Theoretical Medicine and Bioethics (2007) 28:157–179
DOI 10.1007/s11017-007-9036-y

LISA BORTOLOTTI and BERT HEINRICHS

DELIMITING THE CONCEPT OF RESEARCH: AN ETHICAL PERSPECTIVE

ABSTRACT. It is important to be able to offer an account of which activities count as scientific research, given our current interest in promoting research as a means to benefit humankind and in ethically regulating it. We attempt to offer such an account, arguing that we need to consider both the procedural and functional dimensions of an activity before we can establish whether it is a genuine instance of scientific research. By placing research in a broader schema of activities, the similarities and differences between research activities and other activities become visible. It is also easier to show why some activities that do not count as research can sometimes be confused with research and why some other activities can be regarded only partially as research. Although the concept of research is important to delimit a class of activities which we might be morally obliged to promote, we observe that the class of activities which are regarded as subject to ethical regulation is not exhausted by research activities. We argue that, whether they be research or not, all the activities that are likely to affect the rights and interests of the individuals involved and impact on the rights and interests of other individuals raise ethical issues and might be in need of ethical regulation.

KEY WORDS: research, ethical regulation, demarcation criterion, research ethics, methodology of science, aims of science, falsification, Popper, freedom of research

INTRODUCTION

In this paper, we consider how research is to be delimited against other kinds of human activities in view of the necessity of ethical regulation. Before we can discuss the ethical implications of research activities, we need to clarify the concept of research and to provide a criterion for the distinction between activities that count as research and activities that do not. We start from the working definition of research as a human activity that can assume various forms but that is always aimed at extending a body of knowledge by means of a scientifically respectable methodology.[1] We acknowledge the difficulty in describing what the methodology includes in any more detail, as it might vary considerably

according to the discipline in which the research is conducted. By taking into consideration the two dimensions of the demarcation criterion for research activities, i.e., aims and method, we can make sense of the fact that some activities count only partially as research.

Research activities have a *procedural* dimension. The disciplinary area in which researchers operate dictates which methodology is followed. Both the results obtained and the steps leading to those results are open to rational scrutiny. Research activities also have a *functional* dimension, that is, they have a different function from other activities such as therapeutic interventions or demonstrations of knowledge in educational contexts in so far as they are mainly aimed at extending or further developing a body of knowledge.

Delimiting research in this way can be useful for the purposes of ethical regulation, but we observe that ethical issues are raised not exclusively by research activities, but by all those activities that risk violating individual rights, or frustrating interests of individuals with rights and interests. As a result, the scope of ethical regulation might include activities that are not *research* activities.

FREEDOM OF RESEARCH AND THE NECESSITY OF REGULATION

Under the conditions of the modern liberal state, freedom of scientific research is deemed to be a fundamental right, as important as freedom of expression and freedom of assembly and association. Since the age of the Enlightenment, it has come to be accepted that scientific research must be granted vigorous freedom of inquiry as a protection against undue influence from the political sphere. Within the limits set by other fundamental rights, it guarantees both the individual researcher and scientific institutions the right to select objectives for scientific enquiry, to perform research to achieve these objectives, and to publish results without constraints. The importance of freedom of research is reflected in the fact that it is incorporated as Article 13 in the Charter of Fundamental Rights of The European Union (2000).[2]

Some argue that we also have a moral duty to pursue the results of those instances of scientific inquiry that can be utilised to improve the conditions of individuals or societies, because we have moral reasons to prevent harm and do good when possible.[3] Both the *pure* and the *applied* dimensions of science, if a meaningful distinction between these categories can still be made, [4] have a recognised value in our

society: they deepen our understanding of the natural and social phenomena around us, and they can often contribute with their current and future applications to a general improvement of the quality of our lives.

However, freedom of research should not be unlimited. Modern history teaches us that there is the need for ethical reflection on the practice of science. As Jonas writes:

> We must take a closer look at the interlocking of theory and the practice in the actual way science is nowadays 'done' and essentially must be done. We shall then see that not only have the boundaries between theory and practice become blurred, but that the two are now fused in the very heart of science itself, so that the ancient alibi of pure theory and with it the moral immunity it provided no longer hold.[5]

With the centrality of empirical investigation in modern science, the practice of science is now understood for the most part as the process of generating hypotheses and actively testing them by operating on or intervening in the research objects, both in the natural and social sciences. This was probably not the case in pre-modern accounts of science, when the practice of science was by and large a deductive exercise based on observations and general metaphysical principles and the role of empirical testing was very limited.[6] Actively intervening in nature and the environment is now a constitutive part of what it means to engage in science. If the means by which research is conducted involves individuals with rights and interests which might be affected by any aspect of the research activity, practitioners of science are confronted with ethical issues.

This is why research ethics has assumed an increasingly important role.[7] If the consequences of research on research participants and other affected individuals can sometimes be serious and irreversible, the emphasis on freedom of research needs to be accompanied by a reflection upon the ethical principles that apply to research as a special kind of human activity. In several fields, for instance, biomedical research, such principles have already been formulated and developed (although some are controversial) and are taken into consideration both by researchers and funding institutions.

But which activities raise ethical issues and might be in need of regulation? The accepted answer is: *research* activities. This leaves us with some difficult conceptual problems to solve, among others how research activities should be delimited. It seems as if we need to be able to account for the concept of research in order to decide which human activities should, on the one hand, be granted the freedom

and moral value that research activities have, and, on the other hand, be constrained by the respect for the rights and interests of the individuals that might be affected by them. In this paper, we are going to challenge the assumption that ethical regulation should apply only to those activities that count as research.

TOWARDS A DEFINITION OF RESEARCH

What characterises a human activity as research? Let us have a look at the following definitions:

> Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to geenralisable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted and supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.[8]
>
> Systematic study directed toward more complete scientific knowledge or understanding of the subject studied.[9]
>
> Focused, systematic study and investigation undertaken to increase knowledge and understanding of a subject. The term is used inclusively to refer to scholarly, empirical, creative, critical, and/or expressive activities in the sciences, humanities, arts, and other scholarly fields, which expand, clarify, reorganize, or develop knowledge or artistic perception.[10]
>
> Research and experimental development comprises: (1) Creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of humanity, culture and society, and the use of this stock of knowledge to devise new applications. (2) Any activity classified as research and experimental development is characterized by originality; it should have investigation as a primary objective and should have the potential to produce results that are sufficiently general for humanity's stock of knowledge (theoretical and/or practical) to be recognizably increased. [11]

By reflecting on the shared elements of the above definitions of scientific research, two distinct sets of questions seem to emerge which we shall explore before moving onto the issue of ethical regulation. First, we have a *procedural* demarcation question: should an activity that counts as research be systematic and, if so, in what sense? Second, we have a *functional* demarcation question: what is research aimed at?

PROCEDURAL QUESTIONS

There are various procedural questions that are relevant to the demarcation of research activities. Research activities need to be, to

some extent, systematic and to follow methodological prescriptions that generally depend on the disciplinary area within which research is conducted. Whereas natural and social sciences might require rigorous empirical testing, other disciplines might just require that their standard practices be transparent and open to rational criticism. Among the procedural aspects of human activities that could be regarded as research, an important role is played by the *sociology* of research. For instance, it is legitimate to ask whether anyone can do research, or whether some form of training or status is needed by the people conducting a systematic investigation before the activity can count as research. These issues cannot be exhaustively addressed here. In what follows, we shall focus on the general issue of *methodology*.

When we think about the scientific method, we seem to encounter a tension that is reflected in the development of twentieth-century philosophy of science. On the one hand, science is so compartmentalised and has such varied scientific procedures that only specialised scientific communities can determine if some particular activity conforms to the often abstract requirements of correct methodology. On the other hand, some demarcation criterion is needed for the purposes of public understanding and policy-making. Although it is not realistic to aspire to describe one ultimate method for all the disciplines that can be regarded as 'scientific',[12] there seem to be two essential procedural elements which can help us distinguish research from other activities.

First, scientific research must be conducted in a way that allows 'reality-checks', that is, some form of testing of the hypotheses used. More generally, some sensitivity to evidence must be part of the way in which conclusions are reached and justified. Second, both the conclusions reached and the reasoning necessary to reach them must be transparent and open to criticism. When we refer to the human activities that satisfy these two requirements as following a critical method of investigation, this is just shorthand for susceptibility to empirical testing of the working hypotheses and sensitivity to available evidence in the formulation and justification of the conclusions reached.

The notion of scientific research we are attempting to clarify includes research in the humanities as well as in those disciplines traditionally called 'sciences'. So when we refer to testing and critical method, we do so broadly. We do recognise that there is an important distinction between research activities that are deemed as natural and

social sciences and other research activities, such as research in art history. But we believe that both types of research potentially have moral value and ethical consequences and therefore the distinction is not relevant to our present purposes. That aside, there is more continuity in the functional and procedural aspects of these types of research than has been stressed in the literature. Our way of fleshing out the procedural dimension of research is also an attempt to identify commonalities between the practices of researchers in these apparently very different areas.

The requirements of transparency and openness to rational criticism have been traditionally described in terms of the distinction between science and pseudo-science. We now turn to this issue and to the functional account of research.

FUNCTIONAL AND PROCEDURAL QUESTIONS

It is fairly uncontroversial that the main aim of research in the natural sciences and many of the social sciences is to obtain generalisable knowledge. Although frequently used it is not easy to say what the term 'generalisable knowledge' exactly means. Here is a simple example to illustrate how we understand it. One can generate knowledge by checking the temperature of the water in a bathtub. After inspecting the water one knows whether it is too hot, too cold or just fine. However, the knowledge generated in this vein is valid only for a very specific and limited context. If, in contrast, one puts boiling water into a bathtub and measures the time until it has cooled down to 37° the result is applicable to all similar bathtubs.

Knowledge of the latter kind is—to a certain extent—context-independent. This is how we use the term 'generalisable'. We are aware of the fact that this usage is problematic for a number of reasons. The distinction between knowledge that is generalisable and knowledge that is not might put pressure on our attempt to provide criteria for delimiting research activities in general, rather than research activities in the natural and social sciences more specifically. It raises the question of what criteria the knowledge produced by research activities should satisfy in order to be generalisable in the sense we described. Absolute context-independence is not achieved even in the physical sciences, as all scientific knowledge is subject to *ceteris paribus* clauses, but arguably in some disciplines the target knowledge is more susceptible to generalisations than in others

(e.g., the target knowledge for political science is more generalisable than the target knowledge for history, where we might seek explanation for a unique event).[13]

What one might want to note here is a distinction between the knowledge we typically seek in everyday life, which can be local and context-specific, and the knowledge acquired in academic disciplines, including both natural and social sciences, which is typically aimed at explaining single events on the basis of laws or generalisations. Even this very general characterisation is not completely satisfactory, since there can be continuity between ordinary attempts to explain unique phenomena and the generation of explanatory hypotheses in scientific research. For this reason, in the rest of the paper, we shall assume that what makes research activities different from other activities in terms of function is the aim is to contribute to an organised and minimally unified *body* of knowledge rather than acquire information about particular events.

Any appeal to generalisable knowledge or to a body of knowledge needs to be further qualified. Not all knowledge is equally important as a target for those activities we regard as research. In science, researchers are after *relevant* knowledge—that is, they work towards the confirmation of hypotheses that can contribute to explaining the phenomena they are interested in. An additional problem is posed by the requirement of novelty or originality in research outcomes. There seems to be consensus on classifying the confirmation of results and the re-organisation of previously known data as research, when confirmation is needed or when there is an element of originality or novelty in the activity. This element of originality might be exhausted by the possibility of drawing further conclusions or making further generalisations on the basis of a different way of re-organising the data.

For Imre Lakatos, who depicts science as the dynamic succession of research programmes and not as a collection of theoretical statements, a research programme is scientific if it is *progressive*.[14] In order to be progressive with respect to a previous stage of scientific development, the research programme must have at least as much empirical content and must be able to offer an explanation for the same phenomena in a way that is at least as satisfactory. In addition, it must make *novel* predictions that can be corroborated by experience. A research programme is degenerating (i.e., it is science, but bad science) if the novel predictions that are made are not corroborated by experience.

Although Lakatos' account has been so far extremely influential within scientific methodology, some problems have been raised concerning the notion of 'novel' facts and 'novel' predictions. With respect to what should the facts and the predictions be novel? There are different answers in the literature, ranging from temporal novelty to novelty of interpretation.[15] The consequences of which type of novelty we select are very important for the definition of progressive research programmes. All that is required by temporal novelty is that facts that were not considered likely before can now be predicted. Novelty of interpretation, instead, is much weaker and demands just that old facts be revisited and re-evaluated by the research programme. For the purposes of our general discussion here, novelty of interpretation will be regarded as necessary for an activity to count as *original* research.

The issues raised here (the *ceteris paribus* nature of knowledge, the explanatory role of acquired information, and novelty) and other issues that we have not explicitly addressed (such as consilience) generate lively debates in contemporary philosophy of science about the nature of laws, the correct model of scientific explanation, and progress in science. Although these debates potentially have an impact on the way in which we choose to characterise the aims of scientific research, it would be too ambitious to attempt to address their relevance in this paper. What we have done so far is highlighted some typical features of the knowledge that research activities aim at obtaining, and some of the difficulties in further qualifying the target knowledge independently of an explicit reference to the specifications of individual disciplines.

The next step is to establish whether the knowledge produced needs to be falsifiable. The major question in the literature on demarcation is how to distinguish science from pseudo-science; metaphysics on the one hand and from logic and mathematics on the other. Major contributions to the classical problem of demarcation have been made by Karl Popper who believed that science should aim at the production of *falsifiable* hypotheses.[16] Popper's solution is based on the insight that general statements can never be verified by experience, because for their verification an infinite number of observations would be necessary. However, general statements with empirical content can be *falsified* by experience, since a single experience that contradicts a prediction based on a theory by means of *modus tollens* is sufficient to prove the theory wrong. According to Popper, only scientific statements are falsifiable, whereas pseudo-

scientific and metaphysical ones are immune from empirical failure. Hence, he thought that falsifiability was the best way of distinguishing between science and non-science.

Critics of Popper have undermined falsifiability as a demarcation criterion.[17] Some elements of a scientific theory (such as laws in theoretical physics) are not directly falsifiable, whereas pseudo-sciences (such as astrology) can generate falsifiable statements. Moreover, predictive failure does not always indicate that a scientific theory is proven wrong. Even when observations seem to contradict the tenets of a theory, in the practice of science, it is possible and sometimes perfectly acceptable to adjust the theory with the help of auxiliary hypotheses.[18]

Traditionally, the demarcation criterion in the philosophy of science has been characterised as the attempt to distinguish science from pseudo-science. Although the literature on the demarcation of science might be relevant to the aim of delimiting research activities, our approach is significantly different. If we regard research as an activity, what matters to its delimitation is the *function* of this activity rather than the field to which the activity contributes, as long as procedural requirements are satisfied. We are interested in research with the main function of extending a body of knowledge in contrast with activities whose main function is, for instance, providing effective treatment for a patient (therapy) or providing evidence of attainment in higher education (investigation leading to a master thesis). Pseudo-science does not constitute a functional area in this sense. It might still be aimed at extending a body of knowledge, but it is not characterised by a critical method of investigation. That is why we believe that a discussion of the limitations of pseudo-science might be better situated within the procedural dimension of the demarcation of research activities.

As a contribution to the procedural dimension of research, the Popperian notion of falsifiability is vulnerable to various counterexamples. However, a weaker notion of falsifiability can capture the sense in which the practice of conducting research is different from the practices we engage in when we follow artistic inspiration, participate in a religious cult, or read someone's palm. Research activities are characterised by susceptibility to reality-checks, transparency, and openness to rational criticism. As shorthand for this idea, we shall refer to the procedural dimension of research activities as the adoption of a critical method of investigation. This use might create confusion in borderline or controversial cases. A project in

metaphysics that is not sensitive to any empirical evidence and has no ambition to produce results that are at least compatible with the understanding of the physical world as provided by the sciences might adopt a critical method in the sense that it is open to objections and criticism, but might fail to satisfy the other criteria that constitute the procedural dimension of typical research activities.

A DELIMITATION SCHEMA

How can we combine the previous considerations on functional and procedural dimensions to delimit the concept of research? We could start by saying that scientific research is a human activity that aims at extending a body of knowledge by adopting a critical method.[19] If this is the case, interesting distinctions arise. In particular, it becomes apparent that research shares certain features with other human activities which may, as a consequence, sometimes be confused with research. We will place research in a broader schema of activities in order to highlight such similarities and differences and, thereby, clarify the concept of research itself.

An activity can be aimed at extending a body of knowledge without adopting a critical method—some people would say that some studies in astrology or creationism fall into this category. An activity could be conducted via a critical method without aiming at extending a body of knowledge—for instance the 'research' conducted by a master's student in physics might be methodologically indistinguishable from the work done by leading researchers in the field, but its main function is to demonstrate the student's competence, rather than contributing to the knowledge shared by the community of physicists.

This category might also help us make sense of the much debated research-therapy distinction in biomedicine.[20] The same data, obtained via a respectable empirical method, can be used to extend biomedical knowledge or to provide immediate therapy, although these functions are definitely non-exclusive. One can argue that knowledge in biomedicine has always a long-term therapeutic function. Therapeutic attempts using non-validated methods or drugs might generate a hypothesis that could then be tested in a trial.

Some caveats are in order. The distinction between research and non-research does not carry any evaluative judgement. One might believe that there is more to the dimension of human rationality than

what scientific research allows us to achieve. Knowledge in fields in which investigation has not yet met the criteria for scientific research might nonetheless be extremely valuable. And the distinction between research and non-research has no bearing on the quite separate distinction between good and bad scientific research. For instance, an investigation aimed at extending a body of knowledge can be good, if the critical methods that are used can be shown to be reliable and produce results, and bad if they cannot.

The following schema can help visualise the dimensions of the demarcation between research and non-research we have explored so far (Table 1).

As the schema illustrates, some types of activities share certain features with scientific research and may, therefore, be falsely considered as research. An illustration of this case is offered by those activities that follow a critical method but do not mainly aim at extending a body of knowledge (II.). For example, experiments undertaken by students in the course of their studies *look like* research, because in performing such experiments students apply a critical method. However, such activities are not mainly aimed at extending a body of knowledge. The main purpose of these activities is to demonstrate the students' competencies and, consequently, *they are not research*. A more complex case is the application of new unproven therapies in medicine. In many cases, it is not easy to decide whether this is done in the first place to help individual patients or to validate the efficacy of a new therapeutic agent. It is perfectly possible to conceive of circumstances in which an activity is aimed at both providing therapy for a patient or a group of patients and extending a body of knowledge.

A good example can be found in a case in which the court decided that it would be lawful to administer experimental therapy to an incompetent patient, Jonathan Simms, affected by variant Creutzfeld-Jakob Disease (vCJD).[21] The drug administered, pentosan polysulphate, had never been used on humans affected by vCJD and was infused directly into the brain, via a risky surgical procedure. The decision of the court was motivated by the serious prognosis of Jonathan Simms and the lack of available alternatives. The case suggests that there are no sharp boundaries between research and therapy and that an activity can have both functions.

In contrast, some activities do contribute to knowledge and are nevertheless not research for they do not follow a critical method (III.). If, for instance, a researcher gains an important insight by pure

Table 1. Delimitation of research activities

	Follow critical method	Do not follow critical method
Are mainly aimed at extending a body of knowledge	(I.) Activities that count as scientific research.	(III.) Activities that result in new findings by alternative strategies, such as pure inspiration, chance, divine revelation, metaphysical speculation and so on.
Are not mainly aimed at extending a body of knowledge	(II.) Activities such as therapy in biomedicine or postgraduate research in the sciences.	(IV.) Activities that are not research but are similar to research in certain aspects such as writing funding proposals.

chance she might well contribute to knowledge. It does not seem appropriate, however, to call her activity research. Yet, activities that are *similar* to research in this sense, such as important discoveries made by chance, are rare in modern science. At first glance, 'discoveries by chance' contribute to science, but not as a consequence of the correct application of a research methodology. However, the most famous instances of such discoveries (e.g., the discovery of penicillin) are episodes embedded in a methodologically respectable research.

Another type of activities that might be subsumed under category (III.) and that may occur more frequently in modern research is exemplified by an activity that *is aimed* at making a contribution to knowledge by applying a critical method but *fails in the application of a critical method*. Whether this activity is bad research or not research at all will depend on the nature of the failure. Bad research should fall under (I.). However, if the agent not only fails to follow a critical method consistently, but applies entirely scientifically suspicious or corrupt methods it is no longer appropriate to call such an activity research. Hence, it must be subsumed under category (III.).

Finally, there are activities that do neither follow a critical method nor are they mainly aimed at extending a body of knowledge (IV.). Even in this case it may sometimes be difficult to tell them apart from scientific research. If, for instance, a healer applies an unproven measure in order to cure a patient but does it in a totally unsystematic and uncritical way, what she does is, for sure, not research. The activity in question is, however, in certain respects similar to activities of type (II.) and (III.), since the actions performed by the healer might be given some form of justification and rely on some theoretical background. As a result of this (sometimes superficial) similarity with proper research activities, healing might be taken in the public perception to be an instance of science. The same can be said about activities such as preparing proposals for research funding,[22] or writing fiction. These activities neither have as their main purpose the production of knowledge, nor they consistently follow a critical method, but might involve aspects of research at different stages.

ETHICAL CONSTRAINTS ON RESEARCH

There are many reasons why research as we conceive it today could be seen as needing ethical regulation. For instance, one might ask

whether it is legitimate to experiment on humans or animals at all. There is one argument for the claim that in research activities involving human or animal subjects, human beings or animals are used as means only to gain knowledge. Even if the risk of research participants or research subjects being harmed is negligible, one can argue that the use of individuals with rights and interests for purposes that might not directly benefit them is morally dubious. As Paul Ramsey stated, a 'subject can be wronged without being harmed'.[23]

The argument might be traced back to Kant, who believed that we should never use our fellow humans as a means only.[24] In recent years, the view has been extended by animal rights theorists to the protection of some animals. For instance, Tom Regan has argued on this basis that mammals aged one year or more should never be used in research.[25] According to this line of thought, various activities can lead to (a morally wrongful form of) instrumentalisation. It is argued that the use of other individuals with rights and interests solely as a means for accomplishing one's own ends should be avoided even if the actual risk of harming those individuals is low. We are not going to expand on this point here, although we feel that for the argument to succeed, the notion of instrumentalisation needs unpacking. In some contexts (e.g., scientific research), using humans as participants in an activity might not be at all morally problematic, at least if certain principles such as the principle of informed consent are respected. If it is true that scientific research benefits all humans, whether it be pure or applied, then research participants themselves might have an interest in research activities to be pursued and developed. Almost all human activities (e.g., politics, all commercial enterprises, advertisement) and all forms of social interaction (e.g., friendship, marriage) involve instrumentalisation and manipulation to some degree, and these are not necessarily negative aspects of our human practices. Instrumentalisation becomes morally objectionable when it is a form of exploitation—that is, when the autonomy of the individuals who are used for a certain purpose is not respected or their use negatively affects their well-being (e.g., slavery). The issue becomes more controversial when we consider the use of non-human animals for our benefit, as there is no consensus on what the moral status of animals is and on whether they can be considered to some extent autonomous. To sum up, instrumentalisation is not always morally problematic, because it does not necessarily lead to exploitation. Exploitation, which we have described as a treatment of

others which does not respect either their autonomy or their interests, is always morally problematic.

Leaving aside the issue of instrumentalisation, ethical issues can emerge with respect to the aims and objectives of an activity that counts as research and with respect to the interests and rights of the individuals involved in the activity. We will explore these issues in turn.

The objectives of a research proposal could come under ethical scrutiny for two quite independent reasons. There can be moral arguments to the effect that public resources for research are not unlimited and should be distributed fairly, by prioritising research areas in which greater benefits can be obtained for—e.g., the greater number of people or the most needy—depending on the underlying concept of justice. This kind of limitation on the objectives of research is controversial, as it might subject the progress of science to political decision-making on resource allocation issues.

There can also be reasons to stop a research proposal which has as its aim the demonstration of a thesis that is ethically dubious, for instance, the superiority of one race over another. Research in biological or chemical warfare may serve as another example here: the objectives of such research projects must be clearly rejected from an ethical point of view, independent of the means being used to achieve them.[26]

When we think about the way in which the research is conducted and the consequences of the experimental situations for the research participants, other issues come into play. There are moral reasons to make sure that the well-being and autonomy of persons are taken into account and individuals are not harmed unnecessarily. A practice that has come into scrutiny from an ethical point of view is the use of deception in psychological research. In social psychology, for instance, research participants are often misinformed about the real purpose of the experiment in which they are to take part in order for the results to be valid. The rationale for some instances of deception can be illustrated with an example: if researchers are interested in the occurrence of altruistic behaviour, to inform participants of the object of the study would make them more sensitive to those situations in the experimental setting in which they could help others. Consider the Good Samaritan experiment in which Darley and Batson wanted to demonstrate that altruistic behaviour is affected by external and contextual factors rather than by personality traits.[27] They wanted to show that people in a hurry are much less likely to

offer assistance in emergencies, independently of their personality. Darley and Batson devised an experiment in which some seminarists were told that they had to reach a building in a hurry to complete a task (ironically, talk about the story of the Good Samaritan). Participants found a man slumped in an alleyway on the route to the building, but most of them did not stop to help him. Those who believed they were late exhibited less altruistic behaviour than those who were not as rushed.

Although the research objectives might not be well-served by being honest to the participants, misinformation and deceptions could be regarded as violations of autonomy and if debriefing is not properly done, the results of a study in social psychology when communicated to the participants might cause them to suffer from long-term psychological harm and low self-concept. Learning that you are not an altruistic person might adversely affect your sense of self. Moreover, it might cause you to resent the researchers and arouse your suspicion in the scientific community in general. This use of deception has been heavily criticised and now, in the American Psychological Association Code of Ethics, deception is admissible only if there are no other effective procedures to obtain the desired experimental results and the results are expected to have scientific, educational, or applied value. Experimenters are instructed never to deceive participants about aspects that would affect their willingness to participate, such as physical risks, discomfort, unpleasant emotional experiences, and to debrief them as soon as possible after the experiment. And there is a lively debate among ethicists about whether these measures guarantee sufficient protection to research participants.[28]

In biomedical research, the principles of nonmaleficence is well-established and incorporated in the various codes on research ethics.[29] Generally, the principles of nonmaleficence require that a risk-benefit analysis be carried out before an experiment is undertaken. An experiment involving humans is considered to be morally acceptable only if this analysis is positive. Additionally, the principle calls for an immediate termination of the experiment if unexpected events imperil the life or well-being of the participants. Only recently, on 17 December 2004, the U.S. National Cancer Institute suspended a large clinical trial—the Adenoma Prevention with Celecoxib trial—because data analysis revealed a 2.5-fold increased risk of major fatal and non-fatal cardiovascular events for participants taking the drug compared to those on a placebo.[30]

WHICH ACTIVITIES ARE CANDIDATES FOR ETHICAL REGULATION?

Looking at the various reasons that support ethically regulating research, it is clear that ethical issues can be raised by almost any research activity, but the extent to which they affect the interests and rights of the individuals involved can vary considerably. There are perfectly respectable instances of research that do not seem to be candidates for ethical regulation (such as literary criticism) and activities that do not count as research that seem morally problematic (as government-funded extended surveys for the purposes of policy-making which involve sensitive personal data).

Apparently, the class of activities raising ethical issues and needing ethical regulation does not coincide with the class of activities that count as research according to our criteria. Presumably, the reason for this is that what really matters from an ethical point of view is that the rights of the individuals involved in the activity are safeguarded and their interests taken into careful consideration. When we think about which activities should come under ethical scrutiny, the main issue should not be whether they count as scientific research according to the analysis that has been presented or other demarcation proposals, but whether the interests and rights of individuals are likely to be affected.

Another way of approaching this issue is to say that from an ethical point of view, some activities should be reviewed in the same way that research is, even if they are not aimed at extending a body of knowledge via a scientifically acceptable method. This does not mean that these activities qualify as research, but that they should be monitored for the effects that they might have.

The use of innovative, non-validated drugs in a therapeutic setting can serve as a good example. According to our criteria, this is an activity that might not count as research, if extending a body of knowledge is not its main function. However, in some cases ethical reviewing can be appropriate. If the risks are high, one could argue that an IRB should review the application although it is not really research. It might be appropriate to appoint special committees for such reviewing that have special expertise in view of *therapeutic* interventions. More generally, arguing that it might be indicated to review some non-research activities does, of course, not imply that *research* ethics committees are the right instances for this task. To be sure, the therapeutic freedom of choice is one of the main elements of

the medical profession. However, if physicians apply a non-standard procedure that risks being dangerous for their patients, their activity might be as ethically problematic as an instance of research. After all, physicians might be unrealistic in their evaluation and, as a result, cause unnecessary harm to their patients. In view of medical research involving human subjects, it is justifiable to consider all actions initially to be ethically sensitive and therefore in need of review. If a research protocol appears to be not ethically sensitive in any aspect, an IRB can simply let it pass.

Research activities might not be the only human activities to come under the scrutiny of ethical regulation, but that does not make the concept of research redundant or uninteresting, even from an ethical perspective. It does not only denote a special class of human activities that are well distinguished from other human activities in terms of scientific methodology. It also marks the terrain for which a particular and important liberal right is applicable—the freedom of scientific research—and an enterprise which we have ethical reasons to promote and support as communities and individuals.

Lisa Bortolotti (University of Birmingham)
Bert Heinrichs (German Reference Centre for Ethics in the Life Sciences)

ACKNOWLEDGEMENTS

In the preparation of this paper, the authors acknowledge the stimulus and support of the EURECA project on delimiting the research concept and the research activities, sponsored by the European Commission, DG-Research, as part of the Science and Society Research Programme – 6th Framework. Our gratitude goes to all the partners and consultants of the EURECA project who have provided valuable feedback on the ideas contained in this paper after we presented an earlier version of it at the second EURECA workshop in Bologna.

NOTES

[1] As it will become clear in the rest of the paper, the way in which we use the word ''science'' and ''scientific'' is meant to cover the humanities and social sciences as well as the natural sciences.

[2] European Parliament, the Council and the Commission, Charter of Fundamental

Rights of The European Union (2000), chapter II, article 13. Freedom of the arts and sciences: ''The arts and scientific research shall be free of constraint. Academic freedom shall be respected.'' URL: http://www.europarl.europa.eu/charter/pdf/text_en.pdf. Accessed 2nd February, 2007.

[3] John Harris, ''Scientific Research is a Moral Duty,'' *Journal of Medical Ethics* 31 (2005): 242–248.

[4] The distinction between pure and applied disciplines can be convenient in some contexts, but when we consider the moral duty to pursue research and the ethical implications of the practice of scientific research, the distinction might turn out to be misleading. After all, it is difficult to predict what aspects of pure science can generate relevant and useful applications in the future and both the scientific research aimed at developing a theory and at testing applications of the theory might affect the rights and interests of individuals.

[5] Hans Jonas, ''Freedom of Scientific Inquiry and the Public Interest,'' *Hastings Center Report* 6(4) (1976): 15–17, page 16.

[6] See the famous account of science given by Aristotle in *Posterior Analytics* and Book VI of the *Nicomachean Ethics* (Aristotle, *The Complete Works of Aristotle*, ed. and trans. Jonathan Barnes. (Princeton: Princeton University Press, 1995.)

[7] In the following the term 'research ethics' is used in a broad sense, in particular it is not limited to 'a subset of the professional responsibilities of researchers' as suggested in Whitbeck (1997).

[8] US Code of Federal Regulations, Title 45, Public Welfare 46.102(d). URL http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr46_06.html. Accessed 2nd February, 2007.

[9] American Association for the Advancement of Science, Science and Policy, Definition of Key Terms, 2006. Adapted from National Science Foundation, Federal R&D Funding by Budget Function: Fiscal Years 2004–2006, Arlington, VA, 2006. URL: http://www.aaas.org/spp/rd/define.htm. Accessed 2nd February, 2007.

[10] Board of Trustees of the Southern Illinois University, Office of Research Development and Administration, Glossary of Research Terms, 2006. URL: http://www.siu.edu/orda/general/glossary.html. Accessed 2nd February, 2007.

[11] Swinburne University of Technology, 2005, URL: http://www.swin.edu.au/research/collection/2004_collection/eligibility_def.html. Accessed 2nd February, 2007.

[12] One additional reason why talking about *one* scientific methodology seems misleading, apart from the diversification of scientific disciplines, is that the scientific method as well as the scientific theories arrived at by that method can be subject to revision.

[13] The German Philosopher Wilhelm Windelband introduced the complementary terms 'nomothetic' and 'idiographic' in order to characterise the different methodological approaches of the natural sciences on the one hand and the 'historical' sciences on the other hand. In a presidential address at the University of Strasbourg given in 1894 Windelband explicated: 'So, we can say: in seeking knowledge of what is real, the empirical sciences are looking for the general in terms of natural laws or for the singular in historically determined shape; they consider partially the steady form and partially the unique self-determined content of the real events. Those are sciences of natural laws, these are sciences of events; those teach what always is, these what once has been. Scientific thinking is—if one likes to introduce new artificial terms—in one case nomothetic in the other case ideographic. If we like to

adhere to common expressions, we may in this sense further speak of the opposition of natural and historical disciplines [...]. (Wilhelm Windelband, "Geschichte und Naturwissenschaft. Straßburger Rektoratsrede," in Wilhelm Windelband, *Präludien. Aufsätze und Reden zur Philosophie und ihrer Geschichte*. Tübingen: J. C. B. Mohr., 1894, 136–160; page 145. English translation from Gerhard Faßnacht., *Nomothesia, Ideographia, and Bemetology*. Draft., 2004. URL: http://www.lse.ac.uk/collections/methodologyInstitute/pdf/QualPapers/Fass-Nomo_Ideo%20revi.pdf. Accessed 2nd February, 2007.

[14] Imre Lakatos, "Falsification and the Methodology of Scientific Research Programmes," in *Philosophical Papers*, vol. I. Cambridge, Cambridge University Press, 1970.

[15] Colin Eman and Miriam Eman, "How not to be Lakatos Intolerant," in *International Studies Quarterly* 46 (2002): 231–262.

[16] Karl Popper, *The Logic of Scientific Discovery*, 5th edition. New York: Routledge, 2002. Original publ. 1935.

[17] For an overview, see Alan Chalmers, *What is this thing called science?* Queensland: University of Queensland Press, 1999; chapter 7.

[18] Thomas Kuhn, *Structure of Scientific Revolutions*. Chicago: University of Chicago Press, 1996. Original publ. 1962.

[19] We are aware that there are two ways in which the function of an activity can be tracked: *subjectively*, looking at the primary intentions of the people engaging in the activity, and *objectively*, looking at what the outcomes of the activity actually contribute to. Here we shall not explore this distinction and we shall assume that in most cases the subjective and objective aspects are 'correlated', i.e., someone intends to extend knowledge and—from an objective point of view—does it. In the case where someone intends to contribute to science but fails, say, to apply critical methods of investigations the two aspects diverge. In that case we have two possibilities, depending on the extent of the deviation from the objective criteria: either (1) the activity can be a bad instance of research, that is, since some objective criteria are not met and the activity is somehow 'corrupted'; or (2) the activity is not research at all, because there is no correlation between the people's intentions in initiating and performing the activity and the fulfilment of the objective criteria.

[20] Jon Tyson, "Dubious Distinctions Between Research and Clinical Practice Using Experimental Therapies," in *Ethics and Perinatology*, eds. Ammon Goldworth, William Silvermann, David K. Stevenson, Ernlé W.D. Young, Rodney Rivers (New York: Oxford University Press, 1995), pp. 214–230.

[21] Simms v Simms and An NHS Trust [2002] EWHC 2734, Fam.

[22] This is not to deny that fund raising is an integral part of modern science. To the contrary, it certainly is. However, it is not research but may, at times, be mixed up with research, especially from an outside perspective.

[23] Paul Ramsey, *The patient as person. Exploration in medical ethics*. 2nd ed. Yale University Press, 2002, p. 39.

[24] Immanuel Kant, *Groundwork of the Metaphysics of Morals*, ed. Mary J. Gregor, (Cambridge, Cambridge University Press, 1998). Original publ. 1785.

[25] Tom Regan, *The Case for Animal Rights*. University of California Press, 1983.

[26] Sheldon Harris, *Japanese Biological Warfare. Research on Humans: A Case study of Microbiology and Ethics*, Annals of the New York Academy of Science 666 (1992): 21–49. As Harris states in his article, nations still engaged in biological

warfare frequently claim that their research is purely defensive in nature. Harris observes, however, that 'when this rationale was used in the past, it led inevitably to offensive biological warfare research.' (page 43).

[27] John Darley and C. Daniel Batson, ''From Jerusalem to Jericho: A study of Situational and Dispositional Variables in Helping Behavior,'' *Journal of Personality and Social Psychology* 27 (1973): 100–108.

[28] See for instance Stephen Clarke, ''Justifying deception in social science research,'' *Journal of Applied Philosophy* 16(2) (1999):151–166; and Lisa Bortolotti and Matteo Mameli, ''Deception in psychology: moral costs and benefits of unsought self-knowledge,'' *Accountability in Research* 13, no.3 (2006): 259–275.

[29] See Council for International Organizations of Medical Sciences (CIOMS), *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, 2002, URL http://www.cioms.ch/frame_guidelines_nov_2002.htm; and World Medical Association (WMA), *Declaration of Helsinki*, 2004, URL http://www.wma.net/e/policy/b3.htm. Both accessed 2nd February, 2007.

[30] See National Cancer Institute (NCI), ''NIH Halts Use of COX-2 Inhibitor in Large Cancer Prevention Trial'', 2004, URL: http://www.cancer.gov/newscenter/pressreleases/APCtrialCOX2; and National Institutes of Health (NIH), ''Questions and Answers NIH Halts Use of COX-2 Inhibitor in Large Cancer Prevention Trial'', 2004. URL: http://www.nih.gov/news/pr/dec2004/od-17Q&A.htm . Both accessed 2nd February, 2007. See also: Scott D. Solomon, John J.V. McMurray, Marc A. Pfeffer, Janet Wittes, Robert Fowler, Peter Finn, William F. Anderson, Ann Zauber, Ernest Hawk, Monica Bertagnolli for the Adenoma Prevention with Celecoxib (APC) Study Investigators, Cardiovascular Risk Associated with Celecoxib in a Clinical Trial for Colorectal Adenoma Prevention, *New England Journal of Medicine* 352 (2005): 1071–1080.

REFERENCES

American Association for the Advancement of Science, Science and Policy, Definition of Key Terms, 2006. URL: http://www.aaas.org/spp/rd/define.htm. Accessed 2nd February, 2007.

Aristotle. *The Complete Works of Aristotle*. Edited and translated by J. Barnes. Princeton: Princeton University Press, 1995.

Board of Trustees of the Southern Illinois University, Office of Research Development and Administration, Glossary of Research Terms, 2006. URL: http://www.siu.edu/orda/general/glossary.html. Accessed 2nd February, 2007.

Bortolotti, L., and M. Mameli ''Deception in psychology: moral costs and benefits of unsought self-knowledge.'' *Accountability in Research* 13, 3. (2006): 259–275.

Chalmers, A. *What Is this Thing Called Science?* (3rd ed.). Queensland: University of Queensland Press, 1999.

Clarke, S. ''Justifying deception in social science research.'' *Journal of Applied Philosophy* 16, no.2. (1999): 151–166.

Council for International Organizations of Medical Sciences (CIOMS). *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, 2002. URL http://www.cioms.ch/frame_guidelines_nov_2002.htm. Accessed 2nd February, 2007.

Darley, J., and C. Daniel Batson. "From Jerusalem to Jericho: A Study of Situational and Dispositional Variables in Helping Behavior." *Journal of Personality and Social Psychology* 27 (1973): 100–108.

Eman, C. and M. Eman. "How not to be Lakatos Intolerant." In International Studies Quarterly 46 (2002): 231–262.

European Parliament, the Council and the Commission, Charter of Fundamental Rights of The European Union. (2000), chapter II, article 13. URL: http://www.europarl.europa.eu/charter/pdf/text_en.pdf. Accessed 2nd February, 2007.

Jonas, H. "Freedom of Scientific Inquiry and the Public Interest." *Hastings Center Report* 6, 4. (1976): 15–17.

Harris, J. "Scientific Research Is a Moral Duty." *Journal of Medical Ethics* 31 (2005): 242–248.

Harris, S. "Japanese Biological Warfare. Research on Humans: A Case study of Microbiology and Ethics." *Annals of the New York Academy of Science* 666 (1992): 21–49.

Kant, I. *Groundwork of the Metaphysics of Morals*. Edited by M. J. Gregor. Cambridge, Cambridge University Press, 1998. Original publ. 1785.

Kuhn, T. *Structure of Scientific Revolutions*. Chicago: University of Chicago Press, 1996. Original publ. 1962.

Lakatos, I. "Falsification and the Methodology of Scientific Research Programmes." In *Philosophical Papers*, vol. I. Cambridge, Cambridge University Press, 1970.

National Cancer Institute (NCI). "NIH Halts Use of COX-2 Inhibitor in Large Cancer Prevention Trial." 2004. URL: http://www.cancer.gov/newscenter/pressreleases/APCtrialCOX2. Accessed 2nd February, 2007.

National Institutes of Health (NIH). "Questions and Answers NIH Halts Use of COX-2 Inhibitor in Large Cancer Prevention Trial." 2004. URL http://www.nih.gov/news/pr/dec2004/od-17Q&A.htm. Accessed 2nd February, 2007.

Popper, K. *The Logic of Scientific Discovery*. 5th ed. New York: Routledge, 2002. Original publ. 1935.

Ramsey, P. *The Patient as Person: Exploration in Medical Ethics*. 2nd ed. Yale University Press, 2002.

Solomon, S.D., et al. "The Adenoma Prevention with Celecoxib (APC) Study Investigators, Cardiovascular Risk Associated with Celecoxib in a Clinical Trial for Colorectal Adenoma Prevention." *New England Journal of Medicine* 352 (2005): 1071–1080.

Regan, T. *The Case for Animal Rights*. University of California Press, 1983.

Tyson, J. "Dubious Distinctions Between Research and Clinical Practice Using Experimental Therapies." In *Ethics and Perinatology*. *Edited by* A. Goldworth et al. 214–230 (New York: Oxford University Press, 1995).

US Code of Federal Regulations, Title 45, Public Welfare 46.102(d). URL http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr46_06.html. Accessed 2nd February, 2007.

Whitbeck, C. *Research Ethics: Encyclopaedia of Applied Ethics*, vol. 3. Edited by R. Chadwick. 835–843. San Diego, Academic Press, 1997.

Windelband, W. "Geschichte und Naturwissenschaft. Straßburger Rektoratsrede." In *Präludien. Aufsätze und Reden zur Philosophie und ihrer Geschichte*. Tübingen: J. C. B. Mohr., 1894, 136–160. Translated by Gerhard Faßnacht., *Nomothesia, Ideographia, and Bemetology*. Draft., 2004. URL: http://www.lse.ac.uk/collections/methodologyInstitute/pdf/QualPapers/Fass-Nomo_Ideo%20revi.pdf. Accessed 2nd February, 2007.

World Medical Association (WMA), *Declaration of Helsinki*, 2004. URL http://www.wma.net/e/policy/b3.htm. Accessed 2nd February, 2007.

Philosophy Department
University of Birmingham
Edgbaston, B15 2TT
UK
E-mail: l.bortolotti@bham.ac.uk

German Reference Centre for Ethics in the Life Sciences (DRZE)
Bonner Talweg 57, 53113 Bonn
Germany
E-mail: heinrichs@drze.de