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**Working Paper**

## New Methods in Human Subjects Research: Do We Need a New Ethics?

RatSWD Working Paper, No. 80

**Provided in Cooperation with:**

German Data Forum (RatSWD)

*Suggested Citation:* Weber, Karsten (2009) : New Methods in Human Subjects Research: Do We Need a New Ethics?, RatSWD Working Paper, No. 80, Rat für Sozial- und Wirtschaftsdaten (RatSWD), Berlin

This Version is available at:

<https://hdl.handle.net/10419/186188>

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Working Paper

No. 80

### New Methods in Human Subjects Research: Do We Need a New Ethics?

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Karsten Weber

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March 2009

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Federal Ministry  
of Education  
and Research

## Working Paper Series of the Council for Social and Economic Data (RatSWD)

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# New Methods in Human Subjects Research: Do We Need a New Ethics?

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## **Abstract**

Online surveys and interviews, the observations of chat rooms or online games, data mining, knowledge discovery in databases (KDD), collecting biomarkers, employing biometrics, using RFID technology - even as implants in the human body - and other related processes all seem to be more promising, cheaper, faster, and comprehensive than conventional methods of human subjects research. But at the same time these new means of gathering information may pose powerful threats to privacy, autonomy, and informed consent. Online research, particularly involving children and minors but also other vulnerable groups such as ethnic or religious minorities, is in urgent need of an adequate research ethics that can provide reasonable and morally justified constraints for human subjects research. The paper at hand seeks to provide some clarification of these new means of information gathering and the challenges they present to moral concepts like privacy, autonomy, informed consent, beneficence, and justice. Some existing codes of conduct and ethical guidelines are examined to determine whether they provide answers to those challenges and/or whether they can be helpful in the development of principles and regulations governing human subjects research. Finally, some conclusions and recommendations are presented that can help in the task of formulating an adequate research ethics for human subjects research.

**Keywords:** Human Subjects Research, Online Research, Biomarkers, Biometrics, Autonomy, Privacy, Informed Consent, Research Ethics

## Preface

Social researchers today regularly use questionnaires, interviews, or observation in the conventional paper-and-pen style to gather data (including methods like Computer Aided Telephone Interviews (CATI)). Yet it seems more promising, cheaper, faster, and more comprehensive to deploy new means of collecting information: Online surveys and interviews, observations in chat rooms or online games (cf. papers in Hine 2005; Kaye and Johnson 1999; Lyons et al. 2005), data mining in online social networks like Facebook or on individual websites, knowledge discovery in databases (KDD, cf. Tavani 1999a; 1999b; Vedder 1999), collecting biomarkers such as tissue samples or hairs, employing biometrics like face recognition to identify persons (e.g. Clarke and Furnell 2005; Crosbie 2005), using RFID<sup>1</sup> technology to monitor, for instance, consumer behavior in supermarkets (e.g. Lockton and Rosenberg 2005), or even implanting RFIDs into the human body. (cf. EGE 2005).

With the exception of online surveys and interviews, as well as the implantation of RFIDs, these methods can be employed without the awareness and knowledge of those who are being scrutinized. These new techniques are urgently in need of an adequate research ethics. The ethical dimension is critical, for it is almost impossible to administer research completely by legal precepts. Moreover, this option is even not desirable since it implies interference with academic freedom, reduces flexibility, and delays research projects. In addition, national law cannot typically be applied to international research programs. Thus, a research ethics that is widely acceptable across national and cultural borders could potentially serve as a kind of soft law. It is important to stress that, while ethics can be effective in controlling human behavior in general and academic research in particular, it cannot replace law, something made clear by the recent data crime violations in Germany. If people are willing to break the law, laws will not inhibit them and ethics will not either. Nevertheless, the following discussion will deal with ethics rather than law, under the assumption that all means and actions deployed in human subjects research have met all legal requirements.

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1 In their rather technical article, Goodrum et al. (2006) provide an overview of what RFID technology (Radio Frequency Identification) is, how it works, and how it can be used. Roughly speaking, RFIDs are very small computer chips which can store and process information as well as receive and transmit data wirelessly across distances. In the case of passive devices without a power source, this distance ranges from a few centimeters to as far as one or two meters. In the case of active devices with a power source, the broadcasting range can be increased to around ten meters. RFIDs can be used as identification labels for products, animals, and even human beings; they often are mentioned as serious threats to privacy (e.g. Lockton and Rosenberg 2005).

## Research Ethics

### *Different Understandings of Research Ethics*

In the search for an adequate research ethics one does not have to start from scratch. Certain organizations, institutions, and professional associations have already done valuable work in this area that will be referenced in this expert report (e.g. AAAS 1999; AoIR 2002). And yet it is clear that what is understood by research ethics is sometimes quite different in different cases, if one compares, for instance, Germany and the United States.

Research ethics in Germany (*Forschungsethik*) is often used in reference to principles first proposed by Max Weber (1904) or Robert K. Merton (1942). Merton's CUDOS scheme in particular is often cited, according to which science must fulfill the demands of: *communism* or *communalism* (results must be shared with the scientific community), *universality* (everybody shall be able to participate in science regardless of nationality, religion, culture, etc.), *disinterestedness* (scientists shall present results as if they had no personal interest in their rejection or acceptance), *originality* (researchers shall aim to develop novel claims), and *skepticism* (science and its claims shall always be subject to critical examination).

Of course, these demands are widely accepted in the United States too, but they are complemented by principles and rules that guide daily research routines and the application of research methods. These principles and rules will be identified below. It is important also to note that German codes of conduct and ethical guidelines regarding social science or marketing research (ADM 2001; DGS/BDS 1992) already include some similar rules. However, these documents seem more concerned with the relationship of principal and agent rather than with the relationship of researcher and research subject - for instance in the DIN ISO 20252.

### *Principles in Research Ethics*

It does not make sense to try to find moral rules specifically for guiding either online surveys, data mining, collecting biomarkers, or the application of RFIDs. Instead, it is important to identify more general principles that can be applied to all new techniques of gathering information. Since these principles are, of course, principles it should not make a big difference whether they are being applied to conventional social science methods or to newer ones.

At the same time, principles are abstract in that they do not tell us which action to take in a certain situation. For instance, Immanuel Kant's moral imperative demands generalizability of reasons for taking a certain action but is silent with regard to morally acceptable actions. Thus

it is necessary to supplement principles with advice on how to implement them in the research process.

In its *Scientific Freedom, Responsibility and Law Program* (AAAS 1999), the American Association for the Advancement of Science identifies three basic principles to guide research on human subjects: autonomy, beneficence, and justice. This document also introduces supporting principles such as privacy and informed consent. Thus, in the first section of this article, these principles are described in general and then applied to new techniques of gathering information. This is followed by a short discussion and concludes with the presentation of some conclusions and recommendations. Due to a lack of space, it is impossible to provide a comprehensive discussion on the problem of new techniques in human subjects research. Therefore, this text focuses on some of the most pressing issues.

## **Basic Principles and Their Application**

In approaching the following discussion, it is important to note that the way that concepts like autonomy, beneficence, and privacy are understood is culturally determined. This does not necessarily imply moral relativism; however, the understanding advanced here is not the only possible and existing one. Nonetheless, this paper takes the position that respect for the following ethical principles should form a kind of default option in human subjects research. It is always possible to reduce the requirements that have to be respected, but a research ethics based upon universal human rights and dignity should not allow research that does not respect these principles. They can be understood as absolutes that can only be abandoned if, and only if, research subjects deliberately consent. Such a position makes it possible to adapt these principles to other cultural contexts without diminishing the core values of our own ethics.

### *Autonomy, Informed Consent, and Privacy*

Whether a person is to be granted autonomy or is already, by virtue of being a person, autonomous, is a question that has been discussed at least since the beginnings of Greek philosophy. The debate over informed consent has a more recent twentieth-century history, particularly as it pertains to the ethics of medicine and bioethics (cf. Sade 2001). The significance of privacy has been formulated at least since the hallmark paper of Warren and Brandeis, “The Right to Privacy,” published in 1890.

## General Remarks

The concept of autonomy is a versatile one that can be filled with diverse meanings. In general, one can use “autonomy” as a descriptive term as well as ascriptive term. As *descriptive* term, it “[...] refers to people’s actual condition and signifies the extent to which they are meaningfully ‘self-governed’ in a universe shaped by causal forces” (Fallon 1994, 877). To be autonomous, a person must meet certain criteria like being able to make decisions on rational grounds. Simultaneously, the term presupposes set of conditions, such as the absence of coercion. Used as *ascriptive* term, “[...] autonomy represents [...] their right to make and act on their own decisions, even if those decisions are ill-considered or substantively unwise.” (Fallon, 878) It is important to stress that this understanding of autonomy focuses on the individual. In non-western societies it is the case that either some adults, frequently women, are not granted autonomy, or the idea that individuals should or do have the opportunity to make independent decisions is essentially denied (cf. Olinger et al. 2005). Since autonomy in its descriptive sense is a matter of degree, it has often been argued even in western societies that certain circumstances allow for interference with a person’s individual decision; such as perspective is often called “paternalism” (cf. Scoccia 1990) and will be discussed with reference to beneficence below.

In order to make autonomous decisions some conditions must be met; being informed is one of these basic requirements. But informed consent is not always required of human subjects research. Gathering information that is publicly accessible - for instance, the content of television and radio programs or conducting observation in public spaces - does not require consent (cf. ASSS 1999, 7). That means that the distinction between private and public sphere is extremely important to human subjects research. If a researcher interferes with a person’s private sphere or privacy, informed consent must be obtained (cf. Jacobson 1999, 135).

The shortest definition of privacy probably was coined by Samuel D. Warren and Louis D. Brandeis in 1890, who defined privacy as “the right to be let alone.” Although their definition was and remains influential, far more detailed theorizations of privacy have emerged in recent years. In the context of human subjects research, and particularly with regard to new techniques of information gathering, the “control theory” and the “restricted access theory” of privacy (Tavani 1999b) should be mentioned. In control theory “[...] one has privacy if and only if one has control over information about oneself.” (Tavani, 267). According to restricted access theory, “[...] an individual has privacy in a ‘situation’ if in that particular situation the individual is ‘protected from intrusion, interference, and information access by others’” (Tavani). It must be again stressed here that the notion of privacy, like that of autonomy, is



culturally biased.<sup>2</sup>

## Application

Although autonomy has been discussed for a much longer time than informed consent and privacy the latter two seem to be more important for human subjects research ethics. Privacy and informed consent are necessary prerequisites of autonomy insofar as it concerns the application of the new methods of information gathering mentioned above.

To respect privacy it is essential to develop at least a working definition of private and public spheres. For instance, there is currently an intense debate about whether web pages, chat rooms, Usenet forums, and the like are public or private spaces. Often web pages are compared to radio and television broadcasting, which are publicly accessible and therefore allowed to be scrutinized without asking for any kind of consent from the broadcaster (AAAS 1999, 7).

However, without further indications one cannot presume that the creation and publication of Internet web pages automatically implies consent to their use for research purposes. One indication, for example, that authors of web pages do not consent to certain types of research use is when their pages contain so-called meta-tags which say that the respective web page must not be included in the index of a search engine like Google.<sup>3</sup> According to the control/restricted access theories of privacy, the use of such technical strategies is a way that authors of web pages try to take control over the flow of information.

Additionally, one main difference between radio and television broadcasting on the one hand and web pages on the other is that web pages regularly contain information directly related to identifiable persons. Since human subjects research must meet the requirement of beneficence (see below), collecting information from such web pages potentially can cause harm to their authors. Clearly, these are cases that call out for informed consent. Finally, gathering data from web pages might interfere with copyright and intellectual property rights, which would also make informed consent mandatory (cf. Allen et al. 2008; Berry 2004; Carusi 2008; Grimes 2008; Hudson and Bruckman 2004; Jacobson 1999).

Some of the arguments mentioned above imply that the information to be collected is publicly accessible and that public accessibility offers necessary as well as sufficient criteria for abandoning the requirement of informed consent. Under this assumption, new methods of gathering data like observations in chat rooms or online games, data mining in online social

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2 See, for example, the papers in the journal *Ethics and Information Technology* 7 (1) 2005. Yet, with reference to Newell (1998) one can arguably deny that such differences really exist.

3 Or in cases the website includes a file called "robots.txt," again with specific entries.

networks, or knowledge discovery in databases, regularly demand informed consent because it cannot be presumed that these sources of data are supposed to be publicly accessible (cf. Tavani 1999a; 1999b; Vedder 1999). Rather, they must be understood as belonging to the private sphere of a certain group of individuals or a subculture. Consequently, to support autonomous decision making with regard to participation in human subjects research it is vital to ask for consent.

With regard to other methods like collecting biomarkers, such as tissue samples or hairs, employing biometrics, or using RFID technology to monitor persons' behavior, researchers must regularly assume that those who are being observed conceive of their behavior as something that belongs to their private sphere. Typically biomarkers are not intentionally but rather accidentally put into circulation. Therefore one cannot assume consent has been given to further investigation in human subjects research. The collection of biomarkers in the context of medical treatment proves this as a general rule, for it is mandatory to ask explicitly for consent and to inform the individual of potential risks and consequences. Therefore, if human subjects research conducted outside contexts like medical treatment is at stake, particularly if information about health status or the consuming habits of individuals are being gathered, informed consent, from an ethical point of view, seems mandatory (cf. Bayertz et al. 2001; see also below on "Beneficence").

Lastly, using RFID implants for research purposes seems entirely inappropriate. After implantation, subjects have virtually lost their ability to autonomously stop the research process. Simultaneously, the risks of scarring, infection, and other health risks are quite difficult to evaluate, particularly for non-specialists (EGE 2005, 18; see below). Thus, for the application of RFIDs, well-informed consent is difficult or even impossible to obtain.

## *Beneficence*

### General Remarks

Generally speaking, beneficence as a moral claim means that with our actions we aim to promote the good of others and increase their benefits, and also try to prevent harm from others. As a guiding principle for our behavior, beneficence requires us to take the consequences of our actions into account. Therefore, it is necessary to try to forecast the possible and likely outcomes of current and future decisions. Obviously, such forecasts often are difficult or even impossible.<sup>4</sup> However, that is not the main problem posed by beneficence;

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<sup>4</sup> One important response to this problem is represented by the "precautionary principle" (cf. Morris 2000). Except for the EGE Opinion No. 20 (EGE 2005, 17) the precautionary principle has not been explicitly taken into account in those codes of conduct or ethical guidelines referred to in the text at hand.

rather, it is that beneficence may collide with the principle of autonomy. In moral as well as in political philosophy there is rigorous debate over whether the benefit to a person can be objectively measured or whether it can only be evaluated from an individual point of view. The latter view purports that, for instance, what is harmful for one person could be a benefit for another.

### Application

Human subjects research in general can expose individuals to certain risks of harm. Although it might be difficult or even impossible to define one single standard of good and harm that is acceptable for every person, it is obvious that some consequences of human subjects research are unambiguously intolerable: mental or physical harm, discrimination, damage or loss of property, and the like. Particularly where methods are employed that make subjects (potentially) identifiable, and thus may expose them to such consequences, it is extremely important to take the principle of beneficence into account. With regard to, for instance, data mining, KDD, biomarkers, or biometrics, the risk assessment of possible identification is therefore mandatory. It could be that a single set of data does not allow for identification of subjects, but a combination of several different databases would present this possibility. In such cases research subjects must be informed and asked for their consent—regardless of whether publicly accessible data is used or not. Particularly if risk assessment is impossible or does not provide viable evidence, the principle of beneficence may even require a cessation of research.

### *Justice*

#### General Remarks

The third basic principle that shall guide research is justice, which demands a fair distribution of risks and benefits resulting from our actions. As described in the report of the AAAS (1999, 3): “Since the fruits of knowledge can come at a cost to those participating in research [...] justice [...] seeks a fair distribution of the burdens and benefits associated with research, so that certain individuals or groups do not bear disproportionate risks while others reap the benefits.” In fact, justice can be interpreted as impartial beneficence. It is important to stress that a fair distribution of burdens and benefits does not necessarily imply equality but equity in distribution.

## Application

With regard to human subjects research “[...] justice is perhaps the most elusive [principle] in terms of application and understanding” (AAAS 1999, 14). As already mentioned, it is quite difficult to make exact determinations around the notions of good, harm, and beneficence. If the term “justice” is understood as impartial beneficence, it is still unclear how to benefits and burdens of human subjects research might be shared. In fact, it might be argued that since it is difficult to determine positive as well as negative outcomes of research it would not make sense to talk about the just distribution of these outcomes. Nonetheless, there is one notion of justice that has a direct impact on human subjects research: The principle of justice does not allow for the instrumentalization of individuals or groups of individuals who certainly will never be, not even potentially, beneficiaries of a specific research program.<sup>5</sup>

## A Special Problem

A very important question concerning autonomy, privacy, and informed consent is the problem of research on children and minors, for example in the behavioral sciences, social sciences, epidemiology, or pedagogy and educational sciences. This kind of research is continuously growing as the critical importance of the first years of the life course becomes more and more obvious, for example, in research pertaining to school and preschool education. Yet, if one takes a closer look at the existing codes of ethics and codes of conduct as well as at the literature concerning ethics in general, children and minors are occasionally mentioned, but it is very difficult to find concrete advice for research.

For instance, in the report, *Ethical and Legal Aspects of Human Subjects Research on the Internet*, only two sentences on minors can be found: “For example, minors could respond to a study involving inappropriate materials for their age without the researcher’s knowledge” (AAAS 1999, 8) and “Researchers are obligated by federal policies and professional ethics to provide special consideration for vulnerable members of the community, such as children and persons of diminished mental capacity” (AAAS, 5).

In the *ICC/ESOMAR International Code on Market and Social Research* one comes across statements like, “Market researchers shall take special care when carrying out research among children and young people” (ICC/ESOMAR 2007, 2), or “Researchers shall take special care when interviewing children and young people. The consent of the parent or

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<sup>5</sup> To use an example from biomedical research: Pharmaceutical tests in developing countries which test drugs that will not be sold in the respective countries or that are not affordable for the research subjects themselves.

responsible adult shall first be obtained before interviewing children” (ICC/ESOMAR, 6).

The *EGE Opinion No. 20* says that “ICT devices should be implanted in minors and legally incapacitated only if this is done in accordance with the principles set out in the Council of Europe Convention on Biomedicine and Human Rights” (EGE 2005, 31).

Finally, both the code of ethics adopted by the German Sociology Association (DGS/BDS 1992) as well as the 2001 report, “Standards for Quality Assurance for Online Surveys” (*Standards zur Qualitätssicherung für Online-Befragungen*) by the German Working Group for Market and Social Research Institutes (ADM), are almost completely silent on the question of ethics in human subjects research. Furthermore, neither the ADM’s “Guidelines on the Use of Mystery Research in Market and Social Research” (*Richtlinie für den Einsatz von Mystery Research<sup>6</sup> in der Markt- und Sozialforschung*) from 1995, nor its “Guidelines for Online Surveys” (*Richtlinie für Online-Befragungen*) from 2000 refer to children or minors at all.

To summarize, scholars will on the whole find few if any references to legal regulation, but even fewer instructions concerning the design of research on children and minors. However, one can find detailed recommendations in, *Ethical Decision-Making and Internet Research*, a document put out by the Association of Internet Researchers in 2002.<sup>7</sup> Unfortunately, one must derive these recommendations from three sample consent forms for parents and children involved in Internet research. Nevertheless, this might be a useful point of departure for considering this question in individual contexts.

## Conclusions, Requirements, and Recommendations

The above-mentioned principles of autonomy, privacy, informed consent, beneficence, and justice are important as ethical principles in themselves. As guiding principles for human subjects research, they have particular potency. However, they must be supplemented by rules for their application in research design and on research processes. So far, some deficits can be identified that point directly to some specific requirements and recommendations.

- Human subjects research programs should employ risk assessment procedures concerning the potential for identification of research subjects if multiple databases

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6 “Mystery Research” includes covert observations in chat rooms and other similar online sites. Significantly, the ADM assumes that mystery research does not require informed consent. Nevertheless, it should be noted that the ADM does provide “Guidelines for Interviewing Minors” (*Richtlinie für die Befragung von Minderjährigen*) (ADM 1996) that contain comparable recommendations to those of the AoIR (2002). However, a detailed interpretation of all the ADM’s guidelines would probably reveal some incompatibilities and even contradictions, for example with regard to informed consent in the case of online (“mystery”) research on children and minors.

7 Association of Internet Researchers, for more information refer to <<http://www.aoir.org>>, last visited 01/05/2009.

are combined;

- Thresholds must be defined concerning acceptable risks for research subjects that also differentiate between children, minors, and adults;<sup>8</sup>
- A more appropriate definition of beneficence must be developed that focuses on preventing individual harm. The goal of working for the good for each research subject is highly implausible, difficult, and perhaps even impossible to obtain;
- Specific and concrete rules concerning human subjects research on children and minors must be developed and then incorporated into codes of ethics and codes of conduct. Specific attention must be given to the issue of data collection that involves children and minors who are now adults, particularly with regard to panel surveys. In such situations it is recommended that research subjects be asked for the renewal of informed consent. In the case of a denial it would then be mandatory to delete all personal data, for example names and addresses, out of respect for autonomy, privacy, and beneficence (sometimes it might even be necessary to consider to delete *all* existing data to comply with copyright and intellectual property rights);
- As far as possible, thresholds, definitions, and rules concerning human subjects research must not be based on particular, culturally determined customs and traditions. Reference to customs and traditions makes it more difficult to adopt a general research ethics to different cultural contexts;
- Because such definitions and thresholds are often difficult to generalize - particularly in case of long-term research projects - projects involving a very large number of participants, or projects involving subjects with greater vulnerability like children or members of ethnic or religious minorities, it might be necessary to establish ethics committees specifically for human subjects survey research, similar to those that exist in (bio-)medical research programs.

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8 Such thresholds already exist in animal research but are probably not sufficient for human subjects research. Animal-related research does not deal with questions concerning autonomy, privacy, and informed consent. However, it might be helpful to study the history of how such thresholds developed.

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