The Ethical Assessment of Research and Innovation – A Reflection on the State of the Art (based on findings of the SATORI project)

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1. Introduction

This chapter presents major findings and recommendations of the SATORI project¹ in its first eighteen months. Starting in January 2014, the SATORI project is a fortyfive month project on ethics assessment of research and innovation (R&I) that is supported by the European Commission through its FP7 funding scheme. The SATORI project aims to support mutual learning about ethics assessment and ethical guidance in different fields, organisations and countries, and strives to identify best practices, to support harmonisation and shared standards, and, to the extent that it is possible and desirable, develop common principles, protocols, procedures and methodologies for the ethical assessment of research and innovation in the European Union and beyond. The aim of this substantial research effort is to improve ethical assessment practices and strengthen respect for ethical principles in research and innovation. The project is carried out by 17 participating organisations, including universities, national ethics committees, organisations of research ethics committees, industry, civil society organisations, standardisation organisations, and UNESCO. The SATORI project is divided into three phases: a fact-finding phase, a framework construction phase and, an elaboration and communication phase. This chapter shares the key findings and recommendations of work package 1 (Comparative analysis of ethics assessment practices) and its corresponding report, deliverable D1.1, which constitutes the largest element in the fact-finding phase, the aim of which involved the mapping and comparative analysis of the ethics assessment landscape for R&I in the EU, the US and China. Deliverable D1.1, which is the result of extensive investigations totalling 69.75 person months, includes a main report² as

¹ http://satoriproject.eu/media/

² Shelley-Egan, Clare, Philip Brey, Rowena Rodrigues, David Douglas, Agata Gurzawska, Lise Bitsch, David Wright, and Kush Wadhwa. SATORI Deliverable D1.1: Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and Selected Other

well as 47 separately downloadable, annexed reports³ that cover the following topics: ethics assessment principles and approaches (8 reports), ethics assessment in different fields (17 reports), ethics assessment in different types of organizations (9 reports), ethics assessment in different countries (11 reports) and ethics assessment at the EU and global level (2 reports).⁴ In total, the deliverable counts more than 1600 pages.

Ethics assessment is a key element of Responsible Research and Innovation (RRI), involving the identification and assessment of ethical issues in research and innovation. However, ethical assessment of research and innovation (R&I) faces many challenges: it currently lacks unity, recognised approaches, professional standards and proper recognition in some sectors of society. At the same time, different actors – including universities and research institutes, corporations and government organisations – are flagging the importance of ethics assessment and are developing different initiatives and mechanisms to address ethical issues. The rapid expansion of ethics assessment has not, however, been accompanied by significant efforts to harmonise approaches in different fields and organisations, to raise standards, and to introduce quality assurance. There is a need for improvement and coherence in the ethical assessment of R&I in Europe and beyond. The SATORI project addresses this challenge.

In the SATORI project, ethics assessment, or ethical assessment, is defined as any kind of institutionalised assessment, evaluation, review, appraisal or valuation of practices, products and uses of research and innovation that primarily makes use of ethical principles or criteria. The objects of research or innovation that are assessed may be research or innovation goals, new directions, projects, practices, products, protocols, or new fields. An example of an ethical assessment would be a reasoned moral judgement that human cloning is morally wrong, and should be banned. There are many organisations that engage in some form of ethics assessment of R&I. Ethics assessment is furthermore distinguished from ethical guidance, which is the statement of ethical guidelines, principles, rules, codes, and recommendations to which scientific practices, innovation practices, developments in science and technology, etc. are expected or recommended to adhere. An example of ethical guidance would be a statement of ethical guidelines for biomedical research on human participants. Ethics assessment and ethical guidance can be directed at (1) R&I plans, practices and products, (2) R&I policies, and (3) professional conduct in R&I, and each of these forms of assessment and guidance is different. In the SATORI project, we study all three, although our emphasis is on ethics assessment of R&I plans and practices.

Countries. SATORI, June 2015. http://satoriproject.eu/media/D1.1 Ethical-assessment-of-RI a-comparative-analysis.pdf

³ The individual annex reports are available at: http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/

⁴ http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/

Ethics assessors are defined as agents (organisations or individuals) that engage in ethics assessment, usually on a professional basis. Sometimes, this term is used by SATORI in a broader sense to include agents that engage in any type of ethics assessment, guidance, awareness raising or advisement. Our notion of ethics assessor does not imply that an ethics assessor has to have ethics assessment as her primary mission, or even that she recognises herself to be doing ethics assessment. It merely means that the agent repeatedly and systematically engages in activities that can be analysed as involving ethics assessment.

The methodology used in arriving at the findings and results presented in this chapter is fully documented in Deliverable 1.1 of the project⁵. Interviews and case study reports were used to gather data regarding ethics assessment and its stakeholders across scientific fields, organisations and countries. The aim of the interviews was to gather information and opinions from, and about different ethics assessment organisations, countries, scientific fields and non-assessor stakeholders regarding practices of, and attitudes towards, ethical assessment of research and innovation. In total, over 230 interviews were conducted, the vast majority of which were carried out in person (others were carried out via phone and online media). The interview data were then used in the various reports compiled for D1.1.

In what follows, we offer the main findings and recommendations that were presented in SATORI Deliverable 1.1. Section 2 offers a discussion of the results of a comparative analysis of ethics assessment in five major scientific fields – medical and life sciences, natural sciences, engineering sciences, social sciences and humanities. Section 3 describes the results of the analysis of the current state of ethics assessment legislation, policies, standards and guidelines at European level and at the global level. Section 4 reports on the comparative analysis of ethics assessment and guidance frameworks, principles and practices in different types of organisations such as research ethics committees, universities, research funding organisations and civil society organisations. Section 5 comprises the results of an analysis of specific ethics assessment structures and agents (in both the public and the private sector) in ten countries – eight European countries, the United States, and China. Finally, section 6 summarises some of the main findings presented in this chapter and discusses future work within the context of the SATORI project.

2. Ethics assessment in the scientific fields

In SATORI Work Package 1, a systematised inventory of current practices and principles was made of ethics assessment in the five major areas of science: the

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⁵ Shelley-Egan, Clare, Philip Brey, Rowena Rodrigues, David Douglas, Agata Gurzawska, Lise Bitsch, David Wright, and Kush Wadhwa. SATORI Deliverable D1.1: Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and Selected Other Countries. SATORI, June 2015. http://satoriproject.eu/media/D1.1 Ethical-assessment-of-RI acomparative-analysis.pdf

medical and life sciences⁶, natural sciences⁷, engineering sciences⁸, social sciences⁹, and the humanities¹⁰. On the basis of this inventory, a comparative analysis was conducted of: (1) the major traditions of ethics assessment that have developed within the five fields; (2) the main ethical issues in the fields; (3) national, EU and international legislation, standards, frameworks and protocols regarding ethical principles and issues that specifically concern or impact the fields; and (4) evaluations as to the state-of-the-art of ethics assessment in the respective fields, in addition to future developments in these fields. The aim of the analysis was to determine differences and similarities between approaches to ethics assessment across the five fields, with a view to determining the feasibility of transferring ethics frameworks, principles and practices from fields with well-developed ethics assessment frameworks to other fields.

SATORI's main findings with regard to ethics assessment in the scientific fields are as follows. Ethics assessment exists to different degrees in the five scientific fields. The most extensive institutions, policies and activities exist in the medical and life sciences, followed by the engineering sciences, and then the social sciences. EU and supranational organisations have an important role in giving guidance to ethics assessment in the medical sciences in particular. The humanities have not really managed to establish their own tradition in ethics assessment. Nevertheless, there is a growing institutionalisation of ethics assessment in non-medical fields, and it appears that this institutionalisation is developing somewhat independently of the influence of medical research ethics. Shared concerns of the five fields are: research integrity, social responsibility, intellectual freedom, and professional attitudes such as honesty, collegiality and impartiality. In addition, many fields share a concern for the protection of human subjects and for the welfare of animals used in experimentation. There are, however, many ethical issues that appear to be specific to the fields, and this also seems to be true for many ethical principles, even though they may often be analysed as based on the same underlying values. For example, ethical issues in the social sciences include the proper treatment of human subjects, privacy of data, and issues such as bias and unequal treatment (in theory and intervention), whereas in the engineering sciences they concern impacts, especially those concerning health, well-being, and harms and benefits to society and the environment, as well as corresponding risks (that harmful impacts will occur), and responsibility for these impacts.

Attempts to transfer and take up the *principlism* approach to biomedicine (which is based on the four ethical principles of autonomy, beneficence, non-maleficence and justice) in other areas such as the social sciences have been met with limited success. For example, the "Generic Ethics Principles in Social Science" that are being

⁶ http://satoriproject.eu/media/2.c-Medical-Life-sciences.pdf

⁷ http://satoriproject.eu/media/2.a-Natural-Sciences.pdf

⁸ http://satoriproject.eu/media/2.b-Engineering.pdf

⁹ http://satoriproject.eu/media/2.d-Social-Sciences.pdf

¹⁰ http://satoriproject.eu/media/2.e-Humanities.pdf

developed by the UK's Academy of Social Sciences are taking a step away from biomedically imposed principlism to explore the benefits of virtue ethics.¹¹ Thus, there is reason to doubt the feasibility of transferring ethics frameworks, principles and practices from fields with well-developed ethics assessment frameworks to other fields. While there are certainly aspects that can be usefully transferred, some areas such as the social sciences and humanities are faced with the challenge of dealing with familiar issues, such as informed consent and data protection, in rather novel, and largely unknown, contexts. Moreover, different topics and methods of research in the social sciences (as discussed in more detail in our report on *Ethics assessment in different fields: Social sciences*¹²) generate significant differences in the nature of risks and benefits and consequentially in the measures taken to avoid or achieve them. This is why transferring an ethical assessment framework, developed for example for biomedicine, may lead to a misjudgement of the risks at stake in an individual research project in the social sciences.

3. EU and Global Ethics Assessment and Guidance

In addition to the comparative analysis of ethics assessment in the scientific fields, SATORI D1.1 provides a summary of the ethics assessment landscape at both EU¹³ and global¹⁴ levels, specifically with regard to: (1) the relation between EU and global counterparts in particular areas including organisational structures, laws, policies and procedures for ethical assessment and guidance; (2) the role of publicly funded and private research and innovation systems in addressing ethical issues in research and innovation; and (3) the manner in which ethical assessment plays a role in the activities of professional groups and associations for research and innovation.

SATORI's main findings are as follows. Ethics assessment and guidance of research and innovation takes place across both private and public research and innovation systems in the EU. Ethics review is well organised at European Commission level and is supported and enhanced by European research funding organisations. In

¹¹ See: Iphofen, R., R. Dingwall, J. Lewis, & J. Oates, (n.d.). Developing Generic Ethics Principles for Social Science Research. Academy of Social Sciences. http://www.acss.org.uk/developing-generic-ethics-principles-social-science/

¹² Gurzawska, A., & R. Benčin, "Ethics assessment in different fields: Social sciences", Annex 2.d, Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries, Deliverable 1.1, June 2015. http://satoriproject.eu/media/2.d-Social-Sciences.pdf

¹³ Shelley-Egan, Clare, & Rowena Rodrigues, "Ethics Assessment and Guidance at the European Union Level", Annex 5.a Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries, Deliverable 1.1, June 2015. http://satoriproject.eu/media/5.a-EA-and-Guidance-at-the-EU-level.pdf

¹⁴ Rangi, Sudeep & Siya Bhatt, "Ethics Assessment and Guidance at the EU level". Annex 5.b Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries, Deliverable 1.1, June 2015. http://satoriproject.eu/media/5.b-EA-and-Guidance-at-the-Global-level.pdf

addition, there are a variety of organisations at both the Commission and European Parliament that carry out ethics assessment/guidance as part of their mandate, or encounter ethical issues in other kinds of assessment activities. With regard to ethics assessment at European Commission level, the European Group on Ethics in Science and New Technologies (EGE)¹⁵ is a particularly important body, which has adopted Opinions on issues ranging from nanotechnology to internet governance. Other notable organisations include: the Ethics and Research Integrity Sector at the Directorate General (DG) for Research and Innovation,¹⁶ which is responsible for organising ethics assessment of proposals submitted to the Commission for funding; the National Ethics Councils Forum (NEC Forum),¹⁷ which is a European Commission expert group; and the Parliament's Science and Technology Options Assessment unit,¹⁸ which provides policy advice to decision-making bodies concerning the impact of science and technology on EU policy.

Specific laws and policy mechanisms form a solid foundation for ethics assessment of R&I. The incorporation of the European Charter of Fundamental Rights¹⁹ into the Lisbon Treaty has generally enhanced the consideration of ethics and human rights at EU level and the work of advisory bodies such as the EGE.²⁰ Other prominent international legislation and guidelines that define ethics assessment practices in the EU include, for example, UNESCO's Universal Declaration on Bioethics and Human Rights and the Council for International Organizations of Medical Sciences' (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects. The importance of international guidelines and frameworks at EU level is clear, particularly in the ethics review of research proposals and projects.

At the global level, the main intergovernmental and supranational organisations engaged in policy development for ethics in R&I include the United Nations (UN), The United Nations Educational, Social, and Cultural Organisation (UNESCO), the Organisation for Economic Co-operation and Development (OECD), the World Health Organization (WHO), the Council for International Organizations of Medical Sciences (CIOMS) and the Council of Europe. These organisations have been involved in the formulation of important principles, legislative instruments, policies, standards, and guidelines. In addition to these institutions, there has been an increase in collaborative efforts between ethics committees in different regions. The

¹⁵ European Group on Ethics in Science and New Technologies.

http://erawatch.jrc.ec.europa.eu/erawatch/opencms/information/country_pages/eu/euorganisation/europeanorg_mig_0043

¹⁶ Ethics and Research Integrity Sector at the Directorate General (DG) for Research and Innovation http://ec.europa.eu/research/dgs/pdf/organisation en.pdf

¹⁷ National Ethics Councils Forum.

 $[\]underline{http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail\&groupID=1806}$

¹⁸ European Parliament's Science and Technology Options Assessment unit.

http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail&groupID=1806

¹⁹ European Parliament and the Council, Charter of Fundamental Rights of the European Union, OJ C 364/1, 18.12.2000. http://www.europarl.europa.eu/charter/pdf/text_en.pdf

²⁰ http://europa.eu/legislation_summaries/institutional_affairs/treaties/lisbon_treaty/ai0033_en.htm

Global Summit of National Bioethics Advisory Bodies,²¹ which is a platform for the exchange of information about the on-going work of national ethics committees, is a good example of such efforts.

4. Ethics assessment in various types of organisations

SATORI D1.1 distinguishes fifteen types of organisations that routinely or professionally engage in ethics assessment or guidance: research ethics committees (RECs); associations and networks of research ethics committees; national ethics committees (NECs); government organisations and councils; universities and research institutes; associations of universities and research institutes; research funding organisations; science academies and associations of science academies; academic and professional organisations in R&I; companies; business and industry associations; civil society organisations (CSOs); standards organisations; certification and accreditation organisations; and academic ethics centres and departments. SATORI studied each type of organisation in detail with regard to: (1) the aims and institutional structure of the organisation; (2) the extent to which the organisation type carries out ethics assessment, including aims, beneficiaries, objects and motivations for assessment; (3) the institutional set-up for ethics assessment; (4) procedures for ethics assessment; (5) principles and issues in ethics assessment; and (6) the main strengths and weaknesses in the area of ethics assessment for the organisation. The aim of the comparative analysis was to understand the ways in which principles and practices of ethics assessment vary for different actors who engage in ethics assessment (both explicitly and implicitly) and to determine the extent to which similarities and differences exist in the use of frameworks and procedures.

Our main findings are as follows. We found that principles and practices for the fifteen kinds of ethics assessor we studied vary, both in the particular role of the respective organisations in ethics assessment and in the objects or foci of assessment and guidance. Perhaps unsurprisingly, given the strong tradition of ethics assessment in the medical and life sciences, research ethics committees and national ethics committees have a well-established role in ethics assessment and ethics guidance, respectively. In other organisations such as companies and CSOs, ethics assessment or guidance is less well established. In general, it can be said that research ethics committees, research funding organisations, companies, and certification and accreditation organisations predominantly focus on conducting ethical assessments, whereas associations and networks of research ethics committees, national ethics committees, academic and professional organisations in R&I, business and industry associations, and standards organisations focus mostly

²¹ The Global Summit of National Bioethics Advisory Bodies. http://www.who.int/ethics/globalsummit/en/

on providing ethical guidance. The other organisations we studied focus on both ethics assessment and ethics guidance.

The objects of assessment or guidance are numerous, and include research and innovation agendas, technological innovations, scientific conduct of professionals, research grant applications, principles of research ethics, draft laws, the conduct of companies, professional conduct, societal impacts of R&I, and others. The beneficiaries of assessment are similarly diverse.

In addition, there is great diversity in the institutional setup and procedures for ethics assessment, along with the ethical principles and guidelines that are used. For certain types of organisations, ethics assessment or guidance is an optional activity. For example, not all companies or industry associations see a role for themselves in setting or following ethical or CSR standards.²² It is rather more surprising that *some* universities and research funding organisations do not pay much attention to ethics assessment, given their undeniable link to potential ethical issues in research. Indeed, whether they do may depend on the presence of hard and soft law, incentives, and the individual choices made by these organisations. Many organisations consider the manner in which ethics assessment and guidance are practiced to be problematic to some degree. Challenges in this respect include a lack of clear procedures and guidelines, lack of time and resources, lack of training, lack of awareness of ethical issues in the organisation and ways of approaching them, and an insufficient ability to recognise and incorporate new issues and challenges. Thus, it appears that the baseline from which organisations develop and practice ethics assessment and guidance varies.

5. Ethics assessment: findings from the study of select EU and non-EU countries

The final part of the comparative analysis of the SATORI D1.1 report comprises an analysis of ethics assessment structures and agents (in both the public and the private sector) in ten countries, including seven European Union countries (Austria, France, Germany, the Netherlands, Poland, Spain, and the United Kingdom), one candidate for EU membership (Serbia), the United States, and China. Each country was studied in detail with regard to: (1) the organisational structures, laws, policies and procedures that have been established for ethical assessment; (2) the ways in which publicly funded and private research and innovation systems address ethical issues in research and innovation; and (3) the role ethical assessment plays in the activities of professional groups and associations for research and innovation and civil society organisations. The country studies²³ also include basic information about the country's research and development landscape and the historical development of

²³ Available here: http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/

²² http://satoriproject.eu/media/3.h-Industry.pdf

its ethics assessment institutions. The aim of the analysis was to make an international comparison of the ethics assessment infrastructure in the respective countries, with a focus on understanding those structures and agents that comprise the ethics assessment landscape, including their funding and scope.

The main findings of our comparative country analysis are as follows. All countries that were studied are currently expanding their ethics assessment and guidance infrastructure. They are experiencing an expansion of (non-medical) RECs, and efforts to address ethical issues by governments, universities, research funding organisations, CSOs and industry. The expansion of ethics assessment in nonmedical fields is especially noteworthy. There are also significant differences in the extent to which ethics of R&I is institutionalised, ranging from limited (Serbia, Poland, China) to extensive (Netherlands, Germany, Austria) institutionalisation. The degree of institutionalisation might nominally be linked to the role of government in ethics assessment and guidance, ranging from strong (China) to weak (US) regulation and intervention. The EU countries are somewhere in the middle, although there are large differences in this regard within Europe as well. We also observed interesting national differences in the kinds of ethical principles and issues that receive attention. For example, in Germany one sees an orientation towards deontological argumentation which focuses on human dignity, autonomy of persons, and privacy; the UK and the US, in contrast, tend to have a more utilitarian approach. We also found the role of government in ethics assessment and guidance to be different, ranging from strong (China) to weak (US) regulation and intervention, with EU countries located at different points in between. We also observed that governments stimulate CSR for industry to different degrees and with different means. Finally, CSOs engage in informal ethics assessment and guidance in public discussion and have a role in ethics assessment procedures carried out by other organisations in some countries.

6. Conclusion: looking to the future

This chapter presented the key findings and results of work package 1 of the SATORI project. It demonstrated the ways in which ethics assessment and guidance of research and innovation are practiced in different scientific fields and in different countries and types of organizations in Europe, the US and China.

In the analysis of ethics assessment in different scientific fields, SATORI found that the most extensive institutions, policies and activities in the areas of ethics assessment and guidance exist in the medical and life sciences, while the humanities have not yet established a clear tradition in ethics assessment. Nevertheless, there has been a growing institutionalisation of ethics assessment in non-medical fields, and many approaches exist to doing ethics assessment within and across different fields. Attempts to take up biomedicine's principlism approach in other fields have been met with limited success, most likely due to the different ethical issues that

these fields face. While the five major scientific fields that we studied share the same concerns, many ethical issues and principles appear to be specific to the fields.

In our analysis of ethics assessment at EU and global levels, we observed increasing coordination and cooperation across regional levels. While many international guidelines and documents set the benchmark for ethics assessment in the EU, the EU has a very well-developed system of ethics assessment which is reinforced by the collective effort of a variety of organisations within the R&I system. The incorporation of the European Charter of Fundamental Rights into the Lisbon Treaty has generally enhanced the consideration of ethics and human rights in these organisations. At the global level, there are also many intergovernmental and supranational organisations that are involved in the formulation of important principles, legislative instruments, policies, standards, and guidelines.

In our analysis of ethics assessment in different kinds of organisations, we observed that each of the fifteen types of ethics assessors performs a significant but different role in ethics assessment. In some cases the role is well-established (e.g., RECs, NECs); in other cases it is less well established (e.g., companies and CSOs). For certain kinds of organisation, such as companies and industry associations, ethics assessment is an optional activity or an implicit part of activities that are specifically mandated. It appears that incentives, hard and soft law, and organisational context play an important role in encouraging and facilitating ethics assessment for these and other organisations. Various challenges have been identified in the practice and implementation of ethics assessment and guidance, ranging from a lack of clear procedures and guidelines to insufficient capacity to incorporate new issues and challenges.

In our analysis of ethics assessment in countries, we found that all of the countries we studied are currently expanding their ethics assessment and guidance infrastructures. The expansion of non-medical research ethics committees and ethics assessment in non-medical areas is particularly striking. Significant differences exist in the degree to which ethics assessment of R&I is institutionalised, ranging from limited to extensive institutionalisation. It is interesting to observe national differences in the kinds of ethical principles and issues that receive attention and in the role of certain organisations in ethics assessment. For example, governments stimulate CSR for industry to different degrees while CSOs engage in informal ethics assessment and guidance in public discussion and have a role in ethics assessment procedures carried out by other organisations.

The results of SATORI's work package 1 offer a major repository of information on the state of the art in ethical analysis, assessment and guidance of research and innovation, in particular in the EU, the US and China and at the supranational level. For the SATORI project, it is, in addition, an important means by which we will take our next steps: the identification of best practices, the development of proposals for harmonisation and shared standards, and, to the extent possible, the proposal of common principles, protocols, procedures and methodologies for the ethical assessment of research and innovation in the European Union and beyond.

We believe that through careful analysis of existing approaches, institutions and protocols, and through mutual learning between scientific fields, organizations and countries, it will be possible to arrive at improved practices in ethics assessment and guidance, and to a certain extent, shared standards. Further steps towards this goal will be made in the deliverables of work package 4 (*Roadmap for a Common EU Ethics Assessment Framework*) in the SATORI project, as well as in deliverables in later work packages. Our proposals will be based on our findings to date regarding the state of the art, and the opinions and recommendations of hundreds of stakeholders who have been and will be consulted, including the partners in the SATORI consortium. We invite readers of this chapter to consider our constructive proposals in the forthcoming SATORI reports.

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