pre-Screening Actions</i>	Start Date:	End Date:
<i>HSE Health practitioner who will control & direct you in this HSE Entity</i>	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



 <p>PRE-SCREENING ACTIVATION CARD</p>	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