Principles and Approaches in Ethics Assessment

Ethics and Risk

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June 2015

Annex 1.h

Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries

Deliverable 1.1

This deliverable and the work described in it is part of the project *Stakeholders Acting Together on the Ethical Impact Assessment of Research and Innovation - SATORI* - which received funding from the European Commission's Seventh Framework Programme *(FP7/2007-2013)* under grant agreement n° 612231

Contents

Abstract

This report aims to study and discuss the ethical aspects of risk assessment and management, and how risk plays a role in the ethical assessment of research. It introduces the central concepts – risk and ethics – and examines the different phases of the risk management process from the ethical point of view. It also describes the ethical principles used to determine whether the risks of conducting research are acceptable. The increasing complexity of systems, products and services due to new technological and social developments is making risk assessment and management more challenging and emphasizes the need to consider ethical issues systematically in the risk assessment process.

1. Risk, risk assessment and risk management

From ancient history the concept of "risk" has described the uncertainty about the outcome when making decisions about future actions or activities, such as: can I fly if I jump down from the steeple, or is there a rock in the sea if I sail to this direction? In the industrial era, risk came to mean the "possibility of loss or injury, or, possibility of loss, injury, disease, or death"[1] and measures have been developed to define risks quantitatively. Hence, Risk = $f\{P,C\}$ meaning that risk is a function or combination of the probability P and the consequence C.[2] It must be noted that the probability can be assigned to a defined consequence and the total risk, therefore, is the set of risks assigned to all possible scenarios:[3]

$$R = \{<S_i; L_i; X_i>\}_c$$

where:
S_i denotes risk scenario i;
L_i denotes the likelihood of that scenario; and
X_i denotes the consequences of that scenario.
The angle brackets < > enclose the triplets, the curly brackets mean 'a set of,' and the subscript c denotes complete, meaning that all of the important scenarios are included in the set.

Risk is also considered in situations that result in positive outcomes. The best traditional examples of this can be found in banking and financing applications where risk assessment and stress tests have been put to use. Similar thinking spread to industry as well with the consequence that the 'technical' definition of risk was revised to become:

Risk = effect of uncertainty on objectives.[4]

This definition highlights the significance of uncertainty, which is a complex but key issue in risk assessment and management, and which is also relevant to the ethics of risk assessment in many ways.

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[1] Merriam-Webster, "Risk". http://www.merriam-webster.com/dictionary/risk
[2] IEC 60300-3-9, "Dependability Management. Part 3: Application Guide. Section 9: Risk Analysis of Technological Systems". Finnish Electrotechnical Standards Association, 2000.
[3] Garrick, B. J., Hall, J. E., Kilger, M., McDonald, J. C., O'Toole, T., Probst, P. S., Zebroski, E. L., "Confronting the risks of terrorism: Making the right decisions." *Reliability Engineering and System Safety*, Vol. 86, 2004, pp. 129–176.
[4] SFS-ISO 31000, "Riskienhallinta. Periaatteet ja ohjeet (Risk management. Principles and guidelines)", Finnish Standards Association (Suomen Standardisoimisliitto), 2011.

Risk assessment in technology includes the following steps: scope definition, hazards and scenarios identification, probability assessment and consequence assessment, and risk assessment.[5] Risk evaluation[6] considers whether the assessed risk is acceptable. The final step is then risk management,[7] which defines the necessary risk management measures in order to keep the risk on the acceptable level.

The names and parts of the risk assessment and management process may differ in other sectors like food and health. The main idea, however, is that the phenomena must be known and they must be controlled and managed in order to be safe.[8] Specific tools (such as HAZOP,[9] fault tree analysis,[10] consequence analysis,[11] HACCP (Hazard Analysis and Critical Control Point)[12,13], etc.,) have been developed to identify hazardous phenomena, to model the cause-consequence scenarios, to assess the consequences and probabilities, and to calculate the risk.

Risk assessment offers transparency as the basis for decisions can be communicated which adds the understanding and helps in decision making in cases of known risks. If the risks – hazards, threats, potential consequences and the related probabilities – are unknown, risk assessment process may help to identify which data or knowledge is missing and must be obtained.

Risk evaluation is the phase of the risk management process where the acceptance of the assessed risk is evaluated. Risk evaluation is a value and morality based task. Usually, the (bigger) risk is acceptable if the resulting outcome is valuable. For example, gene technology has not been accepted in Europe in farming. In case of GMOs (genetically modified organisms) in Europe, the risk is perceived as being very high.

Zero risk does not exist: all decisions and actions involve some degree of risk. The straightforward risk assessment works fine in a known situation when there is data available and the risk acceptance criteria are known. This is more or less the case in the nuclear industry. In the chemical industry, the focus of risk assessment is in the identification of hazards and hazardous events and in managing them to avoid the loss of life, health, and property.[14] Risk awareness, a healthy organisational culture and resilience are the current focus in the chemical industry.

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[5] IEC 60300-3-9, "Dependability Management. Part 3: Application Guide. Section 9: Risk Analysis of Technological Systems". Finnish Electrotechnical Standards Association, 2000.
[6] Ibid.
[7] Ibid.
[8] Koivisto, R., *Safety-Conscious Process Design*, VTT Publications 264, Technical Research Centre of Finland, Espoo.
[9] IEC 61882, "Hazard and operability studies (HAZOP studies) – Application Guide", IEC 2001.
[10] IEC 61025, "International Standard, Fault tree analysis (FTA)", IEC 2006.
[11] CCPS, *Guidelines for Consequence Analysis of Chemical Releases*, 1995. http://www.aiche.org/ccps/publications/books/guidelines-consequence-analysis-chemical-releases
[12] U.S. Food and Drug Administration, "Hazard Analysis & Critical Control Points (HACCP)". http://www.fda.gov/Food/GuidanceRegulation/HACCP/
[13] FAO/WHO, *CAC/GL 30-1999: Principles and Guidelines for the Conduct of Microbiological Risk Assessment*, 2014. http://www.codexalimentarius.org/download/standards/357/CXG_030e_2014.pdf
[14] European Commission, Proposal for a Directive of the European Parliament and of the Council on control of major-accident hazards involving dangerous substances, COM(2010) 781, Brussels, 21.12.2010 http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52010PC0781&from=EN

In the current complex world, new techniques, materials, procedures, attitudes, values, etc., turn up more and more frequently with no available data for risk assessment. Sometimes even the underlying phenomena are unknown. For example, how do nanoparticles disperse in the human body and how do they affect it? What are new phenomena (risks) related to the Internet of Things (IoT)? What are the risks involved in the application of new gene technology? The uncertainties related to risks are not only connected to the probabilities but also to the different types of consequences. In these situations the issue is not only technical but new guidance is needed to tackle the human, moral and ethical aspects of risks: methods for ethical analysis are needed which can deal with probabilities.[15]

2. EU legislation on risk assessment and management

In EU the safety and security of citizens, environment and societies are ensured through different directives and regulations involving risk as the measuring tool. In the following, some few examples of risk related EU legislation are listed.

In the chemical industry, the processing and handling of hazardous materials, for example, are governed with the so-called Seveso directive,[16] packaging regulation,[17] and the REACH regulation.[18] The occupational health and safety of workers are protected by several directives and regulations.[19,20] The environment is also protected by the Seveso directive and REACH regulation, and emissions are controlled by Directive 2010/75/EU.[21] The use of energy, energy related products, and energy performance are governed by several directives.[22,23,24,25]

The health of citizens is the issue of several food related regulations: the use, labelling and traceability, food additives and packaging are regulated, for example. Several directives and regulations exist on the medical products and clinical practices. Genetically modified organisms (GMOs) and their deliberate release into the environment, their use as food and feed, traceability and labelling, and trans-boundary movement are regulated with several directives and regulations.

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[15] Hansson, Sven Ove, *The Ethics of Risk: Ethical Analysis in an Uncertain World*, Palgrave Macmillan, 2013.
[16] European Parliament and the Council, Directive 2012/18/EU of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC, OJ L 197/1, 24.7.2012.
[17] European Parliament and the Council, Regulation (EC) No 1272/2008 of 16 December 2008 on classification, labeling and packaging of substances and mixtures, OJ L 353/1, 31.12.2008.
[18] European Parliament and the Council, Regulation (EC) No 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 396/1, 30.12.2006.
[19] European Parliament and the Council, Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, OJ L 183, 26.6.1989.
[20] European Parliament and the Council, Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work, OJ L 131, 5.5.1998.
[21] European Parliament and the Council, Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control), OJ L 334/17, 17.12.2010.
[22] European Parliament and the Council, Directive 2010/31/EU of 19 May 2010 on the energy performance of buildings, OJ L 153/13, 18.6.2010.
[23] European Parliament and the Council, Directive 2009/125/EC of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products, OJ L 285/10, 31.10.2009.
[24] European Parliament and the Council, Directive 2009/28/EC of 23 April 2009 on the promotion of the use of energy from renewable sources, OJ L 140/16, 5.6.2009.
[25] European Parliament and the Council, Directive 2006/32/EC of 5 April 2006 on energy end-use efficiency and energy services and repealing Council Directive 93/76/EEC, OJ L 114/64, 27.4.2006.

Other sectors that are carefully regulated include information and communication technologies, aviation and the nuclear industry. Aviation and nuclear industry were the first sectors that applied quantitative risk assessment and they both have their own specific regulations and codes of conducts.

3. Values and principles

Ethics concerns our ideas of right and wrong. It helps us to reflect on our moral intuitions about what we find valuable in life and on the ways that we can promote them in ourselves and in how we interact with others. Ethical values are things that we believe are good and worth striving for. Values include justice, equality, duty, and respect for others and ourselves. Ethical principles are general accounts of how to implement values through our actions. Ethical issues are situations or problems that require ethical reflection to decide how to ensure that our values and principles are reflected in our response to them. This section presents a brief account of the most important ethical values and principles in risk assessment, while the next section discusses some of the major ethical issues within this field.

Risk assessment is motivated by the desire to reduce the possibility of harm occurring. The prevailing methodology of risk assessment is mainly based on probabilities of the identified outcomes (consequences). The emphasis on consequences closely aligns risk assessment with the ethical theory of consequentialism, which uses the outcomes of actions to determine their moral worth.[26] An action is morally good if the overall positive consequences of it occurring are greater than the negative consequences. Each person affected by an action is treated equally: an action that gives a minor benefit to a few people while harming many more would be rejected, regardless of who the people affected are.

Consequentialism has a broad range of versions that differ in how they evaluate consequences. One form of consequentialism, called utilitarianism, evaluates consequences based on how they affect the utility (which is usually understood as happiness or well-being) of those affected.[27] Actions that cause greater happiness or pleasure than they cause pain are morally good for utilitarians. The emphasis on happiness leaves utilitarianism open to criticism, especially if the sources of happiness would otherwise be considered morally objectionable.[28] Other forms of consequentialism consider how well an action satisfies the preferences of those affected.[29] Preference satisfaction does not necessarily have to bring happiness, so it avoids the problems that focusing on pleasure that affect utilitarianism.

As consequentialism necessarily deals with future actions, it must address the inherent uncertainty about the actual effects of an action will be. There are two broad approaches to addressing the problem of uncertainty about outcomes: actual utility and expected utility. Actual utility takes into account only the actual outcomes of the action. As a result, it can only be applied retrospectively, and cannot guide our decisions about which action to take.[30] Relying solely on actual utility is also often counter-intuitive, as it would justify unnecessarily

[26] Sinnott-Armstrong, Walter, "Consequentialism", in Edward N. Zalta (ed.), *The Stanford Encyclopedia of Philosophy*, Spring 2014. http://plato.stanford.edu/archives/spr2014/entries/consequentialism/.
[27] Ibid.
[28] Ibid.
[29] Ibid.
[30] Hansson, Sven Ove, "Risk", in Edward N. Zalta (ed.), *The Stanford Encyclopedia of Philosophy*, Spring 2014. http://plato.stanford.edu/archives/spr2014/entries/risk/.

risky but successful behaviour while rejecting otherwise uncontroversial actions that nevertheless fail. For example, a driver who ran red lights without causing any traffic accidents would not be regarded as having done something morally wrong on this basis.

Expected utility is a more promising response to uncertainty. This form of consequentialism considers the probable consequences of an action. An action with a high probability of moderately good consequences would be a better choice than an action with a small chance of extremely good consequences. Similarly, actions with a significant chance of causing harmful consequences (such as running red lights while driving) would be rejected.

Despite these advantages over relying on actual utility, expected utility faces its own difficulties. If each person affected is considered equally, it creates the possibility that a single person facing a great risk is preferable to a large number of people facing a very small risk.[31] For example, if one person faces a 90% chance of death and a one hundred have a 0.01% of death, expected utility consequentialism would recommend the first option, regardless of its apparent unfairness.[32] While this does not necessarily mean that consequentialism should be rejected, it does suggest that other concerns such as fairness and responsibility also need to be taken into account.

The precautionary principle is another response to risk. It captures the intuition (expressed in adages like 'it is better to be safe than sorry') that it is better to avoid significant harms than to address them after they have occurred.[33] This response is described in the 1992 Rio Declaration of the United Nations Environment Programme (UNEP):

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.[34]

References to the precautionary principle can be found in the EC Treaty and in various European policies and legal decisions.[35] While the precautionary principle is usually a guideline in environmental policy, it has applications to any field where there is genuine scientific uncertainty about the level of risk associated with a potential damaging and irreversible threat.[36]

The lack of a commonly accepted definition and the wide variety of formulations suggest that it is clearer to refer to precautionary *principles* rather than a single principle.[37] Some common features can be identified, however. Per Sandin identifies four dimensions common to

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[31] Ibid.
[32] Ibid.
[33] Stirling, Andy, "The Precautionary Principle", in Jan Kyrre Berg Olsen Friis, Stig Andur Pedersen, and Vincent F. Hendricks (eds.), *A Companion to the Philosophy of Technology*, Wiley-Blackwell, Malden, MA, 2013, pp. 248–262 [p. 248].
[34] United Nations Environment Programme, "Rio Declaration on Environment and Development.", http://www.unep.org/Documents.Multilingual/Default.asp?DocumentID=78&ArticleID=1163.
[35] European Commission, Communication from the Commission on the Precautionary Principle, COM (2000)1, 2.2.2000. http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=URISERV:l32042&from=EN
[36] Stirling, Andy, "The Precautionary Principle", in Jan Kyrre Berg Olsen Friis, Stig Andur Pedersen, and Vincent F. Hendricks (eds.), *A Companion to the Philosophy of Technology*, Wiley-Blackwell, Malden, MA, 2013, pp. 248–262 [pp. 248-250].
[37] Beauchamp, Tom L., and Childress, James F., *Principles of Biomedical Ethics*. 7th ed, Oxford University Press, New York, 2013, pp. 236-237.

statements of the principle: threat, uncertainty, action, and command.[38] From this, a generalized version of the principle can be stated:

> If there is (1) a threat, which is (2) uncertain, then (3) some kind of action (4) is mandatory.[39]

Critics of precautionary principles argue that they are excessively conservative and prevent potentially beneficial new developments and actions from occurring, and it can be abused to protect existing industries and practices from new technologies.[40] It also does not indicate what kind of response is appropriate for the threat.[41] These concerns may be addressed by interpreting the precautionary principles as a process for broadening the discussion about risk rather than as a rule of evaluating risk on its own.[42] Methods such as stakeholder deliberation, public discussion, and targeted research into specific aspects of the problem will play a significant role in deciding whether the risk is acceptable and how it should be addressed.[43]

With these concepts in mind, we now turn to the role risk plays in the ethical assessment of research. Research proposals must consider both the risks to those involved in the study (either as researchers or participants) and the risks to society.[44] The risks are then judged using a consequentialist framework that compares the potential benefits to the potential harms of conducting the research. For research involving human or animal participants, it is necessary to evaluate the benefits to society as a whole against the risks faced by the individual participants. The likelihood and the severity of the risks must be taken into account.[45] For example, a drug trial that has a high likelihood of causing minor harmless side effects would be considered less risky that a similar trial that has a small likelihood of being fatal to the participants.[46] Similarly, a study that has a minor possibility of producing significant benefits to society might be considered a better risk than a study that has a moderate possibility of a minor benefit to society.[47]

The relevant risks for ethical assessments of research also extend beyond those participating in the study itself. Risks to society from research include environmental damage, biosafety, the development and use of dual use technologies, and the possibility of the research outcomes being abused. Environmental damage may occur as a result of accidental release of hazardous materials. Biosafety risks consider the possibility that infectious agents or genetically modified organisms (GMOs) may escape from containment and enter the broader

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[38] Sandin, Per, "Dimensions of the Precautionary Principle", *Human and Ecological Risk Assessment: An International Journal*, Vol. 5, No. 5, August 10 1999, pp. 889–907.
[39] Ibid.
[40] Stirling, Andy, "The Precautionary Principle", in Jan Kyrre Berg Olsen Friis, Stig Andur Pedersen, and Vincent F. Hendricks (eds.), *A Companion to the Philosophy of Technology*, Wiley-Blackwell, Malden, MA, 2013, pp. 248–262 [p. 250].
[41] Bodansky, Daniel, "Scientific Uncertainty and the Precautionary Principle", *Environment: Science and Policy for Sustainable Development*, Vol. 33, No. 7, September 1991, pp. 4–44 [p. 43].
[42] Stirling, Andy, "The Precautionary Principle", in Jan Kyrre Berg Olsen Friis, Stig Andur Pedersen, and Vincent F. Hendricks (eds.), *A Companion to the Philosophy of Technology*, Wiley-Blackwell, Malden, MA, 2013, pp. 248–262 [p. 251].
[43] Ibid., pp. 251-254.
[44] European Commission, "Ethics for Researchers". http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf.
[45] Beauchamp, Tom L., and Childress, James F., *Principles of Biomedical Ethics*. 7th ed, Oxford University Press, New York, 2013, p. 230.
[46] Shamoo, Adil E., and Resnik, David B., *Responsible Conduct of Research*, 2nd ed, Oxford University Press, Oxford, 2009, p. 247.
[47] Ibid.

ecosystem. Dual use technologies are those with both useful and harmful applications.[48] One part of the dual use problem is the potential abuse of research results, such as the concerns about published research on infectious agents being used in biological warfare and terrorism.[49] The researchers must explain how they intend to mitigate these risks: for example, they might employ specialists in biosecurity to ensure the safe storage and testing of infectious agents.[50] Recognising and addressing the potential risks of the research increases the ethical permissibly of the proposed study.

4. Ethical issues

Any assessment of risk necessarily requires a decision of what level of risk is acceptable. This in itself is a significant ethical issue. Risks that are regarded as being too insignificant are called *de minimis* risks.[51] This can be regarded as a 'limit of concern' or a threshold that determines whether potential risks should influence our judgment.[52] This limit is arbitrary and may differ between various risk assessors and regulators. It is important to recognize that the level of acceptable risk is not based solely on scientific evidence and will necessarily reflect political, social, and ethical beliefs about risk.

Another ethical concern about determining the level of acceptable risk is the difference between risks that are detectable and risks that are acceptable: Sven Ove Hansson calls this the 'ethical gap'.[53] If the acceptable level of risk is below what can be detected, it is not possible to determine whether the actual risk is at or below acceptable levels. As a result, it is necessary to reduce the acceptable level of risk until it overlaps with levels that can be detected, thus removing the gap between the detectable and the acceptable.[54]

Another significant ethical issue in risk assessment is the difficulty of capturing all of an action's morally relevant aspects. There are important moral differences between risk taking (where someone voluntarily chooses to take a risk) and risk exposure (where others are placed at greater risk of harm through another's actions).[55] The knowledge and intentions of the people involved in the action also inform our intuitions about the acceptability of risk. Sven Ove Hansson distinguishes between several morally relevant aspects of risk:[56]

- **Intentional risk exposure:** Someone exposes herself and/or others to additional risk and who is aware that she is doing so.

[48] Miller, Seumas, and Selgelid, Michael J., "Ethical and Philosophical Consideration of the Dual-Use Dilemma in the Biological Sciences", *Science and Engineering Ethics*, Vol. 13, No. 4, December 2007, pp. 523–80, [p. 524].
[49] Ibid.
[50] European Commission, "Ethics for Researchers". http://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf.
[51] Beauchamp, Tom L., and Childress, James F., *Principles of Biomedical Ethics*. 7th ed, Oxford University Press, New York, 2013, p. 233.
[52] Hansson, Sven Ove, "Philosophical Perspectives on Risk", *Techné,* Vol. 8, No. 1, Fall 2004, pp. 10–35.
[53] Ibid., p. 20.
[54] Ibid.
[55] Hansson, Sven Ove, "Risk", in Edward N. Zalta (ed.), *The Stanford Encyclopedia of Philosophy*, Spring 2014. http://plato.stanford.edu/archives/spr2014/entries/risk/.
[56] Ibid.

- **Unintentional risk exposure:** Someone exposes herself and/or others to additional risk but is unaware that she is doing so. This may be due to ignorance of the risks involved with an act or imperfect knowledge of additional factors that affect the risks.
- **Voluntary risk-taking:** Someone is aware of and accepts the risks associated with an action of her own choice.
- **Accepted imposed risks:** Someone is aware of and accepts the risks associated with an act performed by someone else that affects her.
- **Unaccepted imposed risks:** Someone does not accept the risk associated with an act performed by someone else that affects her.

These different aspects of risk emphasize various ethical issues. In cases of intentional risk exposure, there are questions about the willingness of those exposed to risk in accepting it. It is important to consider whether those affected have any choice in being exposed to this risk, and whether the decision maker was acting appropriately. Intentional and unacceptable risk exposure is advertent negligence.[57]

Unintentional risk exposure raises questions about how well informed those making the decision are about the risks associated with their available choices. All decisions are made in the face of imperfect knowledge, so it is unreasonable to morally condemn unintentional risk exposure without considering whether the knowledge of risk was something the decision maker could be expected to be aware of. Otherwise, it may be an instance of inadvertent negligence.[58]

Voluntary risk-taking is an important aspect of individual autonomy. The ability to decide for one's self what risks gives someone control over her own life and the ability to express her individuality through the chances she takes (and those she does not). While individual autonomy is valuable, there are often areas where it is desirable to limit autonomy for both the benefit of the individual herself and for society. For instance, there are many decisions in everyday life that require specialized expert knowledge to make an informed choice. This creates the possibility of unintentional risk exposure, which may have significant harmful consequences for the individual. Individuals may also ignore risks and act recklessly.

While it may be desirable to limit individual autonomy when there is a strong possibility than individuals may act recklessly, imposing limitations on individuals' actions faces the charge of paternalism: deciding for the benefit of someone else what actions she is able to take or prevented from doing.[59] Paternalism can be further divided into hard and soft versions: Hard paternalism prevents others from performing a given activity, while soft paternalism will only prevent others from performing a given activity if it is uncertain that those wishing to perform it are aware of the risks involved.[60] Soft paternalism therefore permits voluntary risk-taking when it can be determined that it is intentional risk exposure. In contrast, hard paternalism attempts to prevent voluntary risk-taking, regardless of whether the exposure to risk is intentional or unintentional.

Both forms of paternalism involve others making a decision on another's behalf about the level of risk that another should accept. Even a soft paternalist is making this choice by

[57] Beauchamp, Tom L., and Childress, James F., *Principles of Biomedical Ethics*. 7th ed, Oxford University Press, New York, 2013, p. 155.
[58] Ibid.
[59] Ibid., p. 215.
[60] Ibid., pp. 216-217.

deciding which activities receive warnings and which do not. Paternalism also features in the issue of whether an individual accepts the risks imposed on her by others. Risks may be imposed on others for their own benefit: if they do not accept this risk, performing that action is paternalistic.

Informed consent is one response to the problems raised by imposed risk. It ensures that patients and participants in research studies have been informed of the potential risks associated with their treatment or research participation, and that they agree to have the proposed actions performed on them.[61] A patient or participant's informed consent to a procedure or trial makes the risks involved accepted imposed risks. Informed consent must also be obtained voluntarily, and the patient or participant must be able to withdraw at any time. This also ensures that the risks are voluntary, since if the patient or participant believes that the risks have become too great she is able to withdraw.

5. Organisations

As a general rule, the responsibility for acting safely and securely is the duty of all organisations. Directives and regulations (such as those mentioned in chapter 2) set the minimum requirements: there are EU (i.e. EU-OSHA[62] or ECHA[63]) and national level agencies responsible of the regulation and monitoring. The risk assessment itself is the duty of individual organisations that can perform the assessment itself or buy the service of a consulting company or research institute. In case of national health issues like influenza or food or other bio-agents, the national (or international) respective organisations are assessing the risk.

The risk assessment tools and methods themselves are developed by universities, research institutes and private companies. There are standardization bodies such as ISO, CEN, CENELEG and API, for example, which facilitate standards on risk, risk assessment and safety. Safety also has encouraged voluntary actions and different associations work for safety on international, EU and national level. One well-known example of that is the chemical industries' responsible care programme.[64]

6. International frameworks and protocols

Some examples of international frameworks and protocols concerning risk, risk assessment and risk management include:

- Various EU Directives
- Precautionary principle[65]
- Responsible Research and Innovation[66]

[61] Ibid., p. 122.
[62] European Agency for Safety and Health at Work. https://osha.europa.eu/
[63] European Chemical Agency. http://echa.europa.eu/fi/
[64] International Council of Chemical Associations, "Responsible Care". http://www.icca-chem.org/en/Home/Responsible-care/
[65] European Commission, Communication from the Commission on the Precautionary Principle, COM (2000)1, 2.2.2000. http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=URISERV:l32042&from=EN
[66] European Commission, "Responsible research & innovation", *Horizon 2020*. http://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation

- Corporate social responsibility (CSR)[67]
- RIO declaration[68]
- Responsible Care[69].

Risk assessment also features in many international standards for research practice. For example, the Declaration of Helsinki of the World Medical Association requires medical researchers to ensure that the benefits of research on human participants outweighs the risks of harm, and that the risks to participants must be minimized and monitored.[70]

7. Examples of journal and conference series

- Accident Analysis and Prevention – Elsevier
- Ecotoxicology and Environmental Safety – Elsevier
- Fire Safety Journal – Elsevier
- Food and Chemical Toxicology – Elsevier Journal of risk research – Routledge
- Journal of Chemical Health and Safety – Elsevier
- Journal of Hazardous Materials – Elsevier
- Journal of healthcare risk management: the journal of the American Society for Healthcare
- Journal of Loss Prevention in the Process Industries – Elsevier
- Journal of risk and governance – Nova Science Publishers
- Journal of risk and uncertainty – Kluwer Academic Publishers
- Journal of risk model validation – Risk Waters Group
- Journal of Safety Research – Elsevier
- The International journal of risk & safety in medicine – Elsevier Science Publishers B.V
- The journal of risk – Risk Publications
- The Journal of risk and insurance – American Risk and Insurance Association
- Reliability Engineering and System Safety – Elsevier
- Risk analysis: an international journal – Society for Risk Analysis
- Risk Management – American Society for Healthcare Risk Management
- Safety Science – Elsevier

[67] United Nations Industrial Development Organisation (UNIDO), "What is CSR?" http://www.unido.org/en/what-we-do/trade/csr/what-is-csr.html
[68] United Nations Environment Programme, "Rio Declaration on Environment and Development." http://www.unep.org/Documents.Multilingual/Default.asp?DocumentID=78&ArticleID=1163.
[69] International Council of Chemical Associations, "Responsible Care". http://www.icca-chem.org/en/Home/Responsible-care/
[70] World Medical Association, "Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects," October 19, 2013. http://www.wma.net/en/30publications/10policies/b3/index.html