SEVENTH FRAMEWORK PROGRAMME

HEALS

Health and Environment-wide Associations based on Large population Surveys

FP7-ENV-2013- 603946

http://www.heals-eu.eu/

D20.2: Final report on compliance with ethical review requirements

Lead beneficiary: UPMC (now SU)

Date: 28/08/2019

Nature: Report

Dissemination level: Public

Document Information

Grant Agreement Number	ENV-603946	**Acronym**	HEALS
Full title	Health and Environment-wide Associations based on Large population Surveys		
Project URL	http://www.heals-eu.eu/		
EU Project Officer	Tuomo Karjalainen - Tuomo.KARJALAINEN@ec.europa.eu		

Deliverable	**Number**	20.2	**Title**	Final report on compliance with ethical review requirements
Work Package	**Number**	20	**Title**	Project Management

Delivery date	**Contractual**		**Actual**	
Status	Draft		Final ×	
Nature	Demonstrator ☐	Report X	Prototype ☐	Other ☐
Dissemination level	Confidential ☐	Public X		

Author (Partners)	Annesi-Maesano I (UPMC), Sarigiannis (AUTH),			
Responsible Author	Isabella Annesi-Maesano (UPMC)		**Email**	Isabella.annesi-maesano@inserm.fr
	Partner	UPMC	**Phone**	+3344738449

Document History

Name	Date	Version	Desciption

Aim

The aim of this deliverable is to show that one important concern of the HEALS project was to ensure compliance with the 'ethics requirements' set out in this project.

Description of Work and Role of Partners

A working group led by UPMC was set out to identify, clarify and fulfil the 'ethics requirements' that the HEALS project had to comply with during its activities. This included one member per country as well as .

Three types of requirements were dealt with:

1. The conduction on the field of the European Exposure and Health Examination Survey (EXHES) in which children and parents were recruited and followed-up in time to investigate the relationship between the exposome and health. One of the most basic ethical principles of medicine and epidemiology is the moral obligation to cause no harm to participants (non-malfeasance), whether physical or psychological. Although the risk in an epidemiological investigation is usually minimal, most people who take part gain no personal benefit. However, in EXHES will be informed on the result of the survey through an EXHES Newsletter sent to their address. The respect of ethics requirement in the conduction of EXHES was tested in each country by local Ethics committee (see table below).

Country	**Date of submission**	**Date of the approval**
Italy	July 2017	July 2017
France	May 2017	December 2019 The long delay in getting the approval is due to the the change of the law in France.
Croatia (2 centers)	April 2016	April (Medri) and June 2016 (Rijeka)
Slovenia	October 2016	October 2016 Due to the prolongation of the project an amendment was obtained in October 2018
Spain	December 2015	June 2016
Poland (3 centers)	Mars 2016 (Bioethical Committee in NIOM), March 2017 (Bioethical Committee at Medical University of Lodz), February 2017 (Bioethical Committee at Polish Mother's Memorial Hospital Research Institute)	April 2016 (Bioethical Committee in NIOM), April 2017 (Bioethical Committee at Medical University of Lodz), October 2017 (Bioethical Committee at Polish Mother's Memorial Hospital Research Institute)

Portugal (4 centers)	May 2016	September 2016 (Center 1) June 2017 (Center 2) December 2016 (Center 3) February 2017 (Center 4)
Germany	December 2014	December 2014
Greece	December 2017 And in September 2019 to be in compliance with GDPR rules	December 2017 And final approval in November 2018
UK	April 2017	April 2017

The table clearly shows disparities in procedures in getting ethics approvals.

2. The transfer of materials between the partners. A special example is the transfer of biospecimens in view of –omics to AUTH, TNO and FERA, all situated in Europe. All material exchange was covered by Material Safety Data Sheets (MSDS), while all other required authorizations will be provided.
3. The obligation to comply with ethical principles in general, as set out for instance in the European Code of Conduct for Research Integrity. Examples within the framework of this European Code of Conduct include avoiding falsification, plagiarism and other research misled.
4. Besides, the activities were in compliance with international, EU and national law of the different partners. There will be also an exclusive focus on applications at the population level.

The management team was in charge to collect all the relevant ethics clearances required to move forward with proper approvals and oversight including those for EXHES. A portfolio of the relevant ethics approvals can be found on the restricted part of the website.

Finally, all partners have declared that they will act in compliance with the EU regulation on Access and Benefit sharing (ABS regulation). In short, this regulation ensures the fair and equitable benefit sharing with a country when use is made of a genetic resource originating from that country. Of course, this is especially valid when this genetic resource leads to a commercial product.