Principles and Approaches in Ethics Assessment

Human Subjects Research

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Annex 1.d
Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries
Deliverable 1.1

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Contents

1. Introduction

This report on human subjects research provides an overview of the use of humans in research in different scientific fields, examines central values and principles central for the area, in addition to providing a discussion of some key ethical issues. Section 2 provides a basic description of human subject research, including a short historical overview. Section 3 provides a brief description of regulatory frameworks in the area. Section 4 offers a discussion on human participation in social science and the humanities. Section 5 introduces and discusses ethical principles and values prevalent in human subjects research and introduces some key ethical issues.

2. Description of the issue

This section gives an overview of human subjects research relating to historical examples. History has provided us with a number of hideous experiments on humans related to research. Among the most well-known experiments are the ones conducted at concentration camps during World War II and were revealed during the Nuremberg trials. Prisoners at the camps were used for testing pharmaceutical drugs and methods for treating injuries and illnesses. Examples show that harmful experiments were conducted on human beings without them giving their consent.

In Dachau, physicians wanted to discover the maximum altitude humans could manage without using oxygen. By using a low-pressure chamber they simulated high altitude. The human test subjects were tested at an altitude of 8,000 to 12,000 meters with and without oxygen. The physicians observed the conditions under which the human subjects developed altitude sickness, when they lost consciousness, under what conditions consciousness and full mobility could be regained, and at what height and under which conditions death occurred. Dr. Sigmund Rascher, physician at Dachau, reported the results to Heinrich Himmler:

> [The test] concerned an extended trial without oxygen at 12 kms altitude with a 37 year-old Jew in good general condition. Breathing was maintained up to 30 minutes. At four minutes the test subject began to perspire and could not hold his head still.
>
> After five minutes cramp attacks commenced, between 6 and 10 minutes breathing became faster and the test subject lost consciousness, from 11 to 30 minutes breathing grew progressively slower, down to three breaths a minute, to then cease entirely.
>
> At times severe cyanosis occurred with foaming at the mouth.
>
> At five-minute intervals electrocardiogram readings were taken with three leads and such were then recorded continuously after the cessation of breathing until all cardiac activity had terminated completely. In conjunction with this, that is roughly half an hour after breathing ceased, dissection began…[1]

Similar things happened in other parts of the world. In Harbin in Northern China, the Japanese Unit 731 undertook lethal experiments on human beings from 1935 to 1945. The experiments included chemical and biological warfare experiments that were tested on human beings. The experiments on human beings in Germany and China in the 1930s and '40s showed mankind that

[1] From a report from Dr Sigmund Rascher to Heinrich Himmler on 5 April 1942 on experiments with a low-pressure chamber in Dachau concentration camp.

research must be controlled and ethically assessed. The German experiments were thus one reason for regulating research in the post-war period when the atrocities were revealed in the Nuremberg trials. The Nuremberg Code of ethics (1947) and the Helsinki Declaration (1962 and on) were some of the outcomes.

It has, however, been debated as to how the atrocities of the time around the World Word II are of relevance for today.[2] Roelcke and Maio (2004) differentiate between two interpretative traditions regarding how we should relate to the experiments on humans that were conducted by the Nazis:

> Physicians, researchers, and bioethicists who claim that the difference between the Nazi research practices and present day human subjects research are so great that the atrocities of the past have no relevance for today; and those who argue that historical research on the topic has been valuable precisely because it illustrates the differences and discontinuities between the Nazi medicine and contemporary research practice, but apart from that, the Nazi experience is irrelevant to present day moral debates.[3]

However, Roelcke and Maio do not agree with this view. They argue that the arguments that were advocated by the offenders at the Nuremberg trials "showed similarities, as well as specific differences to ethical reasoning before and after the Nazi period" and that these are continuities that raise questions for the ethical debate on research involving human subjects today.[4]

Harmful experiments conducted without consent obtained from the research subjects are not something that only occurred during wartime. Numerous cases of abuse occurred both during World War II and afterwards. The Tuskegee syphilis study in US is one example, while the Swedish Vipeholm experiment is another. The Tuskegee syphilis experiment was part of a long-term study on syphilis which took place from 1932 to 1972 and was initiated by the US Public Health Service. The research subjects in the study were approximately 600 African American men diagnosed with syphilis who were never told they had the disease. In order to understand the disease better, the researchers wanted the research subjects left untreated even though penicillin could have cured them. The purpose was to observe the effects of syphilis over time. The studied men were given the impression that they had another disease for which they would get free treatment. The treatment was however ineffective, and two-thirds of the studied men died before the end of the experiment.

The Swedish Vipeholm experiments - the Vipeholm Dental Caries Study - were experiments conducted at the Vipeholm mental hospital – a state hospital in Sweden for individuals that were "intellectually disabled". The purpose of the study was to investigate the kind of effect carbohydrate, especially sugar, had on dental health. Between 1947 and 1949, a group of patients at Vipeholm were given enormous amounts of sweets and sugar in their diet in order to investigate the link between dietary consumption and caries formation. The experiment resulted in ruined teeth for many of the involved subjects.

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[2] Lederer, Susan E., *Subjected to Science. Human Experimentation in America Before the Second World War,* The John Hopkins University Press, London,1997; Roelcke, Volker and Giovanni Maio, *Twentieth Century Ethics of Human Subjects Research. Historical Perspectives on Values, Practices and Regulations,* Franz Steiner Verlag, Stuttgart, 2004.
[3] Roelcke, Volker and Giovanni Maio, *Twentieth Century Ethics of Human Subjects Research. Historical Perspectives on Values, Practices and Regulations,* Franz Steiner Verlag, Stuttgart, 2004.
[4] Ibid.

Research involving humans does not only include biomedical research. One of the most famous psychological studies is the obedience study that was carried out by Stanley Milgram at Yale University in the 1960s. Milgram conducted a psychological experiment on individuals regarding their tendency to choose obedience to authority over personal conscience. The research subjects recruited for the study were told that the experiment would study the effect of punishment on learning ability. They were told that they as research subjects would be randomly chosen to play either the role of the learner or the role of the teacher. In reality none of the research subjects were assigned the role as the learner – that role was played by a cohort of the experiment. During the experiment, the subjects were asked to give the learner an electric shock each time he or she gave the wrong answer to a question. Every time the learner gave a wrong answer, they received an electric shock. If the learner continued to give the wrong answer or being unable to answer, the voltage would increase – from slight shock and, eventually to severe shock. The learner responded to the shocks by grunting and – after more intense shocks – also by screaming out in agony. The result from the study was that 65% of the teachers (the research subjects) progressed to the maximum shock level.[5] Notwithstanding this finding, verbatim transcripts show that the research subjects experienced anxiety and distress during the experiments.

3. Comparative analysis of scientific fields and disciplines related to human subjects research

This section aims at elaborating on human subjects research within the social sciences and the humanities. The regulations that have been considered here thus far all centre on biomedical and behavioural research – even though relevant principles (e.g. from the Declaration of Helsinki) have been applied to social science and the humanities as well.

The. issues concerning human subjects research that arise in relation to social science and/or humanities differs from those in biomedical and behavioural research. The potential harm for participants in social sciences and the humanities are, in general, of a psychological nature and/or linked to how cultures and/or and ethnicities are represented in the community. Research involving humans in within the humanities and social science is often overlooked. Interviews with members of Swedish and Norwegian research ethics committees reveal that the requirement to submit research involving human subjects to ethical assessment is relatively unknown to the researchers within these fields of research.[6] Anthropologists working with living human communities are most likely among researchers to obtain the voluntary and informed consent of research participants. Sometimes performing arts can be considered research, because other performers and/or the audience can be considered to be research subjects.

Research within the field of social science has been discussed in the EU Code of Ethics for Socio-Economic Research.[7] The EU code provides guidelines intended "to form the basis of a voluntary code of practice covering the conduct of socio-economic research in Europe".[8] The code comprises 18 principles divided into three sections: (1) responsibilities to society, (2)

[5] Milgram, Stanley, *Obedience to Authority: An Experimental View*, Harper and Row, New York, 1974.
[6] Interview with Åsa Nilsson Dahlström, member of Linköping Regional Board for Vetting Research Involving Humans, Sweden and Erling Sandemo, The National Committee for Research Ethics in the Social Sciences and the Humanities (NESH), Norway. Both interviewees are members of RECs assessing research in the fields of behavioral science, social sciences and the humanities.
[7] RESPECT Project, "EU Code of Ethics for Socio-Economic Research". http://www.respectproject.org/ethics/412ethics.pdf.
[8] RESPECT Project, "The RESPECT Code of Practice". http://www.respectproject.org/code/.

professional expertise and standards, and (3) responsibilities to research participants. The third section concerns principles regarding voluntary participation, informed consent, confidentiality, and protection from undue intrusion, harm or distress.

Another set of guidelines for social science is the Ethical Guidelines for International Comparative Social Science Research, published by UNESCO and developed within the Management of Social Transformations (MOST) Programme that aims to foster and promote social science research.[9] The MOST guidelines comprise 19 principles and includes principles relevant for human subjects research such as the following: The relation between research risks to the research subjects and potential benefits; relations between researchers and the individuals and groups among whom they do their fieldwork; informed consent; welfare of the informants; providing adequate information by the researchers about their research in all publications; and so on.

4. Organisations

The table below lists some of major organisations that are involved in human subjects' research policy and addressing human subjects research concerns.

Name	Aim	Weblink	Relation to human subjects research
The Association for the Accreditation of Human Research Protection Programs, Inc., AAHRPP	Protection of the rights and welfare of human research participants	http://aahrpp.org	AAHRPP is an independent accrediting body that works to protect the rights and welfare of research participants. The organisation promotes ethically sound research by increasing awareness of ethical and professional conduct of agents engaging in research with human participants.
The Council for International Organizations of Medical Sciences, CIOMS	CIOMS is an international NGO established by WHO and UNESCO with the aim of facilitating and promoting international activities in the field of biomedical sciences.	http://www.cioms.ch	CIOMS has developed guidelines for biomedical research involving humans (International Ethical Guidelines for Biomedical Research Involving Human Subjects)
Council of Europe	The Council of Europe is an inter-governmental organisation with the main purpose of promoting cooperation	http://www.coe.int/en/ http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm	The Council of Europe sets out general standards (the Oviedo convention) for the protection of the dignity of the human person in relation regarding biomedical sciences.

[9] UNESCO, Management of Social Transformations (MOST) Programme. http://www.unesco.org/new/en/social-and-human-sciences/themes/most-programme/.

	between European countries in different areas, e.g. human rights and democratic values.		
European Network of Research Ethics Committees, EUREC	EUREC is a European network with the aim to bring together national research ethics committees or comparable initiatives with other organisations relevant for research involving human participants.	http://www.eurecnet.org	The network forms an infrastructural basis promoting awareness of specific working practices of research ethics committees across Europe in order to meet new challenges and emerging ethical issues related to e.g. human participation in research.
The European Union Agency for Fundamental Rights, FRA	FRA sets out standards to ensure that persons are treated with dignity.	http://www.fra.europa.eu	One of FRA's focal points is children participation in research.
The Hastings Center	The Hastings Center is a bioethics research institute with the aim to address fundamental ethical issues in the areas of health, medicine, and the environment as they affect individuals, communities, and societies.	http://www.hastingscenter.org	The Hasting Center publish two periodical journals: (1) IRB: Ethics & Human Research, which explores issues in research with human subjects. Six issues are published each year, containing peer-reviewed articles and columns, http://www.thehastingscenter.org/Publications/IRB/; (2) The Hastings Center Report, which is a bi-monthly journal inquiring into ethical issues related to health, medicine, and the environment, http://www.thehastingscenter.org/Publications/HCR/
The Office for Human Research Protections, OHRP	OHRP is part of the Office of the Assistant Secretary for Health in the Office of the Secretary, U.S. Department of Health and Human Services with the aim to inform and advice on ethical and regulatory issues in biomedical and behavioral research.	http://www.hhs.gov/ohrp/	OHRP deals with the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP supports the Secretary's Advisory Committee on Human Research Protections (SACHRP) which advises the HHS Secretary on issues of human subject protections.

World Medical Association, WMA	The central aim of the WMA is to establish and promote high standards of ethical behavior and care by physicians.	http://www.wma.net	The WMA has adopted global policy statements on a range of ethical issues related to e.g. research on human subjects.
WHO Research Ethics Review Committee, ERC	ERC is a committee with the purpose to ensure the highest ethical standards in research supported by WHO. It is mandated to review all research projects that involve human participants supported by WHO.	http://www.who.int/ethics/research/en/	ERC reviews all research projects, involving human participants supported either financially or technically by WHO.

Table 1: Key organisations

5. Frameworks and regulations for human subjects research

The experiments on human beings in Germany and China in the 1930s and '40s showed mankind that research must be controlled and ethically assessed. The German experiments also laid the ground for regulation of research in the post-war period. The Nuremberg Code of ethics (1947) and the Declaration of Helsinki (1962 and on) were two outcomes. The Nuremberg Code and the Declaration of Helsinki formulated ethical principles regarding voluntary consent and rules regarding the avoidance of harm of the research subjects.

However, the awareness of research ethical issues and the importance of obtaining formal consent from the research participants are in fact older than post-World War II. Already in the early 20th century, the clinician William Osler tried to identify "the limits of justifiable experimentation". Only when physicians had obtained "full consent" could the experiment could be justified. He also argued that "we have no right to use the patients entrusted to our care for the purpose of experimentation unless direct benefit to the individual is likely to follow."[10] Nevertheless, it was not until after World War II that more systematic attempts to formulate principles for assessing research involving human subjects were developed. The following offers an overview of some of the frameworks and guidelines that were developed following World War II:[11]

[10] Cited from Lederer, Susan E., *Subjected to Science. Human Experimentation in America Before the Second World War,* The John Hopkins University Press, London, 1997.

[11] Besides the declarations, codes and other frameworks related to research that have been developed after the World War II, the Universal Declaration of Human Rights is of course a central document for human subjects research. Article 7 of the Convention states ''No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation''. It is through this statement that society expresses the fundamental human value that is held to

- *The Nuremberg Code*[12] from 1947 was created as a direct result of the atrocities carried out during the World War II and exposed during the Nuremberg trials. The code comprises 10 principles that set out when experimentation on humans is admissible.[13] As the first international code addressing voluntary participation and informed consent, it has served as an important document for research that involves humans.

The first and the most important principle of the code is **informed consent**, that "voluntary consent of the human subject is absolutely essential". A prerequisite for voluntary consent elaborated on in the code is the research subject's capacity to consent. This involves free choice "without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion". Moreover, the subject should also receive enough information on the study (the nature of the study, purpose, duration, possible hazards to be expected, effects upon health or person) so that he or she can make an informed decision. An essential part of voluntary consent is that the participant also has the right to terminate their participation in the experiment at any stage.

Another important provision is **the principle of beneficence**, that the experiment should be expected to produce fruitful results beneficial for society. A third important provision that deserves to be highlighted is **the principle of nonmaleficence** – research involving humans can only be conducted if it is designed so as to avoid all unnecessary physical and mental suffering and injury. Other provisions for research involving humans are that the results should not producible by other means, tests on humans should be preceded by tests on animals, and that qualified researchers should carry out the experiment.[14]

- *The Belmont Report*[15] was published in 1979 with the purpose of providing for the protection of human subjects involved in biomedical and behavioural research. The report identifies ethical principles for research involving humans and provides a guideline to ensure that research is conducted in accordance with those principles. The Belmont report is a US national document, but has international reach.

The Belmont report identifies and explicates three basic ethical principles that should serve as the framework for ethical assessment of research involving humans: respect for persons, beneficence, and justice.

i. **The principle of respect for persons** is based on the value of autonomy. In cases where the autonomy of the research subjects is diminished, there is a requirement for extensive protection of those individuals. The value of autonomy demands that research subjects enter into research voluntarily, without coercion and/or deception. This requires that the research subjects should be provided with adequate information about their participation.

govern all research involving human subjects — the protection of the rights and welfare of all human subjects of scientific experimentation.

[12] http://www.hhs.gov/ohrp/archive/nurcode.html

[13] Nuremberg Code, 1947. http://www.hhs.gov/ohrp/archive/nurcode.html

[14] Nuremberg Code, 1947. http://www.hhs.gov/ohrp/archive/nurcode.html.

[15] http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

ii. **The principle of beneficence** provides an obligation to secure the wellbeing of the research subjects. Two general rules are provided as complements to the principle: (a) "do not harm", and (b) "maximize possible benefits and minimize possible harms.[16]

iii. The report conceives **the principle of justice** as treating people equally when it comes to the distribution of burdens and benefits. The application of the principle of justice in regard to research subjects will lead to prescriptions regarding how to select research subjects. Justice demands that the research community does not involve research subjects that belong to a group that is unlikely to benefit from the research.

The three general principles lead to the consideration of informed consent, risk/benefit assessment, and the process under which human research subjects are selected.

- *The Declaration of Helsinki*[17] (last revision 2008) contains 37 paragraphs regulating research on human beings and is primarily developed for the medical community. The declaration was adopted by the World Medial Association but has relevance for all research involving humans. Here follow some excerpts relevant for human subjects research:[18]

> §16. Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent.
>
> §21. Medical research involving human subjects may only be conducted if the importance of the objective **outweighs the inherent risks and burdens to the research subjects.**
>
> §22. Participation by competent individuals as subjects in medical research must be **voluntary**. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.
>
> §23. Every precaution must be taken to protect the **privacy** of research subjects and the **confidentiality** of their personal information and to minimize the impact of the study on their physical, mental and social integrity (…).

- *UNESCOs Declaration of Bioethics and Human Rights*[19] contains several articles regulating research on human beings:

> Article 2. Scientific research should only be carried out with the prior, free, expressed and **informed consent** of the person concerned.
>
> Article 9. The **privacy** of the persons concerned and the **confidentiality** of their personal information should be respected (…).[20]

[16] Belmont Report, "The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research", 1979. http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
[17] http://www.wma.net/en/30publications/10policies/b3/index.html
[18] WMA, "Declaration of Helsinki: ethical principles for research involving human subjects", 2008. Retrieved 2015-06-30 from http://www.wma.net/en/30publications/10policies/b3/index.html.
[19] http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html
[20] UNESCO, "Declaration of Bioethics and Human Rights". http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

- *CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects*[21] are guidelines adopted by The Council for International Organizations of Medical Sciences (CIOMS). The guidelines were first developed in 1993 and revised in 2002. The aim of the revision was to include ethical issues after the outbreak of the HIV/AIDS pandemic.

According to CIOMS, all research involving human subjects should be conducted in accordance with three basic ethical principles, namely **respect for persons**, **beneficence** and **justice**. The principles set forth in CIOMS are, to a large extent, consistent with the broad principles in the Belmont report. However, one major difference is that CIOMS introduces a proposal of how to deal with informed consent in a culturally sensitive manner, which is not present in the Belmont report. The former states that cultural values should be taken into account in the application of ethical principles, provided that research involving human subjects does not violate any universally applicable ethical standards.[22]

- *Oviedo Convention, Convention on Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* No. 164 (1997)[23] is a European legal framework with the aim to promote the protection of human rights ("the dignity and the identity of human beings") in the biomedical field. It sets out the fundamental principles relevant for medicine as well as to new technologies in human biology and medicine. The principles set forth in the convention are **human dignity** (article 2, 11, 14, 21), **autonomy** (article 5, 6), **confidentiality** (article 10), **beneficence/non-maleficence** (article 4, 16), and **justice** (article 3).[24]

Article 6 in the convention specifies the protection of persons not able to consent. The article states that an intervention (e.g. research) may only be carried out on a person not able to consent if the intervention is of his or her direct benefit. The intervention can only take place after the authorisation of person's representative (e.g. parents in the case of minors).

6. Principles and issues for ethics assessment of human subjects research

As we can see, the declarations include some core values (in bold). These declarations express universal values. Obviously, morality has developed within different cultural traditions like the Confucian, Muslim, Christian, and liberal traditions, etc. Different traditions emphasise different values but there is also a universal basis underlying the differences. Human beings have some needs and interests in common. For example, as human beings, we need both community and autonomy, although the former value receives greater emphasis in the Confucian tradition, while the latter is dominant in the liberal tradition. From a Confucian viewpoint, values like *ren* (humaneness or humanity/benevolence, *yi* (righteousness or justice), *zhen* (truthfulness or sincerity) and *xing* (faithfulness) are important for research ethics.[25] From the universal

[21] http://www.cioms.ch/frame_guidelines_nov_2002.htm
[22] Council for International Organizations of Medical Sciences, "International Ethical Guidelines for Biomedical Research Involving Human Subjects", 2002. http://www.cioms.ch/frame_guidelines_nov_2002.htm.
[23] http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm
[24] The Council of Europe, "Oviedo Convention, Convention on Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine", No. 164 (1997). http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm.
[25] Nie, Jing-Bao, "Challenges of Japanese Doctors' Human Experimentation in China for East-Asian and Chinese Bioethics: Commentary on Tsuchiya", *Eubios Journal of Asian and International Bioethics,* 11 (2001), pp. 3-7.

declarations for research, one can deduce the principles of non-maleficence (do not harm), respect for autonomy, informed consent, privacy and confidentiality.

In the declarations above, we can see some values that are more prominent than others, namely, autonomy, beneficence (nonmaleficence) and justice. In turn, they are the basis for ethics assessment relevant for human research subjects. From those values, we can derive the requirement of informed consent, the requirement of risk/benefit assessment, and the requirements for the process under which human research subjects is selected.

Informed consent is, as we have seen, an ethical requirement for research involving human participants. It is the process whereby a participant is informed about all aspects of the experiment or the trial, and under which the participant makes his or her decision to participate. We saw that the concept of informed consent is embedded in the principles in all of the codes and declarations described in the previous section.

Informed consent is associated with certain difficulties. First, some groups of participants are particularly vulnerable to coercion in a research setting. These groups are, for example, children, prisoners, persons who are mentally disabled, pregnant women, and people that belong to groups that are socially and/or economically vulnerable. Children and mentally disabled persons are vulnerable since they might lack the ability to understand the risks of being involved in research. Others are vulnerable because they are sensitive to coercion, or because they lack certain capacities. Does this mean that those subjects should be excluded from participating in research? After all, some of them might not be able to give an informed consent. Tom L. Beauchamp has argued that the quest for autonomy has led to frameworks for ethics assessment being overly protective of research participants.[26] The problem with being over-protective is that vulnerable groups may be excluded from participating in research and thus not represented in research results, which may not benefit the group or even particular individual in the group.

Another problem with informed consent concerns the difficulty of meeting regulatory requirements. Rosamund Rhodes (2014) mentions public health surveillance, the Internet and its rapid pace of change as issues that have given rise to new and distinctive questions. When conducting research on the Internet, it is often unclear if or how the principle of autonomy and the requirement to collect the participants' informed consent could be met at all. Consider a social scientist who wants to study individuals' online behaviour in social media. How can we apply the "old" principles to these new issues? The Norwegian national research ethics committee for the social sciences, theology, law and the humanities, The National Committee for Research Ethics in the Social Sciences and the Humanities (NESH), has a comprehensive guideline for Norwegian researchers. In order to meet new issues raised by e.g. new technology, the guidelines are under continuous revision. In December 2014, NESH published specific guidelines for Internet research (e.g. if the researcher wants to collect information from an internet forum). NESH argues that there are at least two aspects that have to be considered: First, what is the nature of the social media that the researcher wants to study? Should it be viewed as part of a *private* sphere or in the *public* sphere? Second, can informed consent be obtained? NESH argues that there are several reasons why consent should be obtained before the researcher begins to study the social media in question: It is important to take precautions to ensure that only persons who should participate in the study are the ones recruited. People behind aliases may not

[26] Beauchamp, Tom L., "The Belmont Report", in Ezekiel J. Emanuel et al (eds.), *The Oxford Textbook of Clinical Research Ethics*. Oxford University Press, 2008.

belong to the age group they claim they belong to (e.g. children may perceive themselves as adults). If there are significant problems obtaining informed consent, the researcher should consider refraining from studying the specific social media altogether.[27]

How, then, can the principles of autonomy (informed consent), weighing benefit over harm, and justice be applied? We bring this study to a close by illustrating the application of principles with the following case of research on breast cancer.

> A clinician will carry out a medical experiment and try a new treatment. He will involve 15 of his patients. The aim is to develop a new method for curing cancer. He will use two methods; blood samples and interviews.

The principles mentioned above provide a moral framework for his research. The principle of benevolence, as well as the principle of non-maleficence, are both the basis for his research; he wants to improve the treatment of this widespread and fatal illness. These principles also guide him when he is doing his research. He must minimize the pain inflicted on the patients who participate in the research.

In order to respect the patients, the doctor must follow the principle of informed consent. This means that he must inform the patients about the research and possible harm connected to it and give them the chance to decide whether they want to participate or not. A fair procedure of informed consent presupposes that the patients have the capacity to understand the information and take a decision, that the information is understandable, relevant and comprehensive, and that the women are free to either choose to take part in the experiment or not to take part. Freedom to act does not simply mean that they are not forced to participate. In other words, there should be no manipulation of research subjects. For example, the research subjects must be assured that they have access to the best treatment available even if they chose not to participate.[28] The principle of privacy is secured if the patients consent to the research and if information about them is handled in a confidential manner.

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