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UNDINE

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Executive Summary

A requirement for the conduction of the UNDINE project is the appointment of an external independent Ethics Advisory Board (EAB) to oversee any ethical concerns involved in its research. A first report by the board will be submitted as D9.2 in Month 6 of the project. The EAB will further produce annual reports on all potential ethical issues, and this report will be made available to the PO. Finally, the EAB will also participate in future meetings, stay informed on the progress of the project's activities, and have the opportunity to get in direct contact with UNDINE's PIs.

Three qualified researchers have been identified to serve as ethics advisors for UNDINE, who are specialists in different ethics aspects and who complement each other's expertise. The three board members are Prof Antonio G. Spagnolo (Catholic University of the Sacred Heart, Rome), Dr Benjamin Fairfax (University of Oxford) and Prof Jacob Giehm Mikkelsen (Aarhus University). A brief description of the advisors' expertise and their respective affiliation is listed below. More elaborate CVs are attached as appendices.

1. Antonio G. Spagnolo

Full Professor of Bioethics

Affiliation

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Expertise

Prof Spagnolo's education lies in medical and ethical fields with a specialization in the medico-legal field (more details in the CV attached). His area of expertise relevant to the advisory board is the well know ELSI (ethical, legal and social impact) analysis of the research and its methodologies, here with particular reference to ethical aspects.

Specifically, he will be assessing the implications of the research in the context of the autonomy of the subjects involved (privacy) and the principle of safety and precaution in accordance with Application of the EU Precautionary Principle.

2. Benjamin Fairfax

BM BCh, MRCP, PhD

Affiliation

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Expertise

Dr Fairfax is an Academic Clinician and works as a Principal Investigator in the Weatherall Institute for Molecular Medicine, University of Oxford where he oversees a laboratory. In addition he works as an Honorary Consultant Medical Oncologist at Oxford University Hospitals Trust. His academic interests focus on understanding the genetic determinants of human immune function. Dr Fairfax investigates how germline genetic variation influences the response to cancer immunotherapy, in order to modify clinical outcomes and the development of toxicity. He has extensive experience in the use of anonymised clinical samples and the analysis of large genetic and immunological datasets.

Dr Fairfax' speciality is the management of skin cancer and the immunotherapy in the adjuvant and metastatic setting, treating both melanoma and non-melanoma skin cancers. His own medical practice follows the ethical standards as set out by the Good Medical Practice guidelines from the General Medical Council (UK), which undergoes revalidation every five years (most recently in 2021).

3. Daniel Strech

Professor

Affiliation

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Expertise

Prof. Dr. Dr. Daniel Strech leads the Translational Bioethics at the Charité – Universitätsmedizin Berlin and has taken over a research group at the BIH QUEST Center for Transforming Biomedical Research. Daniel Strech is an internationally recognized expert on ethical and regulatory issues in pre-clinical and clinical research and in big data. He is a pioneer for a particularly practice-oriented bioethics, which is closely linked to meta-research and stakeholder research.

Daniel Strech has developed recommendations and approaches to improve biomedical research and increase its transparency. Among other things, he plays a leading role in the development of national guidelines for medical informatics and biobank research. At BIH he supports the implementation of innovative science-related guidelines and the development of the new research platform Clinical-Translational Sciences.

Abbreviations

D	Deliverable
EAB	Ethics Advisory Board
EC	European Commission
PI	Principal Investigator
PO	Project Officer UNDINE at EC
WP	Work Package
WT	Work Task