Opinion on the ethics of research in the sciences of human behaviour. Report.

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Opinion (1)

The Director of the Life Sciences Department of the Centre national de la recherche scientifique (CNRS - National Scientific Research Centre) has consulted the National Consultative Ethics Committee for Health and Life Sciences (CCNE) on the subject of the ethics of research on human beings in the behavioural sciences, and especially in psychology.

The CCNE observes that in France, since the " Opinion on the testing of new treatments on humans" , pronounced by the CCNE on October 9th 1984, and then the " law on the protection of persons who consent to biomedical research" of December 20th 1988, all " trials or experiments organised and practised on the human being, with a view to developing biological or medical knowledge" are taking place within a precise ethical and legal framework. On the other hand, the legislator does not seem to have brought his attention to bear on the protection of persons who consent to behavioural research, and investigations with human subjects, that aim to develop our knowledge in the behavioural sciences, have less explicit ethical references.

The CCNE recalls that any experimental investigation with human subjects, whether for the purpose of developing biomedical knowledge, or in order to gain behavioural understanding, must be carried out in accordance with an irreproachable scientific method, and with full respect for the freedom of action of persons, of their safety and of the principle of justice; and that free, informed and expressed consent of the persons, who consent to the research, does not discharge researchers of their moral and scientific responsibility.

The CCNE has been attentive to methodological and ethical difficulties specific to scientific investigation of human behaviour. After having heard out a number of researchers, it recalls that a study with human subjects must not be an occasion for manipulation or discrimination, and that the chain of professional confidentiality must remain strong throughout.

In the event, that subjects who consent to the study cannot be completely informed before

the experiment, because providing them with complete information could modify the behaviour one wishes to study, the CCNE recommends:

(1) that, when they give their initial consent, the subjects be warned that certain aspects of the research objectives or methodology are being deliberately held back, in the interests of the study, that they may interrupt their participation at any time, and that all their questions will be answered when the study is over;

(2) that the subjects be given, at the end of the experiment, an exhaustive explanation of the objective of the work, of the observations made of themselves, and of the use to be made of the data, allowing them, once fully informed, to confirm or to withdraw their consent. Whenever researchers collect data that (directly or indirectly) identifies a subject, his explicit consent is absolutely necessary for any use to be made of such data.

The sharing, for research purposes, of medical and/or psychological information about individual subjects is presently prohibited in France both by the law, and by deontology. However, the CCNE feels that some research work, whose value is recognized, could be done under the umbrella of shared professional confidentiality. If, as part of a research project, psychologists were to process certain personal medical data, under their own responsibility, it would be necessary that these psychologists be formally entitled to do so, and the physician be explicitly authorized in advance by the persons concerned to communicate these data. Analogously, if medical researchers, were, as part of a research project, to use identifying data collected by practising psychologists in the course of their work, it would be necessary that these medical researchers be formally entitled to do so, and that the psychologist be explicitly authorised by the persons concerned to communicate these data. The entitlement could be given by a multidisciplinary body, under the aegis of the ministries responsible for research and health. If ever the law does come around to permitting such sharing of professional secrets for research purposes, the conditions, under which a person may release his physician or his psychologist from the confidentiality obligation, would have to be spelled out very carefully.

The CCNE believes that research protocols in the human behaviour sciences should be submitted, for opinion and before execution, to *Consultative Committees for the Protection of Persons consenting to Behavioural Research* (CCPPRC), whose composition would guarantee enough diversity of competence, to examine research protocols in various human sciences other than medicine.

These committees would be entrusted, in particular:

(1) with evaluating the scientific relevance of research projects,

(2) with ensuring that the freedom and safety of subjects are protected:

- by making sure that proposed experiments do not threaten either the safety or the dignity of persons who consent to them,

- by assessing the procedures in the protocol for information of and consent by persons participating in the study, especially when this information is to be incomplete, in the initial phase of the project,

(3) to hear out researchers or subjects, at their request, should a particular ethical problem arise in the course of a study.

On a provisional basis, and until the legislator is inspired by the example of the corresponding biomedical committees (CCPPRB) to create such committees, and to set out the main guidelines for their action, the French experience previous to the 1988 law would point in the direction of creating " Research Ethics Committees for Human Behavioural Sciences" , at institutions where such research is done: CNRS, INSERM, universities, etc. These committees would be the consciences of these institutions, and an expression of their

will to ensure that their research is of high quality, and that subjects are adequately protected.

This opinion is a first stage in the CCNE's thinking, which will have to develop together with that of human sciences researchers, scientific institutions harbouring human sciences research (whether the research is basic or applied), the competent administrative authorities, and the legislator, with a view to setting out the ethical and legal framework, in which it seems desirable that experimental investigations into human behaviour be conducted in the future.

Report

By a letter dated January 15th 1993 to the Chairman of the National Consultative Ethics Committee for Health and Life Sciences (CCNE), the Director of the Life Sciences Department of the Centre national de la recherche scientifique (CNRS) submitted five files, for the CCNE's opinion, describing psychology research carried out in university laboratories supported by the CNRS, or carried out in part by CNRS researchers, together with an overall description of psychology research at the CNRS. Among the five files in question, which had been approved by the competent scientific commission of the CNRS, two (the Duyme and Carlier files(2)) relate to the laboratory headed by Professor Roubertoux, and correspond to research that was interrupted, following the appearance on December 17th 1992 of an article in the weekly *L'Express* .

The CCNE set up a working group.

This group familiarized itself with the great variety of research done at the CNRS in the human sciences. For psychology alone, about fifteen research units (mostly Applied Research Units), representing 150 researchers and about 200 teaching researchers, are grouped together in Section 29, called " Mental functions, integrative neurosciences and behaviours" , and co-managed by the Life Sciences Department and the Human and Social Sciences Department. The objective of this research is " to understand the skills and the performances of the human being in the course of different periods of his life, in habitual situations as well as in exceptional circumstances" . The methods range from simple observation in a natural or standardised situation, to tests of reactions in " extreme situations" . The subjects are recruited on a volunteer basis. The identified subdisciplines are: psychology of the child and of development, social psychology, cognitive psychology, psychology of work, ergonomics, psycholinguistics, psychopathology, clinical psychology, neuropsychology, psychopharmacology. There is frequent interface with neighbouring disciplines: anthropology, neurosciences, psychiatry, linguistics, sociology, education sciences, artificial intelligence, etc.

The working group met approximately once per month between January and June 1993. It met with the Operational committee for ethics in the life sciences of the CNRS (COPÉ, January 22th 1993). It heard from several researchers. It gathered information on problems specific to research in human sciences, on professional codes of ethics, and on the way in which experimental human sciences investigations with human subjects are organized in other countries.

The CCNE notes that in France, since the " Law on the protection of subjects in biomedical research" of December 20th 1988, " trials or experiments organised with and practised on human subjects, with a view to increasing biological or medical knowledge" take place within a precise and constraining legal framework. On the other hand, the legislator has not brought his attention to bear on the protection of persons who consent to behavioural research, and investigations with human subjects, that aim to develop knowledge in the disciplines collectively known as the " human sciences" , have been left in a fuzzy legal situation.

The CCNE hereinafter recapitulates:

- the ethical principles that must guide any investigation with human subjects,

- the particular problems it has identified in the case of behavioural research, and the approaches or solutions it proposes.

With this work having been done, the CCNE invites all human sciences researchers, scientific institutions that harbour human sciences research (whether the research is basic or applied), the competent administrative authorities, and the legislator to engage in joint reflection and broad consultation, with a view to setting out the ethical and legal framework, within which our society would like to see experimental investigations into human behaviour conducted in the future.

In its report *Ethique et Connaissance* (Ethics and Knowledge), the CCNE writes: " *seeking to gain scientific knowledge of the human being is a good, but this cannot be done at the expense of justice, or of the safety and autonomy of individuals* " (p. 74, 1990).

This applies to any research on human beings, just as much in the behavioural sciences as in the biomedical sciences. In fact, in this 1990 Report (Chapter 2), the CCNE took into consideration a whole range of research work at the intersection of the biomedical and behavioural domains: studies on learning, on adaptation to the environment and to work tasks (ergonomics), on reactions of the human organism to extreme conditions (hyperbaric, hypobaric, microgravitational, extreme climates, perturbation of nyctohemeral cycles, competitive or endurance sporting, civilian or military exploits), on the quality of life and harmful environmental effects.

In France, the protection of persons who consent to biomedical research depends on law N° 88-1138 of December 20th 1988 (amended as N° 90-86). The protection of persons who consent to behavioural research depends, for the time being, on the deontology of the researchers (for example, the psychologists' code of ethics(3)).

The recommendations that the CCNE is going to formulate on the ethics of behavioural research must, in the interests of consistency, be in line with the law N° 88-1138 of December 20th 1988. The main principles of directives concerning research with human subjects, as formulated in the United States by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-78), or in Canada by the Medical Research Council (1986), and then by the National Council on Bioethics in Human Research (NCBHR), are the same for all such research, whether in the biomedical sciences or the human sciences, even if specific problems are then identified, as a function of the discipline (cancerology, psychiatry, ethnology, etc.), or for different categories of subjects (children, captive or exiled populations, old people with reduced autonomy, etc.).

Thus, it can be accepted that the main ethical principles governing research with human subjects (which the American National Commission refers to as the principles of justice, of beneficence, and of respect for the autonomy of individuals), as well as the rules flowing therefrom (rule of equal treatment or non-discrimination, rule of minimization of risk and optimization of benefit, rule of consent), are the same, whether the research is biomedical or behavioural. It can also be accepted, that the procedure, consisting in submission of human subject research protocols, before their execution, for review by an " independent committee" , an " ethics committee" or a " committee for the protection of persons" , is applicable to behavioural research. In the sequel, we refer to " CCPPRCs" (Consultative Committees for the Protection of Persons consenting to Behavioural Research), without prejudging their relationship with the CCPPRBs instituted by the law N° 88-1138 of December 20th 1988 (which will be discussed below).

Main principles

The freedom of persons

Freedom has a negative dimension (independence): not being forced to do something one does not want to do, and a positive dimension (autonomy): acting in accordance with what one really wants for oneself. It is generally accepted, that respecting the freedom of persons implies that one accepts the rule: no investigation shall be conducted with human subjects, unless these persons give their " free, informed and expressed" (L.209-9) consent(4) to the investigation.

Interpreting the law N° 88-1138 of December 20th 1988 (Article L.209-9):

- The consent is *expressed* , if it is " given in writing, or, should that be impossible, attested by a third party (...) independent of the investigators" .

- The consent is *informed* , if the subject has been sufficiently informed, has understood the information, and has had time to reflect before making his choice known. For the information to be sufficient, the law of December 20th 1988 specifies that the investigator must make known to the subject:

- the research objectives, methodology and duration,

- the expected benefits, and the foreseeable constraints and risks, even when the research is halted before its planned ending date,

- the opinion of a CCPPRC.
- The consent is *free* if the investigator abstains from all forms pressure, coercion and strong incentive (money, passing an examination, career advantage, affective blackmail, etc.).

Moreover, consent for the research is revocable. Subjects must be informed that they may cease to participate, at any time, without incurring any penalty or reproach.

Safety. The human cost

In biomedical research, it is accepted that certain research protocols may involve a " *direct individual benefit* " (Article L.209-1) for consenting persons. This concept of (potential) benefit for the subject serves, in medicine, to authorize the inclusion in research protocols, but under certain conditions (Article L.209-6), persons whose consent is dubious or even impossible (minors, adults under guardianship, persons residing in a public health or social institution, patients in an emergency situation).

In behavioural research, there may also be cases of investigations " with direct individual benefit" , for example, in clinical psychology, in the case of a comparative study of two psychotherapeutic methods (if the benefit for consenting subjects of at least one of the methods is established), or in cognitive psychology (if the fact that children consent to a study gives them an educational advantage, as was stated in the CNRS file regarding the Lautrey protocol). But given the absence of vital emergencies that obligate the practitioner to intervene, and given how difficult it is to argue that research is done " for the good" of included subjects, or " in the interest of their health" , the " with/without direct individual benefit" distinction is not sufficiently applicable to behavioural research, to justify relaxing the consent conditions, even in the case of applied research. This distinction is applicable only within the framework of the risk-advantage balance.

In its report of 1990, the CCNE noted that, as a general rule, persons who consent to an investigation, whose objective is gaining knowledge about human beings, do not see this as to their personal advantage. The CCNE considered this to be admisible, " *provided there is*

an acceptable risk-advantage balance, that is, a definite advantage for the community, and a zero or minimal risk for the individual" (p. 70).

To assess the risk-advantage balance means to ask whether the risks, constraints or discomfort imposed on the subjects (" human cost") are sufficiently justified by the scientific significance of the question posed, and by the assurance that the suggested protocol will serve to resolve this question.

In behavioural research, apart from the need explicitly to evaluate physical risk, one must pay particular attention to the psychological risks of experiments, and to their possible consequences (no humiliating, degrading or traumatizing experiments).

Justice. Human dignity

In biomedical research, the principle of justice serves primarily to recall, that scientific research must never involve exploitation (for example, exploitation by researchers in developed countries of poor populations in developing countries, which serve as " guinea pigs" for the acquisition of knowledge, whose therapeutic spin-offs are of benefit mainly to populations in rich countries: see WHO-CIOMS, 1982). It then serves to recall, as the CCNE has done in its 1990 Report (p. 72), that participation in a research protocol calls for " *fair indemnity* " or " *compensation"* for the subjects, but to the exclusion of any remuneration.

In behavioural research, cases of (North-South) exploitation have been brought (in ethnology, in anthropology), but in the background there was usually a problem of ethnic or cultural discrimination (attitude of the " developed" to the " savage"). Clear risks of *discrimination* have been raised in the case of investigation of distinctive characteristics, that are a source of social worth or the opposite (" intelligence quotient" , " crime chromosome" , etc.). On the other hand, the practice in behavioural research of remunerating subjects (for example, on a fee basis) has not given rise to many objections as yet. There are salaried professionals (test pilots, underwater divers) who accept being guinea pigs in the exercise of their profession. Conversely, many volunteers are not indemnified (when their contribution is minimal, or when, as in the case of students, they receive an intellectual or didactic benefit). Therefore, it cannot be said either that all volunteers should be indemnified, or that any remuneration is contrary to ethical principles.

From the point of view of equity, the central problem in behavioural research seems to be the problem of possible discrimination, whether connected with the research protocol itself, or with the research results and the way they are understood and utilised (socio-cultural " spin-offs").

Ethical review by "independent" bodies

In the case of biomedical research, French law submits to review by CCPPRBs any " trials or experiments" . It exempts " studies" (research work done only on paper, or with samples collected independently of the study, for example, taken from a blood bank).

The American federal directives (DHHS, 1981) set out three categories of research with human subjects: exempted from ethical review, submitted to a simplified procedure of ethical review (" expedited review" by the bureau of an IRB), and submitted to in-depth ethical discussion (discussion in session by an IRB).

For the human sciences, one could propose a distinction between simple observation and construction of an experimental situation, in order to provide for a rapid procedure (simple review of the protocol), and a normal ethical review procedure (possibly requiring the actual presence of the investigators). However, this distinction is tricky to make, for in fact, as

D. Widl\'9acher has quite rightly pointed out, there are " quite innocent experiments" and potentially traumatizing observations.

Problems specific to behavioural research, as identified from the protocols submitted by the CNRS

Consent

- Under what conditions is behavioural research admissible, when the subjects have a problematic *ability to give consent* (limited competence, dependence)?

The general rule is that persons, whose consent is dubious, should be protected against the possibility of serving as research " subjects" , in a manner proportionate to their incapacity and their dependence.

Some of the vulnerable categories, requiring special protection in behavioural research, are: children, the mentally infirm, persons easily manipulable because of their own weakness or dependence (for example, drug addicts), captive institutionalized populations (prison inmates, pupils, adolescents in reform schools, young people in residential institutions, soldiers).

- For *minors and adults under guardianship* , the rule accepted in biomedical research (L.209-10) can be generalized: consent of the parents or legal guardians, information given to the child or disabled person to the greatest extent possible, respect for the child's or disabled person's possible refusal.

- For institutionalised *captive populations* (prison inmates, pupils, adolescents in reform schools, young people in residential institutions), the usual rule is to assess the project as admissible, only when it is (1) " minimal risk" and (2) non-discriminatory. Consent must be obtained both from the responsible officials of the institution, and from each subject individually (if the subjects are minors, from the person who exercises parental authority).

- The use of " rewards" must be looked at very closely at the time of ethical review (for example, recruitment of homeless or native people as research subjects by offering them alcohol).

- In so far as inmates are concerned, the law of December 20th 1988 prohibits research without direct individual benefit, when the persons concerned are deprived of their freedom. In the behavioural sciences, such research can be harmless for the persons concerned, and socially useful, or even necessary; therefore they cannot be prohibited without individual review.

- How can one reconcile the obligation of consent, that is to be *informed* , with the methodological necessity (which can arise in the case of certain experimental protocols *) of not saying everything* ?

This is a question that has arisen with regard to biomedical research, but it is particularly relevant in psychology, social psychology(5), and research of sports performances.

The Canadian Medical Research Council has dealt with this issue as follows:

Deception (6)

" ... Given the critical importance of free and informed consent, it seems incongruous to take up the issue of deception.

" Deception means deliberately providing potential subjects with erroneous information, or

concealing information from them, with a view to having them believe that the research objectives, or the procedure to be followed, are different from what they are in reality. Deception can also consist in deliberately providing them with false information, in dissimulating important information, or in revealing only bits of information, so as to give the persons concerned an erroneous picture of the research.

" As deception is diametrically contrary to the principle of respect for the individual, the Committee had enormous difficulty in accepting the idea, that it could sometimes be justifiable from an ethical point of view. But if, for one reason or another, it really is indispensable that the subjects not be made aware of the nature of the research, and this for reasons of scientific integrity, then one must make sure that the following rules are strictly adhered to:

- One must never have recourse to deception, when there is another way of achieving the research objectives. The researcher must demonstrate, in the protocol, that there is no other way of proceeding.

- One must abstain from conducting deceptive research, when there could be risks for the subjects: it is impossible to justify exposing a subject to risk when he has not given his consent.

- The CDR must be assured that there will no dissimulation of any item of information, whose revelation would result in refusal to participate.

- The CDR must be assured that the research could result in considerable scientific progress, to justify the use of even the slightest deception.

- Deception can only be accepted, when it is possible fully to inform the subjects, and to report to them as to the experimental procedure, once the research is over, and to obtain their consent for the use of the data. The reporting method must be indicated in the research protocol, and this step must occur immediately after participation in the research, when the data still allow for identification of subjects. However, one should not lose sight of the fact that such reporting does not fully cancel out the deception. Data concerning subjects, who refuse to give their consent to the study, must be destroyed or returned to the persons concerned. In our view, this condition will serve to dissuade researchers from using deception." (MRC, 1986, A, Chapter 5, Paragraph F).

The following rules may be proposed:

- The protocol must include arguments, demonstrating that the acquisition of the knowledge being sought is of scientific value, that the dissimulation of certain aspects of the protocol is indispensable for achieving the objective aimed at, and that none of the aspects concealed from the subjects is likely to threaten their safety or their dignity, or to dissuade them from consenting if it had been revealed to them.

- The CCPPRC has to have accepted these arguments, judged that the situation in which the study's subjects will be placed is an acceptable one, and given an opinion in favour of the study.

- The subjects are informed, at the time of initial consent, that certain aspects of the methodology are being withheld from them deliberately, that this is necessary for the study, that such are " the rules of the game" , that the CCPPRC has judged that nothing dissimulated from them represents a threat to their safety or to their dignity, and that everything will be explained, and all their questions answered at the end of the study.

- At the end of the study, the subjects who so desire are made completely aware of the purpose of the research, and of observations made of themselves(7), and all their questions are answered. They are informed of the use to which the resulting data will be put. If identifying data (for example, photographs or films) were collected, the persons concerned

must give explicit consent for their use. Identifying data concerning persons, who refuse to consent to the desired use, will be destroyed or returned to the interested persons.

Safety

- How can *one evaluate the psychological risk* , and the possible *consequences* for subjects of a behavioural research project?

In the case of biomedical research, it has been argued that, by definition, when one searches the risks are not known, and therefore cannot be evaluated. The usual counter-argument is that all research relies on hypotheses, which are themselves based on previously acquired knowledge, and that this background knowledge allows for at least an approximate assessment of the risk to subjects involved in the experiment. The same reasoning applies to psychology.

We recall that, technically speaking, *risk* is the product of an event's severity and its probability. Hence the evaluation of risk involves estimation of both the *severity* of disorders that might be provoked in the experiment's subjects, and of the *probability* of occurrence of these disorders.

The distinction between *" minimal risk* " (or negligible) and *" non-minimal risk* " (or non-negligible, serious(8)) was introduced in 1978 by the American National Commission. " Zero risk" does not exist in human endeavours. " Minimal" risks are risks of the same order of magnitude as risks commonly accepted without thinking in everyday life. For children, for instance, minimal risk is defined as risk whose " probability and severity are of the order as those of physical or psychological damage, to which children in good health are normally exposed in their lives, or in routine medical or psychological examinations" (National Commission..., 1978-12, Appendix 1)(9).

Examples of serious risk: isolation with no temporal references, sensory deprivation experiments, endurance under " extreme" conditions, etc.

For categories of vulnerable subjects, only experiments whose risk is at a minimal level can be proposed, or, to use the terminology of the French Law of 1988, experiments that do not involve " any foreseeable serious risk" .

It is only to adult subjects in good health, in full possession of their mental faculties, and fully informed, that one may offer, for the purposes of human sciences research, involvement in experiments with risk at a higher level than the minimal level (no matter how small the difference).

- How can one reconcile the imperative of data *confidentiality* with the communication to non-physician researchers of confidential medical files, when the purpose is to advance research?

The ethical problem is one of respect for the personal domain, and of non-divulgation of confidential data, of which the treating physician is the depository. One can rely on Articles 7 to 13 of the Psychologist's Code of Ethics (footnote 3), which are almost literal copies of the rules governing medical confidentiality.

Beyond the ethical problem, there is also a legal and regulatory problem in France. Some of the reference texts include: Articles 226.13 and 226.14 (previously 378) of the Penal Code(10), law N° 78-17 of January 6th 1978 on Computerisation, Records and Liberties, decree N° 79-506 of June 28th 1979 proclaiming the Medical Code of Ethics. These texts prohibit the communication by the physician of identifying data to anyone, save to another physician and solely in the interests of the patient's health (for example, consultation of a specialist for a therapeutic opinion).

The problem of data communication for research purposes was studied extensively in the

eighties, in connection with cancer registers and epidemiological research, by the CNIL, the CCNE and the Ordre des Médecins (French Medical Association). The proposed solution was that of *shared confidentiality* . This solution is not yet legal (11) .

In the present state of the legislation, the only admissible kind of study (for example, within a hospital) is one that uses personal medical data within the department where the patients were treated, and under the responsibility of a chief physician. The procedure followed by Professeur M. Carlier (CNRS file, Carlier project) is not correct.

It is the physician responsible for the ward (and not the psychology researcher) who should have contacted the families, and sollicited their consent to the research. The families could legitimately complain that a psychologist contacted them (by telephone, then directly) for a research project about their twins, which implied that this psychologist had knowledge of their medical files before any consent had been given, and hence that the head of the department did not observe medical confidentiality.

It is obligatory that the use of identifying medical data for research purposes remain under medical responsibility, the persons concerned having the right to be informed in advance of the use that is to be made of their data, and the right to oppose that use.

One could imagine that psychology researchers (or statisticians, or biologists, or anthropologists, etc., but non-physicians) could now be formally entitled to obtain knowledge of certain nominal medical data for research purposes, and to process them under their own responsibility. For the sake of equity, this would imply, inversely, that physicians could be entitled to gain knowledge for research purposes of nominal psychological data.

This would suppose (1) an entitlement procedure, (2) a change in the legislation, in order to render admissible the concept of shared confidentiality between physicians and non-physicians.

We note that the " Computerisation and Liberties" law of January 6th 1978 does not authorise any exception to medical confidentiality for the purpose of research, unless the persons concerned have agreed. Now the French Medical Code of ethics does not provide for the patient being able to release the physician from confidentiality (the only cases of confidentiality waivers are those prescribed by the law) (see Villey, 1986, p. 135). The Psychologists' Code of ethics goes further: " With the exception of cases of legal obligation, the psychologist cannot be released from confidentiality by anyone, not even by those whom the confidential information concerns" (Article 13). The justification for the rule, that even the person concerned cannot release the physician or psychologist from confidentiality is that, in order to allow someone to share a secret, one has to know what the secret is. But a clinical psychologist is not obligated to communicate his files to his client. And the French patient has only indirect access to his medical file, and he usually does not know what it contains.

If French legislation is moving in the direction of a new form of waiver to medical confidentiality, for the purposes of scientific research, this would then also imply a change in the Medical Code of ethics, a change in the Psychologists' Code of ethics, and no doubt, in the longer term and for all patients, a right of direct access to their medical files, and hence a change in the " Computerisation and Liberties" law, and in the Law on access to administrative documents.

Problems of equity

- How can one reconcile research on *discriminating characteristics* with the imperative of *non-discrimination* ?

This is a delicate issue, precisely because the identification of significant differences and of

discriminating characteristics is a plausible research objective. For instance, it is of interest, and of importance for the evaluation of assisted maternity techniques, to ask whether there is a significance difference between the cognitive development of children born of artificial insemination and other children (CNRS file, Duyme project). But if one finds that artificial insemination children develop less well than the others, and if such research results are made public, then children already born through artificial insemination (or their parents) are put in a difficult situation, even if confidentiality of origins is well protected (the danger of guilt feelings).

In the case of the Duyme protocol, all precautions were taken to ensure that the research would not be a source of discrimination through its methodology.

Apart from the methodology, a research project may involve explicit or implicit risk of discrimination against individuals, because of the hypotheses on which it is based (for example, experimentation with " aversion therapies" to treat homosexuals, or psychosocial follow-up of a cohort of children born to alcoholic mothers). A project may also involve a risk of discrimination against an entire population, because of the way its results will be interpreted (for example, determination of statistically poorer results on several intelligence tests among blacks than among whites).

In the United States at the end of the sixties, the interest in a " science for the people" caused some investigations to be stopped, on the grounds that their theoretical implications were slanderous for certain categories of individuals. There is even reference to attempts to force researchers to " revise" their conclusions, and/or to publish only expurgated results.

The discrimination risk is a function of the social level of tolerance of a given " difference" . One could propose the following rule: the discrimination risks must be identified, and weighed in the balance against the collective interest, and the theoretical interest of obtaining the expected result.

- Should promoters of behavioural research take out *insurance* to cover the risks, to which research subjects are exposed because of the investigation?

In biomedical research, French law obligates the promoter to take out insurance (Article L.209-7), guaranteeing his third-party liability, in the event of damaging consequences of the research for the consenting person. It is known that this provision of the law cause no problems, when the promoter is the pharmaceutical industry, but that it causes problems for research carried out by university teams and/or in hospitals of modest size, which have trouble finding a promoter with sufficient financial depth to take out insurance. In behavioural research, are the large research bodies (CNRS, university laboratories) in a position to stand as research promoters? Without identification of the promoter, one cannot, in fact, tackle the problem of insurance in a satisfactory manner.

It could be argued that, in the case of minimal risk behavioural research, the insurance is not indispensable, even though consideation must be given to physical risks, which, without being a direct consequence of the research as such, occur in the course of the research (falls, accidents during transit). One could also argue that, for research with more risk, such as that proposed only to adult, responsible and fully consenting volunteers, it is up to them to take out insurance, as for other risky activities (for example, certain sports). But in the event of litigation, it can always be argued that the researchers responsible for the project should not have offered volunteers such a risky situation. To our knowledge, there has been at least one example in France of a suicide following risky behavioural research (prolonged isolation with no temporal references).

The problem of insurance for behavioural research with human subjects must at least be put clearly. Solving it in the general case is the business of the legislator.

Review of protocols. How would CCPPRCs (Consultative Committees for the Protection of Persons consenting to Behavioural Research) operate?

It would seem to be out of the question that the biomedical CCPPRBs be able, in their present composition, to review research protocols in the human sciences. They were not designed for it.

It is not included in the mission statement of the CCNE's technical section, that it should undertake systematic review of research protocols in the human sciences.

French experience prior to law N° 88-1138 of December 20th 1988 (for example, the Assistance Publique-Hôpitaux de Paris), as well as the North American model, would point in the direction of creating " Ethics Committees for Human Sciences Research" at institutions that actually engage in behavioural research with human subjects: CNRS, universities. According to R.J. Levine (1986), these Committees are " the conscience of the institution" , and an expression of its interest in ensuring that its research is of high quality, and that the persons who consent to it are adequately protected. Rules concerning the composition of these committees (which should include a certain proportion of members from outside the institution, and/or outside human sciences, for example, lawyers, philosophers, physicians) could be drawn up by a joint commission (CNRS, universities, CCNE, ministries and professional organizations). A procedure for entitling these committees could be determined by a text of the Minister of Research. This would probably be a provisional solution, but one that could be implemented rather quickly.

In the French context, it seems difficult to imagine a longer term solution other than that of legislative constitution of several *regional CCPPRCs on the model of the CCPPRBs* , but with a composition giving them the expertise required to review research protocols with human subjects in the human sciences other than the biomedical: anthropology, ethnology, various branches of psychology, sociology, linguistics, history, education sciences, etc. This is the business of the legislator.

Any file submitted to a CCPPRC should provide the following information, as a minimum: 1) the research objectives and the working hypotheses; 2) the study's target population and the ways in which subjects are to be recruited (including the text of any advertisements) 3) the detailed methodology; 4) steps taken to ensure anonymity of collected data, their storage and access to them for consultation; 5) evaluation of the risks, costs, constraints and potential benefits; 6) presentation of information to persons participating in the study, and the modalities of their consent, including the study presentation document distributed to such people, and the consent form (consent to the study, and, as appropriate, to the use of results).

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Notes

1. In the following, it is accepted that speaking is a behaviour, and that the term " sciences of human behaviour" does not exclude clinical disciplines, such as analytically inspired psychology. This term has the advantage of stressing that we are dealing with research on the human being, other than biomedical research.

2. See the report drafted by Y. Laporte.

3. A Code of Ethics was adopted in 1961 (and revised in 1976) by the French Society of

Psychology. It applied to members of the Society. This Code was taken over and brought up to date by the National Association of Organizations of Psychologists (ANOP), following " the evolution of the profession and its legislation" (Law of July 25th 1985). The Code of Ethics of Psychologists (1987) now applies to all French psychologists, as well as to students of psychology.

This is a professional code of ethics, analogous to the code of ethics of French physicians. It is not a code of research ethics (as in the case of the World Medical Association's Helsinki-Tokyo Declaration for physicians).

This Code includes rules that also apply to research activities, in as much as they apply to all activities of psychologists. There are general rules: " implement only such measures as respect human dignity" (Article 2), " avoid doing harm" (Article 15), and there are specific rules concerning confidentiality (Articles 7 through 12):

" 7
- The psychologist is subject to the rule of confidentiality, defined herein as psychological confidentiality."

" 8
- This rule must be applied under conditions analogous to those defined by Article 378 of the Penal."

" 9
- In particular, it is recalled that this confidentiality must be extended, in the private domain of persons concerned, to anything that the psychologist " sees, hears or understands" in the course of his practice or research."

" 10
- Confidentiality must be ensured as much with respect to oral transmission, as in the storage and dissemination of documents. The psychologist must make sure that all the products of his work (minutes, conclusions, reports, exposés, etc.) are always drafted, presented and filed in such a way, as to preserve and safeguard confidentiality."

" 11
- In his cooperation with other specialists, who are also subject to the rule of confidentiality, the psychologist shares with them only such information as is strictly necessary for a team to be able to take care of the " client" ."

" 12
- He makes sure to protect the identity of individuals, when making up data files, in accordance with the Law of April 6th 1978 on information and personal liberties."

" 13
- With the exception of a legal obligation, the psychologist cannot be released from the confidentiality rule by anyone, not even those directly concerned by the confidential information."

Two rules pertain to scientific work through the responsability to be well trained:

" 17
- Every psychologist, whatever his speciality, must constantly keep abreast of scientific progress in his discipline, and consequently keep up his training. He takes such progress into account in his work, and strives to contribute to it. He accepts all the rules, requirements and constraints imposed by scientific work."

" 19
- Every psychologist seeks to determine and to apply scientifically validated and communicative criteria and methods, thereby rejecting the principle of authority."

One rule can be applied to the informed consent request:

" 18
- The psychologist refrains from restricting any other person's autonomy, and, in particular, his access to information, and his freedom of judgement and decision-making."

A special rule covers the treatment of experimental animals:

" 26
- When his activities relate to animal behaviour, with a view to understanding human behaviour, he strives to ensure the welfare and the survival of the animals being studied."

The absence of an equivalent rule, covering the treatment of persons consenting to behavioural research, implies that research subjects are not treated differently from other sujects, with whom the psychologist is in contact on a professional basis (hence, for example, that different treatment in the " therapeutic" and " non-therapeutic" situations is not envisaged).

4. On the concept of consent and its ambiguities, see: Thouvenin (1992).

5. See Stanley Milgram's experiments, evoked in the film " 'I' as in Icarus" . Reference publication: Milgram S. (1963), " Behavioral study of obedience" , J Abnorm Psychol, 67: 371-378.

6. Also known as " deceptive research" (" tromperie" in French).

7. This is refered to as " debriefing" .

8. The French Law of December 20th 1988 uses the term " serious risk" , and stipulates that, for persons belonging to vulnerable categories, research " without direct individual benefit" is admissible, only if it involves " no serious foreseeable risk" (Article L.209-6).

9. The Report of the Royal College of Physicians (1986) shows that risk is deemed minimal, either because the potential disorder is not very serious at all, or because the probability of the event is very low. In the latter case, the risk " is comparable to that run by an airplane passenger taking a regular flight" (see the Menard Report, 1990).

10. Article 226.13 - " The revelation of confidential information, by a person who is its depository, either by dint of his state or by profession, either by dint of a permanent function or a temporary mission, is punishable by one year imprisonment and a fine of 100,000 F."

Article 226.14 - " Article 226.13 is not applicable, when the law imposes or authorizes the revelation of the confidential information. Moreover, it is not applicable: 1) To any person who informs the judicial, medical or administrative authorities of maltreatment or deprivation of which he has knowledge, and which has been inflicted on a minor of fifteen years or less, or a person unable to protect himself, because of his age or physical or mental state; 2) To a physician who, with the agreement of the victim, brings to the attention of the Prosecutor of the Republic maltreatment he has observed in the exercise of his profession, and which gives him grounds for supposing that sexual violence of some kind has been committed."

Law N° 92.684 of July 22th 1992, Official Gazette of July 23th 1992, making amendments to the Penal Code. This Law enters into force on March 1st 1994.

11. A change to the 1978 Law in favour of epidemiological research is foreseen in the Draft Law on the treatment of research oriented nominal data with a view to protecting or improving health, adopted in first reading at the National Assembly on November 25th

1992.

This draft law does not take up the concept of research oriented shared confidentiality between physicians and non-physicians. It authorizes the sharing of a secret among physicians for the purposes of research. The case of psychology research is not taken into consideration by the draft law, which essentially covers statistical processing of nominal data for the purpose of public health research.

The transmission of data from a hospital department to a research institute for the purposes of investigation (for example, statistical processing) is authorized by the draft law, on condition that the future " National Consultative Committee for Information Processing in Health Research" has given its approval to the study, that the persons concerned have been informed individually and have been able to exercise their right of opposition (unless that is impossible), and that the data are received by a physician, designated by the research body, and entrusted with the safety of these data, and with ensuring respect for the research goals.