Point of Registration (PORE) SGA3 SOP

Project Number:	945539	Project Title:	HBP SGA3

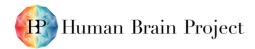|	
Document Title:	Standard Operation Procedure: HBP SGA3 Point of Registration (PORE)
Document File Name:	HBP SGA3 Point of Registration of Ethical concerns (PORE)_SOP.docx
Version:	Version 2
WP(s)/Task(s):	WP9/T9.4.2
WP Objective(s):	WPO9.2
Output(s):	OP9.9
Dissemination Level:	
Date:	SGA3 NOVEMBER 2021
Partner(s) Responsible:	UPPSALA UNIVERSITY, P83
Author(s):	Manuel GUERRERO, UPPSALA UNIVERSITY (P83)
Compiling Editor:	
Contributor(s):	Ethics Advisory Board, WP9, RIU-Hub, Ethics Rapporteur Programme
STC Review:	
Editorial Review:	
Abstract:	Point of Registration (PORE) Standard Operation Procedure for SGA3
Keywords:	Responsible Research and Innovation, Standard Operation Procedure
Target Users/Readers:	WPs; EAB; RIU-Hub

Table of Contents

1.   Problem statement

Requests to address ethics, regulatory and social issues in HBP research and innovation may come from any person at any time, from within the project community or from outside. Having a POint of REgistration (PORE) is a way to register and identify these issues and keep track of how they are dealt with.

2.   Stakeholders

Stakeholders of the POint of Registration (PORE) and for whom this SOP is intended are:

- HBP WPs Ethics Rapporteurs
- The EAB
- WP9 and the RIU-Hub Team
- The Data Protection Officer
- The Ombudsperson
- The community of HBP and HBP infrastructure users
- The Public

3.   Implementation

The PORE utility provides a way to identify and track ethical issues that anyone chooses to raise. It enables anyone to follow "issues" from start to finish.

PORE requests may be submitted anonymously or by identified requestors:

Open Requests - By completing an online form, any person may ask that the HBP ethics governance bodies advise on specific ethical, regulatory and social issues. Such submitted requests are registered in PORE. The PORE registrar performs triage to ensure that requests are appropriate; for example, the registrar redirects issues already addressed or for which standard operating procedures (SOPs) exist. The PORE registrar then recommends distribution to the attention of HBP's Ethics Coordination; and, typically, to the EAB, the Ombudsperson or the Data Protection Officer. Open requests are reported in simple and executive PORE reports (see below).

Anonymous Requests - Using the same online form, any person may choose to remain anonymous while asking that a specific ethical, regulatory or social issue be brought to attention.

PORE requests can be submitted using the following URLs:

- A PORE dedicated website: https://www.humanbrainproject.eu/en/social-ethical-reflective/about/register-ethical-concern/
- An online form, which appears in all Responsible Research and Innovation dedicated websites: https://nettskjema.uio.no/answer/99747.html

Where it is unclear how a PORE issue is to be addressed after discussion with the Ethics Director, the PORE registrar will forward them to the Ethics Coordination team (WP9 T9.4) for guidance.

Reporting and discussion of PORE registrations will be a standing item in the regular agendas of i) for all RIU-HUB, ii) WP9 Steering Committee and iii) EAB meetings.

4. Reporting

Completing and submitting the PORE form automatically initiates a **Simple PORE Individual Submission Report[1]** to be permanently stored in a Tresorit file. From these initial simple reports, an **Executive PORE Report** is prepared that summarises all live PORE issues.

4.1 The Simple PORE Individual Submission Report

The Simple PORE Individual Submission Report contains individual PORE submissions, with information, including the case number, the name of the person who submitted the request, the title of the full report (if there is one), and a brief background, a summary of facts, an opinion, if any, and plan for disposition, except in the cases where the requestor chooses to remain anonymous. The information included in anonymous entries is the case number, the title of the full report, a brief background, a summary of facts, an opinion if any, and a plan for or an indication of ultimate disposition.

The Simple Pore Individual Submission Reports are maintained in a secure location accessible to the PORE registrar and the Ethics Director.

4.2 The Executive PORE Report

Anonymous requests are reported in simple PORE individual and summary submission reports, but only anonymously. All names, institutional affiliation and other potentially personally-identifying information are removed.

The executive reports are distributed when appropriate to specific bodies, such as the Ethics Director, WP9 Steering Committee, EAB, Ombudsperson or the Data Protection Officer.

5. Review schedule

This SOP will be reviewed annually at the first RIU-Hub meeting.

---

[1] A report is issued with content in the following fields: IP address of sender's e-device; Submission ID; Submission Date; Enter name (or write "anonymous"); Select relevant work areas, if any; E-mail (If anonymous, leave blank); Title: (Provide a title which covers the content of the request, maximum 25words); ID-Number; Issue specification: (Describe); Affected parties: (specify); Who is to receive the advice?; Additional notes; No Label; Assigned; Disposed.