



Factsheet: Informed Consent SOP

Standard Operating Procedure Name:	Date Written:	Date Approved by SIB:	Written by:	Keywords:
Informed Consent	06/02/17	17/08/17	Stephen Rainey	Informed consent, consent, templates, patients, participants

Purpose:

The IC SOP provides a set of minimum required standards and procedures for informed consent (IC) to be obtained by researchers in the Human Brain Project. These standards and procedures must form the basis of HBP IC. A single template covering all stakeholders' requirements on IC is not feasible. For this reason, the SOP does not prescribe IC documentation in detail. Rather, it sets out a format for what is required of such documentation for HBP purposes.

Key Concepts:

1. Obtaining IC involves providing research participants, or their proxies, with a written **information sheet**, describing the research and the participants' role in it, and a **consent form**, which each participant (or their proxy) must sign. Directive 2001/20/EC ought to feature as the touchstone for IC templates.
2. [Minimal Requirements](#) **MUST** be met.
3. Prior to signing the consent form, participants or their proxies, must also be given adequate opportunity to ask questions about the research and their participation in it.
4. A copy of the information sheet and a blank consent form, must be forwarded to the HBP's Ethics Management team in order to demonstrate ethics compliance
5. A decision might need to be taken about how to deal with '[incidental findings](#)' in the event that these arise.

Application to HBP Research:

"Consent should be a continuing process, especially in long-term trials or projects, researchers should foster a continuous dialogue with participants and inform them of anything new related to the trial."

The HBP is one such long-term project, and so this principle should ideally inform HBP researchers' approach. This will be reviewed periodically, at relevant stages of a given Task's progress (e.g., half way towards completion; following data collection; in advance of data source selection).

Related Documents:

[Compliance Checklist](#)