MELCAYA

NOVEL HEALTH CARE STRATEGIES FOR MELANOMA IN CHILDREN, ADOLESCENETS AND YOUNG ADULTS

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D10.7 Plan for ethic-legal monitoring and ethical submissions 2

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Executive Summary

The content of the present document is the revision of the document *Plan for ethic-legal monitoring and ethical submissions 1* scheduled at M12 of the project. The latter covers the issues related to the ethical and legal monitoring planning of the MELCAYA project. Indeed, to address potential ethical and legal issues at the earliest stage and throughout the whole project, all consortium participants have been provided with a plan to ensure the same standard of knowledge for everyone. Thus, the main scope of this deliverable is to list both the activities performed and the checks made in order to ensure compliance with national and local legislations, as well as with the ethical requirements and guidelines of the European Commission.

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Acronyms & Abbreviations

Term	Description
CAYA	Children, Adolescent and Young Adults
MDTA	Material and Data Transfer Agreement
AI	Artificial Intelligence
M	Month
POPD	Protection of Personal Data
EC	European Commission
UCSC	Università Cattolica del Sacro Cuore
EMB	Ethics Monitoring Board
DKFZ	German Cancer Research Center

1 Introduction

The content of the present document is the revision of the document *Plan for ethic-legal monitoring and ethical submissions 1* scheduled at M12 of the project. The main scope of this deliverable is to list both the activities performed and the checks made in order to ensure compliance with national and local legislations, as well as with the ethical requirements and guidelines of the European Commission. However, the document will be further updated when and if needed, according to the technical progress and aligned with possible evolutions concerning relevant national legislations and directives of the countries where data will be collected, as well as international (i.e., European) ones.

Such activity ensures that matters of legality, ethics, and general conduct regarding different aspects of the project and research results are considered and implemented properly in the research process. Each partner has been asked to comply with the plan entitled *Plan for ethic-legal monitoring and ethical submissions 1*. Thus, all partners have been made responsible for ensuring that their specific research is carried out in accordance with the plan, and for ensuring that clients and other parties in the research agree to comply with the requirements as well.

In order to provide constant advice about ethical and legal issues that may arise during the project's lifecycle, a centralized service represented by Università Cattolica del Sacro Cuore (UCSC) team has been established starting from month 1. This team is responsible for the implementation and management of the ethical and legal issues entailed in all procedures in the project, ensuring that each of the partners adequately participates to MELCAYA and its code of conduct with respect to the participants.

2 Ethical and legal requirements

The Consortium is aware that the MELCAYA project must conform to a number of fundamental legislations, including:

- The United Nations Universal Declaration of Human Rights.
- The Charter of Fundamental Rights of the European Union (2000/C 364/01) and its Supplementary Protocols.
- The Declaration of Helsinki of World Medical Association in its latest version.
- The European Human Rights Convention.

- The principles enshrined in the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine**:** Convention on Human Rights and Biomedicine (Oviedo Bioethics Convention).
- The General Data Protection Regulation (GDPR) of the European Union.

Moreover, the Consortium is aware that the MELCAYA project must conform to several ethical guidelines to be followed for any research project in the EU, including:

- Guidance on "How to complete your ethics self-assessment".
- The Guidelines on FAIR (Findable, Accessible, Interoperable, and Re-usable) Data Management for Horizon Europe.
- The Guidelines to the Rules on Open Access to Scientific Publications and Open Access to Research Data in Horizon 2020.
- The Guidelines for Responsible Research and Innovation of the European Commission's Horizon 2020 Programme.

Finally, Article 14 of MELCAYA's Grant Agreement identifies several ethical references called "Ethics and values" to take into consideration by the Consortium.

3 Ethical and legal submissions

The Consortium is aware that the MELCAYA project includes a large number of ethical and legal sensitive activities. MELCAYA consortium intents to ensure that all the activities and outcomes of the project will comply with the abovementioned list of ethical-legal requirements. Due to the complexity of the subject, specific tasks have been assigned to those sensitive activities. Here is an overview of all the ethical-legal submissions of the project which were expected from these tasks:

- **Joint Controller Agreement** (M5): legal document to regulate data transfer relationships between the participant institutions.
- **Consortium Agreement** (M5): private agreement to set out the rights and obligations of the project beneficiaries. This includes organization, decision-making and financial questions, as well as the handling of intellectual property rights. A Material and Data Transfer Agreement (MDTA) will also be outlined in the Consortium Agreement to regulate the transfer of tangible research materials among institutions in the consortium.

- **Initiation packages of the clinical studies** (M9 for Immuno-Ped I, M11 for ExpoMel, NevustoMel, Mol-Mel, AI-Mel and Precis-Mel, M16 for Immuno-Ped II): the initiation package includes the final version of the study protocol approved by the regulators/ethics committees.
- **Data Management Plan** (M6): document detailing the mechanisms put in place to collect, store and process the large quantity of data generated in the project according to FAIR principles and considering the GDPR regulation. This document will also include information about how data will be curated and preserved during the project and after its end. The plan will be periodically revised, and an updated version will be submitted to the EC at M24 and M36.
- **Quality assurance and risk management plan** (M6): it monitors and evaluates the activities performed, the respect for gender dimension in research, and risk management.
- Additional ethical requirements:
  - ✓ **Protection of Personal Data (POPD) Requirement No.3** (M1): document including a clarification of how all the collected personal data will be limited to the purposes of the research project, that the project has lawful basis for data processing and a description of the anonymization/ pseudo-anonymization techniques to be implemented.
  - ✓ **H-Requirement No.2** (M3): document clarifying if and how incidental or secondary findings will be communicated to participants of the clinical studies.
  - ✓ **Artificial Intelligence (AI)-Requirement No.4** (M3): document with a detailed explanation on how humans will maintain meaningful control over the decision-making process for the use of prediction and diagnostic tools to be developed in the project.

4 Ethics Monitoring Board (EMB)

In order to provide constant advice about ethical and legal issues that may arise during the project's lifecycle, an Ethics Monitoring Board (EBM) has been established from month 1. It is responsible for the implementation and management of the ethical and legal issues entailed in all procedures in the project, ensuring that each of the partners adequately participates to MELCAYA and its code of conduct with respect to the participants.

The board is chaired by the Università Cattolica del Sacro Cuore (UCSC) team and composed of the following members:

Table 1 Composition of the EMB

Role	Name	Institution	Email
Coordinator	Dario Sacchini	UCSC	dario.sacchini@unicatt.it
Board member	Pietro Refolo	UCSC	pietro.refolo@unicatt.it
Board member	Costanza Raimondi	UCSC	costanza.raimondi1@unicatt.it

The EMB's main objective is to provide ongoing support to the MELCAYA consortium on all ethical and legal issues that may arise. The board consists of a centralized service that provides the essential advice, support and supervision regarding ethical issues that may be encountered within the project as it progresses. The Board also looks to raise awareness through initiatives regarding the ethical issues that are of interest to the Consortium.

The EMB ensures:

- That for all tasks carried out by all participating partners, adequate ethical procedures as described in the MELCAYA Consortium and Grant Agreement will be applied.
- That for all tasks carried out by all participating partners, adequate ethical procedures compliance with legislations and ethical guidelines are applied.
- That all participating partners will act within a common ground on ethical issues.

The general responsibilities of the EMB include:

- Overseeing the work throughout the entire course of the project to help the Consortium move forward and address possible issues that might arise (i.e., assuring a state of compliance with ethical standards within the relevant research fields).
- Validating reports and statements regarding the ethical adequacy of the planned research.

The EMB has been gathering monthly to supervise and review all the ethical and legal issues related to the development of the MELCAYA activities. The main points of action are listed in the next section.

5 Ethical-legal monitoring

The methodology adopted by the EBM for ethical-legal monitoring comprises of 2 fundamental steps, which are described below:

5.1 Documentation

The EMB performs the following activities when reviewing the ethical-legal documents:

- Verifying that all plans and documents comply with principles and norms established by legislations, ethical guidelines for research projects in the EU and MELCAYA's Grant Agreement.
- Verifying that authorizations/approvals from due institutions (for ex. Data Protection Authorities, Ethics Committees, etc.) are obtained.
- Verifying that all of the project's research and outcomes comply with the ethical-legal requirements established.

Here is an overview of the status of all the ethical-legal documents monitored by the EMB:

- **Joint Controller Agreement**: the document has been drafted, reviewed, and accepted by all partners. At the present time it is in the signing phase.
- **Consortium Agreement**: the document has been negotiated, drafted, reviewed, approved and signed by all the partners of the consortium (including associated partners).
- **Initiation packages of the clinical** studies (M9 for Immuno-Ped I, M11 for ExpoMel, NevustoMel, Mol-Mel, AI-Mel and Precis-Mel, M16 for Immuno-Ped II):
  - ✓ Study 1 (ExpoMel): the protocol awaits approval at the leading institution (UT).
  - ✓ Study 2 (NevustoMel): the protocol has received approval at the leading institution (HCB).
  - ✓ Study 3 (Mol-Mel): the protocol is awaiting approval at the leading institution (UNIFI), but it has been approved at participating institution HCB.
  - ✓ Study 4 (ImmunoPed 1): the protocol has been approved at the leading institution (UNIPG), and at a participating institutions HCB and INT.
  - ✓ Study 5 (AI-MEL): the protocol has been approved at the leading institution (DKFZ) and at participating institution HCB.
  - ✓ Study 6 (Precis-Mel): the protocol has been submitted and awaits approval at the only participating institution HCB.
- **Data Management Plan**: the document has been drafted, reviewed, accepted by all partners, and submitted to the EC for revision.
- **Quality assurance and risk management plan:** the document has been drafted, reviewed, accepted by all partners and submitted to EC for revision.
- Additional ethical requirements:

- ✓ **Protection of Personal Data (POPD) Requirement No.3**: the document has been submitted, reviewed and approved by the EC.
- ✓ **H-Requirement No.2**: the document has been submitted, reviewed and approved by the EC.
- ✓ **Artificial Intelligence (AI)-Requirement No.4**: the document has been submitted, reviewed and approved by the EC.

The EMB has also supported the German Cancer Research Center (DKFZ) in developing algorithms compliant with the "Ethics by design approach" supported by the European Commission (*Ethics by Design and Ethics of Use Approaches for Artificial Intelligence*). It is an approach for systematically and comprehensively including ethical considerations in the design and development process of new technological systems and devices. Although the approach can be applied to any technology, historically its focus has been on the design of AI systems. To do so, a web meeting was organized on November 27th 2023. The purpose of the meeting was to identify and discuss the ethical, social, and legal implications of utilizing AI-driven technologies for early detection of melanoma.

5.2 Internal reporting

In order to identify all possible ethical and legal concerns that may arise during the project lifecycle, a series of internal reports will be sent to all partners in order to receive feedback and be continuously aware of all the considerations or requirements. In that way, all partners will be in line with ethical-legal requirements and this will help us build a solid ethical-legal framework. This exchange of internal reports will continue until the end of the project. A first internal report about the ethical-legal issues encountered has been compiled for the period from 01/12/2022 to 31/05/2023 and a second one is underway for the period ranging from 01/06/2023 to 30/11/2023.

6 Conclusions

The present deliverable constitutes the second version of the management of ethical and legal aspects of the project at the time of delivery (November 2023). This deliverable presents the ethical-legal structure of MELCAYA, clarifying the ethics-legal monitoring activities. In doing so, the project will be compliant with relevant legislations and ethical guidelines, also identified in this document.