The lesson from the SATORI project

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Aim of SATORI

- Development of a framework of common principles, protocols, procedures and best practices for the ethical assessment and guidance of research and innovation (R&I) in the European Union and beyond.

Project information

Project partners:	**17**
Number of staff:	**50+**
Budget:	**4.8 M (of which 3.8 EU-subidised)**
Funding scheme:	**FP7 (EU Science in Society)**
Running time:	**January 2014 – September 2017**
Total time spent:	**448 person months**
Interviews:	**250+**
Stakeholder input:	**500+**
Reports	**88; 32 main + 56 annexed (63 with findings, 25 with recommendations)**
Pages:	**3000+**
Website:	**satoriproject.eu**

Requirements

- The framework should include all scientific disciplines.

Requirements

- It should involve mutual learning

Requirements

- and stakeholder and public engagement

Requirements

- **and balance uniformity and diversity**

Requirements

- And be useful to a wide variety of ethics assessors

Our focus

Ethics Assessment

Any kind of assessment, evaluation, review, appraisal or valuation of practices, products and uses of research and innovation that makes use of primarily ethical principles or criteria.

- **"The proposed experiment does not live up to standards of informed consent."**
- **"The web browser that is proposed uses cookies in a way that violates privacy."**

Our focus

Ethical Guidance

The statement of ethical guidelines, principles, rules, codes, and recommendations to which research and innovation are expected to adhere.

- **"Experiment involving human subjects should involve informed consent."**
- **"Software should not violate the privacy of users"**

Ethics assessment and guidance

Three major kinds:

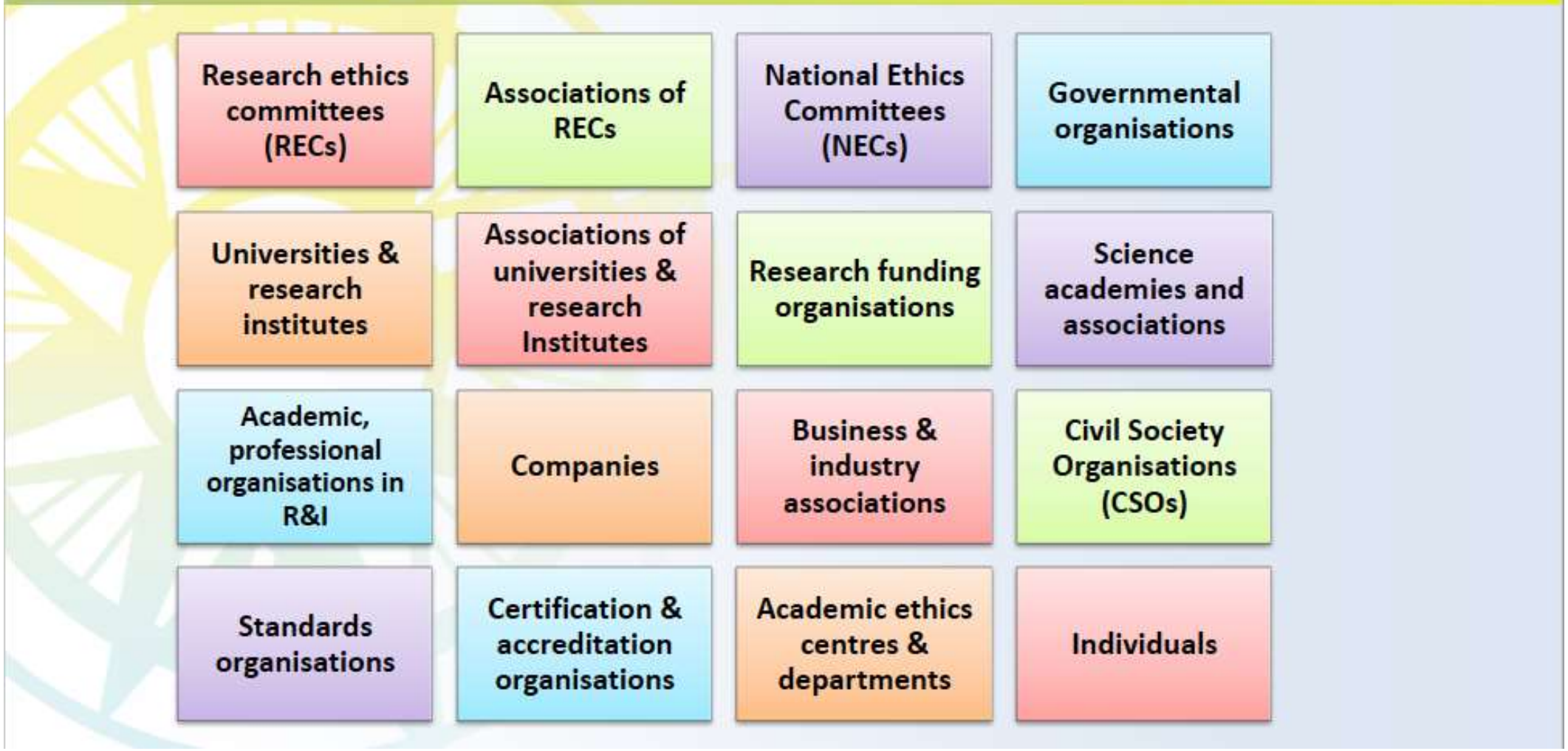
- Project- and practice-oriented
- Policy-oriented
- Oriented towards professional conduct

Our main focus: project-, practice- and policy-oriented ethics assessment

MAIN RESULTS AND RECOMMENDATIONS

1. FINDINGS

Organisations with a role in ethics assessment or guidance



Problems highlighted by organisations

Lack of clear standards, protocols, guidelines, tools

Heterogeneity in approaches/implementation

Fragmentary nature of procedures

Lack of resources

Overburdened ethics committees

Inconsistent reviews

Political conflicts, issue avoidance

Increase in bureaucracy

Lack of assessment of the effectiveness & impact of ethics assessment practices

Lack of public engagement

Lack of awareness

Lack of user friendly policies

Opinions on a shared approach

(n = 153)

- Desirability of a shared European approach for ethics assessment of research and innovation:

Yes:	52%	No:	9%
Conditional yes:	30%	Unsure:	9%

- *Perceived benefits:* harmonisation, convergence, platform for discussion and best practices, ethics promotion
- *Perceived obstacles:* national differences (law, culture, politics); ethical differences (values, norms); scientific differences (fields and disciplines)

Comparative analysis: scientific fields

- **Shared ethical concerns**: research integrity, social responsibility, protection of human research participants, protection of animals used in research, protection and management of data

- **Differences** in:
  - **specific ethical concerns** raised by distinct methods and subject matter
  - **degree** to which methods of ethics assessment are formal and institutionalised (e.g. medical sciences vs. humanities)
  - the **particular risks of different harms** caused by research

Comparative analysis: scientific fields

Medical sciences: **Focus on the *relationship between medical researcher and human subject*. Medical ethical principles such as autonomy, informed consent, beneficence, human dignity, and justice.**

Life sciences: **Focus on *relationship of researchers to living biological systems, ecosystems and the environment*. Ethical principles include animal welfare, ecosystems integrity, sustainability, health and environmental risks, naturalness and playing God.**

Comparative analysis: scientific fields

Natural sciences: **Focus on *truth and accuracy.* Principles: scientific integrity, data integrity, freedom from bias, and honesty**

Social sciences: **Focuses on the *relation between the researcher and human beings and social structures. Principles:* informed consent, equality, anonymity, confidentiality, privacy, fairness, nondiscrimination, human rights, avoidance of cultural and social bias, and respect. Also: data integrity, research integrity, objectivity**

Computer and information sciences: **Focus on the *processing, storage and dissemination of information*. Ethical principles: informational privacy, security, intellectual property, censorship and freedom of information.**

Comparative analysis: scientific fields

Engineering sciences: **Focuses on the *technological intervention into society.* Ethical principles include social responsibility, well-being, impacts on rights, the precautionary principle, sustainability, and the good of society.**

Humanities: **Focuses on *the study of human culture and the human condition*. Ethical issues include concern the proper conduct of the interpretation and construction of narratives, the proper role of works of imagination and art in society and our evaluation of them, and our responsibilities in the preservation of cultural heritage.**

Comparative analysis: scientific fields

Institutionalisation:

- **Very strong for medical sciences**
- **Somewhat weak but increasing for engineering sciences and social sciences**
- **Fairly weak for natural sciences (mostly limited to research integrity)**
- **Very weak for humanities**

Comparative analysis: countries

Countries examined: Austria, China, Denmark, France, Germany, The Netherlands, Poland, Serbia, Spain, UK & USA.

All countries are currently expanding their efforts in the area of ethics assessment and guidance.

Significant differences in the extent to which ethics of R&I is institutionalised.

Different focuses on ethical principles & issues

Role of government and law varies significantly

Role of CSOs also varies; some more significant than in others.

Comparative analysis: organisations

- National Ethics Committees (NECs): are mostly restricted to bioethical issues
- Research funding organisations: Same, and often limit themselves to legal issues
- CSOs: Interested to do more, but lack know-how to participate in ethics debates and reviews
- Industry: focus is on CSR, which is however much broader than ethics. Little attention to ethics assessment.
- Etc.

EU & global EA and guidance

EU

- Ethics review is **well organised at European Commission level**; supported and enhanced by European research funding organisations.
- **Variety of organisations** at Commission and European Parliament carrying out EA/guidance as part of their mandate
- **Specific laws and policy mechanisms** set a **solid base** for ethics assessment of R&I.

GLOBAL

- **Increasing interconnectivity** between regional actors.
- **Varied implementation** of global standards
- **Practical barriers** to implementing global ethical standards: language, timing
- **Concerns expressed**: adaptability to local conditions, existence of excess of standards.

Globalisation

Current ethics assessment procedures do not sufifciently account for the globalisation of R&I.

Globalisation of R&I gives rise to ethical issues pertaining to:

- outsourcing of R&I to low-income countries (ethics dumping);
- informed consent in low-income countries
- unfair proportion of risk to benefit in low-income countries;
- ensuring standards of care for research participants;
- sharing of benefits of R&I, bio-piracy

2. RECOMMENDATIONS

Ethics Assessment Procedures

Recommendations for the structure of ethics committees and the procedures they should adopt

- CEN-Standard
- Recommendations for different fields, organization types, etc.
- Covers:
  - Composition and Expertise
  - Appointment and Training
  - Procedures Before, During, and After Assessment
  - Quality Assurance
  - Efficiency Considerations
  - Organisational and Cultural Factors

Specific types of assessment and guidance

We outline standards, tools and best practices for:

1. **Assessment of R&I plans and practices by research ethics committees**
2. **Policy-oriented assessment and guidance of new fields, developments and practices in R&I**
3. **Specific procedures for ethical assessment of innovation and technology development plans**
4. **Guidance and assessment of ethical professional behaviour by scientists and innovators**

Ethical Impact assessment

A procedure for (1) anticipating, (2) identifying, (3) evaluating and (4) resolving current and future ethical impacts of research and innovation

Ethical impact = impact that raises one or more ethical issues

Ethical Guidance and Assessment for Specific Types of Organisations

- **Universities**
  - We recommend an integral approach towards ethics at universities that includes research ethics committees for all fields, ethics education, university-wide codes of conduct, ethics awareness raising, and scientific integrity policies and boards

- **CSOs (Civil Society Organisations)**
  - We disuss how CSO's can incorporate ethical guidance and assessment in their activities, how they can increase their involvement in RECs as representatives for interest groups, and how they can create ethics-assessment-related CSO networks for the exchange of best practices

Ethical Guidance and Assessment in Specific Types of Organisations:

- **Industry**
  - We define responsibility for ethics assessment for units across all organisational levels, we establish a company-wide ethics assessment strategy based on a structured, step-by-step procedure that links up with the company's CSR strategy

- **RFOs (Research Funding Organisations)**
  - We propose units procedures for in-house ethics assessment that extend to all funded fields

Proposals for the institutional structure of ethics assessment

We develop recommendations for the general institutional structure of ethics assessment in:

- Particular EU member states
- The EU as a whole
- The global institutional landscape

Proposals for the institutional structure of ethics assessment

- **Each EU member state should have**
  - National laws, policies and guidelines for ethics assessment (covering a broad range of organisations and issues)
  - one or more NECs that cover all scientific fields
  - A national association for RECs
  - Ethics assessment policies and support systems for the private sector (linked to CSR)
  - Mechanisms for incorporating ethic assessment in research and innovation policy

Proposals for the institutional structure of ethics assessment

- R&I ethics networks and platforms should be established at national, EU and international levels that cover multiple scientific disciplines and connect different types of organisations

- Ethics assessors and stakeholders should commit to national or international standards for the operation of RECs

CWA2: Ethical Impact Assessment

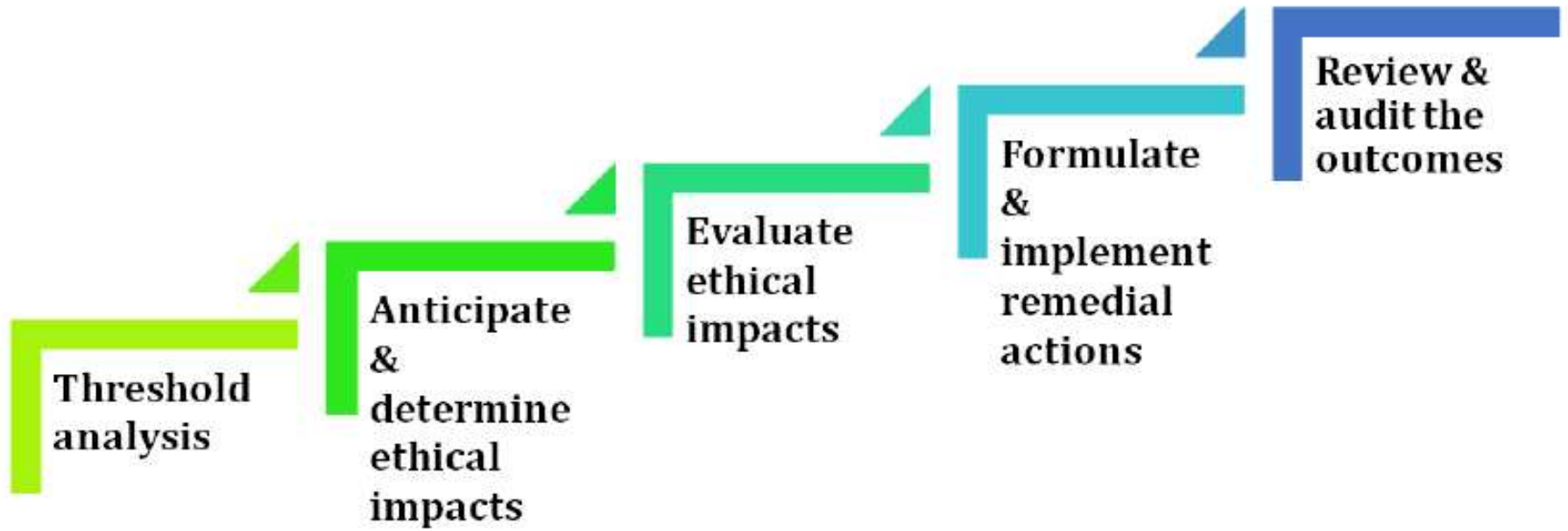
Shortcomings of Ethics Assessment

Ethics assessment often focuses on ethical issues that occur DURING R&I processes

No good method to address potential and actual IMPACTS of R&I on SOCIETY, and thus give content to SOCIAL RESPONSIBILITY

Main Structure

- Five stages:



Ethical impact anticipation and determination

- This is the determination of possible, probable and/or preferable ethical impacts of research and innovation
- Appropriate foresight methods are selected and used
- As a result, ethically problematic potential impacts are identified

Ethical impact evaluation

- This is the stage at which ethical issues are analysed and evaluated
- The precise nature and relative importance of ethical impacts is assessed
- Potential or actual conflicts of values are identified and, if possible, resolved

Remedial actions

- Recommendations for involved R&I actors to mitigate negative ethical impacts

A POSSIBLE MODEL FOR POLICY MAKERS

Scientific foresight for policy-making

Looking to the future

Mission of STOA

- STOA: Science and Technology Options Assessment
- STOA Panel: Scientific advisory body at the European Parliament
- To inform the MEPs with impartial, independent scientific evidence

THE ROLE OF MEDIA

The role of science journalist in ethics

- **Journalists are informal ethics assessors** -> see Satori interviews
- **Watchdog of science and scientists** -> professional misconduct, scientific frauds, conflict of interest… but also **moral values**, ethics, norms that will regulate or impact on new discoveries/technologies, or on new policies
- They **select** the key issues to be adressed and the problems for the society in the development of new technologies, products or discoveries, or in the application of new polices
- They **influence the policy makers** (see GMOs)
- They can **foster the public debate**, raise awareness and facilitate the dialogue among the different stakeholders

SATORI

The SATORI lesson on media representatives

- Science journalists can contribute to a more ethical science production and science policies by doing their job: investigate!
- Science journalists are indipendent actors, they are not spokepersons of RRI
- Science journalists can learn a lot from ethics of research and RRI, they can use the tools developed for RRI, can be trained in ethics of research for the purpose to enhance their professional skills and increasethe general level of awareness toward ethical and societal issues among the society
- There is a “EU problem” toward science journalism and RRI (embedded vs. indipendent) as sustainability is becoming a key issue for the scijourno profession
- We used the threshold anlysis to develop 16 key questions on ethical and societal impact of innovations and polices that can be used to tackle the possible issues and communicate them

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