BELGIAN ADVISORY COMMITTEE ON
Bioethics

Opinion no. 36 of 11 September 2006 on the ethical testing of research in certain branches of the life sciences

Request for an opinion submitted on 6 February 2004

by Professor B. Mouvet, Chairperson of the Ethics Committee of the Faculty of Psychology and Educational Sciences of the University of Liège, concerning:
(1) the expediency of setting up ethics committees in faculties of psychology and educational sciences, and
(2) the expediency of arriving at inter-university harmonisation of criteria and procedures for ethical consultation on research in Belgian faculties of psychology and educational sciences.

CONTENT OF THE OPINION

Question put to the Committee

Professor B. Mouvet, chairperson of the Ethics Committee of the Faculty of Psychology and Educational Sciences of the University of Liège, sent the Advisory Committee for Bio-Ethics a letter, on 6/2/2004, which was followed by another letter dated 4/5/2005.
The Advisory Committee for Bio-Ethics declared this request for an opinion admissible during its session of 8/3/2004. Since the Committee's term of office came to an end in June 2004, the Committee entrusted the subsequent Committee, which took office on 21/4/2005, with the drafting of the opinion paper.

The Advisory Committee for Bio-Ethics has decided in this opinion paper to answer the questions concerning the expediency of setting up ethics committees in the faculties of psychology and educational sciences, and the expediency of an inter-university harmonisation of the criteria and procedures for ethical consultation in research in these disciplines in Belgian faculties.

Another question raised by Professor B. Mouvet concerns the scope of the law of 7 May 2004 on experiments involving human subjects, in particular in the field of the life sciences. This question will form the subject of a separate opinion paper.

Introduction

In this opinion paper we deal with Professor B. Mouvet's original question concerning the degree to which it is expedient for ethics committees to be set up in faculties of psychology and the degree to which it is expedient for inter-university harmonisation to be achieved.
These ethics committees would have the task of assessing research projects submitted to the faculty of psychology, just as the medical ethics committees have to assess medical protocols. The Committee deemed it expedient from the outset to extend our reflection to include all faculties in the life sciences.

The ethical testing of research projects involving human subjects is carried out by medical ethics committees when the experiment involves patients or healthy volunteers making themselves available for experiments of a medical nature, such as clinical studies with new medicines, for example.
As regards medical ethics committees, a distinction needs to be made between medical ethics committees as defined in the law on experiments involving human subjects of 7 May 2004 (committees authorised to assess research projects, either as a committee authorised to publish a final opinion, or as a committee of one of the cooperating centres, provided the centre meets the official competence criteria), and local ethics committees which should exist in all hospitals and health establishments but which are not legally "recognised" when it comes to experiments involving human subjects.

There is the possibility of medical ethics committees that are authorised to assess protocols also having to assess certain protocols for experiments in the life sciences. Indeed, the Belgian legislator has given a wider interpretation to European Directive 2001/20/EC on the conduct of clinical trials on medicinal products for human use. However, many studies in the field of the life sciences do not fall within the legal or scientific competence of medical ethics committees. The question that then arises is whether the research protocols in life sciences that have a specific character (more especially as regards methodology) should not be subject to review by an ethics committee specific to each field within the life sciences.

1. The specific character of research in the life sciences

Every research assignment and every study is constructed according to a hypothetical-deductive working method. Whilst the term "research" can refer to very wide-ranging approaches such as "surveys", "experience" and "experiments", an experiment is an empirical research strategy aimed at demonstrating the causal links between a series of selected variables. Experiments play a fundamental role in sciences such as chemistry, physics, biology and biomedical sciences. Three conditions have to be met in order to be able to talk of an experiment: 1) the reduction of the problem to a small number of variables; 2) the search for a causality between the variables through use of the probability theory; 3) the researcher's direct contribution to the observed situation. At this stage there is no significant difference between the meaning of experiment adopted here and the meaning used in medical studies and clinical trials. In clinical trials with medicines the basic hypothesis plays an important role. The aim is precisely to confirm (or negate) this. It is on the grounds of this basic hypothesis that the trial set-up is conceived, and therefore the formulation of the relevant variables, and the conditions and methods according to which the treatments are administered or the interventions carried out. It is also in function of the hypotheses that comparable groups are put together.

In some branches of the life sciences, more especially in experimental psychology and neuropsychology, the approach closely resembles that of experimental sciences. In other branches it can differ considerably. The approach in social psychology (and no doubt even more so in sociology) is more "open", in the sense that more correlations and causal links are sought which do not catch the eye at first sight but which the researchers attempt to bring to light.
Whereas we can certainly talk of experimental psychology, we cannot talk of experimental sociology in the sense of the above-mentioned definition, not even in the trends of sociology that use quantitative methods based on statistics.

What links in most closely to traditional experiments in the quantitative trends is termed "causal" or "multivariable" analysis. "Suicide" by Emile Durkheim (1897) is a good example of this approach. In this study the author shows that the increase in the number of suicides, where other data are identical, is directly proportional to the number of Protestants. According to the statistical material Durkheim had at his disposal, the suicide figures in the Swiss cantons increased as the number of Protestants increased. Here the first two experiment conditions are met (or met to a greater or lesser degree): the reduction to variables and the demonstration of causality or at least a correlation. However, the third condition is missing: the sociologist has no influence on the protestant ethos or on suicidal tendencies.
It would therefore be a major error to reduce sociology to trends that are based on statistical methods. Qualitative sociology is chiefly founded on hermeneutics. Without wishing to engage in a far-reaching epistemological debate – although this is where the difference and the controversy lie –, the distinction needs to be made between "explaining" and "understanding". The explicit intention of a large number of sociologists is the understanding and explanation of complex processes and mechanisms through painstaking - ethnographic and *quasi* "entomological" - observation of human behaviour, methods that are not reconcilable with the statistical approach. We can refer to these studies as involving experiments. Harold Garfinkel, an American sociologist, asked his students to approach their parents as friends when they got home. The aim here was, via transgression, to reveal the precise rules that govern the parent-child relationship. The moral rules are often very clearly demarcated, yet may of course differ considerably from the agreements existing between friends. In this example, the "manipulation factor" is very much present: the student interferes in the type of relationship with his parents. The other two conditions, however, are not present. The epistemological preconception does not permit reduction to a few simple variables, and demonstrating the causality is not the end objective. Therefore here we can only refer to a perception or observation, but not an "experiment" in the meaning used in experimental social psychology and in medicine when clinical trials are involved.

2. Risks for test subjects taking part in research in the life sciences

Whilst experiments on patients or on healthy test subjects involving certain health risks for the test subjects have to be subject to an assessment by a medical ethics committee, this is not necessarily the case for surveys which in principle do not have any medical purpose. However, these are not always without risk for the parties involved.

Possible risks are lack of confidentiality, invasion of privacy, stigmatisation, discrimination, psychological effects and even health risks. It must be possible for these risks to be assessed. By way of illustration, a few examples of the possible risks are presented below.

We may be talking about experiments on patients or healthy volunteers, but also surveys of a varyingly exhaustive nature depending on the subject.
For example, some surveys are used to study changes and developments in the holiday destinations chosen by a particular population group. Other surveys are intended to study the incidence of smoking and non-smokers' tolerance of other people smoking. These apparently simple and neutral surveys may require an analysis of the correlation with the respondents' age, sex, income and even educational level. These are examples for which provision is made in the law for anonymisation of the data. What is more, the development of these lists is subject to the regulations of the privacy committee. The significance in 2005 of the fact that someone smokes may not have any immediate effects for the interviewee, but that might not always be the case. The World Health Organisation has already decided henceforth not to hire staff who are smokers, and there is no reason to suppose that other employers will not follow this example. So saying that you smoke is not such a harmless declaration if you are identifiable and do not know what will happen to the survey data.
In other studies, for example in anthropogeography, an attempt is made to demarcate neglected areas. This can be done on the basis of data from the National Institute for Statistics, without the residents of the districts in question having to be bothered. Then in-depth surveys can be used to gauge the subjective and objective health situation of the residents of those districts. Their informed consent has to be obtained in order for them to be interviewed. It therefore seems necessary to explain the purpose of the study to them, a purpose consisting in ascertaining whether or not their living conditions have an adverse effect on their state of health. Discovering that there is a link between the location of their house and their health can bewilder some residents.

When researchers in sociology, educational science or criminology try to find lines of reasoning to explain why some young people drop out of school by interviewing young people who are ambling around in the street at times of the day when they should normally be in the classroom, this is a situation that provokes a whole host of questions. Is the young person old enough to give his informed consent? Does he remain identifiable thereafter, and how are the data subsequently anonymised? Does the mere fact of a pollster showing an interest in him have an effect on him, and if so, what is that effect?

Neither is it harmless to ask a random passer-by who knows he is suffering from cancer, about the fear of dying, even if he has agreed to answer a questionnaire on this.

Research into grieving processes when someone loses their job can also trigger unpredictable reactions among the persons affected, which not only hamper but even harm their adaptation to unemployment.

Even some surveys that look into the quality of a company's management by asking employees a number of questions, are not per se inoffensive and can destabilise some of the respondents, all the more since their freedom to choose whether or not to take part in the interview is *de facto* often limited.

The same goes for studies carried out by university lecturers among their students and for all studies involving persons who fall under some form of judicial measure, irrespective of whether they are detainees or not.

In anthropology and the life sciences in general there are certain studies that take the form of interaction or participatory role models, which, by describing or depicting types of persons, aim to formulate a number of hypotheses on the cultural determinants of their behaviour and attitudes. It is often laid down in the study protocol that the researcher must obtain the prior agreement of the person in order to publish his observations of this person's behaviour or attitude. From an ethical standpoint that is certainly a good thing, and even an essential condition for a person's inclusion in a study. Nevertheless, merely confronting a person with what for him is a stigmatising description can be harmful.
The examination of intentional or unintentional racist reactions, which are present in all of us, or of potential aggression in some people in certain situations, does not mean that it is acceptable to place people, who have been pre-selected to provoke hostile reactions in other study participants, into physical or psychological danger.

It is undeniable that acceptable risks sometimes have to be taken in order to make progress in the life sciences. These risks should be carefully studied and described, even if the survey in question is for all other intents and purposes quite inoffensive. There is therefore reason to be concerned about the procedures followed in the life sciences to weigh up the potential risks of a study against the result one is hoping to achieve. At the same time it is useful to pose questions in advance about the potential risks of research procedures and the methodology used to limit the risks as far as possible.

3. The current ethical reflection in the life sciences

a. The situation in France

The laws on research in the health sector have in recent years often been applied to experiments in behavioural science further to a 1994 amendment to the law of 1988 (Huriet-Serusclat law, France, 20 December 1988).

In October 1993 the French National Advisory Committee for Ethics (*Comité consultatif national d'éthique* - CCNE) published an opinion paper on research in behavioural science (*la recherche dans les sciences du comportement humain* – opinion no. 98).
The ethical aspects concern the protection of persons, the respective responsibility of the commissioning authorities, researchers and participants, and the collective interest or individual interest of the participants in the study.
The researcher has the duty to avoid any foreseeable harm and to redress any harm. The concept of harm concerns damage sustained to the person's physical integrity, goods or psychological balance. This scarcely differs from what we know in the biomedical field.
In the opinion paper the objectives of biomedical research are clearly distinguished from those of behavioural research. The CCNE is of the view that the main ethical principles governing research involving human subjects (justice, well-doing, respect for autonomy) and the rules stemming from them (fairness, non-discrimination, consent, limitation of the risks), are the same whether they be in respect of biomedical research or behavioural research. In the case of behavioural research, too, the research protocols would also have to be submitted to an independent and professional ethics committee before the research is carried out.

There is also an Ethics in Science Committee (*Comité d'éthique pour les Sciences* - COMETS), which was set up in 1994 by the National Centre for Scientific Research (*Centre national de la Recherche scientifique* - CNRS), to deal with the ethical aspects of scientific research which is not handled by

the CCNE. The subjects dealt with include studies into the influence of audio-visual techniques and into environmentally related problems, but also behavioural research.

There is also an Operational Committee for Ethics in the Life Sciences (*Comité opérationnel pour l'éthique dans les sciences de la vie* - COPE), which is linked to the CNRS and has a threefold task: to inform researchers of the existing legislation, to trace any ethical problems so as to present these to the competent bodies (for example CCNE), and to take stock of the obstacles encountered by researchers, in order then to forward these to the CCNE or the COMETS.

The CNRS's life sciences department (*Département des sciences de la vie*) has a document entitled "*Ethique en sciences de la vie"* (Ethics in the Life Sciences), which was published to help researchers assess the stress and risk level to which study participants are exposed and the degree of invasiveness of the research techniques. Some studies are considered as stress-free, in particular when they relate to everyday activities carried out by the participants where it is known that these do not entail any special risk whatsoever (for example a study of a physiological movement which is not of any unusual scope or duration, an observation of test subjects in a driving simulator, and so on). In the case of research "with stress", on the other hand, the study participant runs a heightened, variable risk (for example a study of a movement carried out in unusual circumstances, an experiment conducted after sleep deprivation, and so on). A distinction is made between the techniques, according to their "invasive" or "non-invasive" character. Examples of these are the recording of the electrocardiogram and electroencephalogram which are considered as non-invasive, unlike invasive techniques such as injecting and implanting of electrodes, the administration of contrast mediums or tracer materials, and X-ray imaging.

b. The situation in the United Kingdom

In 2003 the British Psychological Society published[1] new "Ethical Principles for Conducting Research with Human Participants", which replaced the ethical principles that the same society had issued in 1978.
This publication contains the general ethical principles surrounding consent, the right to withdraw from the study at any time, respect for privacy, etc.

The Society also stresses the need for a debriefing after every study, which in particular should see to it that when the study is over the participants can resume their normal course of action, should the study have provoked the reverse.

The Society stresses the importance of avoiding test subjects being subjected to experimental situations or test situations implying a greater risk than that which people are prepared to take in normal life.

At any event the implications and psychological consequences of the study for the participants should be taken into consideration. If the study targets people of different generations, of a different sex, or from different backgrounds, then, in our multicultural and multiethnic society, the research protocols should also be submitted to persons from the same background as the participants, so as to ascertain in advance that the test subjects concerned do not feel as though the study constitutes an affront to their dignity.

In the case of studies based on observation, the British Psychological Society stipulates that, with the exception of studies in which the observed test subjects have agreed to the observation, observation is only acceptable in situations in which the observed person is aware that he or she can be seen by strangers. Account must inevitably be taken of local cultural values. The

[1] The British Psychological Society, in Sue Eckstein (editor) "Manual for Research Ethics Committees: Centre of Medical Law and Ethics, King's College London", Cambridge University Press, 2003, pp. 269-273.

observation, even in public places, of people who could reasonably assume that they are not being watched, is absolutely forbidden.

c. Existing codes

The Caverni code

The aspects of psychological research are also specifically covered in "*Un code de conduite des chercheurs dans les sciences du comportement humain*" (a code of conduct for researchers in behavioural sciences), drafted by J.-P. Caverni (Research Department of the French Psychological Society*, Un code de conduite des chercheurs dans les sciences du comportement humain, 2003*). A few of the key ideas contained in this are discussed below.

According to this code, the purpose of behavioural research is to develop a body of fundamental knowledge that is scientifically validated according to an objectivised, entirely communicable and reproducible methodology. Behavioural research concerns all aspects of human behaviour, at all ages, equally in the case of the foetus as in the case of healthy or sick individuals, insofar as that is ethically acceptable. The study must, if possible, aim at contributing to the improvement of human welfare, both individually and socially.
The researcher must be a professional person who is responsible at scientific and ethical level for the studies he plans and conducts. Assessment by an ethics committee is not specifically laid down in the code, but it is stated that whenever there is the possibility of a study exceeding the generally recognised rules, the researcher should obtain the positive opinion of his peers and if necessary, also of recognised bodies in which there are representatives of society who are not members of the scientific community. These aforementioned bodies resemble local medical ethics committees or ethics committees in life sciences faculties.
According to the Caverni code researchers should guarantee respect for and protection of the people taking part in the study and should moreover vouch for respect for human beings and for life in general. They are obliged to respect confidentiality vis-à-vis everything they may have learnt about the participants in the study. The researcher is responsible for protection and confidentiality of the data.
Before participation in any study, the people approached must explicitly give their informed and free consent. They must be informed, in a manner comprehensible to them, of all aspects that could influence their consent (risks, inconvenience, immediate or deferred negative effects, limitation of confidentiality, etc.), as well as the study's objectives and the procedure to be used. The position of authority that the researcher generally has may not be used to induce the potential participant to give his consent.
The party concerned may withdraw from the study after he has obtained information, or even when the experiment is under way.
Before their possible participation, people must know that they are free to take part or not to take part, without a refusal on their part having any negative consequences of any kind for them (here we are thinking of students or members of staff). That is precisely what is applied in the case of medical experiments.
Now, there may be cases of certain people not being in a position to give their free and informed consent (children and vulnerable people, for example). In such cases the researcher has to obtain "*autorisation appropriée*" (suitable authorisation) from a legally authorised person. However, he must give the person wishing to take part in the study "*des explications appropriées*" (suitable explanations) at all times, and obtain his "*assentiment*" (consent) in circumstances that are as close as possible to the circumstances in which ordinary people find themselves.
The researcher does not have to secure the consent of the test subjects if non-identifiable data are collected which only relate to observations in a natural setting or relate to isolated data from archives.
The freedom to consult certain elements of an archive does not yet give entitlement to consultation of the entire archive or file.

Whenever possible and relevant, the researcher must inform the public of the knowledge collected, the method followed to obtain that knowledge, and the reliability thereof. He may not fail to mention the fact that the bulk of this knowledge is of a provisional and incomplete nature. He must see to it that the scientific knowledge is put to good use. In particular, he must oppose any distorted reproduction of it and the use of it for purposes that run counter to ethical principles.
One heading in this code also relates to confidentiality of the data and the conditions for dissemination of the results.

"Deception" in research

One special point in the Caverni code concerns the possibility of the information supplied by the researcher being incomplete or even inaccurate. The aforesaid code states that: "(our translation) *when, for scientifically valid reasons, the test subject cannot be fully informed of the objectives pursued before the study gets under way, it is agreed that he is informed only in an incomplete fashion beforehand and that the information knowingly contains incorrect elements. However, he must be fully informed at the end of his participation. The incomplete and incorrect nature of the information originally supplied must always have an indisputable scientific justification. A check should also be made to see whether any other procedures are possible, whether the participants will be adequately informed as soon as possible, and whether advice will be obtained as to the way in which the complete information will be assimilated by the test subjects when it is passed on to them (for example consulting of people who come from the same cultural and social environment as the study participants). The incompleteness and inaccuracy of the information may never concern aspects that could influence the prospective participant's willingness to take part (physical risks, inconvenience, negative emotions, etc.). The fact that comprehensive information is provided at the end of the study cannot in itself justify the fact that the original information was incomplete."*
In biomedical sciences, situations where it is necessary to deceive the participant for the purposes of the result of the experiment hardly ever arise. In the very frequent situation in biomedical sciences in which a new medicine is tested by means of comparison with a placebo, the participant is always told beforehand that he might be given a placebo, but as soon as the patient has given his agreement and the experiment has started, he is of course not told whether he was given the experimental drug or the placebo.
In behavioural sciences the "deception" of the test subject would occur very often. In the March 2005 issue of the journal *Bioethica Forum*, B. Baertschi[2] estimates that deception is used in 58% of research protocols in psychology. The concept of "deception", as the American Psychology Association sees it ("deception in research"), tends to mean a lie on account of omission or the concealing of a part of the truth. Baertschi takes account of the possibility of a "permitted deception" if the test subject is specifically informed beforehand that he will not be told everything before the experiment starts. He is of the opinion that deception in experiments can be justified on the grounds of the foreseeable advantages that the results of the experiment will entail. Other authors feel that test subjects should have it pointed out to them beforehand that some information will not be given to them before the experiment, but that they will be given this information after the experiment and only then have to give their consent for use of the data concerned (such as in the case of programmes of the "Candid Camera" variety, where recordings, made without the knowledge of the person concerned, are broadcast on TV). Recommendations for this have been drawn up by the American Psychology Society ("Ethical principles of psychologists and code of conduct", June 2003).

[2] *L'éthique de la recherche en psychologie*, Bernard Baertschi, University of Geneva, in Bioethica Forum (a publication of the "Société Suisse d'Éthique Biomédicale"), no. 44, March 2005, pp. 9-11.

In the same Bioethica Forum, Ron Berghmans[3] of the University of Maastricht states that "deceiving or misinforming subjects should be considered prima facie wrong and thus unjustified from an ethical point of view". Nonetheless, he adds that people can validly agree to be given only some of the information, or not to be informed at all.

d. The situation in Belgium

With the exception of ethics committees in certain faculties of psychology, the Committee concludes that there are no ethics committees in the life sciences in Belgium. Experiments in the field of behavioural science, and more generally experiments in the life sciences, are not necessarily presented to medical ethics committees and are not assessed by ethics committees in the corresponding faculties.

Studies in psychology, criminology, educational science or sociology are often conducted on people but are not necessarily carried out in a medical framework, and still less in a hospital. Some studies belong to the field of labour psychology, others relate to language use or other subjects for which there is no reason for submission to medical ethics committees, which in any case are not well grounded in these matters. Just like every biomedical study, behavioural research can also relate to vulnerable populations, such as children, prison inmates, the elderly, and students, and in those cases the ethical issue is all the more pertinent.
The circumstances in which people take part in experiments in the field of behavioural science are very wide-ranging. All kinds of behaviour are studied: during diverse development phases, during learning processes, in normal situations, or in pathological circumstances. The stimuli used can also vary considerably: physical (images, noise, etc.), symbolic, psychological, foreign to the body or body-specific. The observed tasks or reactions can vary considerably, as can the characteristics of the environment concerned.

As regards studies into human behaviour, these can relate to studies on premature births, babies, children, twins, teenagers, normal adults, or adults who are representative of a specific social group (teachers, sports freaks, etc.).

Although the test subjects are usually informed and freely agree to take part, in some studies in the field of the life sciences special terms and stipulations may be required which violate the principle of freely informed consent applicable in biomedical science. We recall the generally applicable principle in medical experiments that the test subject must always retain his freedom to take part or not to take part, that a person's refusal may not have any negative consequences whatsoever, and that no refusal may entail a change in the quality of the care administered. However, in psychology the researcher may deem that giving comprehensive information on the purpose of the study and the study methods to be used makes it impossible to obtain valid data. Indeed, it is accepted knowledge that a person who is aware that he is being observed will adjust his behaviour, which is what the study aims to describe. In that case it should be ensured that the test subjects or their representatives are informed, *after the study*, of the results of the experiment and the justification for it, and are given the possibility of agreeing to these being used. As a rule these situations are regulated by codes of good practice.

Moreover, the rules for the testing of research projects are very diverse. In many cases no thought is given to the ethical aspects of the study, other than by those responsible for the study and the people actually carrying out the experiments. These studies can thus be conducted under the leadership of lecturers, recognised researchers or individuals holding a doctorate, but these studies can also include studies carried out in the context of a thesis for a master's degree.

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[3] *Moral aspects of deception in psychological research*, Ron L.P. Berghmans, University of Maastricht, in Bioethica Forum (a publication of the "Société Suisse d'Éthique Biomédicale"), no. 44, March 2005, pp. 2-4.

People who take part in behavioural analysis studies, in particular in the field of psychology, thus do not necessarily receive the same attention, and therefore perhaps not the same degree of protection, as participants in a clinical experiment in the medical field or in the study of a new drug, for example as regards insurance cover in the event of damage or accident.

Finally, some aspects of research conducted in the field of the life sciences differ from the aspects of medical research, whilst other aspects show many similarities.
Some projects in the field of the life sciences are clearly distinguishable from medical experiments when it comes to the objective: biomedical research always strives for advancement in medical knowledge and has a therapeutic goal in the shorter or longer term. Like fundamental research, research in the life sciences can aim for a better knowledge of our surroundings and of people's response and adjustment mechanisms.

e. Conclusions regarding general ethical requirements in experiments involving human subjects

From the foregoing it emerges that experiments involving human subjects, irrespective of the framework in which they are conducted, must meet a number of common conditions:

- The study must be scientifically justified and should be carried out in a scientifically flawless manner.
- Respect for people's freedom should be guaranteed and their free and informed consent must be obtained before participation in the study. Here it ought to be recalled that some experiments, especially in the field of psychology, are very specific in nature, and imply that the participants cannot be comprehensively informed beforehand because this could impact on the results. The test subjects should have it clearly explained to them that they will not be comprehensively and accurately informed before the experiment begins, but that they will receive all the information after they have taken part.
- The safety of the participants must be guaranteed; here it should be stressed that this concerns physical and mental safety, especially that of minors, prison inmates, etc.
- Confidentiality must be guaranteed and access to the data and results should be controlled. The experiments should be carried out with respect for privacy. In some cases the data should be anonymised so that it is impossible to identify the participants in an experiment either directly or indirectly. The protection of personal data implies an irreversible anonymisation of sensitive data obtained during certain studies.

4. Thoughts on the role and place of ethics committees in the life sciences

Ethics committees in the life sciences should have the responsibility of monitoring the various points discussed above: scientific pertinence, assessment of the possible risks for the participants, conditions for inclusion of the participants, information supplied, observance of confidentiality, and so forth.
Following on from interviews with colleagues and experts, we would like to emphasise the following. In sociological, criminological or psychological studies, various different – and sometimes conflicting – theoretical bases can be used within one and the same discipline. If the job of an ethics committee is to assess the scientific basis of a study, it should do so without prejudice to the theoretical basis from which the study draws its inspiration. There may indeed be contradictions at theoretical level which do not, however, challenge the relevance of the research.

The French-speaking experts, and the Dutch-speaking expert, who were interviewed by the select committee are in favour of ethics committees being set up. The faculties of psychology and educational sciences are also reportedly advocates of ethics committees being set up in the faculties.

As regards sociology and criminology, the experts who were heard by the select committee display a certain reservation about the setting up of an ethics committee that would assess the ethical value of their research projects. Of the view that they are the preferential witnesses of society's growing interference in people's private lives and the increased social pressure (at economic, political and other levels) that this exerts on individuals on a day-to-day basis, they fear that ethics committees could curb their studies and thereby prevent them from bringing certain dysfunctions or pressures to light.
On the other hand, they advocate the setting up of a code of professional practice specific to their profession and containing ethical guidelines for researchers. These guidelines of course relate to the informed consent of the persons studied and respect for their privacy.
One expert is of the view that an ethics committee at inter-university level could be useful. This committee would only be allowed to have an advisory role.
Two experts who were interviewed also complained of the existence of collusion between life sciences research and the political establishment, which is often the party subsidising the studies and tends to orientate the research according to its objectives.

Some members of the Committee and the experts interviewed stress that university research budgets have been severely scaled down in the last few decades. The possibility of the various centres taking on researchers, carrying out research and producing publications, depends more on research budgets from outside the university, which are often granted by the government. For example, a minister is looking for an answer to a particular problem and commissions a study, in the pursuit of political efficiency. Unfortunately, research seldom delivers unambiguous solutions for contemporary social problems. If the result of the study does not answer the question posed by the commissioning authority, or does not meet the latter's wishes, there is a good chance that the centre will not receive any further subsidies for a subsequent study. When the study attempts to reach a solution that tallies with the commissioning authority's expectations, the researchers may feel manipulated. If the centre refuses to comply, this leads in any case to a drop in its productivity.

5. Conclusions

a. Ethics committees in the faculties of psychology

Expediency

The experts whose opinions were heard and the members of the Advisory Committee for Bio-ethics are in favour of ethics committees being set up in faculties of psychology. Some faculties already have their ethics committee and there are many arguments advocating the establishment of such committees. Even though the risk for the participants in such studies is seldom one of physical and mental harm, it is nonetheless important that that risk be examined. The examples in point 2 illustrate certain risks of stigmatisation or undesired consequences that are associated with some experiments. The people's protection is therefore at issue.
Ethics committees in the faculties of psychology could play an advisory role and could have preferential contact with the medical ethics committees when the protocol falls under the scope of the law on experiments involving human subjects and therefore has to be submitted to these latter committees.
It is up to the faculties of psychology and educational sciences to work out in greater detail the composition and operation of their committees.

In a letter to us dated 27/10/2005, in answer to a request made by the co-chairmen of the 2005/5 select committee for information on research in the faculties of psychology and educational sciences and on whether or not an ad-hoc ethics committee existed, Professor B. Harmegnies told

us that the faculties of psychology and educational sciences of the universities of the French Community of Belgium "(translation) *recently decided, each individually, to set up and/or restructure their own ethics committee per faculty, out of a concern that opinions on the ethical validity of research studies in psychology and educational sciences be published by specific bodies in psychology and educational sciences*".

Inter-university harmonisation

Professor B. Mouvet also asked us for an opinion on the expediency of harmonising the activities of ethics committees in psychology. The Committee is of the view that a harmonisation of the working procedures and methods used by ethics committees in psychology should certainly be encouraged.
In the same letter of 27/10/2005, Professor B. Harmegnies tells us that the *Conférence des Doyens* (Conference of Deans) of the universities of the French Community of Belgium "(our translation) *has set up a consultative structure which it has asked to prepare the convergence measures that have to be implemented so that the four faculty ethics committees can organise their operation swiftly on a harmonised basis*".

b. Ethics committees in other branches of the life sciences (sociology, criminology, etc.)

The Advisory Committee for Bio-ethics is of the opinion that ethics committees could have a supporting function in areas of the life sciences other than psychology, for the ethical reflection on research protocols.
These ethics committees do not have to be a copy of the medical ethics committees, but would have to focus on the protection of the people taking part in research and be organised in cooperation with the researchers in those fields. Those working in the life sciences would have to work out how we could arrive at an optimal operation of such ethics committees and the fair representation in them of the various members of the life sciences fraternity. Thought should also be given to the idea of including "outsiders" on these committees, i.e. people who are not involved in the research or in the field being studied. Such committees could also form a buffer against the incidence of certain bodies that commission research interfering in the objective, progress or financing of the research study itself. These committees could thus help guarantee the autonomy and freedom of the research.
Apart from the reflection on the usefulness of ethics committees being set up in the life sciences in order to avoid conflicts between the government, the financing bodies and the researchers, the Committee advocates a refinancing of research at universities so that they are able to work in a totally independent fashion.

The opinion was prepared by the select commission 2005-5, consisting of:

Joint chairpersons	Joint reporters	Members	Member of the Bureau
M. Roelandt	M. Roelandt	M. Bogaert	J.-A. Stiennon
J.-M. Maloteaux	J.-M. Maloteaux	F. Caeymaex	
		M. Dumont	
		E. Eggermont	
		M. Eisenhuth	
		R. Rubens	
		G. Verdonk	
		From 13-03-2006: M.-L. Delfosse G. Lebeer	

Member of the secretariat
Veerle Weltens

Experts consulted in 2005 / beginning of 2006

- Prof. B. Mouvet, Chairperson of the Ethics Committee of the Faculty of Psychology and Educational Sciences of the University of Liège
- Prof. I. Kristoffersen-Ponjaert, Psychologist attached to the Free University of Brussels and member of the Committee
- Prof. M. Jacquemain, Sociologist attached to the University of Liège and member of the Committee
- Prof. G. Lebeer, Sociologist attached to the Free University of Brussels and member of the Committee
- Prof. Y. Cartuyvels, Dean of the Faculty of Law of the Facultés Universitaires Saint-Louis

The working documents of the select commission 2005-5 – the question, personal contributions of the members, minutes of the meetings, documents consulted – are kept at the Committee's documentation centre, where they are available to be consulted and copied.

This opinion is available on the website www.health.belgium.be/bioeth under the "List of Opinions" section.