



SOP Title:	Point of Registration (PORE)
Partner Responsible:	Karolinska Institutet
SP / WP / Task Involved:	SP12, WP12.4, Task 12.4.3
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1 Introduction

Requests to address ethics, regulatory and social issues in HBP research may be made by a person any time - during initial planning of an experiment through phases of implementation, from within the project community or from outside. Having a POint of REgistration (PORE) is a way to keep track of these issues.

2 Background

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.

3 How it works

Open Requests - By completing an online form (see below) any person may ask that the HBP ethics body 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 that have already been addressed or for which standard operating procedures (SOPs) exist. The PORE registrar then recommends distribution to the attention of Ethics Management; and, typically, to the EAB and the SP12 Steering Committee. 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. 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 is removed.

Completing and submitting the PORE form automatically initiates a **simple report**¹ to be permanently stored in a Tresorit file. From these initial simple reports, an executive report is prepared that summarises all live PORE issues. The executive reports are distributed when

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 25 words); ID-Number; Issue specification: (Describe); Affected parties: (specify); Who is to receive the advice?; Additional notes; No Label; Assigned; Disposed.



appropriate to specific bodies, such as the Ethics Manager, SP12 Steering Committee, EAB or HBP management bodies.

PORE requests can be submitted using this URL:

[HBP_PORE](#)

Where it is unclear how a PORE issue is to be addressed after discussion with the Ethics Manager, the PORE registrar will forward them to the SP12 Steering Committee for guidance.

Regular reporting and discussion of PORE registrations will be a standing item in the regular agendas of *i)* for all Ethics Management , *ii)* SP12 Steering Committee, and *iii)* EAB meetings.

3.1 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. Information included in anonymous entries are 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 Manager.

3.2 Executive PORE Individual Submission Report

An overview of the main points of a PORE registration will be made publicly available in an Executive PORE Individual Submission Report.

3.3 Public PORE report

The PORE information will be publically available in a summary form, placed periodically, every quarter, on the Ethics Management webpages of www.humanbrainproject.eu that are made available to the public.

The Public PORE report will include tabled summary information, but after removing personally identifying information, including identity of the person who submitted the request,



names of persons participant in the matter, names of persons who will be provided with results.

3.4 Responsibility, Transparency and Quality Performance Improvement

All PORE process will be reviewed by the SP12 Steering Committee. PORE input and outcomes will be made publicly available in a suitably anonymised form, to ensure that the HBP members, the EC and the EC's expert ethics reviewers, and the general public have access to the current state of ethical thinking and processes within the HBP.

The SP12 Steering Committee has oversight and is responsible for delivering support.

The following table displays who has access to reports of different levels of information as described above.

Type of information	Source...		Routine access by:						
	Origin	person who submitted the request	PORE Registr.	EM	EAB	SP12-Steering Comm.	Board of Dir.	Public	EC
Simple PORE Individual Submission or Summary report	PORE Registrar	X	X	X					
Public PORE Individual Submission Report or Summary Table	PORE Registrar	X	X	X	X	X	X	X	X