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English version

## Ethics assessment for research and innovation - Part 1: Ethics committee

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## European foreword

CWA 17145-1:2017 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 2017-03-27 in a Workshop by representatives of interested parties, approved and supported by CEN following a public call for participation made on 2017-08-01. It does not necessarily reflect the views of all stakeholders that might have an interest in its subject matter.

The final text of CWA 17145-1:2017 was submitted to CEN for publication on 2017-04-03.

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.

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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](http://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 document, (CWA 17145-1:2017) sets requirements and provides guidelines for ethics assessment in research and innovation (R&I).

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

The CWA has two parts:

- part 1: Ethics committee. This part provides recommendations for ethics committees on practices and procedures;
- part 2: Ethical impact assessment framework. Part 2 provides a practical, policy-oriented guide for researchers and ethics committees on the different stages of the ethical impact assessment (EIA) process.

Both parts of the CWA are of interest to organisations or agents who are 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

#### **avoidance of bias**

principle of avoiding partial data or participants selection, conclusions or presentation of findings due to prejudice, conflict of interest, etc

### 2.2

#### **avoidance of harm to human subjects and participants**

principle of minimising the potential harms to research subjects and participants as much as possible, if the risk of harm is unavoidable, with a primary goal of reducing unnecessary suffering

Note 1 to entry: This principle is applied in conjunction with the principles of beneficence and non-maleficence.

### 2.3

#### **beneficence**

principle of acting to the benefit of the participants and society; guaranteeing that any risk to people involved in or impacted by research is proportional to the expected benefits of the research, meaning that expected benefits always outweigh the risk involved

[SOURCE: adapted from Brey et al., 2016, and Beauchamp et al., 2001]

### 2.4

#### **care for animals used for scientific purposes**

principle of humane and considerate treatment, proper care and housing of animal subjects and avoiding unnecessary suffering by following the three Rs: replacing, reducing and refining the use of animals in experimental settings