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Science & Technology in childhood Obesity Policy

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Start date of project: 1st June 2018 Duration: 48 months

D1.3 Ethics Report – Period 1

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Dissemination Level

PU	Public	☒
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

Abbreviation	Definition
STOP	Science and Technology in childhood Obesity Policy
GDPR	General Data Protection Regulation
DoA	Description of Action
WP	Work package

Science and Technology in childhood Obesity Policy

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1 Executive Summary

This report is presented under deliverable 1.3, it details the status of the STOP Project in relation to its ethics requirements. This Ethics Report has been completed by the STOP independent Ethics Advisor, Prof. Amandine Garde (University of Liverpool). The role of the independent Ethics Advisor is to monitor the ethics issues involved in the project and how they are handled. This is the first ethics report submitted by the independent advisor, further reports will follow at the end of each reporting period (D1.4 for period 2 due in month 36 and D1.5 for period 3 due in month 48).

The ethics requirements needed by STOP originate from:

- national and EU regulations
- the requirements stated in the STOP contract (including its DoA)
- the requirements of the Horizon 2020 Programme

This report will focus on:

- informed consent
- the collection, storage, sharing and transfer of personal data
- cohort samples
- the management of conflicts of interest

2 Project Context

The STOP project brings together a range of key health and food sector actors to generate scientifically sound and policy-relevant evidence on the factors that have contributed to the spread of childhood obesity in EU Member States[1] and on the effects of alternative policy options available to address the problem. This evidence will complement, systematise and partly reframe the findings of an established body of prior research by leveraging the latest scientific findings. The STOP project will translate the evidence gathered and generated into:

1. A comprehensive set of indicators and a measurement framework for the regular monitoring of relevant dimensions of childhood obesity, its determinants and actions to address it in all European Countries.

2. Policy toolkits, providing practical guidance and tools for the design and the implementation of effective and sustainable policies and actions by governments and private sector stakeholders.

3. A novel, evidence-based, multi-stakeholder framework, to enable and promote a shared understanding of problems and solutions by key actors, relying on a structured process leveraging cognitive mapping and policy simulations validated by empirical data and empowering individual actors to take action within an agreed accountability and monitoring framework.

STOP will generate timely, comprehensive and policy-relevant measures of childhood obesity in all European countries; it will generate new trans-disciplinary evidence of the role of key determinants of childhood obesity, emphasising the role of different environments surrounding children, from analyses of detailed multi-dimensional measurements taken on several established EU children cohorts, including epigenetic and biological mediators of obesity; it will assess the impacts of policies

[1] The relevant EU countries are Belgium, Croatia, Estonia, Finland, France, Germany, Italy, Portugal, Romania, Slovenia, Spain, Sweden, and the United Kingdom. Switzerland, New Zealand and the United States are used as comparators.

and actions to address childhood obesity based on observations in the same children cohorts and policy simulations of the health, social and economic outcomes of policies.

Importantly, limiting health inequities is an integral part of the STOP project. Specific attention has been given to understanding why childhood obesity is most prevalent in disadvantaged children (primarily, but not exclusively, based on socio-economic status) and what policies can be most effective in addressing the problem for those children.

3 Ethical Issues

Work Package 12 sets out the ethics requirements that the project must comply with. The ethical issues in STOP arise from the use of biological samples from children with overweight and obesity. However, the collection of primary data will be minimal:

- Data collection for WP2 “Measuring childhood obesity, disparities and geographical variations” (lead: ICL) was carried out between M1 and M12 (June 2018-May 2019);
- Within WP3 “Key determinants of childhood obesity” (lead: ICL) and WP8 “Health Care” (lead: KI), biological samples will be collected and analysed.

The collection of this data will require particular attention be paid to ethical procedures, as laid out in WP12, to ensure that the STOP consortium is complying with national and European requirements, alongside those laid out in the conditions for funding under Horizon 2020.

4 Informed consent

- Participants involved in the study within WP8 have provided their written informed consent. This includes:
    - Informing participants about the project and its outcomes;
    - informing participants of their rights, including the right to withdraw;
    - ensuring participants are aware of any potential risk of harm involved in taking part;
    - ensuring confidentiality and anonymity.
- All informed consent documents have been supplied to the European Commission
- Pre-existing studies underwent ethical approval at inception with informed consent obtained by participants
    - Work complied with national legal and ethical frameworks
    - Approval was obtained by Ethics Committees

5 Data Protection

- The project will monitor compliance with the GDPR
- All STOP partners involved have a Data Protection Officer (or similar, if institutions are outside of the EU) in place who has confirmed compliance with the GDPR; deliverable 12.3 “POPD – Requirement” requires signed statements from these officers. This deliverable was submitted on the Portal on 30th June 2018.
    - Partners not bound by GDPR have submitted a statement which ensures an appropriate protection of personal data in accordance with its applicable rules and procedures. In particular, this applies to the World Health Organization (WHO), who, as a public international organisation consisting of 194 Member States and

Specialised Agency of the United Nations, is not subject to EU and/or national data protection legislation.

- Data collected before the GDPR became applicable does not fall under new requirements for consent and data collection retrospectively. However, transfer, storage, processing and destruction of previously collected data and material will refer to the GDPR. Moreover, the data collected was gathered following the obtention of ethical approval in the relevant institutions.

6 Data storage, sharing and transfer

- Data is stored on the restricted cloud storage software, STOP BOX. The software ensures that every file stored with them is maintained and encrypted using AES 256-bit encryption in geographically diverse areas.
- Access to data will only be to those working teams directly involved in the analysis and processing of the data.
- STOP works with partners in the USA, New Zealand and Switzerland. As such, some data may be exported to these countries for further analysis. These partners will comply with EU data protection rules.
- Data transfer will occur over secure servers to other members of the consortium with prior agreed access rights to the data.
- Data Protection Officers in place at all institutions.
- Data sharing agreed upon by all cohorts in the research agreement, with details provided in the information sheet supplied to participants.

7 Data processing/analysis

- Data will be pseudonymised
- Anonymity of participants is ensured

8 Cohort Samples

- Some biological samples have already been collected in the context of pre-existing research projects implemented by the project partners
- New biological data was obtained for some subsets, which was compliant with all ethics requirements under GDPR, ethics approval and informed consent obtained
    - When new participants were recruited or existing participants re-consented, the informed consent procedures were submitted to the European Commission as a deliverable, as specified in WP12 “Ethics Requirements”, deliverable 12.1 - requirement number 1.
- Particular care has been given to WP8 “Health Care”, which contains many large-scale experimental studies. In particular:
    - Blood samples collected in the study are optional and not a criterion for participation.
    - When taken, blood samples are taken by experienced nurses and a pain reducing cream is used to reduce any discomfort.
    - Urinary samples are non-invasive and thus cause no risk to the participants.

- The investigators have extensive experience conducting behavioural weight control studies, and active efforts will be taken by the staff to ensure the participating families' safety.

- Ensuring the avoidance of stigma for families and children with overweight and obesity is paramount in the WP8 study and was built into the research design. Positive encouragement rather than negative comments and blame will be critical to achieving this.

9 Conflict of Interest

- The Horizon 2020 call, Sustainable Food Security – Resilient and resource-efficient value chains, call ID: H2020-SFS-2016-2017 under the topic *How to tackle the childhood obesity epidemic?* (ID: SFS-39-2017), states that in order to tackle this epidemic 'societal challenge requires both interdisciplinary and multi-actor approaches engaging academics, policy makers, civil society and relevant industry and market actors.' As such, the STOP project engages with industry, and through doing so must be aware of the potential for conflict of interest.
- In particular, WP6 has commissioned four industry-led pilot projects, which aim to make an impact on the childhood obesity epidemic through various means such as technological innovations and the reformulation of food products.
- Each project team has been granted 150,000 EUR by the STOP project and will implement their pilot over the course of an 18-month period, with input from relevant STOP partners and third parties along its life course. The projects' success will be comprehensively evaluated at the end of the 18-month period by STOP partners and independent experts.
- Two of the four agreements have been signed and do not seem to raise major ethical concerns. However, the potential for real, perceived or potential conflict of interest between industry involvement and the STOP project must be continually monitored and the risk effectively managed.