CEN

WORKSHOP

AGREEMENT

CWA 17145-2

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English version

Ethics assessment for research and innovation - Part 2: Ethical impact assessment framework

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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No.:CWA 17145-2:2017 E

Contents

Page

European foreword

CWA 17145-2:2017 was developed in accordance with CEN-CENELEC Guide 29 "CEN/CENELEC Workshop Agreements – The way to rapid agreement" and with the relevant provisions of CEN/CENELEC Internal Regulations - Part 2. It was agreed on 2017-05-22 in a Workshop by representatives of interested parties, approved and supported by CEN following a public call for participation made on 2015-08-01. It does not necessarily reflect the views of all stakeholders that might have an interest in its subject matter.

The final text of CWA 17145-2:2017 was submitted to CEN for publication on 2017-05-24.

A list of the individuals and organisations that supported the technical consensus represented by the CEN Workshop Agreement is available from the CEN-CENELEC Management Centre. These organisations were drawn from the following economic sectors industry, universities, civil society organisations, technology boards, European organisations.

Among the organisations and representatives who developed and approved CWA 17145-2:2017 are the following:

— Associazione Italiana per la Ricerca Industriale (AIRI), Italy	Andrea Porcari
— Austrian Agency for Research Integrity (OeAWI)/European Network of Research Integrity Offices (ENRIO), Austria	Nicole Foeger
— Bio Save Group, Serbia	Aleksandar Antovic
— Center for the Promotion of Science (CPN), Serbia	Dubravka Vejnovic
— Danish Board of Technology, Denmark	Lise Bitsch
	Rasmus Nielsen
— Danish Standards (DS), Denmark	Signe Annette Bøgh
	Katrine Bergh Skriver
— European Union of Science Journalists' Association (EUSJA)	Daniela Ovadia
	Dino Trescher
— Helsińska Fundacja Praw Czlowieka, Poland	Zuzanna Warso
	(Helsinski Foundation of Human Rights)
— Institute for advanced studies, Austria	Erich Griessler
	Robert Braun
— Lingköping University, Centre of applied ethics (LIU), Sweden	Göran Collste
	Johanna Romare
— National Cyber Security Centre, the Netherlands	Jeroen van der Ham
— Scientific Research Centre of the Slovenian Academy of Sciences and Arts, Institute of Philosophy (ZRC-SAZU), Slovenia	Rok Benčin
— The Castlegate Consultancy, Belgium	Diane Whitehouse
— Trilateral Research Ltd, United Kingdom	David Wright
	Rowena Rodrigues

— University of Bath, School of Management, United Kingdom	Konstantinos Iatridis
— University of Twente, the Netherlands	Philip A.E. Brey
	Philip H. Jansen
	Wessel Reijers

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Introduction

The increasing pace of technological developments such as genetic technologies, geo-engineering, ICT and synthetic biology has been stimulating questions and discussion on the desirability and governance of their societal impacts. Ethics assessment and ethical impact assessment help ethicists to investigate ethical challenges. Ethics assessment and ethical impact assessment help researchers, policy makers and relevant stakeholders to deal with the ethical impacts of research and innovation.

The need for agreed methods for ethics assessment and ethical impact assessment arises out of the increasing focus on responsible research and innovation in policy contexts and in collaborative efforts by researchers, as well as from new legal regulations for research and innovation at the European level. The European Commission, has been a driving force behind the development of ethics assessment and impact assessment practices, by incorporating the need for responsible research and innovation in its framework programmes.

The SATORI (Stakeholders Acting Together On the ethical impact assessment of Research and Innovation, www.satoriproject.eu) research project, funded by the European Commission, developed a framework for common basic ethical principles and joint approaches and practices with the objective of harmonizing and improving ethics assessment practices of research and innovation.

The SATORI project developed a framework based on research into existing practices. These research findings are the basis of this CWA. This CWA consists of two parts.

Part 1, outlined here, makes recommendations for the composition, role, functioning and procedures of ethics committee. Organisations can use part 1 to strengthen and/or improve the ethics assessment of their research and innovation projects. Ethics committees include, but are not limited to, research ethics committees, institutional review boards, ethical review committees, ethics boards, and units consisting of one or more ethics officers. Part 1 of the CWA is applicable to all ethics committees, regardless of their size, scope or research and innovation area.

Part 2 provides researchers and organisations with guidance on ethical impact assessment; a comprehensive approach for ethically assessing the actual and potential mid- and long-term impacts of research and innovation on society. Researchers and ethics committees will find this information useful as it describes ethical impact assessment at different stages of the ethical assessment. Part 2 is applicable to all researchers and innovators, regardless of the context they are working in or their research and innovation area.

1 Scope

This CEN Workshop Agreement (CWA) sets requirements and provides guidelines for ethics assessment of research and innovation.

The CWA aims to improve the quality of ethics assessment and harmonize ethics assessment practices.

The CWA consists of two parts:

— part 1 Ethics committee; Part 1 provides recommendations for the ethics committees on practices and procedures;

— part 2 Ethical impact assessment framework. This part provides a practical, policy-oriented guide for researchers and ethics assessors on the different stages of the ethical impact assessment (EIA) process.

Both parts of the CWA are of interest to organisations or agents involved in performing, commissioning or funding research and innovation, and therefore have a responsibility to address ethical issues.

The focus of the CWA is on ethics assessment, not on ethical guidance.

2 Terms and definitions

For the purposes of this document the following terms and definitions apply.

2.1
Delphi survey
method for estimating future measures by asking a group of experts to make estimates, recirculating the estimates back to the group, and repeating the process till the numbers/answers converge

[SOURCE: Global Foresight Glossary, 2013]

2.2
design intervention
deliberate action aimed at bringing about changes in the design of the R&I project and its outcomes in order to resolve identified ethical impacts

2.3
ethical impact
impact that concerns or affects human rights and responsibilities, benefits and harms, justice and fairness, well-being and the social good

2.4
ethical impact identification
use of foresight methods to describe different future applications of research and innovation (R&I)

[SOURCE: adapted from SATORI deliverable 4.3.1.2]