SCALE-UP

User-Centric & Data Driven Solutions for Connected Urban Poles

D10.2 – Ethics monitoring report
Version 1.0

D10.2 – Ethics monitoring report			
WP No.	10	WP Title	Project Management and Ethics
Deliverable owner		ETRA	
Author(s)		Raquel Alario	
Reviewer(s)		ANTWERP, STA	
Due Date		30.11.2021	
Delivery Date		30.11.2021	

Version history		
Version	**Date**	**Summary of changes**
0.1	12.11.2021	ToC
0.2	19.11.2021	First draft ready for the peer review
0.3	25.11.2021	F. Kühl of STA review
1.0	30.11.2021	Final version

List of Acronyms	
Acronym	**Meaning**
AB	Advisory Board
EC	European Commission
EIGE	European Institute for Gender Equality
FUA	Functional Urban Area
GA	Grant Agreement
GDPR	General Data Protection Regulation
GEAR	Gender Equality in Academia and Research
GEP	Gender Equality Plan
PSC	Project Steering Committee
RRI	Responsible Research and Innovation
TEN-T	Trans-European Transport Network
UNE	Spanish Association for Standardisation
UNP	Urban Nodes Platform
WP	Work Package
PSC	Project Steering Committee

Legal Disclaimer

This project is co-funded under the European Framework Programme for Research and Innovation Horizon 2020 as part of the Societal Challenges call 2018 "Smart, Green and Integrated Transport".

Contents

List of Tables

1. Introduction

1.1. Aim

This document is aimed at describing the ethics monitoring procedure along the SCALE-UP project as well as how the Responsible Research and Innovation (RRI) strategy is addressed. This deliverable provides guidelines on how to manage ethical issues to ensure compliance with applicable international, EU and national laws. Moreover, it addressed the RRI which involves the participation of all stakeholders in all stages of the research and innovation process, and all the levels of governance of research and innovation.

This deliverable also describes the procedures and criteria to be used to identify and recruit research participants and the informed consent procedures to be implemented for the participation of humans, while the potential involvement of vulnerable individuals and groups is assessed.

Moreover, this report describes the role of a gender dimension within SCALE-UP to enable project partners to take it into account in their research tasks. Besides, the report aims at encouraging project partners to implement gender equality tools in their research teams within the project by explaining benefits and providing examples e.g., gender equality plans (GEP) and gender equality training.

This deliverable is an output of T10.3 "Ethics monitoring and Responsible Research & Innovation (RRI)", belonging to WP10 "Project Management and Ethics". This task addresses the ethical aspects of the SCALE-UP project and has been specifically created to also assume the workload of WP11 "Ethics requirements" which is a WP without allocated resources.

1.2. Scope

The scope of this document is to outline the role of ethical guidelines within the SCALE-UP project and to describe the modus operandi for managing ethical issues that may arise involving the relevant stakeholders in the project. Another aspect described in this document is RRI, with a focus on the gender dimension of SCALE-UP and gender equality of the participating research teams.

1.3. Structure

This deliverable starts with a short introduction of the scope and aim of the document, followed by a description of the ethics monitoring in the context of the SCALE-UP project. The Responsible Research and Innovation (RRI) strategy will be presented, deepening in the gender dimension and the public engagement topics. The instruments to achieve gender equality in research teams are outlined in section 4, while section 5 will focus on the procedures and criteria for participant recruitment. Complementing the recruitment procedure, section 6 will present the informed consent procedures and section 7 the *Information Sheet* and *Informed Consent Form* templates. Finally, the participation of vulnerable users, which is one of the key elements of SCALE-UP, will be addressed in section 8.

2. Ethics monitoring

The main goal of the ethics monitoring, which is part of T10.3, is to help SCALE-UP project partners to comply with the ethical principles to be taken into account in the research activities carried out along the project development.

2.1. Legal foundations of ethical principles

The Regulation No 1291/2013, more specifically Art. 19, defines the requirements to follow ethical principles while carrying out research activities within H2020 projects (1).

All the research and innovation activities carried out under Horizon 2020 shall comply with ethical principles and relevant national-, EU- and international legislation, including the Charter of Fundamental Rights of the European Union (2) and the European Convention on Human Rights (3) and its Supplementary Protocols. Particular attention shall be paid to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection.

2.2. Ethical research conduct

Apart from its legal foundation, ethical research practices are also based on fundamental principles of good research. The SCALE-UP Grant Agreement (GA)[1] defines in Article 34.1 the obligations of the project to comply with ethical and research integrity principles by means of complying to ethical principles (including the highest standards of research integrity) and applicable international-, EU- and national law.

Therefore, the beneficiaries must respect the fundamental principle of research integrity, as set out in the European Code of Conduct for Research Integrity (4). That implies compliance with four essential principles:

1. **Reliability** in ensuring the quality of research is reflected in the design, the methodology, the analysis and the use of resources;
2. **Honesty** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way;
3. **Respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment;
4. **Accountability** for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts.

Based on these foundations of ethical principles, all research activities in SCALE-UP are obliged to follow these principles. An assessment whether the research activities comply with these principles or not needs to be considered. Guidelines for monitoring and assessment are described in the following section.

2.3. Guidelines for ethics monitoring

To guarantee ethics monitoring of all of the research activities carried out along the project, two tools are set it place.

The first one is the ethics self-assessment, which was already carried out at the proposal stage so that partners can be aware of the ethical dimension of their research task and ethical issues are identified. Special care should be placed on ethical issues already detected: "Humans (research involving human participants)" and "Personal data (research involving personal data collection and/or processing)".

[1] SCALE-UP Grant Agreement 955332

In case new ethical issues arise during research tasks along the project, they need to be communicated to the Ethics Advisory Board (lead by ETRA and with the support of the cities Turku, Madrid and Antwerp) by using the *Ethics Issues* template as seen below in Table 1.

Discussion to find a solution may take place in a bilateral way, between the project partners identifying the issue and the ethics advisor, or among the whole consortium if transdisciplinary ethical issues arise.

Table 1. Ethics Issue Template

Date:	
Work Package:	
Specific Task:	
Project partner:	
Site:	
Contact of project partner who has identified the ethical issue:	
Specific ethics issue	
Relevant legal aspects (note: legal aspects might not be applicable for the ethical issue):	
Proposed Solution or mitigation measures:	
Ethics Advisor assessment:	
Reasoning behind the Ethics Advisor assessment:	
Date of decision:	

3. Responsible Research and Innovation (RRI) strategy

This section describes the Responsible Research and Innovation Strategy to be applied in H2020 research projects.

Responsible Research and Innovation (RRI) implies that "societal actors work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of society" (5).

As described in the SCALE-UP GA, "ETRA holds the UNE (Spanish Association for Standardisation) 166002 certificate, which establishes the requirements for a research & development and innovation management system. Furthermore, innovation management in SCALE-UP is based on a decision framework which is implemented within the Project Steering Committee (PSC). It helps to identify the type of innovations and evaluate these in terms of potential impact and the scope required to turn innovations into effective and sustainable solutions. The Communication and Exploitation Manager, STA, oversees related activities, supported by partners with different views involving a good mix of players from cities and industry to cover a broad perspective to address society needs and new city business models.

To this end, the joint workshops to be held during the project will be instrumental with external stakeholders, mainly the Urban Nodes Platform, as well as with other related research projects in H2020 and on national levels. These meetings will bring together different knowledge areas that are complementary to SCALE-UP and will be used to explore opportunities and for raising awareness on trends and certain technological issues such as roadblocks hindering the deployment of innovative solutions and city business models. Some of the SCALE-UP solutions may have complex value chains that require a range of actors to cooperate to find suitable city business models, as well as very specific innovation frameworks.

SCALE-UP will follow the Responsible Research and Innovation (RRI) precepts of the EC, involving the participation of all stakeholders (from people in the research community to the different levels of institutions), in all stages of the research and innovation process, and all the levels of governance of research and innovation (since the establishment of the agenda to the design, implementation and evaluation).

RRI is subcategorised in different elements, such as public engagement, open access, gender, ethics, as well as science education (5).

There can be different, creative, and innovative approaches for addressing RRI in H2020 projects. The approach that is undertaken in SCALE-UP has a strong focus on

ethical issues, in terms of data protection and therefore privacy rights of research participants. The access to sensitive information will be carefully controlled with restriction policies where appropriate. This topic is addressed in D10.3 "Data Management Plan", D11.1 "POPD Requirement No. 1" and D11.3. "H-Requirement No. 3". SCALE-UP will also provide open access to its scientific publications and research data, as explained in detail in D10.3. Academic institutions from SCALE-UP as well as the cities, through their educational sections, will ensure that research is put on the level of citizens to promote the interest of these fields, thus addressing the science education element.

Moreover, SCALE-UP will focus the RRI strategy on the topic of gender and public engagement, which will be addressed in the following subsections.

3.1. Gender equality of SCALE-UP

With the topic of gender being one of the relevant aspects of RRI strategies, it needs to be differentiated between two different aspects regarding gender-related questions.

On the one hand, the aspect of gender balance in research teams participating in SCALE-UP needs to be emphasised (addressed in Section 4 of this document) and on the other hand, the gender dimension in research and innovation of SCALE-UP itself needs to be explored.

The position paper of the advisory group for gender for the Horizon 2020 work program defines the concept of "gender dimensions" for research projects (6). It states that the gender dimension is a dynamic concept that ensures that researchers question gender norms and stereotypes and address the evolving needs and social roles of women and men.

It should be stated, first of all, that within the transport sector, gender-related inequality exists in various areas. Some examples are the gaps in access to transport infrastructure and services, inequalities within the transport labour market (e.g. weak representation of women in the decision-making process in the transport sector) and gender-based safety issues, most of which affect women. There is also a remarkable lack of data emphasising the mobility behaviour of women which helps to improve transport policies, and hence, reduce gender-related inequalities. In summary, although transport projects and policies are often considered to equally benefit women and men, there is a large body of professional literature emphasising that transport is not gender neutral.

Considering gender dimensions of innovation and integrating an in-depth understanding of both genders' needs, behaviours, and attitudes at an early stage of solutions' development will foster the societal relevance of the innovation and technologies and will therefore improve the suitability for entering potential markets (7).

Addressing gender dimension in research and innovation entails taking into account sex and gender throughout the whole research process, when developing concepts and theories, formulating research questions, collecting and analysing data and using the analytical tools that are specific to each scientific area.

The SCALE-UP project will guarantee, through its user-centric approach, that the widest possible diversity of sex and gender aspects are considered at an early stage of measure and strategy development to provide maximum safety, security, convenience and confidence to all users.

The SALE-UP partners are committed to addressing the gender-sensitive perspective of planning and working with the cities through proactive engagement mechanisms. The following aspects will be addressed when designing and enacting innovation:

- Assessing the differential impact that urban transport has on men and women respectively;
- Understanding gender-specific travel patterns as a significant factor in accounting for differences in mobility and travel behaviour;
- Planning of gender-sensitive communities keeping an eye on the equitable distribution of space and time and balancing these aspects within the innovation and entrepreneurial community;
- Supporting local authorities to identify the relevant entities and human resources who are able to support the process from this perspective with specific skills and knowledge;
- Identification of targets and indicators that help determine the degree of gender integration to aim for a gender-sensitive type of planning;
- Integration of the gender perspective into all stages of the planning process to avoid developing transport schemes that promote inequitable transport for women.

Additionally, all project partners are encouraged to give special attention to equal opportunities for women and men to participate in the project's co-creation process.

3.2. Public engagement

SCALE-UP will perform inclusive participatory multi-actor dialogues between researchers, policy makers, industry and civil society organisations.

This section introduces the activities of the SCALE-UP extended consortium, the producing of videos about the SCALE-UP project by STA, as well as the SCALE-UP website as three examples of public engagement undertaken within the project.

3.2.1. SCALE-UP Extended Consortium

The SCALE-UP consortium will be supported by an extended consortium, composed by the Urban Nodes Platform (UNP), the SCALE-UP urban nodes' local entities supporting the project, and the SCALE-UP Advisory Board (AB).

The Urban Nodes Platform (UNP) will consist of urban nodes willing to learn from the project, that will follow the project implementation, attend the relevant events and provide feedback but might not replicate the activities. This group will be constituted by Eurocities as part of WP9 activities and will bring together urban nodes representatives, national administrations, EU policy makers and academics. Institutional stakeholders, TEN-T Corridor Coordinators and relevant European networks will be also engaged in this UNP. The TEN-T and FUA-related activities, outputs, experiences and recommendations from SCALE-UP will be presented and discussed with a wider group of relevant stakeholders.

Regarding the SCALE-UP urban nodes, the cities of Antwerp, Madrid and Turku have already liaised with local entities at urban, regional and national level to collaborate and support in the project activities. These organizations will be informed about the project activities and outcomes and will have the opportunity to provide advice and feedback in their field of expertise.

Within the SCALE-UP project, an AB composed of international key experts in the areas related to planning and infrastructure, the TEN-T integration (as recommended by R&D project VitalNodes[2]), the digital/data dimension and the user-centric/passenger perspective has been established. Representatives of the MaaS Alliance[3], the European Passengers' Federation[4] and key experts on environment & infrastructure planning and transport and sustainable development from the

[2] https://vitalnodes.eu/
[3] https://maas-alliance.eu/
[4] http://www.epf.eu/wp/

University College London[5] and the University of Groningen[6], respectively, are part of the AB. The possibility of expanding the AB can be considered if needed.

This AB will be addressed at least 4 times along the project to provide advice from their perspective and field of expertise. Those meetings are also aimed at incorporating different points of views, collecting foreign feedback, and at the same time share the results of the project, so they can be considered to be incorporated in the stakeholder's activities. All of these partners will also have full access to the (intermediate) project results throughout the project.

The first of these meetings took place on November 10th, 2021[7], when Prof. Peter Jones, from University College London, joined the capacity building webinar dedicated to the so-called CREATE indicators, used for evaluating the context of change as a component of the overall SCALE-UP evaluation framework. The webinar was instrumental for the evaluation work within the project, so local evaluation managers and local coordinators from all three urban nodes attended the meeting. However, other project partners and even non-project partners thinking on and implementing innovative urban (mobility) policies were encouraged to attend the webinar.

3.2.2. SCALE-UP videos

Audio-visual productions in form of videos are an interesting tool to transmit key messages in a clear and brief way. Its visual character and its ability to say a lot in a short amount of time are key features to successfully reach a wide audience. Moreover, the possibilities of interaction and re-broadcasting offered by its publication in different social networks are another fundamental aspect to justify its value for the dissemination goals of the SCALE-UP project. A minimum of three videoclips will be produced during the lifecycle of the Project, which will be published on all outlets and embedded on the SCALE-UP website. The videos will be published at strategically important moments of the project, e.g., when specific milestones are reached. The first one will be produced after the first half of the project and the others at the end, to promote the project and to be displayed at events and workshops.

[5] https://www.ucl.ac.uk/
[6] https://www.rug.nl/?lang=en
[7] https://www.scale-up-project.eu/news/create-2021-11-11-zpe5m

3.2.3. SCALE-UP website

The SCALE-UP website[8] is the third example of engagement between the SCALE-UP consortium and the public. The SCALE-UP website was launched in August 2021, at an early stage of the project, and provides an overview of the actions taken and results generated by the consortium. It provides information about the project itself, as well as presentation videos of the cities, which are taking part in SCALE-UP (Antwerp, Madrid and Turku).

News: The news page contains a built-in blog, in which the consortium can publish its own news articles. reports on any ongoing activities. It can contain announcements, calls for collaboration or minutes to large consortium meetings.

There is also a Project's library and a new section containing documents and news that might be of interest for the consortium partners or citizens, serving as the principal and focal information point for partners inside and outside the Project. Finally, through the "engagement" section, visitors can contact the consortium, submit any question they might have, subscribe to the newsletter and in case of external stakeholders, register to become part of the UNP.

4. Gender equality in research teams

This section addresses the gender equality dimension in research teams. The objectives of gender equality in research teams are assessed and a GEP and its implementation are described.

The SCALE-UP consortium is thereby encouraged to explore and question their internal management approach towards gender equality in research teams and evaluate what has been achieved so far. If no gender equality plan is in force in their organisation, the project partners are encouraged to examine, whether a GEP could be implemented in the future.

Gender balance is aimed for at all levels of personnel named in the proposal who will be primarily responsible for carrying out the research and the innovation activities, also the experts engaged in the AB demonstrates the SCALE-UP ambition to achieve gender balance. Next to that, SCALE-UP will actively engage experts of all genders for the Community of Practice, the UNP and event participation.

[8] https://www.scale-up-project.eu/

4.1. Objectives of gender equality in research teams

Besides the gender dimension of the SCALE-UP project itself, the gender equality in research teams participating in the project needs to be emphasised.

Providing gender balance in research teams will catalyse three objectives:

1. Gender equality in scientific careers;
2. Gender balance in decision-making;
3. Integration of gender dimension in research and innovation content.

The first objective, gender equality in scientific careers, and the second objective, gender balance in decision-making, will be fostered to gather updated evidence as the basis of future policy-making. Therefore, the EU as European policymaker has a great interest in promoting gender-equal research teams working within H2020 research projects, in order to create updated evidence, created by professional and scientific talents from both genders (7).

Moreover, the third objective, the integration of the gender dimension in research contents, shows that the gender dimension of projects and gender equality are linked with each other. This objective is stated on the premises, that gender-equal research teams can automatically consider the gender dimension of research projects, as female and male researchers are both familiar with each of the physical differences of women and men as well as societal particularities of gender.

4.2. Gender equality plans

This subchapter describes the toolkit of Gender Equality Plans (GEPs), with a focus on Gender Equality in Academia and Research (GEAR-tool), established by the European Institute for Gender Equality (EIGE).

The EIGE aim is to "contribute to and strengthen the promotion of gender equality, including gender mainstreaming in all EU policies and the resulting national policies, and the fight against discrimination based on sex, as well as to raise EU citizens' awareness of gender equality." The policy areas covered by the EIGE's work range from the digital agenda to the environment and climate change and to the transport, amongst others.[9]

GEPs can be defined as "strategic and tailored initiatives meant to define the legal framework and the operational conditions to implement gender mainstreaming and put them into practice at the workplace". Moreover, they are "characterised by the

[9] https://eige.europa.eu/

identification of a set of strategic actions meant to reach, in a defined length of time, expected results in terms of gender equality." (8)

In the context of research organisations and higher education institutions, the European Commission defines a "Gender Equality Plan" as a set of actions aiming at (9):

1. Conducting impact assessment/audits of procedures and practices to identify gender bias;
2. Identifying and implementing innovative strategies to correct any bias;
3. Setting targets and monitoring progress via indicators.

The scope of GEPs can differ according to the type of organisation they are implemented within. Recently the intersectionality of gender bias has been acknowledged in regard with other inequality grounds such as disability, age, sexual orientation, religion, or ethnicity (10).

The implementation of GEPs can be split up in different phases (10):

1. An **analysis** phase, in which sex-disaggregated data is collected; procedures, processes and practices are critically assessed with a view to detect gender inequalities and gender bias;
2. A **planning** phase, in which objectives are defined, targets are set, actions and measures to remedy the identified problems are decided, resources and responsibilities are attributed, and timelines are agreed upon;
3. An **implementation** phase, in which activities are implemented and outreach efforts are undertaken to gradually expand the network of stakeholders;
4. A **monitoring** phase, in which the process and the progress are regularly followed through and assessed. Findings from the monitoring exercise(s) allow to adjust and to improve interventions, so that their results can be optimised.

The Gender Equality in Academia and Research (GEAR) tool is designed especially for academia and research institutions, providing them with practical advice and tools through all stages of institutional change, from setting up a GEP to evaluating its real impact. However, the defined phases for implementing GEPs (analyse, plan, implement and monitor) can also be used by most GEPs in different working organisations, irrespective of their specific scope (8).

The GEAR guide describes the following approach towards establishing a Gender Equality Plan step-by-step. All the consortium partners are encouraged to consult the GEAR tool guide (which will be uploaded to the project repositorium) in order to have further detailed information on the implementation process.

5. Procedures and criteria for participants recruitment

SCALE-UP will involve human beings on a voluntary and responsible basis (i.e. consent-based and free of charge) to take part in the research activities (i.e. surveys, workshops, etc.), as well as other stakeholders involved as external experts or taking part of project events. Persons willing to participate in some activities and/or being affected by the implementation of the measures at urban node level, will take part in a thorough recruitment and informed consent procedure, that will be particularly stringent to ensure no coercion (not even soft or indirect) is exerted. Voluntary and free participation must be ensured.

The identification and recruitment of research participants will be done in full compliance with any European- and national (i.e. the Belgian, Spanish and Finnish) legislation and directives relevant to the country in terms of General Data Protection Regulation (GDPR, presented in D11.1 "POPD Requirement No.1"), thus ensuring the protection of volunteers and guaranteeing non-discriminatory participation in SCALE-UP project. Research participants willing to take part in one or more activities (surveys, questionnaires, workshops, project events) will be part of a procedure that fulfils ethical standards complying with fundamental ethical principles according to European and national legislation.

The research will be conducted based on the following ethical ground rules:

- **Respect for persons**: research will aim to maximize benefit for individuals and society and minimize risk and harm; the rights, dignity, health, non-discrimination, non-malevolence and well-being of individuals and groups will be respected;
- **Gender balance**: a gender policy will be followed in order to guarantee gender balance during the overall project, according to the research process for Horizon 2020 (section 3.1);
- **Voluntary and appropriately informed participation**: the involved participants will be adults voluntarily engaged, based on direct negotiation on the set-up of the research and the potential risk of being harmed in any way. Their consent to participate will be given freely and based on an understanding of the risks and benefits. The project will avoid invading privacy, maintain confidentiality of data, obtain informed consent and remain available for the whole process for providing any necessary information. Protocols and documents will be implemented and translated in local languages;
- **Responsible conduct of research requiring**: the Consortium will carry both ethical and regulatory responsibilities to protect the welfare and interests of

individuals, to design the study, so as to minimize risks to them, and to obtain adequate training for protecting their interests and welfare. Research will be conducted with integrity, transparency and independence avoiding conflicts of interest, while lines of responsibility and accountability will be clearly defined;

- **Mutual duty of care**: all research partners will have a mutual duty of care to each other and to maintaining the project's autonomy. They also will have a duty of care to participants in ensuring that they are not put at risk of harm, as a result of their participation.

This section further defines the procedures and criteria to be considered when recruiting research participants for SCALE-UP.

5.1. Criteria for the involvement of research participants

For the engagement of suitable research participants along the SCALE-UP project, various criteria are subject to different dimensions, combining both ethical criteria with criteria that enable high-quality research. The Golden Rules to Ethical Research Conduct are taken as a reference (11):

- Respects the integrity and dignity of persons (that this intrinsic worth protects them from being used for greater perceived benefits);
- Follows the "Do no harm" principle. Any risks must be clearly communicated to subjects involved;
- Recognises the rights of individuals to privacy, personal data protection and freedom of movement;
- Honours the requirement of informed consent and continuous dialogue with research subjects;
- Respects the principle of proportionality: not imposing more than is necessary on your subjects or going beyond stated objectives (mission creep).

These criteria need to be considered to build the foundations of informed consent, the most important principle in research ethics. The foundation for informed consent are the three dimensions of adequate information, voluntariness and competence (11).

- **Adequate information:** in order to get a valid consent, general information on the SCALE-UP project and in-depth information on the research study for which the participation is requested should be provided. General information will highlight the scope of the project and the purpose of the research study while specific information on the procedures to be followed, the duration of the

study and how the results will be processed should be detailed. Potential research participants should be provided with adequate information in order to be able to decide if they want to take part on the study or not.

- **Voluntariness:** The *Consent Form* should highlight the voluntary nature of the participation in the study and be particularly stringent to ensure no coercion (not even soft or indirect) is exerted. To remove any type of soft or subtle coercion, the following actions should be undertaken (12):
  - The researcher carrying out the study should not be directly related to the research participant;
  - The consent process should be done via an impartial intermediary;
  - It should be clarified that the decision not to participate do not adversely affect the research participant in any way and that research subjects are free to leave the study at any time without penalty.

  Moreover, inducements are avoided and users participating in the trials will not receive any financial or other compensation for taking part in the studies;
- **Competence:** The person giving the consent should have sufficient mental competence or capacity to understand and retain relevant information about the research study for which their participation is requested and to communicate their views on the research.

5.2. Procedure for the involvement of research participants

The procedure to be followed for requiting research participants along the SCALE-UP project, meet the criteria previously defined and follows a two-step approach.

First of all, before the start of the study, it is of utmost importance that potential research participants fully understand the aim and the scope of the project in general and the research study in particular. Moreover, they should be aware of the implications and impact of their participation in order to make a decision on whether they want to participate or not. To do so, a SCALE-UP *Information Sheet* needs to be handed out to potential participants.

This *Information Sheet* is presented in section 7.1.1 and contains the project goals, duration and purpose of the study, the procedure of research activities and implications for the participant. It contains information regarding the use of data and guarantee of confidentiality and also emphasises the voluntary character of their participation and the rights to withdraw the consents given. The responsible researcher should provide any necessary clarification and answer any question potential participants may have to guarantee that they fully understand the research scope of SCALE-UP and feel fully informed.

In a second stage, the *Informed Consent Form* should be handed out to the eligible participants. The specific informed consent procedure is detailed in the following section.

6. Informed consent procedures

Partners carrying out research studies to achieve some of the objectives of the project or to evaluate the impact of some measures will be in charge of selecting potential participants, ensuring from the very first moment that the participation in the activity will be entirely voluntary. After providing enough information about SCALE-UP and the aim of the study, the responsible partner should hand out *Informed Consent Form* to each participant. By signing this consent form, the participant approves that they have received enough and adequate information (through the "*Information Sheet*") and moreover, the participant confirms their willingness to take part of the study in a voluntary way.

Once the *Informed Consent Form* is signed, the partner responsible of the study should keep a copy of the document on file.

A template of the *Informed Consent Form*, to be adapted as required depending on the particularities of the study, is presented in deliverable D11.3 "H Requirement No.3" and is also included in section 7.1.2.

Both, the *Information Sheet* and the *Informed Consent Form* are presented in Sections 7.1.1 and 7.1.2, respectively in English. However, project partners planning to carry out studies that involve human participation have been requested to translate these templates into an intelligible language for the research participant they are willing to engage. SCALE-UP partners have confirmed that both templates will be kept on file and they pledge to translate them into their local language in case research study is going to be performed. This confirmation is included in "D11.1 POPD Requirement No.1"

7. *Information Sheet* and *Informed Consent Form*

This section presents Template I (*Information Sheet* for research participants), as well as Template II (*Informed Consent Form*). Partners involved in research activities with humans will make use of these templates, although some tailoring may be required depending on the specific purpose/characteristics/format of the study, survey, workshop or activity carried out. The use of these templates guarantees that the relevant legal and ethical requirements for the protection of personal data are met.

7.1.1. Template I – *Information Sheet* for Research Participants

The *Information Sheet* needs to be handed out to the potential research participants in order to guarantee that they receive sufficient information about the project and the study so that they are able to make a decision on whether they want to participate or not.

Therefore, this template includes information about the project goals, duration and purpose of the study, the procedure of research activities and implications for the participant. It also emphasises the voluntary character of their participation and the rights to withdraw the consents given. The responsible researcher should provide any necessary clarification and answer any question potential participants may have about issues that remain unclear within the information process. The *Information Sheet* should be clear and straightforward.

Table 2. Information Letter for Trial Participants

Project Acronym	*SCALE-UP*
Project Name	*Scale up user-Centric and dAta driven soLutions for connEcted Urban Poles*
Grant Agreement No.	*955332*
Start Date of the Project	*01/06/2021*
End Date of the Project	*31/05/2025*
Website	*https://www.scale-up-project.eu/*
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 955332. 	
Dear participant, *You have been invited to take part in a research study within the European Innovation Action project SCALE-UP, focusing on urban mobility. Before deciding whether you want to participate or not in the study, please read this document carefully.* *Please ask any question that may arise, so that you are completely sure to understand all the proceedings of the study, including the risks and benefits.*	

Our goal is to provide you with clear, sufficient and understandable information that allows you to decide if you would like to participate in the SACLE-UP trials.

This information letter may include words or pieces of information that you do not understand. If this is the case, please ask the contact researcher or any member of the study to fully explain and clarify the words or processes you do not accurately understand. We are at your entire disposal to solve the possible doubts you may have. At all times, we assure compliance with applicable legislation on data protection according to the EU General Data Protection Regulation (GDPR) on the protection of individuals with regards to the processing of personal data and on the free movement of such data.

The procedure, duration and implications

The project activities will last for 48 months. Users who agree to join the trials will contribute to the implementation and assessment of some measures by participating in questionnaires, interviews, workshops and/or focus groups. The questions are oriented to get insights on your mobility patterns and to know the usefulness, ease of use and benefits of some of these measures. The trials do neither cause any health risks to the participants, nor do they cause any other disadvantages. Additionally, users participating in the trials will not receive any financial or other compensation for participating in this study.

Use of data and guarantee of confidentiality

The responses you provide in the questionnaires, interviews, workshops and/or focus group will be recorded. All your data will be coded under a pseudonym instead of using your real name, that will be neither stored nor transmitted to third parties. Your personal data will be always treated in compliance with the General Data Protection Regulation. No sensitive data will be collected at any moment (such as health, sexual orientation, ethnicity, political opinion, religious or philosophical conviction).

Your information will be processed in the data analysis stage of the measure implementation process and will be shown in project reports. It will not be possible to identify the source of the information. The results of the research study may be published in scientific journals or conferences and may be used in further studies. Personal data will never be handed out to third parties.

Voluntary participation and the right to withdraw the consent

Your authorization for the use and access to the information is valid until the end of the SCALE-UP project unless you decide to withdraw it before. If you

decide to withdraw your consent, please contact the leading researcher or any member of the study and let them know your intention to leave the study. *It is your decision whether you agree to grant us the to use and diffuse the information provided by you in the research study. You can decide not to participate, or you can withdraw your consent at any time if this is your will. In case you decide not to authorise the researchers to use the information provided by you or if you withdraw your consent later within the duration of the project, you will not be able to participate in the research study anymore.*
Questions and doubts *You have the right to ask any questions that may arise to you with respect to the project either before, during or after the study. Please, feel free to contact the responsible researchers of the SCALE-UP project at any time.*
Confirmation *Your participation in this study is only possible if you freely and independently sign the attached Informed Consent Form to authorize us to use the data you provide. If you do not wish to do so, you cannot participate in the SACALE-UP research study.*

7.1.2. Template II – *Informed Consent Form*

The *Informed Consent Form* needs to be provided to and signed by the potential research participants so as to guarantee that they give freely their conformity for participating in SCALE-UP project. Moreover, it needs to be signed by the responsible researcher of the project partner, who oversees the research participation process.

Table 3. Informed Consent Form for Trial Participants and Researchers

Informed Consent Form *I, Mr./Ms....., (in representation of .....) have received the information concerning the H2020 European project "SCALE-UP", in which I am going to collaborate defining the requirements and/or assessing the measures developed within the framework of the project.* *I have been sufficiently informed about the tasks to be carried out, conditions of these, goals of the project and use of the information obtained.*

I accept the conditions of these research studies, which require my participation for a lengthy period of time. I understand that my participation is voluntary, and that I can withdraw my consent to participate in the study at any moment, according to Art. 7 III 1 GDPR.

The legal basis for the processing of the personal data is the informed consent in accordance with Art. 6 I a) GDPR.

For these reasons, I give freely my conformity for:

☐ *Participating in the present research study.*

I hereby declare:

- *I am 18 years old or older and I am competent to provide consent;*
    - *(In case the research participant is not 18 years old, or not able to give consent: My legal guarding has explained the relevant information to me and has understood the scope of my participation in SCALE-UP. My legal guardian will sign this form on my behalf);*
- *I have been fully informed about the aims of the SCALE-UP project, in general, and the purposes of the present study, in particular. I understand that there is no compulsion to participate in the SCALE-UP trials and, if I choose to participate, I can withdraw my participation consent at any stage;*
- *I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I fully understand the description of the project and research study that is being provided to me (through the Information Sheet);*
- *I agree that my data (collected though surveys, questionnaires, interviews, workshops and/or focus groups) is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity;*
- *I understand that, subject to the constraints above, no recordings will be replayed in any public forum or made available to any audience other than the current researchers/research team;*
- *I freely and voluntarily agree to be part of this research study and I am aware of my legal and ethical rights;*
- *I understand that I may refuse to answer any question and that I may withdraw my consent at any time without penalty;*

- *I understand that my participation is fully anonymous and that no personal details about me will be recorded;*
- *Information may be shared between any of the other researcher(s) and partners participating in this Project in an anonymous form. All information I give will be treated as confidential. The researcher(s) will ensure to preserve my anonymity;*
- *I have received a copy of this agreement.*

This consent form is made pursuant to the relevant national, European and international data protection laws and regulations and personal data treatment obligations. Specifically, this consent document complies with the EU General Data Protection Regulation (GDPR) for the protection of individuals with regards to the processing of personal data and to the free movement of such personal data.

.....

Name and surname of participant

.....

Place, date and signature of participant

Statement of researcher's responsibility

I have explained the nature and purpose of the SCALE-UP project and the present research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and I have fully answered such questions. I believe that the participant understands my explanations and has freely given informed consent.

.....

Name and surname of the researcher

.....

Place, date and signature of the researcher

You can consult, modify or withdraw your consent and get access to the data provided in this research study by contacting the responsible researcher through the modes of contact indicated at the foot of this page.

.....

SCALE-UP responsible researcher: address, telephone number, e-mail address

7.1.3. Confirmation – Copy of *Informed Consent Form, Information Sheet* and informed consent procedure

This sub-section contains the template of confirmation to be filled and signed by SCALE-UP project partners regarding the *Informed Consent Forms* and the *Information Sheets*.

Project partners should confirm that the *Information Sheet* and the Inform consent form (previously presented) are kept on file. Moreover, they compromise to translate both templates into a language that is intelligible for the potential participants. This is included as an Annex in D11.1 "POPD-Requirement No. 1".

Additionally, by filling out this template, partners confirm that the detailed information on the informed consent procedures (detailed in section 5) will be kept on file.

Table 4. Partner Confirmation of Documentation

Confirmation of copy of Informed Consent Forms and Information Sheets

I,..... (Name of the partner representative) on behalf of..... (name of the institution) herby confirm that the templates regarding the:

1. *Information Sheet*
2. *Informed Consent Form*

Both, in English and ..... (specify your local language) will be kept on file, after they have been received.

These templates are part of deliverable "D11.3. H - Requirements No. 3", belonging to WP11 and to be submitted in M6.

Additionally, I hereby confirm that the detailed information on the informed consent procedures in regard to data processing (part of "D10.2. Ethics monitoring report"), will be kept on file.

.....

Date and Signature

8. Participation of vulnerable users

The SCALE-UP project will implement up to 28 innovative technological and non-technological mobility measures with a strong user-centric approach, focusing on the user needs for seamless multimodal transport and for increasing their freedom of choice.

With the purpose of leaving no one behind, vulnerable users are also a key component in the development of most of the measures, being the increased accessibility of sustainable transport modes for vulnerable users by 5%, one of the key impact indicators of the SCALE-UP project. Accurate information on vulnerable users' specific needs will be gathered to estimate their potential risks, concerns and capacities, and propose solutions for handling their situation.

Basic human rights principles, such as the empathy, openness, and security, should guide in general terms all interactions with research participants, while a balanced composition of participants should be kept. When undertaking a participatory assessment involving vulnerable individuals or groups, specific safeguards in terms of research ethics that are applied throughout the data collection activities need to be considered:

- The responsible researcher must strive to ensure that vulnerable users' participation is based on information, comprehension, and voluntariness;
- The users should freely decide whether they want to participate in the assessment or not;
- They should be informed about the purpose and process of the assessment and also be notified about its limitations;
- They should be informed about both the potential risks or inconveniences associated with participation as well as potential benefits arising from the assessment;

- They should be informed and reassured in regards to confidentiality;
- They should be allowed to express themselves freely without interruption or any negative comments;
- They should not be asked to provide information in public which embarrasses them or makes them feel uncomfortable.

Information Sheets will be handed out to the users, as well as consent forms. The information should be written with focus on an easy comprehensibility for the user, without excluding the legal implications, so that users can make an informed decision on their participation. Special needs will be considered in the information and consent form procedure, such as the visual impaired participants, for whom the procedure will be adapted accordingly.

Large events in Antwerp present suitable opportunities to address different kinds of mobility challenges and the inclusion more difficult to reach (vulnerable) target groups into the project. The city of Madrid will deploy car-free areas considering especially vulnerable user's needs, while Turku will deploy mobility guidance in connection with events and exceptional circumstances with a specific focus on the needs of vulnerable groups such as the visually impaired and increase accessibility when developing these elements. Both Turku and Antwerp will develop an incentives platform, a data platform to provide customized incentives towards different groups of end-users including vulnerable groups. These are just some of the measures requiring a deep understanding of the (travel) behaviour and user needs, and for which project partners will dig into user insights paying special attention to vulnerable user groups (low-income, mobility-impaired, etc). Moreover, the project will address the gender-sensitive perspective of planning and working with the cities, giving attention to equal opportunities for women and men to participate in the project's co-creation process.

9. Conclusions

This deliverable provides an overview of the legal foundation together with the fundamental rules for ethical research conduct and some guidelines to address the ethics monitoring in the most suitable way along the SCALE-UP project.

Moreover, this report describes the RRI strategy focusing on the gender dimension of the SCALE-UP project, together with the public engagement activities to be carried out along the project development.

Furthermore, SCALE-UP partners are encouraged to review their internal status on gender equality in their research teams and to implement gender equality tools, such as the GEAR tool, in case they find it suitable.

The ethics monitoring is a task undergoing along the 48 months of the project. Therefore, the Ethics Advisory Board (lead by ETRA and with the support of Antwerp, Madrid and Turku) will be constantly available for the project partners. In case any partner detects ethical issues within their research tasks, the ethics issues template should be used to report it to the Ethics Advisory Board in order to address and solve it in a collaborative way. The Ethics Advisory Board may use the interdisciplinary strength of the consortium to find suitable solutions for ethical issues.

This deliverable also contains all of the needed templates, which should be filled by both participants and partners before the involvement of any participants in studies carried out over the project lifetime. Further, all procedures for successful and ethical recruitment of participants is detailed, with a special focus on gender equality issues and vulnerable travelers, which will take place in an indirect or direct way in most of the 28 measures to be implemented along the project. It is also worth mentioning that the information already provided in deliverables of WP11, corresponding to "Human", "Protection of Personal Data" and "Environmental protection and Safety" also complement the work carried out in the ethics monitoring task.

10. Bibliography

1. **Parliament, European and Union, Council Of The European.** *REGULATION (EU), No 1291/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL.* Brussels, Belgium : Official Journal of the European Union, 2013. p. 11.

2. **Union, European.** *Charter of Fundamental Rights of the European Union.* Brussels, Belgium : Official Journal of the European Union, 2012.

3. **Rights, European Court Of Human and Europe, Council Of.** *European Convention On Human Rights.* Strasbourg, France : European Court of Human Rights, 1950.

4. **ALLEA.** *The European Code of Conduct for Research Integrity (Revised Edition).* Berlin, Germany : ALLEA - All European Academies, 2017.

5. **European Commission.** *Responsible research & innovation.* Brussels, Belgium : European Commission, 2021.

6. **Horizon 2020 Advisory Group on Gender.** *For a better integration of the gender dimension in Horizon 2020 Work Programme 2016-2017.* Brussels, Belgium : European Commission, 2015.

7. **European Commission.** *Work Programme 2018-2020, 16. Science with and for Society.* Brussels, Belgium : (European Commission Decision C(2020)6320 of 17 September 2020), 2020.

8. **Sansonetti, Silvia, et al.** *Gender Equality Plans in the private and public sectors in the European Union.* Brussels, Belgium : European Union, Directorate-General for Internal Policies, Policy Department C: Citizens' rights and constitutional affairs, 2017. p. 9.

9. **European Commission.** *A Reinforced European Research Area Partnership for Excellence and Growth, COM 392.* Brussels, Belgium : European Commission, 2012. p. 13.

10. **EIGE.** *Gender Equality in Academia and Research.* Vilnius, Lithuania : EIGE, 2021.

11. **European Commission.** *Ethics for researchers: Facilitating Research Excellence in FP7.* Brussels, Belgium : European Commission, 2013.

12. —. *European Textbook on Ethics in Research.* Brussels, Belgium : Research*eu, 2010.