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Science & Technology in childhood Obesity Policy

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D1.4: Ethics Report – Period 2

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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
WP	Work Package
RCT	Randomised Control Trial
ALSPAC	Children of the 90s data set
NCD-RisC	NCD Risk Factor Collaboration
BMI	Body Mass Index
EEA	European Economic Area
EU	European Union

Science and Technology in childhood Obesity Policy

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1 Executive Summary

This report is presented as Deliverable 1.4 and details the status of the STOP project in relation to its ethics requirements in period M18-M36. The Ethics Report has been completed by the STOP independent Ethics Advisor, Prof. Amandine Garde (University of Liverpool) as per the ethics requirement detailed in Deliverable D12.5 – GEN requirement no. 5. The role of the independent Ethics Advisor is to monitor the ethics issues that may arise in the project and how they are handled.

This is the second ethics report by the independent advisor covering the period M19-36. The first report focused on M1-18 of the project and detailed the ethical considerations relating to informed consent, the use of personal data, cohort samples, and the management of conflicts of interest. The third and final report will be submitted at the end of the project (M48) for 37-48.

The ethics requirements within the STOP project arise from:

- national and EU regulations;
- the requirements stated in the STOP contract (including its description of action); and
- the requirements of the Horizon 2020 Grant Programme.

This report will focus on:

- the impact of COVID-19 on the project;
- ethical issues by work package;
- the storage, sharing and transfer of personal data; and
- the UK-EU relationship.

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 complements, systematises and partly reframes the findings of an established body of prior research by leveraging the latest scientific findings. The STOP project is in the process of translating 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; and

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 is generating timely, comprehensive and policy-relevant measures of childhood obesity of relevance throughout Europe; it is generating new, trans-disciplinary evidence of the role of key

[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.

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 is assessing the impacts of policies 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 The Impact of COVID-19 on the Project

The COVID-19 pandemic has caused delays to the project and mitigation strategies have been enacted in the relevant areas of work. The ethical implications of such disruptions and mitigation strategies are limited to WP8, in which a randomised controlled trial of a primary care-based approach for addressing obesity in young children. The latter is the WP most affected by the pandemic in the STOP project. Further details of the impact on WP8 can be found below. All other WPs remain unaffected in relation to ethical considerations.

4 Ethical Issues by Work Package

Due to the type of research being carried out in certain WPs (such as primary data collection, or research involving children), the section below details the WPs where ethical considerations have been considered to a larger extent.

4.1 WP2 – Measuring childhood obesity, disparities and geographical variations

WP2 will leverage the NCD-RisC[2] data pooling and analytical approach to estimate, for the first time, mean BMI and prevalence of BMI categories, including overweight and obesity in children and adolescents of different ages and gender in all European countries, based on measured data on height and weight, from at least 1975.

Data on weight and height of children under five might be sought for the completion of Task 2.2 in case the COVID situation permits.

The study is implemented in accordance with the International Ethical Guidelines for Biomedical Research Involving Human Subjects[3]. Depending on local circumstances, ethical permission will be requested from relevant ethical committees.

Prior to the child's enrolment in the study, parents are fully informed of all study procedures, and their informed consent for the measurements and for data treatment (all written in local language) obtained on a voluntary basis. This is done either through a letter or through a school information meeting. The objectives of the study, anthropometric measurements and data treatment are

2 NCD-RisC (NCD Risk Factor Collaboration) is a network of health scientists around the world that provides rigorous and timely data on major risk factors for non-communicable diseases for all of the world's countries.

3 International ethical guidelines for biomedical research involving human subjects. Geneva, Council for International Organizations of Medical Sciences/World Health Organization, 1993.

explained. Depending on local laws and regulations, countries have the option of choosing passive or active informed consent.

Confidentiality of all collected and archived data is ensured. Identification numbers are assigned to the children and each register mentions only those numbers. No information on the subjects is given to anyone external to the research. Forms are stored in safes at the national coordinating centre.

The children's names are not included in the electronic data files.

It is vital that field workers carrying out the anthropometric measurements work in a way that avoids stigmatisation and bullying and that they acknowledge the rights of children and parents to withhold and to withdraw consent from the project at any time.

School-specific results are not provided to the schools.

4.2 WP3 – Key Determinants of Childhood Obesity

The overarching goal of WP3 is measuring and understanding the obesogenic behaviours of children and their families, and their health consequences over the life course, and how this varies by socio-economic status; and identifying the weakest links in the causal pathways that allow effective interventions. This WP makes use of data from existing cohorts, from which information will be extracted on obesogenic home, school and community environments and intermediate molecular pathways based on '-omics' measurements.

The data used is anonymised and does not include any biometric or genetic indicators that would allow for identification of individuals.

4.3 WP5 – Consumer Behaviour: Creating Demand for Healthy Lifestyles

WP5 aims to evaluate how national and local governments have created and promoted demand for health through social marketing and behavioural insights.

Work has started in Task 5.3 to carry out a series of behavioural experiments to test hypotheses around children's and parents' responses to social marketing incentives and behavioural interventions, in the context of obesity policies. These experiments will take place in two primary schools in Slovenia (one for the experiment, and one for the control group) with children from the 1st to the 4th grade, where each has a high proportion of children with the highest BMI.

The closure of schools due to the COVID-19 pandemic has delayed the start of the behavioural experiments. WP5 partners aim to run the experiment in the next school year (September 2021 – July 2022), if COVID-19 is considered to be at a manageable level and external researchers are permitted into schools.

The experiment will utilise an opt-in method in obtaining consent for participation for all parts of the research, unless a particular school prefers the opt-out method. Both options of consent will be explained to the participating schools. The sample pool options will therefore depend on the method relied upon to obtain consent. It will first be made clear to the schools that no child should be forced to participate in the research activities, and clear information sheets will be provided, based on which of the research activities are to be presented to children. To minimise the risk of personal bias of the researchers in choosing overweight children out of the potential sample pool, the researchers will strive towards a balanced sample without positive or negative discrimination of participants.

The research focuses on school lunches and snacks that children eat on their way to school, at the school, or on their way home from school. Interviews will be carried out with children to find out what food items they choose for school lunch, what they actually eat, and to ascertain if and/or why they

do not eat certain food items. These interviews will be carried out in the form of focus groups of three to six children, in order to create an amiable setting for the participants. If a child does not actively participate in the conversation and is uncooperative, researchers will consider this as their revoked consent. The child will be immediately escorted to the teacher, who will also be informed of what has happened. There are concerns of potential unwanted invasion of the research into the children's home environment, especially with snack diaries, which need to be partially filled in at home to document after-class snacks. This could overlap with dietary practices in the home environment, which are not the subject of the research. To avoid possible misunderstandings, the purpose of the snack diary will be clearly explained, as well as the time frame which the entered data should relate to.

The social marketing intervention will be based on the results of the first phase of research activities; therefore, the specifics and the focus of the intervention are not yet known at the moment. With the intervention, the researchers will strive to establish a positive attitude towards healthy components of school lunches and the well-being of children.

Special attention will be paid to planning the intervention so that it respects the personal rights of children and takes account of cultural and individual diversity (e.g. specific dietary limitations due to religious beliefs).

4.4 WP6 – Healthy Food and Food Choice Environments

WP6 seeks to identify ways of effectively promoting the supply and delivery of healthy foods through appropriate food reformulation and formulation programmes and through a redesign of key aspects of food environments to make them conducive to healthy food choices.

It has been decided that the WP6 food reformulation experiments on chocolate chip cookies would be conducted in the labs of a STOP partner (Agro Paris Tech) who had the appropriate facilities on-site. This decision not to rely on an industry partner avoids real, perceived or potential conflicts of interest between industry and STOP partners.

A further component of WP6 is the funding of four industry-led pilot projects, which aim to make a positive impact on childhood obesity through technological
innovations and the reformulation of food products. Each project team has been granted 150,000 EUR by the STOP project and is currently implementing a pilot project over an 18-month period with input from relevant STOP partners and third parties. The projects' success will be comprehensively evaluated at the end of the 18-month period by STOP partners and independent experts.

The four funded projects are:

- FlavorID, an app-based recipe recommender based off individual tastes and preferences with the aim to incorporate more vegetables into children's diets;
- MilaCel, a food reformulation project which uses apple fibre paste to reduce the fat and sugar content of food whilst retaining satiety and taste;
- the SWEET App, an app-based technology which delivers educational content to families with the ability to also browse and self-refer to non-medical sources of support in their own communities ('community assets') which focus on obesity prevention and physical activity; and
- Shift, a meal delivery service which aims to offer a healthy and affordable alternative to current takeaway options in two London boroughs.

28 competitive applications were submitted (one of which was not eligible for funding as it was presented in the wrong format). The 10 short-listed applicants were invited to the annual STOP

General Assembly Meeting in Paris (19-20 June 2019) to present their proposal and answer questions from the project consortium.

Four proposals were selected for funding after an internal evaluation by five WP leaders. One project did not proceed past the contract negotiation stage, due to a disagreement on the terms of project funding. A call for proposals to fund one further project was re-opened in April 2020. A project was selected after review of the seven submitted proposals, and began work in September 2020.

The four funded projects are at different points of completion, with the furthest along (FlavorID) currently trialling its app before an internal evaluation begins. A STOP evaluation of all four projects will be conducted in the final reporting period of the project. Ethical advice has been sought from the Head of the Library at ICL on how these evaluations should be conducted.

Regular monitoring of progress has taken place through monthly catch ups with all four project teams. No ethical concerns have been brought to my attention. Moreover, 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. Regular communication is maintained with the project teams to manage this risk via:

- monthly catch up calls;
- periodic reports at M6, M12 and M18 which detail the work carried out in the given period, deviations, deliverables, impact and risk management. The completion of an acceptable report is linked to the interim payment. Any information deemed concerning by the management team would be followed up with a meeting to provide clarity;
- presentations at STOP consortium roundtables, which offers a forum for questions and answers by partners to the project teams.

4.5 WP8 – Health Care

The first ethics report detailed the work completed in WP8 Health Care regarding the randomised control trial on an obesity intervention in Spain, Sweden and Romania.

Due to the COVID-19 pandemic, adjustments were made to the RCT in light of social distancing restrictions. The intervention originally entailed 10-weekly face-to-face group sessions which utilised evidence-based parenting practices, followed by the use of a mobile app for six months to support healthy eating and physical activity. The pandemic has made running the face-to-face group sessions impossible in both Romania and Spain, so the decision was made to deliver the intervention virtually. For Romania, a revised ethics approval document was submitted and approved in 2020 for this change. For Spain, no revision to the ethics application was required as the original agreement was broad enough to include any contingencies, as long as the objective and the ethics of the project were maintained.

Sweden’s group sessions were unaffected and continued to be delivered in-person.

4.6 WP10 – Multi-Stakeholder Action

The objective of WP10 is to contribute to the improvement of obesogenic environments by structuring stakeholders mobilization and participatory involvement, sharing knowledge, using a whole-of-society approach, promoting shared understanding of ‘health in all policies’ drivers, challenges and solutions of the obesogenic environment in which children live.

The first stakeholder survey was drafted at the time of the introduction of the GDPR. WP10 partners chose to interpret the GDPR in its strictest form, omitting the plan to work with the identified

stakeholders. Instead, stakeholders were anonymised and were identified only though the welfare triangle and field of work.

5 Data Storage, Sharing and Transfer

Data continues to be stored on the restricted cloud storage software, BOX, which ensures encryption in transit using AES 256-bit security.

Access to data is only granted to teams working directly on the analysis and processing of the data.

Many of the datasets used in the STOP project are openly accessible and downloadable online. For WPs which collect primary data, agreements are in place with the other partners involved to allow access.

Data transfer agreements currently exist in WP 2 and WP 3, between the following STOP partners:

WP 2:

- Sciensano and the Federal Public Service of Health (Brussels) and Imperial College London

WP 3:

- Imperial College London and University of Zagreb
- Imperial College London and University of Crete
- Imperial College London and CItta della Salute d della Scienza di Torino
- Imperial College London and University of Ljubljana
- Imperial College London and Barcelona Institute for Global Health (IS GLOBAL)
- Imperial College London and University of Timisoara
- Imperial College London and University College London
- Imperial College London and Children of the 90s (ALSPAC) University of Bristol
- Imperial College London and Swansea University
- Imperial College London and University of Porto
- Imperial College London and Universiteit Hasselt
- University of Torino and University of Helsinki

These data transfer agreements can be submitted to the European Commission on request, as per the project's ethics deliverable D12.3 POPD – requirement no. 3.

6 The UK and the EU

The UK left the EU on 31 January 2020 (with a transition period to 31 December 2020). Imperial College London is the only UK partner in the project and has ensured that appropriate measures are in place to guarantee the ability to continue to share data with STOP's European partners without violating any data protection laws.

There are a limited number of personal data shared between partners in the project. Most data have been anonymised in such a manner that the data subject is no longer identifiable. In the case of personal data transfer, Imperial College has data sharing agreements in place (as listed in the above section). Now that the UK is a 'third country' under the EU GDPR in terms of personal data transfers, Imperial College has ensured Standard Contractual Clause agreements are in place between the partners it shares data with (and vice versa).

Data transfers from the UK to the EEA (and other countries deemed to have effective data protection regulations by the EU) continue unaffected. The UK has adopted all of the existing European Commission adequacy decisions. In addition, the UK has declared that the EEA is a ‘safe place’ to transfer personal data, and therefore no other gateway mechanism is required for UK to EEA transfers. This is reflected in a UK-specific version of the GDPR (known as the “UK GDPR”) which took effect on 1 January 2021. The UK GDPR provides a replica regime for transfers of personal data outside the UK, similar to the rules in the EU GDPR for ex-EEA transfers.