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METICOS

A Platform for Monitoring and Prediction of Social Impact and Acceptability of Modern Border Control Technology

Deliverable D1.6

EPQ-Requirement No.9

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Abstract:	This deliverable report demonstrates the safety measures followed for the staff involved in this project.
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Disclaimer	This deliverable reflects only the author's views and the Commission is not responsible for any use that may be made of the information contained therein.

Document Description

Document Revision History

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v1.4	24/08/2021	Resubmission Draft	EUC
v2.0	06/09/2021	Final Resubmission version	EUC

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Terms and abbreviations

EC	European Commission

Executive Summary

The METICOS project deliverable D1.6 addresses the Ethics Requirement No. 9[1] - provided by the **Ethics Summary Report** as part of the **Horizon 2020 Ethics Appraisal Procedure.**

This deliverable demonstrates the appropriate safety procedures conforming to relevant local/national guidelines/legislation are followed for staff involved in project METICOS.

[1] EPQ - Requirement No. 9: "The applicant must demonstrate that appropriate safety procedures conforming to relevant local/national guidelines/legislation are followed for staff involved in this project.".

1 Introduction

The health and safety of all human participants (subjects, investigators etc.) in research must be a priority in all research studies. The kind of risks to researcher's safety vary according to the nature of the discipline, the topic and the research site. Only the 'researcher in the field' can fully assess safety concerns and/or their willingness to tolerate risks.

Health and safety measures will be put in place to be followed by partners involved in METICOS project as set out in the next sections of this deliverable.

However, research in both familiar and unfamiliar settings can involve health and safety concerns. Even in familiar settings, surprising, non-routine things can happen which pose safety risks. Moreover, in certain types of research, the risk of harm to the researcher is caused by the topic of study or by the actions of the researchers themselves. Lack of caution or failure to obey standard procedures may lead to physical or psychological harm.

This deliverable is prepared in accordance with section 2&7 of the Guidance How to complete your ethics self-assessment[2], sections which refer to any research involving work with humans ('research or study participants'), regardless of its nature or topic.

2European Commission, Horizon 2020 Programme Guidance How to complete your ethics self-assessment. Retrieved from: https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

2 Safety Procedures for staff involved in this project

2.1 Ethics Issues Check list

The Guidance provides an Ethics issues checklist which is hereto set out under Annex 1 and Annex 2.

To deal with the issues raised, the research must comply with:

- Ethical principles; and
- Applicable international, EU and national law (in particular, the legislation on public-health control and safety at work).

This implies that the people are respected, and human dignity and fair distribution of the benefits and burden of research is ensured, and that their values, rights of interest of the research participants are protected.
Following the provisions of the Guidance, for the purposes of METICOS project, participants will need to provide their informed consent and be provided with informed consent forms and information sheets. Templates of an information sheet and a consent form have been included in D1.1 – "H - Requirement No. 2".
Participation of researchers and data subject(s) will be entirely voluntary and will involve only adult individuals.

Participants' informed consent will be documented in advance. Their consent will be given in a form that is written in a language and in terms they can fully understand. That the information sheet and consent form describe the aims of the project, methods and implications of the research, the nature of the participation and any benefits, risks or discomfort that might ensue, explicitly state that participation is voluntary and that anyone has the right to refuse to participate and to withdraw their participation.

The participants will also be informed on how data is collected, protected during the project and either destroyed or reused subsequently.

It must be ensured that potential participants have fully understood the information and do not feel pressured or coerced into giving consent. Participants will be giving their consent in writing (e.g. by signing the informed consent form and information sheets). Templates of information sheet and consent form have been included in D1.1 "H - Requirement No. 2".

Children or other persons unable to give consent or that cannot give their consent in writing or people that lack the mental capacity **will not** be participating in the project and pilots.

2.2 METICOS pilots

METICOS project will involve Pilots that will take place physically in airport and land borders using devices at cross border control points. The METICOS consortium supports that good research via the pilots is possible with the mutual respect and confidence between the pilot activities and the participants if appropriate authorisations and health and safety measures are obtained and followed. For this reason, it is required under this deliverable to demonstrate that appropriate health and safety procedures conforming to relevant local/national guidelines/legislation are followed.

To do so each partner involved in the pilots should identify whether health and safety procedures are imposed by local/national guidelines/legislation and carefully describe these procedures to the responsible partner.

Taking into consideration the above it is not expected that there will be any additional health and safety measures to be applied to during the pilots to protect the physical and mental integrity of the METICOS pilot participants. The reason for this is that:

1) METICOS does not carry out any human research which entails more than minimal risks for physical and psychological harm, and which could threaten subject's integrity.

2) No subject will be involved in any study, experiment, trial, pilot, which entails more than minimal risks (i.e., the probability and magnitude of possible harms from participation in the study are not greater than those encountered in those aspects of everyday life that relate to the study).

3) INTRUSIVENESS: Pilots will never entail any offense to physical and mental integrity of the subject and the degree of intrusiveness will never go beyond any standard human-to-human social interaction. During pilots, only materials and technologies which attest to fulfil harmonized EU essential health and safety requirements, and which qualify for the CE Mark will be used.

4) METICOS will not be connected to the IT infrastructure of the cross border points and no personal data will be collected from the IT infrastructure of those cross border points. All personal data will be collected from the pilot participants through questionnaires, METICOS mobile application and table application.

Further, METICOS does not involve the use of elements that may cause harm to humans and research staff. The research staff will not be handling any toxic chemicals or radioactive materials and no special licenses will be required.

3 Conclusions

Following the above analysis and in accordance with the Guidance, what is required is for the researchers and data subjects participating in the project to provide their informed consent and be provided with a consent form and information sheet.

All participant researchers and data subject(s) will be healthy adult individuals capable of providing their written informed consent.

No additional safety procedures must be established to protect the physical and mental integrity of the METICOS pilot participants.

ANNEX: 1

Section 2: HUMANS		YES/NO		Page	Information to be provided	Documents to be provided/kept on file
Does your research involve human participants?		☐	☐		1) Confirm that informed consent has been obtained.	1) Informed Consent Forms + Information Sheet.
If **YES:**	-Are they volunteers for social or human sciences research?	☐	☐		1) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures.	1) Copies of ethics approvals (if required).
	-Are they persons unable to give informed consent (including children /minors)?	☐	☐		1) Details of the procedures for obtaining approval from guardian/legal representative and the agreement of the children or other minors. 2) What steps will you take to ensure that participants are not subjected to any form of coercion?	1) Copies of ethics approvals.
	-Are they vulnerable individuals or groups?	☐	☐		1) Details of the type of vulnerability. 2) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. These must demonstrate	1) Copies of ethics approvals.

					appropriate efforts to ensure fully informed understanding of the implications of participation.	
	-Are they children/minors?	☐	☐		1) Details of the age range. 2) What are your assent procedures and parental consent for children and other minors? 3) What steps will you take to ensure the welfare of the child or other minor? 4) What justification is there for involving minors?	1) Copies of ethics approvals.
	-Are they patients?	☐	☐		1) What disease/condition/disability do they have? 2) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 3) What is your policy on incidental findings?	1) Copies of ethics approvals.
	-Are they healthy volunteers for medical studies?	☐	☐			1) Copies of ethics approvals.
Does your research involve physical interventions on the study participants?		☐	☐			1) Copies of ethics approvals.

	-Does it involve invasive techniques *(e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies or the brain, TMS etc.)?*	☐	☐		1) Risk assessment for each technique and overall.	1) Copies of ethics approvals.
	-Does it involve collection of biological samples?	☐	☐		1) What type of samples will be collected? 2) What are your procedures for collecting biological samples?	1) Copies of ethics approvals.

ANNEX: 2

Section 7: ENVITONMENT & HEALTH AND SAFETY	YES/NO		Page	Information to be provided	Documents to be provided/kept on file
Does your research involve the use of elements that may cause harm to the environment, to animals or plants?	☐	☐		1) Risk-benefit analysis. 2) Show how you apply the precautionary principle (if relevant). 3) What safety measures will you take? Give details.	1) Safety classification of laboratory. 2) Copy of GMO and other authorisations (if required).
Does your research deal with endangered fauna and/or flora/protected areas?	☐	☐			1) Specific authorisations (if required).