European Commission

Research, Risk-Benefit Analyses and Ethical Issues

A guidance document for researchers complying with requests from the European Commission Ethics Reviews

Research and Innovation

EUROPEAN COMMISSION

Directorate-General for Research and Innovation
Directorate B – European Research Area
Unit B.6 – Ethics and gender

Contact: Isidoros Karatzas

European Commission
B-1049 Brussels

E-mail: isidoros.karatzas@ec.europa.eu
RTD-PUBLICATIONS@ec.europa.eu

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Research, Risk-Benefit Analyses and Ethical Issues

How to ensure research projects meet EU ethics standards

A guidance document for researchers complying with requests from the European Commission Ethics Reviews

2013

Directorate-General for Research and Innovation
Science in society /Capacities FP7

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Introduction

You have received feedback from an ethics panel... – Any points raised in ethical reviews are not meant to be punishments or attempts to interfere with your research. Rather, they are requests for safeguards to ensure that human subjects, animals or the environment are protected and the public perception of research remains positive. If certain research methods may raise ethical concerns, you should take measures to ensure that widely shared societal values are not compromised. This document will help you to identify some ethical issues, take measures to reassure concerns and address any points raised by an ethics panel.

What is a risk-benefit analysis? – A risk-benefit analysis is something we do in any decision-making process. In its basic form, it is a consideration of the risks in relation to the benefits. Where benefits are great or necessary, we concentrate on reducing the exposure to potential risks (where risks are too high or the benefits insignificant, we take precaution). Central to risk-benefit analyses is the consideration of introducing risk reduction measures.

Risks are not just economic, environmental or systemic. There are also societal or ethical risks (challenges to human values, rights, freedoms) which can have an impact on research directions. If research causes loss of life or well-being, confronts basic freedoms like privacy and free movement or challenges shared values, then this research is seen to be a risk. This is the human element that some researchers can easily overlook or downplay. As our personal worth (human dignity) is not something elastic that can be easily traded off, an ethical risk could interfere with the ability to continue along present research lines and should therefore not be taken lightly.

Distinction with cost-benefit analyses – The human element is what distinguishes a cost-benefit analysis from a risk-benefit analysis. Cost-benefits are mathematical (adding up the benefits and subtracting the costs). Return on investments, traffic flow management decisions, land use decisions and management innovations are all examples of cost-benefit analyses. When the human element is brought in (the value of a life, giving up certain rights or freedoms, limiting the quality of one's life ...), cost-benefits become inadequate. If human values are at risk (the loss of life, well-being, fundamental rights ...), one cannot simply subtract costs from benefits – researchers have to find a way to reduce the risks to avoid making hard decisions or compromises to human intrinsic worth. Cost-benefit analyses are amoral, whereas risk-benefit analyses (with potential challenges to human dignity) bring in ethical considerations.

What are ethical risks? – If an ethics review asks for a risk-benefit analysis, you first need to identify where the risks are.

- Does your research use children?
- Could personal information be made public?
- Are there threats to human life or well-being?
- Would animals be treated in ways that could be considered inhumane?

While the benefits may seem greater to the researchers who have devoted their lives to this work, ethical concerns are not something that can simply be calculated (human elements interfere with a straightforward cost-benefit analysis), so introducing risk reduction measures would be prudent. This booklet is intended to help researchers find the best means to address such ethical risks.

Some Common Elements of Ethical Assessments

Research today is proving to be vital to a society's well-being and with the internet communications revolution, scientific issues have become more closely involved with our shared common interests. Questions of how our food is grown, how we treat illnesses or how we produce energy are becoming kitchen table issues with the general public being drawn more and more into the policy discussions over how scientists should conduct their research. Ethics in research then is becoming a topic of common interest and ethical concerns raised in public debates should not be ignored simply because societal actors are not directly involved in the research. The public feels they have a right to be involved and as much research is publicly funded, they have good reason. The engagement and buy-in of societal actors is essential to the research process and any ethical concerns they may have with research practices must be treated like any other research risk.

The Human Element: Not a trade-off, but safeguards – A cost-benefit analysis offers trade-offs (there are benefits, but they come with a cost, which, if the price is right, you should accept) and if the benefits are great, there is really no need to consider the matter further. Ethical values (those involving a person's life, freedom or dignity) are not easily surrendered, so even if benefits are great, certain members of society are not willing to make the trade off. The ethical concerns need to be safeguarded to ensure that there is no need to trade one's intrinsic worth or ideal of humanity for certain benefits. Things have a price and can be traded; man has a dignity (an intrinsic worth) that must not be subjected to trade-offs.

How to safeguard ethical values – Ethical issues can be managed in the same way researchers manage other risks: by safeguarding exposure to threats or hazards. In this case the hazards are not from exposure to dangerous substances or chemical reactions, but threats to human dignity and shared values. You need to consider if your research:

- may challenge commonly shared values like privacy or free movement;
- might confront certain perceptions of the integrity of a person (eg, cloning, technological modifications);
- could interfere with a widely shared view of our place in the world (eg, inhumane treatment of animals or threat to biodiversity)?

Once the threat is identified, the task is to develop means to safeguard these perceptions which underlie our intrinsic worth, ensuring that the research will not challenge human dignity. In other words, the scientist needs to apply risk reduction measures to protect these shared values so that people need never be faced with a decision of trading off their intrinsic worth as persons for the benefits of research. For in such a situation, the scientist will almost always lose to shared societal values (or take a very long time to win). While it may be in a researcher's interest to try to change the values the public holds, attempting this within the context of a publicly funded project would not be the appropriate place.

The need to engage on ethical concerns – Ethical issues should not be an obstacle for researchers but a call to engagement. Evidence of the need for dialogue indicates that the research has attracted interest. To ensure long-term value and credibility for your research (as well as funding sustainability), you cannot simply become benefit salesmen (public trust in certain scientific fields had been easily lost when too many benefits were promised but not delivered). The researcher needs to exhibit an understanding of public concerns and convey a certain reassurance that ethical values are being safeguarded. Long-term sustainability of certain research practices is threatened whenever certain elements of a society strongly feel that a trade-off is being forced upon their values, when scientists do not appear to be listening to their concerns or if they feel they are not part of the dialogue.

Privacy and Data Protection

Privacy and Data Protection issues cover all information researchers may handle from ICT research to genetic sample collection and storage (blood, urine, sperm, cells, anything with DNA) to personal records (financial, criminal, education, ...), lifestyle and health information (including how people spend money), family histories, physical characteristics, gender and ethnic background, location tracking and domicile information.

The Issues – The most important human element is a person's identity (physical, genetic or character) and their right to have their privacy protected is sacrosanct. Identity theft leaves one vulnerable and destroys trust in societal institutions. Personal data is subjective, sensitive and susceptible.

One of the problems is the ubiquitous nature of some of the information. Younger scientists, growing up with social media, often appear less concerned about the personal information that is publicly available and may confuse secrecy (withholding public information) with privacy. Common practice and over-sharing does not make for moral acceptance. Any personal information is personal and even if releasing the information would lead to greater benefits to society, privacy must be respected. In some cases, information made public can be misused (for example, by radical groups looking for confirmation of eugenic or misogynistic theories). Reusing human genetic samples for other ends than that for which it was originally obtained may seem practical and non-intrusive, but it betrays an earlier trust between the subject and the researcher. Consent to reuse or make public is mandatory.

The *principle of proportionality* (only collecting data necessary for the research in question) must be respected. Collecting personal data (e.g., on religion, sexual orientation, race, ethnicity ...) that is non-essential to the research can raise unwarranted ethical concerns (e.g., are there hidden objectives or "mission creep"?). While comprehensiveness and thoroughness may be research virtues, personal data collection must always be limited to what is adequate, relevant and not excessive – it must be proportional to the research objectives. In situations where research may produce incidental findings, researchers will need to have developed a clear protocol in how to manage the information.

Illustration – A southern European research organisation did a cohort study on sexual activity on university campuses across its country. As well as questionnaires and interviews, they took blood samples to measure the levels of sexually transmitted diseases according to gender, race, sexual orientation and economic class. The information coming out of the research, while considered very interesting, was in many cases unethical to release. The researchers could not publish data on response rates per university, gender, race or sexual orientation as this information could promote certain negative preconceptions. Under confidentiality measures, people with samples that tested positive for sexual diseases, including AIDS, were not to be informed (unless they chose to waive their right to anonymity of their data). Some would argue that a researcher who discovers a sexually active person with AIDS should have a responsibility to society to inform that person, but that would imply a mission creep (going beyond the original motive for the research).

Data Collection

During the course of research projects, data or samples are regularly collected and stored. Some of the data may seem innocent to a researcher who has no intention of releasing the information or finds little worth in the data outside of the research itself, but still, some people may feel that information (even about their sex or age) is personal and any external exposure may leave them feeling vulnerable. Other times, more data may be collected than is necessary for the research, raising the question of proportionality. In order to ensure public trust, data protection measures need to be developed and clearly communicated to the research participants. This will not only reduce the risk of personal data being accidentally released or exploited in other research projects, it will also reassure the participants and could lead to better engagement.

Tips

- *Informed consent* – Any data researchers generate that could be determined as personal needs to be protected and the release of any information needs to have gone through a strict informed consent process. Informed consent gives the subject a sense of control over their personal information or alleviates the fear that the data, samples or information will be retained or used in any other unintended manner.
- *Anonymity/confidentiality* – Any data collected should be anonymised so that it is not personally identifiable. Anonymisation keys and cryptographic procedures need to be established with secured access to the keys.
- *Data/sample use and destruction* – Any research should clearly state how long the samples or data will be retained, who will have access to it, and how it will be destroyed after the research is complete.
- *Respect the principle of proportionality* – only collect data necessary and proportionate to the research objectives.
- *Use expertise* - An expert in data management, encryption and data protection should be consulted or employed on sensitive projects. This person or team should also have experience in other ethical issues and serve on the ethics panel or as an ethics adviser.

Relevant EU or international legislation

Regulation (EC) 45/2001 of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:008:0001:0022:en:PDF

Directive 2006/24/EC of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:105:0054:0063:EN:PDF

Directive 2004/23/EC of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:102:0048:0058:en:PDF

UNESCO International Declaration on Human Genetic Data 2003: http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genetic-data/

Research on animals

Projects requiring research on animals which attract ethical attention include in particular research on primates, transgenic or cloned animals and any research that inhibits animal mobility or implies prolonged periods of suffering or constriction.

The Issue – Animal-related ethics issues (from research to livestock) arouse sensitivities as a reflection on how far human expectations of proper treatment should extend to non-humans. In research domains, this reflects on the way animals are housed, treated during and after the projects, how humanely they are killed (if necessary) and how essential it is to use animals in research (options for alternatives to animal research). Ethics issues gain intensity when the animals' cognitive capacity is perceived to be higher (eg, research on primates), when the pain and suffering are graphically evident or when the genetic structure have been manipulated for human benefit (eg, cloning or transgenic animals). Public outrage intensifies when there is evidence of researcher neglect of animals during or after the testing, or when there is no obvious direct benefit to humans from using animals in the research. More hard-line opponents to animal testing argue that even in clear cases of benefit to humans, animals should never be used in research.

Illustration – A lab researching better treatment of kidney disease chose to work with a knock-out mouse line (in this case, transgenic mice with kidneys with human genes). The mice were induced with substances to develop the disease, upon which time an implant was inserted with a transmitter attached to the back of each mouse (for a long duration) to monitor the evolutions in treatment approaches, which involved increasing stress, blood pressure and inducing strokes. At the end of the research, the mice were euthanized and incinerated. The project ethics panel ensured that transmitters were attached in such a manner as to ensure free and painless mobility. As the mice needed to be housed separately to prevent them from removing the transmitters from each other, the cages needed to be aligned to involve some social interaction. The panel was very strict on how the mice could and could not be stressed. It also clearly specified the acceptable euthanasia procedures. The activities of the panel were published in bi-annual reports and the head of the panel was available for consultations with authorities and stakeholders.

Animal testing

The 3 Rs (Replacement, Reduction, Refinement) are a good example of how ethical concerns have been safeguarded in the field of animal testing. In the 1960s and 70s, the public began to react strongly to images of animals being tested for cosmetic or pharmaceutical safety. A cost-benefit analysis would show the benefits of this research (for human safety) outweighing the costs of lost animal lives. But a view of humanity that considers how animals should be treated with a certain respect and compassion led to an ethical confrontation. By introducing safeguards like the 3 Rs, where animals are treated more humanely, or by bringing in alternative testing methods, scientists can enjoy an improved trust and public respect.

Animal welfare

A research project inserted transmitters on the backs of around 100 mice. To preserve the condition and positioning of the transmitters, the researchers chose to isolate the mice (cost-benefit analysis). An ethics panel advised that the cages should be organised in such a way as to allow the mice to have some form of socialisation for the duration of the experiments (risk-benefit). At the end of the research, the mice needed to be put down. The researchers proposed the favoured cost-benefit approach of decapitation while the ethics panel recommended a more humane form of euthanasia.

Tips

- Implement the 3 Rs: Replacement, Reduction, Refinement
- Replacement implies finding alternatives to animal testing whenever possible (including in vitro testing, non-invasive tests on humans, using invertebrates for certain tests ...)
- Reduction means using fewer animals to get the same amount of information
- Refinement refers to a process of improving the animal welfare conditions, reducing suffering or distress as much as possible
- Ensure proper treatment of the test animals post testing phase. If the animals need to be euthanised, they must be done in the most humane manner, and not allowed to suffer long beforehand.
- Be transparent with the authorities and stakeholders. Ensure that the benefits of the research are clearly communicated and underline the procedures to ensure animal welfare.
- Be proactive: While researchers may be complying with the laws in the country of their research, with such a sensitive subject, they need to ensure humane treatment standards beyond the letter of the law. Conducting animal research outside of the EU does not imply avoiding the scrutiny of an ethics panel.

Relevant EU or international legislation

EU Action Plan, Evaluation and the Second Strategy on Animal Welfare: http://ec.europa.eu/food/animal/welfare/actionplan/actionplan_en.htm

Commission Recommendation of 18 June 2007 on guidelines for the accommodation and care of animals used for experimental and other scientific purposes: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:197:0001:0089:EN:PDF

Guidance documents: Guide for the Care and Use of Laboratory Animals (1996) Institute of Laboratory Animal Research, Commission on Life Sciences, National Research Council: http://www.nap.edu/openbook.php?record_id=5140

Research on humans

Research on humans covers a wide scope, from medical testing or drug trials to the collection of data and biological samples (blood, urine, tissue, cells).

The Issue – As free agents, the most important element to respect in research that involves human subjects is their empowerment. People participate in research experiments on their own free will, with full understanding of the consequences and the ability to withdraw as a subject at any time without coercion or manipulation. In cases where people cannot make those decisions themselves (children, certain elderly populations, those judged as incompetent), guardians need to be identified to consent and monitor the research. Participation in research for money is a widely discussed issue. Should subjects be paid for their participation? How much? Should you only refund their costs? In some countries it is unacceptable to pay people for their involvement in research, while in others payment for participation is expected. Research in developing countries, where fundamental rights may not be well protected and economic need makes for willing participants, carries added ethical concerns.

Illustration – A long-term study on diets and exercise was conducted in a major urban area. A cohort of middle-aged overweight women between the ages of 40 and 50 were selected for the study. At the beginning of the project, they had to answer detailed personal questions about their lives. They were put on three different types of diets and were expected to keep a food log to record their calorie intake. They had to keep a diary recording their physical activity and were provided with a pedometer and GPS tracking device to monitor their movements. The diets were related to their blood types and every month samples of blood and urine were taken to be correlated with the data recorded in the diaries. At the end of the project, the findings were published. The original project proposal did not anticipate ethical issues and had not allocated for an ethics advisor.

Many of the ethical issues here may seem ubiquitous, but need proper attention as this project records data on a person's activities, diet, location, personal history and collects biological samples. The project was required to assign an ethics expert who insisted that the records be anonymised and that he alone had the encryption key. He also contractually assured the subjects that their biological samples would be destroyed after analysis and required validation from the lab. In the consent form, the subjects were informed that they were free to turn off the tracking device at any time and were allowed to exit the project should the diet or activities become too stressful. The ethics expert also arranged for a qualified psychologist to be available for the subjects and that he be present when the final results of the project were presented to each subject. As these requirements had not been foreseen, certain project funding allocations needed to be adjusted.

Research on children

Children are not simply small adults so tests that involve children may, at times, provide information that could not otherwise be obtained. Research has been done and data has been gathered regarding issues from children's health and nutrition to their safety and security. But there are great ethical and societal risks in working with juvenile cohorts: as a trusting population, they may be easily manipulated, exploited or abused. Means to safeguard children from these risks include developing an informed consent process for their guardians, ensuring that the research methodology is not invasive and establishing means to protect their identities with the utmost confidentiality.

Tips

- Ensure informed consent – the test subjects need to know all of the risks, what their full involvement will entail, what will happen to the information after the research and whether they will be informed of the findings.
- Allow subjects to drop out – human participation in research is voluntary. Should a subject decide to no longer participate, they must freely and easily be able to suspend involvement. Providing the option to drop out also makes the commitment more palatable.
- Control expectations – subjects may be hoping for positive results from the research (miracle cures, scientific progress, remuneration ...) so it is important for the researcher to communicate transparently all of the conditions and expectations from the project at the outset.
- Provide counselling – in research projects where the activities may be stressful, painful or emotionally difficult, a counsellor or psychologist should be available for consultation.
- Protect privacy – personal information of the subjects needs to be protected through an anonymisation process that ensures confidentiality. Personal data protection is a must with any personal record keeping, and it is strongly advised to apply a cryptographic procedure.

Relevant EU or international legislation

International Ethical Guidelines for Biomedical Research Involving Human Subjects, Council for International Organizations of Medical Sciences (CIOMS): http://www.cioms.ch/publications/layout_guide2002.pdf

Declaration of Helsinki (Edinburgh, 2000), World Medical Association: http://www.wma.net/en/30publications/10policies/b3/

Dual Use (military, terrorist abuse)

The Issue – Critics often highlight how some of the greatest scientific discoveries have been used by military or terrorist organisations to create destruction on a more inhuman scale than we could have ever imagined. Clearly knives and fire can also have dual malignant uses and researchers cannot be made to be responsible for the efficiency and brutality of evil today. But there is, never-the-less, the association of modern technologies with inhumane, mal-intended actions. Chemical and radioactive substances can be used in bombs, viral strains and bacteria can be released in the environment or new technologies can be used to deliver weapons or disable electronic systems.

Illustration – In 2001, there were a series of letters mailed to public figures and media organisations in the United States containing anthrax spores. Five people were killed and 17 injured by the attacks and widespread panic ensued at a period of heightened terrorist alert (shortly after 9/11). While there was much political speculation on the sources, conclusions eventually shifted towards the anthrax spores coming from a US lab where at least ten scientists had access.

Applicants are expected to develop a comprehensive approach: A detailed strategy addressing the specifics of the situation, putting the necessary safeguards in place.

1. *Awareness – Project applicant should be sufficiently aware of the potential risks (the direct risks for the participants and the risks for the society as a whole). Possible measures can be an ex-ante biosecurity assessment, an early flagging system for biosecurity and biosafety problems and education and training.*
2. *A strategy – Project applicants should develop appropriate and detailed procedures to deal with dangerous or restricted materials or information. Biosecurity and biosafety risk management procedures should comply with relevant standards. These procedures can include access controls, assignment of confidentiality levels, the effective control and monitoring of all procedures and the reporting of near misses.*
3. *Independent expertise – Expertise on biosecurity and dual use should be included in the project management structure or in an independent ethics advisory board. It is the role of experts to oversee and assist in the creation of a comprehensive risk management system.*
4. *Dissemination, communication and exploitation of the results – Can the research results be shared with a wider public? What are the risks and possible consequences? How would the public opinion react? Independent experts can assist in the development of a strategy.*

Tips

- Control access to materials, information or dissemination. Even if the information may already be available on the internet, the researcher must be responsible for any personal dissemination by providing a procedure and restrictions for access and dissemination.
- Establish a code of conduct for scientists involved in the research.
- Secure the lab. Find a way to prevent materials and technologies from getting into the "wrong hands"

Clearly these risk reduction measures will never fully safeguard populations or completely deter determined individuals, but researchers must take moral responsibility to do their utmost to ensure that the intention of their research is for the benefit of society and not its destruction.

Relevant EU or international legislation

Council Regulation (EC) no 428/2009 of 5 May 2009: Setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items: http://trade.ec.europa.eu/doclib/docs/2009/june/tradoc_143390.pdf

Guidance document: A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research: ftp://ftp.cordis.europa.eu/pub/fp7/docs/misconduct-misuse_en.pdf

Protecting the environment

The Issue – Biodiversity decline is an important societal concern, and while research is most often seen as protecting or rehabilitating the environment, certain actors have tried to polarise some research as "anti-nature". Science has sought to understand nature, discover its secrets and learn from it for the benefit of man. But the practice of iterating and improving, of protecting and extracting benefits for man have at times led to negative consequences (pollution, environmental destruction, resource exploitation and unsustainable practices) leading to a perception that researchers often may have violated nature. Certain past errors have created a trust deficit where scientist's interventions on environment are frequently feared (as in research in genetic modification, synthetic biology, new chemicals or nanotechnologies). Should researchers be allowed to work in domains where the effect on the environment is uncertain?

Illustration – Biologists have developed a synthetic catalyst to create a more efficient conversion of biofuels. As it was assumed to provide environmental benefits in the fight against global warming, the researchers had not considered any ethical ramifications from their work. While more efficient, there were ethical consequences of expanding biofuel production (land use reorientation away from food production, loss of biodiversity through increased deforestation, water stresses, land grabs in developing countries ...). Secondly, introducing a synthetic product into the fuel generation process intensified the natural/synthetic debate. Concerns were raised over whether the release of the synthetic substance into the environment through combustion would be a risk to humans, animals or the environment. Researchers struggled with a social narrative that argued that science should not "play God" and that industry-led innovations were destructive to the environment. Approval of the catalyst was not granted and more studies were requested under the precautionary principle.

Tips

- Be prepared to listen: Many stakeholders are passionate about defending nature, and tend to vilify those who do not perceive the environment in the same manner. Dialogue and engagement across a multitude of disciplines will help in the search for common ground.
- Stress the environmental benefits: It is rare to find black or white environmental issues and where you can stress the environmental advantages (or benefits to humans), a more balanced debate will ensue.
- Acknowledge that sustainability is a dominant societal virtue: Similar to the 3 Rs in animal testing, it is advantageous to lower your ecological footprint by replacing unsustainable materials, reducing your use of resources and refining your practices to develop a positive environmental balance.

Relevant EU or international legislation

UN Convention on Biological Diversity, 1992: http://www.cbd.int/doc/legal/cbd-en.pdf

Three Tips to be more ethically prepared

Try to integrate ethical and societal expertise into your research projects

While everyone feels that they know right from wrong, sometimes researchers get too close to the work they are doing, and would benefit from someone who can look at their work from another angle. A research project that engages with an independent ethics expert, or an ethics panel that can provide insight and advice, generally tends to address ethical issues or societal obstacles. Multidisciplinary expertise will always add value to research both in opening up potential new research applications and in preventing negative societal reactions. For example, a synthetic biology research project on biofuel catalysts could benefit from a forest management expert to better understand the societal concerns about biodiversity loss from biofuels harvesting. Or, in cases where human samples are taken and stored, an ethicist will design and implement an informed consent process and a data protection system that can also reassure and keep human subjects involved.

Use existing codes of conduct for researchers

It is rarely the case that researchers act improperly. Unfortunately, a few well-publicised instances have created an elevated public fear and distrust of scientists. The public wants the benefits of research and wants to trust science so by articulating a code of conduct, how researchers should behave, the non-scientific community can be reassured that the research process is being managed responsibly. While codes have been expressed in many past activities and much of it is based on common sense, the mere presence of a code on your research project serves as a benchmark for the research community. This in itself can reassure the general public. As many projects have partners from different countries, expressing the code and comparing its elements could have a learning effect for researchers.

Do not hesitate to seek advice

Ethics panels are made up of individuals from different backgrounds in order to provide a multidisciplinary assessment and recommendations from a broad range of societal interests. Sometimes the conclusions of an ethical review may be difficult to understand. The European Commission operates on the principles of openness and engagement. If any conclusions are unclear or contain vocabulary that may seem ambivalent, researchers should not feel inhibited from asking for clarification or guidance. This document, in itself, is a recognition that sometimes the advice from ethical panels is not altogether clear. Remember one of the first sentences of this booklet: points raised in ethical reviews are not meant to be punishments or attempts to interfere with your research. Rather, they are requests for safeguards to ensure that the public perception of research remains positive, within the remit of the law and in line with national, European and international ethics guidelines. The Commission is here to work with you so when in doubt, seek further advice.

Twelve Golden Rules to Ethical Research Conduct

You must ensure that your research:

- Respects the integrity and dignity of persons (that this intrinsic worth protects them from being used for greater perceived benefits)
- Follows the “Do no harm” principle. Any risks must be clearly communicated to subjects involved
- Recognises the rights of individuals to privacy, personal data protection and freedom of movement
- Honours the requirement of informed consent and continuous dialogue with research subjects
- Treats animals with respect and works under humane conditions before, during and after the research
- Designs animal research in accordance with the 3 Rs: Replacement, Reduction, Refinement
- Respects the principle of proportionality: not imposing more than is necessary on your subjects or going beyond stated objectives (mission creep)
- Treats societal concerns seriously – a researcher’s first obligation is to listen to the public and engage with them in constructive dialogue, transparently, honestly and with integrity
- Tries to prevent being openly available for mis-use or malignant dual use by terrorists or military organisations
- Recognises the wholeness of an individual and that any modification (genetic or technological) does not interfere with this principle
- Respects biodiversity and does not impose irreversible change that threatens the environment or ecological balance
- Builds on the understanding that any benefits are for the good of society, and any widely shared expressions of concern about threats from your research must be considered (with the acceptance that perhaps certain research practices might have to be abandoned)

List of European Ethics legislations

List of International legislations

- Declaration of Helsinki (Edinburgh, 2000), World Medical Association (http://www.wma.net/en/30publications/10policies/b3/)
- Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo 1997, http://www.assembly.coe.int/ASP/Doc/DocListingDetails_E.asp?DocID=8416)
- Universal Declaration on Bioethics and Human Rights adopted by UNESCO's General Conference on 19 October 2005, http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/
- CIOMS/WHO International Ethical Guidelines for Biomedical Research Involving Human Subjects (2001, http://www.cioms.ch/publications/layout_guide2002.pdf)
- European Science Foundation, "Human stem cell research, scientific & ethical dilemmas", Briefing, June 2001: http://www.esf.org/research-areas/medical-sciences/activities/science-policy/human-stem-cell-research-scientific-uncertainties-and-ethical-dilemmas.html

Contact details in the European Commission for ethical issues

Your office

Cordis links on ethics review:

http://cordis.europa.eu/fp7/ethics_en.html#ethics_cl

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Ethics in research is a topic of common interest and ethical concerns raised in public debates should not be ignored. However, ethical issues should not be an obstacle for researchers, but a call to engagement. Ethical issues can be managed in the same way researchers manage other risks: by safeguarding exposure to threats or hazards: the task is to reduce risk and to develop means to safeguard shared societal values. The objective of this Risk-Benefit Analyses and Ethical Issues guidance document is to help researchers comply with the requirements of the Ethics Reviews organized by the European Commission. It identifies the most common ethical issues – research on humans, data protection, animal testing, dual use etc. –, gives definitions and illustrates with examples. It provides researchers with practical tips how to ensure ethically sound research and assists them with enlisting the relevant European and international legislation for consultation.

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