

New concept proposal

Standard Operating Procedure

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Project	General interest	Contact	DCC
Dataset release	2024.1	Consulted expert	-

1 Rationale

Experimental processes such as sample preparation and data analysis are usually described in a Standard Operating Procedure (SOP). The SOP is a step-by-step description of how experimental procedures should be conducted within an organization. An SOP is characterised by its name, the textual description, and a version. The purpose of the *Standard Operating Procedure* concept is to provide the textual description as agreed upon within an organization, for the protocol followed in an experimental process.

2 Comparison to other standards/data models

2.1 FAIR Genomes

FAIR Genomes has similar elements (text fields) for recording protocol information, as part of the Material model to describe the sampling protocol, and as part of the Analysis module to describe the Bioinformatics protocol. Each module has three fields: one for the protocol text, one for protocol deviation, and one to provide a reason for deviation. Since this might result in the same protocol text to be duplicated for each Material or Analysis record, we consider it better to factor this information out and compose protocol/SOP-related fields into a first-class concept. It can then be referenced instead of duplicated, and has its own identity. In addition, this also allows for additional context information such as versioning.

2.2 ENA

ENA has a text field as attribute to 'Experiment' to provide the 'Library Construction Protocol'.

3 Concept information

Concept or concept compositions or inherited	General concept name	General description	Contextualized concept name	Contextualized description	Type	Standard	Value set or subset	Meaning binding	Cardinality for composedOf
concept	Standard Operating Procedure	step-by-step instructions for carrying out routine operations imposed by the organization	Standard Operating Procedure	step-by-step instructions for carrying out routine operations imposed by the organization	SPHN Concept				
composedOf	name	name associated to the concept	name	name of the standard operating procedure	string				1:1
composedOf	description	description associated to the concept	description	description of the standard operating procedure	string				1:1
composedOf	version	version of the concept value or code	version	version of the standard operating procedure	string				1:1
composedOf	data file	data file associated to the concept	data file	data file associated to standard operating procedure	Data File				0:1

General concept name	Cardinality for concept to Administrative Case	Cardinality for concept to Data Provider	Cardinality for concept to Subject Pseudo Identifier	Cardinality for concept to Source System
Standard Operating Procedure	-	1:1	-	-

4 Impact on the SPHN Dataset

Optional (if existing concepts need to be adapted because of this new concept, state here the currently released version of the existing concept and the proposed adapted version)

5 Discussion

The documentation of the experimental steps to follow, or that has been followed, can be indicated as Protocol, or more broadly as Standard Operating Procedure (SOP). SOP has a notion that it is prescribed by an organization. It also may be broader than experimental protocols.

SOPs are available within organizations, but are usually available as documents or text that is not typed or classified, apart from an indication in its name. The experimental process that it prescribes and that it is linked to implicitly types the SOP. For instance, an SOP linked to a library construction concept is a library construction protocol/SOP.

It was discussed to name the proposed concept Protocol. However, a protocol generally only dictates *what* needs to be done, whereas an SOP outlines and documents *how* it needs to be done.

Currently, the SPHN model holds a *Procedure* concept that is defined as “invasive or non-invasive intervention performed for, with or on behalf of an individual whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions”. This is a process, in contrast to the procedure meant here, which is a prescription of how to conduct a procedure.

6 Example

A protocol for collecting tumor cells, passaging, and cryopreserving organoids.

name: Isolation, Culture, and Maintenance of Patient-Derived Tumor Biopsy

description: This protocol describes collecting tumor cells, passaging, and cryopreserving organoids [...]

version: V.1

data file: EDAM:format_3508 |PDF|

name: isolation_sop_v1.pdf