

INSTITUTING A RESEARCH ETHIC: CHILLING AND CAUTIONARY TALES¹

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INTRODUCTION

The ethical review of research on human beings, and indeed the ethical review of broader ranges of human activity, is a growth industry. I want to look here at the ethical review of research on humans and raise some questions about the direction it is taking. I am pessimistic about where the institutions that we have set up are leading us and I want to sound a warning note and suggest some changes that are needed in the practice of ethical review.

It is easy to assume that with a policy as high-minded as the policy of reviewing research on human beings, the only difficulties will be the obstacles put in its way by recalcitrant and unreformed parties: by the special-interest groups affected. But this is not always true of high-minded policies and it is not true, in particular, of the policy of reviewing research. Ethical review is endangering valuable research on human beings and, moreover, it is endangering the very ethic that is needed to govern that research. And this is not anyone's fault, least of all the fault of any special-interest groups. The problem is that the process of ethical review has been driven by an institutional dynamic that is not in anyone's control and this dynamic is now driving us, willy nilly, on to some very stony ground.

My argument is developed in four sections. In the next section, section two, I look at a model of policy-making which identifies a reactive, institutional dynamic that lies at the origin of certain policy initiatives. In the third section I argue that this model fits the appearance and development of the ethical review of human research, showing how the process of review has been motored by a dynamic of step-by-step reaction to chilling tales of abuse. In the fourth section I look at the predictions of the future development of ethical review that the extrapolation of that model yields. And then in the fifth and

¹ This is the text, slightly amended, of the Annual Lecture to the Academy of Social Sciences, in Australia, delivered in Canberra, Nov 1991.

final section, I consider some lessons that the model has to teach. These lessons are cautionary in tone and they provide some balance for the chilling tales that I will have told earlier.

A MODEL OF POLICY DEVELOPMENT

In a seminal article on the growth of administrative government in the last century, Oliver MacDonagh developed an interesting model of why the British government sponsored the dramatic growth in regulative legislation and regulative agencies, especially in the period between 1825 and 1875.² The policy initiatives with which MacDonagh was concerned introduced a regulative machinery to govern matters as various as public health, factory employment of children, workplace safety procedures, the condition of prisons, and the ways in which people were treated on emigrant ships. He argued that we could generally find the same elements at work in the generation of policy in these different areas and that we could identify more or less the same stages in the evolution of such policy.

To simplify somewhat, there are four elements to which he directs us. In each case there is an evil to be dealt with by policy, usually an evil associated with the industrial revolution and the results of that revolution for the organisation of social life. Second, this evil is exposed, usually in the more or less sensational manner of the developing 19th century newspapers; the exposure of the evil may be triggered by some catastrophe or perhaps by the work of a private philanthropist or fortuitous observer. Third, the exposure of the evil leads to popular outrage; this outrage connects with the increasing humanitarian sentiments of people in 19th century Britain, sentiments in the light of which the evil appears as intolerable. Fourth, the popular outrage forces government to react by introducing legislative or administrative initiatives designed to cope with the evil; this reactivity of government is due, no doubt, to the increasingly democratic character of 19th century British government.

Evil, exposure, outrage and reaction: these are the elements that play a crucial role in the MacDonagh model. The role they play becomes salient as we look at the different stages distinguished by MacDonagh in a typical process of evolution. I now describe those stages, though not exactly in the terms presented by MacDonagh himself.

In the first stage of evolution some evil is exposed, this leads to popular outrage and the government of the day responds by some change in the law.

² Oliver MacDonagh, 'The 19th century revolution in government: a reappraisal', *Historical Journal*, 1. 1958.

Once it was publicised sufficiently that, say, women on their hands and knees dragged trucks of coal through subterranean tunnels or that emigrants had starved to death at sea, or that children had been mutilated by unfenced machinery, these evils became 'intolerable'; and throughout and even before the Victorian years 'intolerability' was the master card. No wall of either doctrine or interest could permanently withstand that single trumpet cry, all the more so as governments grew ever more responsive to public sentiment, and public sentiment ever more humane. The demand for remedies was also, in a contemporary context, a demand for prohibitory enactments. Men's instinctive reaction was to legislate the evil out of existence.³

The first stage of evolution, described in this quotation, involves a popular scandal and a legislative response. The second stage identified by MacDonagh also involves a popular scandal, but one that is followed in this case by an administrative response. The scandal arises when, a number of years after the original legislation, it is discovered and revealed that the original evil remains more or less as it was. Again there is public outrage and again the government responds to this. But the response now is to appoint some individuals to look into the evil and to investigate how it may be remedied. The response, in short, is administrative rather than legislative.

If the first two stages are characterised by popular scandal, the next two are characterised by surprise on the part of the administrative experts appointed to look into the evil. At a third stage these experts come to realise that the original law was inadequate. They recommend amendments to the law, and they recommend a variety of administrative changes, usually involving a drift towards centralisation. The administrative changes require the systematic collecting of data on the problem, the appointment of officers required to monitor that information, and so on.

The fourth and last stage that we may identify in MacDonagh's evolutionary description involves a second phase of expert surprise: a surprise, this time, at discovering that even the amended law and amended administrative arrangements have not adequately coped with the original problem. The response now is to recognise that the problem cannot be eradicated by a single, once for all legislative or legislative-cum-administrative response. It requires the putting in place of a regulative bureaucracy, concerned with monitoring, reviewing and intervening in the activities where the original evil arose. The evolution is complete. We now have rule by officials and

³ MacDonagh, 'The 19th century revolution in government . . .', p. 58.

experts, we have the appearance of a new area of bureaucracy.

MacDonagh originally introduced this model of the growth of government as an alternative to the view that the changes were driven by an overarching, commonly accepted ideology such as utilitarianism. What he characterises is a reactive dynamic in the formation of public policy. He does not say, nor need we judge, whether the changes introduced in the 19th century made, in the end, for more good than harm. If we think that they were changes for the good, then we will say that MacDonagh describes an invisible hand whereby they emerged. If we think that they were for ill, then we will say that he describes an invisible backhand or, as it has also been called, an invisible foot. In either case we will say that he shows us how a certain novel set of arrangements, a novel order in things, came about without being designed by any individuals or organisations.

The reactive dynamic described by MacDonagh, or at least something fairly well analogous to it, can also be discerned in other areas. Consider the way in which contemporary governments in many different countries have been continually driven back towards law and order measures, in particular tough measures of imprisonment, despite the evidence that other measures may be more effective and cheaper. A crime of a certain sort is committed and receives a good deal of more or less sensational publicity. This creates public horror and outrage. The government is forced to respond to this outrage by showing itself to be tough on that sort of crime. But showing that it is tough on that sort of crime means showing that the relevant offenders are subjected to the harshest measures. No matter if those measures are not effective in the long run in containing the crime involved. The important point is that they present the government to the people in a manner that satisfies the outraged.

For a different example of the same sort of reactive dynamic at work, consider how social work agencies may be, and have been, driven to be very interventionist at taking children into care: taking them away from parents or guardians who are thought to pose some threat. Some child is left with its parents or guardians by a social worker, despite evidence of such a threat; some abuse of the child occurs; and then the offence receives more or less sensational publicity. The pattern should now be familiar. The public is scandalised and outraged. The government is forced to respond to this. And how can it respond other than by initiating an enquiry into the decision of the social worker, or some disciplining of that official? Hence a culture, even a routine, is established which furthers the taking of children into care, even though this may not be for the overall good of those children.

THE MODEL APPLIED

I would now like to show that the growth of the ethical review of research, in particular research on humans, has been driven by something like the reactive dynamic described in the last section. Biomedical and behavioural research enjoyed a huge growth in the late 19th century as the natural sciences extended their reach into human biology, and as the new sciences of human beings were developed on the model of natural science. By the turn of the century biomedical and behavioural research was a steadily growing, if not actually a boom, industry. Inevitably, the industry was bound to generate its scandals. And inevitably, those scandals were bound to elicit government responses.⁴

One of the first scandals occurred in 1916 when Udo J. Wile, Professor of Dermatology and Syphilology at the University of Michigan, reported his research results in two major medical journals. Wile had inoculated rabbits with the treponemes that cause syphilis, which he had obtained by trephining the skulls of six insane patients with syphilis and by then taking a small sample of their brain. Anti-vivisectionists were alerted to the procedure and attacked the sampling of human brain tissue, arguing that animal vivisection had opened the way to this sort of abuse. The American Medical Association (AMA) defended experimentation and animal vivisection but criticised Wile's actions. An AMA committee recognised, however, that there was a need to establish guidelines of ethical research. One of its members, the Harvard physiologist, Walter B. Cannon, admitted:

There is in this present flush of interest in clinical research, a danger that young men just entering upon it may lose their balance and become so interested in the pursuit of new knowledge that they forget their primary duty to serve the welfare of the person who has committed himself to their care.⁵

The abuse was not isolated: there were similar scandals in Germany in the 1920s. As a result of the scandals, guidelines for the ethical conduct of biomedical – and by extension behavioural – research came to be established. Usually they were voluntary guidelines. For example, the German medical profession issued guidelines in 1931, guidelines which superseded some earlier regulations introduced by the Prussian government in 1900.

⁴ In this section I draw heavily for examples on Richard Gillespie, "Research on human subjects: An historical overview", *Bioethics News*, 8, no. 2, 1989, suppl. pp. 4–15, and I follow his descriptions of the examples closely. All otherwise un-referenced examples are described in this excellent overview and further references are provided there.

⁵ Gillespie, "Research on human subjects". p. 7.

The guidelines introduced as a response to this first phase of scandals focussed, as many later guidelines were to focus, on two major issues: that of whether the subjects of research had given their informed consent; and that of whether they were exposed to the risk of harm. Those two issues, together with the issue of whether data on research subjects are held under appropriate guarantees of confidentiality, have continued to dominate the ethics of research up to the present time. It is worth noting, for example, that according to a recent survey, the reason why Australian institutional ethics committees have sought modifications of human research proposals has had to do, in 95% of cases, with the form in which consent is sought.⁶

But the first appearance of guidelines was not, predictably, sufficient to block other scandals. The scandals in the second phase were much more dramatic. They were the scandals associated with the experimentation by Nazi doctors on inmates of concentration camps and by Japanese doctors on prisoners of war. The research explored the effects of chemical weapons, exposure to extreme heat and cold, and fatal infectious disease, among other matters. Revelations of the research at the Nuremberg trials created an international scandal.

The scandals were not limited to Germany and Japan. Some Nazi doctors tried to defend their action by compiling accounts of unethical research elsewhere, accounts that were shocking enough in their own right. In 1904 Colonel Strong, later Professor of Tropical Medicine at Harvard, had injected condemned criminals in Manila with live plague bacteria, apparently without getting their consent. Several years later he had induced experimental beri-beri in other condemned criminals, resulting in the painful death of one subject. And even during the Second World War, it transpired that there had been some ethically dubious, if sometimes defended, research. Illinois prison inmates had consented to participate in experiments on malaria, and had signed statements absolving the government of responsibility, but apparently had been induced to do so by payment and by the reduction of their sentences by Parole Board.

The Nuremberg Military Tribunal formulated a 10 point code for the judgment of Nazi doctors and we may see that code as a more or less internationally supported response to the second phase of scandal. The code was widely supported and it undoubtedly had an impact on the formation of an international code by the World Medical Association in 1962. That code was issued in 1964 as the Declaration of Helsinki and was revised in 1975.

⁶ Paul McNeill, "The function and composition of institutional research ethics committees: preliminary research results", in Jill Hudson, ed., *Can Ethics be done by Committee?*, Centre for Human Bioethics, Monash University, 1988, p. 32.

It will come as no surprise that this second phase of code-making did not put a stop to scandals. We find an early, important scandal in the area of behavioural rather than biomedical research in 1955. That arose with the Wichita Jury Study, which was carried out in 1954 as a part of the University of Chicago jury project.⁷ The enquiry was supported by the Ford Foundation but, without seeking the approval of the sponsor, the researchers persuaded local judges to grant permission for the recordings to be made of the deliberations of juries in a limited number of cases. Contrary to original intentions, an edited version of the deliberations of one of the juries was presented in 1955 at the annual conference of lawyers associated with the court circuit in which the cases had been heard. Thus the existence of the recordings became publicly known and this led to a public hearing by the internal security subcommittee of the Committee on the Judiciary attached to the United States Senate. The scandal did not lead to any response directed at research in general but it did cause a Bill to be passed in 1956 by both Houses of Congress, in which recording the deliberations of any federal jury was prohibited.

The most important scandals in this third phase of publicity broke in the early 1960s. In 1960 a survey commissioned by the National Institute of Health (NIH) reveal that only 9 of 52 responding institutions had formal guidelines for clinical research and only 16 had appropriate consent forms. And in 1962 it became public that an esteemed cancer researcher at the Sloan-Kettering Clinic in New York arranged for cancer cells to be injected into elderly patients, not suffering from cancer, at the Jewish Chronic Disease Hospital in Brooklyn. The patients did not sign consent forms, although it was said by the researchers that they gave verbal consent; however they were not told that they were to be injected with cancer cells. State Medical Board investigation led to two of the doctors being placed on probation.

But there was more to come. A report in 1964 noted that there were wide discrepancies between institutions and individual researchers in the United States as to what constituted acceptable professional conduct. And then in 1966 Henry Beecher of Harvard Medical School published a survey of ethical behaviour in clinical research in *The New England Journal of Medical Research*. By skimming the major journals containing articles on clinical research, he produced 50 examples of ethically dubious research on human subjects. Consent was mentioned in only two of these articles.

⁷ For details on this study see John Barnes, *The Ethics of Enquiry in Social Science*, Oxford University Press, Delhi, 1977, pp. 22–23.

Research included the withholding of effective treatment, in one case resulting in the deaths of at least 23 patients from typhoid; the injection of carbon dioxide during anaesthesia on patients undergoing minor surgery, until cardiac arrhythmias appeared; and the induction of experimental hepatitis at an institution for mentally defective children.⁸

This third wave of scandals led to more dramatic responses than just the issuing of guidelines. As there was an escalation in MacDonagh's story from legislative to administrative responses, so in our story we see an escalation from the issuing of guidelines to the establishment of review procedures. In 1966 the NIH required all recipients of NIH and Public Health Service (PHS) grants in the United States to have had their research proposal approved by an ethics committee at their institution. This committee, so they required, should have looked at the rights and welfare of the subjects, the suitability of the methods used to secure informed consent and the risks and potential benefits of the investigation. The move to committees for the ethical review of research, as illustrated in this response, represented an important escalation in regulation. But naturally, as we shall now see, it did not represent the final stage.

In 1972 a social worker associated with the PHS spoke to reporters about a long running research project conducted by the PHS, a project about which he had already raised questions internally. His revelations caused a storm to break and ushered in a new stage of ethical review.

The study on which the social worker reported had begun in the 1930s as a study of 400 men with syphilis in Alabama. The men were poor, black, rural workers and were given periodic blood tests, clinical examinations and autopsies upon their death. The aim was to study the course of the disease and the subjects were not informed they had syphilis, nor were they treated with any available therapy. It was reported in medical journals and conferences from the 1930s to the 1960s, but without anyone raising doubts about it. In response to the questions raised by the social worker in 1966 and 1968, the PHS set up a panel, much in accordance with the requirement for review by a local ethics committee, but this panel recommended that treatment continue to be withheld. It also argued that the men were too uneducated to be able to give informed consent and that consent should be obtained indirectly from local doctors. As it happened, the local, mainly black doctors endorsed the continuation of the study

⁸ Gillespie. "Research on human subjects: An historical overview" pp. 10-11.

and promised not to treat the men with any antibiotics.⁹

The revelations about the Tuskegee Study, as it came to be known, triggered important reactions and ushered in the era of mandatory ethical review. In 1974 Congress made institutional ethics committees – institutional review boards (IRBs), as they came to be called – mandatory in institutions receiving federal research grants and it established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission issued various reports and recommendations between 1974 and 1978 on various kinds of research and the NIH began conducting on-site inspections of IRBs to ensure that their membership, record-keeping and decisions met appropriate standards. IRBs were required to include members able to represent community attitudes, the law and professional standards, and to include at least one person from outside the local institution.

This wave of response must have been reinforced, and perhaps in part motivated, by the publication in 1973 of Bernard Barber's book *Research on Human Subjects*.¹⁰ Barber conducted a survey in which he found that as many as 18% of researchers were permissive in their ethical decisions. He found that researchers were twice as likely to approve ethically dubious proposals if they involved socially disadvantaged patients. And he found that they were likely to adopt a professional persona that distanced them from the individuals studied.

The 1974 changes in the US left it unclear as to what range of research should be vetted by the institutional ethics committee. This ambiguity was clarified in 1979 when the Department of Health, Education and Welfare published proposed regulations that would have broadened the requirement for prior review to 'all disciplines that collect information about identifiable individuals, living or dead'.¹¹ Although that proposal was withdrawn in 1981, a bureaucratic manoeuvre meant that its effect remained in place. A model of institutional review was circulated to universities by the depart-

⁹ This case will remind many readers of the case in the National Women's Hospital, Auckland where women suffering from cervical cancer were studied over an extended period, without being informed that they were suffering from that disease and without being treated for it according to the best contemporary standards. See Sandra Coney and Phillida Bunkle 'An Unfortunate Experiment', reprinted as a special supplement in *Bioethics News*, Vol. 8, No. 1, 1988.

¹⁰ Russell Sage Publications, New York, 1973. See too Bernard Barber, "The ethics of experimentation with human subjects", *Scientific American*, 234, 1976, pp. 25–31.

¹¹ Edward L. Pattullo, 'Government regulation of the investigation of human subjects in social research', *Minerva*, 23, no.4, 1985, p. 521.

ment, involving the application of relevant rules to all research on humans, and this was accepted without question by most universities.

Thus a majority of universities have voluntarily adopted policies more restrictive than are required either by statute or by regulation as such. Some did so consciously: many, confused or fearful, thought it wise – or easier – to act as officials of the department clearly wished them to act.¹²

The pattern of scandal and response in the generation of ethical review is most clearly found in the USA. But, whether for analogous reasons, or reasons of imitation, the upshot of the pattern is to be found in many different countries. Thus we can see a sequence of initiatives in Australia that closely parallel the ones documented for the US. In 1966 the National Health and Medical Research Council (NH&MRC) issued the Helsinki guidelines as guidelines for the conduct of biomedical research. In 1976 it recommended the establishment of institutional ethics committees. In 1982 it established its own medical research ethics committee, a committee which required the vetting of any research it supported by the ethics committee of the home institution. And in 1985 the NH&MRC issued a guideline requiring that the institutional ethics committee in any institution where it supported research should review 'all research on humans', even research it did not support, even indeed research in nonmedical areas.¹³

The idea of the local institutional ethics committee was supported in the US by the NIH, because it did not want to issue a legalistic code; this is because of the difficulty of fitting such a code to all cases and because doctors and scientists were resistant to a degree of centralised control over their activities.¹⁴ But the idea of having such a locally administered form of control may have had, and may continue to have, other attractions. I suspect that it appeals to government nowadays on at least two different grounds. First of all it goes with the popular culture of decentralisation. And secondly it enables government to pass the buck.

This last point can be illustrated with Australian examples. Case one. The Privacy Act 1988 (Commonwealth) is so strict that it would make much current research on human beings impossible. The Government has avoided that difficulty by identifying ethics

¹² Pattullo, 'Government regulation of the investigation of human subjects in social research', p. 529.

¹³ For a discussion of this initiative see Peter Singer, 'Rats, patients and people: issues in the ethical regulation of research', Annual Lecture Academy of the Social Sciences in Australia, 1989, p. 6.

¹⁴ Gillespie, "Research on human subjects: An historical overview", p 11.

committees as the bodies which should determine whether the public interest in a piece of research is great enough to warrant the breach of an information privacy principle. Case two. The Government has been under pressure from AIDS groups concerned that potentially beneficial drugs take too long to be approved by the government's therapeutic goods administration (TGA). The response of the government has been to allow local institutional ethics committees to approve the clinical trial of drugs on human beings without advice or approval from the TGA.¹⁵ The local committee may of course refer a proposed trial to the TGA, thereby incurring the old delays (up to 60 days). But it does not have to do this; it may choose to expedite research, not referring the trial to the TGA, and bear the responsibility itself. On May 14, 1991 all institutional ethics committees received a letter from the National Health and Medical Research Council (NH&MRC) which contains a paragraph that underlines the extent to which the buck is being passed.

These procedures have a considerable impact for institutional ethics committees particularly in relation to institutional liability which might need to be considered by boards or other governing bodies.

I have been describing the evolutionary process which has led us to the current procedures in the ethical review of research on human beings. I hope that the description is sufficient to bear out the point that here, as in so many other areas of policy-making, we see the operation of something like MacDonagh's reactive dynamic.

In MacDonagh's story the important elements were the existence of an evil, its exposure in the media, outrage at the evil exposed, and a government reaction designed to appease the outraged. In our story of the development of the ethical review of research the elements are of exactly the same kind. In MacDonagh's story the development which was driven by the interplay of those elements came in escalating waves; it began with a legislative response, moved to the appointment of administrators, then to the introduction of administrative routines, and finally it culminated in the establishment of a full-scale bureaucracy. In our story we see the same pattern of escalation in the successive waves of exposure, outrage and reaction. Initially the reaction is to institute guidelines for research, first voluntary, professional guidelines and then often guidelines imposed from without. Next the reaction escalates to requiring review by committee of any research that is funded by certain bodies. And finally

¹⁵ See the document 'Clinical trials of drugs in Australia' issued in May 1991 by the Department of Community Services and Health, Canberra.

it culminates in the requirement of committee review for any research whatsoever.

THE MODEL EXTRAPOLATED

The MacDonagh model serves us well in making sense of how we have got to the present stage in the ethical review of research on humans. But now we must try to put the model to work in looking at where the evolutionary process is likely to lead us next. For we have no reason to believe that the process has played itself out; we have no reason to think that we have reached the stationary state in ethical review.

I am pessimistic about where the process will lead us: pessimistic, in the first place, about the effects it will have on the research practised, but pessimistic also about the effects it will have on the ethics of researchers. I will concentrate mainly on the effects which the process is likely to have on the research practised, only commenting briefly on the effects on research ethics. The reasons for my pessimism go back to certain considerations about the nature of ethics committees, and about the context in which they operate. These considerations combine to suggest that the reactive dynamic we have described may lead to a serious reduction in the current scope of research and to a substantial compromise of the ethic that currently governs research practice.

As we look at the context in which ethics committees operate, then there is one striking consideration that argues for pessimism. We can think of the context as one in which certain sorts of committee decisions and procedures are rewarded, and others punished. Looked at in that way, the striking thing about the context is that things are designed to elicit progressively more conservative postures and to drive out more liberal dispositions. The context is moulded in such a way that as time passes, ethics committees are bound to take on a more and more restrictive shape.

Consider an analogy which we mentioned already. Consider the context within which social workers operate in making decisions about whether to take children into care. The reactive dynamic operates there in such a way that we must expect social workers to be more and more cautious about leaving children with their parents, even if they believe that that is for the best overall. The reason is clear. Social workers get little credit for correct decisions, whether the decisions be cautious or liberal; the only relevant sanctions are the penalties that may follow on incorrect judgments. But the penalties for incorrect decisions are not even-handed. Social workers get little blame for any error they may make in taking a child into care; the child

may be worse off than it would have been at home but who is to tell? On the other side, social workers are liable to attract great blame, even public humiliation and dismissal, for any error they make in leaving a child with its parents; if the child is abused then, short even of newspaper coverage, they will suffer the wrath of their superiors. Little wonder if social workers should begin to become over-cautious and conservative.

As I view the context in which ethics committees work, the situation is very much the same. There are few rewards on offer for correct decisions; the focus, again, is on penalties for mistakes. But the penalties on offer for mistakes are not fairly distributed. Suppose an ethics committee makes a mistake in not allowing a particular research proposal to go ahead. Who is going to blame them? There may be a protest or two from the area of research in question but such protests are easily stilled with declarations about the public interest and, if necessary, with appeals to the Vice-Chancellor to protect the impartial referee against partisan attack. Suppose on the other hand that an ethics committee makes a mistake in allowing a questionable proposal to be pursued. There is always a possibility in such a case that the proposal will come to public attention, becoming a matter for media criticism and even a matter for the courts. And if that happens then the penalty on the ethics committee is going to be enormous.

The contexts of the social workers and the ethics committees have two features in common. One, they deploy lots of penalties and few rewards. And, two, the penalties on offer display a striking asymmetry. In each case there is little or no penalty for a false negative: for saying 'nay' to a proposal, when it deserves support. And in each case there is a potentially enormous penalty for a false positive: for saying 'yea' to a proposal, when it should have been blocked, or should apparently have been blocked. It does not require a great deal of reflection to realise how unsatisfactory this sort of situation is. As social workers tend to be driven towards over-cautious decisions, so I believe that ethics committees are likely to be driven more and more to adopt a conservative and restrictive profile. The incentive structure under which the committees operate is so seriously skewed that any other result would be miraculous. There is an invisible backhand in place which is designed to produce systematically inferior results.

This consideration about the context of ethics committees argues for a growing intrusiveness, even if there is no further wave of scandals. If there are further scandals, of course, then things are likely to happen even more quickly. Think about what will happen if some false positive, some decision judged to have been over-liberal, comes

to light and causes a public outcry. The committee in question will be forced to revise its procedures in a manner that satisfies public outrage, whether or not the revision is really for the best. The revision required will affect every committee in the country, as the extra constraint is centrally imposed or is adopted by committees in a posture of preemptive surrender. And the constraint in question will be ratcheted into place, with little chance of ever coming under later review. The scenario hardly needs labouring.

This consideration about the context in which ethics committees operate is directly prompted by representing the development of ethical review in the MacDonagh model. Wherever the reactive dynamic has been established as a threat to relevant parties, even if it is not actually triggered by any further scandals, we will find the asymmetry of penalties attaching to false negatives and false positives. But this consideration about the context of ethics committees is bolstered by some further considerations too. If we turn now to the character of ethics committees themselves, then I believe that here also we find reasons for pessimism. I will mention two considerations that strike me as relevant.

A first consideration is that any ethics committee is more or less bound to be self-assertive: that no committee is likely to accept a rubber-stamping role. It is a universal experience that the individual members of committees, and indeed committees themselves as a whole, have a disposition to legitimate their presence by showing that they make a difference: to legitimate their presence, in effect, by making their presence felt. This tendency may yet have baneful effects on the ethical review of human research.

Imagine that the present arrangements for ethical review elicit a culture of self-criticism and self-regulation on the part of researchers. Imagine that, aware that certain expectations are in place, and aware that their proposals will be vetted by a local committee, researchers come to heel. They shape their practices to what, at present, most of us would find acceptable. They seek the informed consent of their subjects. They pursue projects where the promise of benefits clearly justifies the risk of harms. They ensure that any data on individuals is held under conditions of secure confidentiality. And so on. What then should we expect of the institutional ethics committee which reviews the proposals from such researchers? If the ethics committee is to be self-assertive, as I suspect it will tend to be, then I fear that it may begin to push for further and further changes in the practices of research. Otherwise it will have to accept that its role is mainly to rubber-stamp. And that is not a self-image that it is likely to espouse very readily.

But there is also a second feature of ethics committees, at least

as currently constituted, that may support an intrusive disposition. This is the tendency of such committees to be, not only self-assertive, but also self-righteous. There are many reasonable research proposals which involve the adoption of procedures that are, in one respect or another, distasteful. The research may offend against a natural human sentiment, say in using foetal tissue in transplantation. The research may involve withholding treatment, or administering a placebo, to subjects who stand a somewhat better chance under the alternative therapy. And so on. In such a case it is bound to be hard for the members of an institutional ethics committee, in particular the lay members who may have little sense of the aggregate benefits involved, to endorse the research. On the other hand, it may not be clear to them that blocking the research can have disastrous consequences. After all, as they may implicitly or explicitly reason, the research in their particular institution is hardly likely to be the crucial contribution. Many institutions will be potentially involved in any area of research and the committee at each institution may hope that the research is done elsewhere. In other words, they may hope to free ride.

When I say that an institutional ethics committee is likely to be self-righteous, what I mean is that in such a case it is likely to move towards a posture of keeping its own hands clean, recoiling from the distasteful aspect of the research to be approved, and ignoring the possible loss associated with that decision. The members of the committee may balk at the thought of allowing the use of foetal tissue or they may be horrified at the possibility of hastening the death of someone to whom a placebo is administered. The possibility can hardly be denied.

The self-assertiveness and self-righteousness of committees combine with the asymmetry of the context within which they operate – the asymmetry of the sanctions to which they are subject – to offer serious grounds for worry about the thrust behind current arrangements for the ethical review of research. The asymmetry of context means that there is little or no penalty for the false negative – for the excessively restrictive decision – and potentially a great penalty for the false positive: the adventurously liberal judgment. And the self-assertiveness and self-righteousness of committees means that there may actually be some rewards attached to false negatives. Every negative, true or false, enables the committee to put itself forward as a committee that is doing something, not just serving as a rubber stamp; and many a negative, true or false, will allow the committee to see itself as the righteous guardian of the weak and ignorant against the overweening pretensions of the researcher.

The prognosis that I offer, then, is bleak. It is bleak, even in the

absence of any further scandals, and any further waves of outrage and reaction. The character of the ethics committees that we have set up, especially given the context in which we have placed them, is sufficient ground for predicting that those committees will grind away slowly into the agenda of behavioural and biomedical research.

What areas of research on humans look to be particularly vulnerable to erosion? It may be useful if I mention a number of types of research which are likely to come under pressure.

A good deal of human research, particularly biomedical research, involves some risk of harm to subjects. The risk may be very small, and the benefits promised by the research may be great, but the risk of harm is still there. Thus, a study conducted by the Survey Research Center of the Institute of Social Research of the University of Michigan in 1977 concluded that harmful effects occurred in 75 of 1,655 biomedical projects surveyed and in 4 of 729 behavioural science studies.¹⁶ I fear that institutional committees may balk more and more at the approval of research projects involving any risk of harm, however slight. I hope I am wrong about that but I do think that there are reasons for being pessimistic.

Many studies, both biomedical and behavioural, involve a further sort of risk also. This is a risk that, however secure the measures adopted, confidential information about individuals may still come to be released. For example, many studies may make individuals or corporations indentifiable to the shrewd eye of the investigative journalist. And many studies may be legally vulnerable, in the sense that the data collected may not prove to be protected by legal professional privilege; this was established in a recent case in Australia, where the original fieldwork notes of an anthropologist were held to be unprotected in the course of a hearing about a land claim.¹⁷ As I think that committees may balk at approving projects involving any risk of harm, so I fear that they may shrink from the approval of projects involving any risk of a breach of confidentiality.

A good deal of research on humans involves some invasion of privacy. It may involve access to records that are so extensive as to make it impossible to approach the individuals involved for their permission. It may involve just the observation of people in public places. But in any case I suspect that ethics committees may begin to worry about endorsing research that occasions such intrusions on privacy. Thus Edward Pattullo reports that the replication of bystander

¹⁶ See Pattullo, 'Government regulation of the investigation of human subjects in social research', p. 530.

¹⁷ See Don Rawson 'Ethics and the social sciences: the state of play in 1988', mimeo, *Academy of the Social Sciences in Australia*, University House, Canberra, 1988, p. 2.

experiments – these may involve simulating an accident in a public place, for example, to see how observers respond – has disappeared under the influence of ethical review.¹⁸

In this connection it may be worth mentioning one study that would certainly not be allowed under current practices. I mention this study, not necessarily because I think it ought to be allowed, but because it points towards the sort of invasion of privacy which ethics committees are likely to deplore. The study is described in Laud Humphrey's book *Tearoom Trade*.¹⁹ Humphrey describes going to a public toilet frequented by homosexual men, pretending to be their lookout, and observing patterns in their behaviour in the course of this pretense. He traced some of the men through their car registration numbers, and later interviewed them, under the guise of conducting an anonymous public health survey. That research may have given us important information on the behaviour of male homosexuals and on their presentation in the wider non-homosexual community. I have little doubt, however, but that it would be blocked under current procedures.

Many people may not regret the fact that this sort of work has been inhibited by the development of ethics committees. But there are other, more urgent forms of research which the concern for privacy may also lead ethics committees to prevent. Norman Swan wrote as follows about an incident in 1988.

Western Australia is one of the best places in the world for epidemiological research. The doyens of Australian epidemiology are in Perth. The NH&MRC funds an epidemiology unit in Perth. But they have had serious trouble getting their work past a lawyer on the university's ethics committee. He has dug his heels in over privacy. . . . The issue wasn't whether people would be harmed by the projects, whether they'd have bits of their brains chopped out or be asked to consume toxic tablets . . . no, the issue obsessing this ethics committee and the lawyer in particular was confidentiality. The research involved no human experimentation but the workers did need to use their world-leading system of linked hospital records which allows them to assess accurately the extent and patterns of cancer, heart disease and birth defects in the Western Australian population. The record linkage system is highly confidential using numbers rather than names with only limited

¹⁸ Pattullo, 'Government regulation of the investigation of human subjects in social research', p. 531.

¹⁹ Duckworth, London, 1970.

access to the data. Yet even so this lawyer felt that privacy laws were being broken.²⁰

I have mentioned three types of research as vulnerable to future review: research involving any risk of harm and research involving any danger of a breach of confidentiality or privacy. A fourth area in which I think that current research may prove vulnerable to the escalation of review practice is the sort of research that involves withholding any information from subjects. Humphrey's study already illustrates such research, for at the interview stage he deceived his subjects into thinking that he was a public health investigator. Other work in sociology and social psychology illustrates dramatically the withholding of information. Indeed the two experiments that have sometimes been described as the crucial experiments of the discipline, those associated with the names of Asch and Milgram, both involved the deception of their subjects.²¹ But we do not have to go to behavioural research for examples of withholding information. The use of placebos in biomedical research also involves such concealment. It is vital that the subject does not know that he is receiving just a placebo. And it may be vital that he does not know even that it is possible that he is receiving a placebo. I worry that institutional ethics committees may yet become so invasive as to try to prohibit even this type of concealment.

A fifth and last area of research that I think is vulnerable is research on humans where the subject cannot give personal consent. I have in mind research on children, on the mentally retarded and on the mentally deranged. There has been great emphasis in recent times on the rights of individuals in these categories. And I applaud that emphasis for its effects in various areas of policy making. But one effect it may have is to inhibit ethics committees about accepting that research in such subjects can be approved by appropriate guardians. I can see the possibility that committees will become more and more loathe to allow such research.

In connection with these last two areas of research, something is worth noting. This is that the original Nuremberg code appears to have left no room for the withholding of information or the absence of personal consent by the subjects of the research. The Helsinki code does allow for the absence of personal consent but says nothing on

²⁰ Norman Swan 'Doctors, Lawyers and the Representatives of God: The 1988 Peter MacCallum Lecture', Melbourne. Quoted, with permission, from typescript.

²¹ See Solomon Asch 'Effects of group pressure upon modification and distortion of judgments' in E.E. Maccoby, T.M. Newcomb, and E.L. Hartley, eds, *Readings in Social Psychology*, 3rd ed., Holt, New York, 1958 and Stanley Milgram *Obedience to Authority*, Harper and Row, New York, 1974.

the withholding of information, as in the administration of placebos. These omissions may be significant. They may point to areas where there is going to be trouble ahead.

I have suggested that certain natural features of institutional ethics committees may lead those committees to intrude further on current research practice. In particular, I have indicated certain areas of research where we may expect committees to be more intrusive. I think that most of us would agree that it would be undesirable if these new forms of intrusion took place. Hence I see reason here for worrying about where the reactive dynamic that has been at the source of ethical review may yet take us.

But before leaving this section I must mention that there is also a second source of worry as to where the dynamic may take us. Not only may ethics committees come to intrude on current research in a way that is undesirable. It is also all too likely that, as they begin to intrude in this way, those committees will engender a culture of resistance among researchers, and that they may thereby undermine the existing commitments of researchers to ethical guidelines.

The scenario I have in mind is this. Researchers come to see ethics committees as over-assertive and over-righteous. They come to see them as putting a stop to research that may be of important benefit to humankind. In this situation, they may well come to scorn whatever restrictions are laid down for the research they are allowed to continue practicing. For example, they may come to be scornful of the informed consent requirements laid down by those committees. It is easy to see that researchers in hospitals, or in the anthropological field, may easily offend against regulations for seeking informed consent by excessive verbal persuasion, by glossing over various details, and so on. If researchers do come to lose a commitment to ethical guidelines, if they do come to be 'demoralised' this way, then I see a further reason for worrying about the trajectory along which we have looked. It may not only lead to a restriction of the research we currently tolerate. It may also lead to a restriction in the commitment of researchers to the ethic which currently prevails.

The point to stress here is that there is no regulation like self-regulation. There are so many areas where researchers on human beings may offend against ethical standards that the only hope of having research done in an ethical fashion is to have those researchers identify strongly with the desired ethical code. If ethics committees continue on the trajectory that I am plotting, then there is a serious danger that they may cause resentment and alienation on the part of the researchers, leading us towards a really sorry state of affairs. Indeed there is some evidence that this is happening already. Norman

Swan reports as follows: 'in the course of my coverage of Australian and overseas medical research I'm coming across more and more researchers – decent people, not Dr Mengeles – who are fulminating against the practice of bioethics'.²²

THE LESSONS

Where does this discussion leave us? I begin with the assumption that we certainly ought not to go back to the days where there was no ethical review. It is clear that there are great dangers in allowing the professional enthusiasm of researchers to go untempered by the need to satisfy ethical reviewers. But I add a further assumption to this starting one. I also assume that we want to put measures in place which will inhibit the drift that I predict in the extrapolation of my model. In this final section I want to mention some proposals which might help to block that drift.

One of the main problems identified in the discussion in the last section is the absence of rewards for the good decisions made by ethics committees and the asymmetry between the penalties attaching to questionable decisions: the false positives are likely to be harshly penalised, while the false negatives attract little or no punishment. There are a number of measures that might be taken to try to cope with this problem, although there is no sure-fire solution.

One measure I propose is the establishment of some appeals procedure whereby a researcher can gain a review of a negative decision made by an ethics committee. Such a procedure would help to redress the present balance in favour of researchers but it might also inhibit the ethics committee which is tending to become over-cautious. It would introduce the possibility of a penalty for the false negative: the penalty, to which any committee is likely to be sensitive, of having its judgment overturned. Of course, if an appeals procedure of this kind is to work then it would need to involve a different sort of body from the ethics committee itself: if it is a twin of that committee, then it is likely to mirror the decisions at the lower level, being subject to the same pressures. I suggest that the appeals body should involve two or three very senior people whose understanding of research, and whose commitment to a research ethic, is beyond doubt. It should involve the sort of people whom it would be difficult to recruit to the time-consuming labours of an ethics committee but who might well be willing to take part in a procedure involving the occasional appeal and review.

A second measure I propose is that each institution maintain and

²² 'Doctors, Lawyers and the Representatives of God'.

publicise the record of its ethics committee in approving research and the record of the committee, where it has reservations, in negotiating a compromise with the researcher or researchers involved. I make this proposal in the hope of establishing a certain sort of reward for the committee that is not over-cautious and that goes to some trouble in facilitating research projects with which it initially finds some difficulties. Where the appeals procedure would help to establish a symmetry of penalties between false negatives and false positives, I hope that this measure would put some rewards in place for the committee that does not run too quickly to cover: the committee that really works at sponsoring ethically satisfactory research activity.

There is also a third proposal which comes naturally to mind in the light of our discussion of the context within which ethics committees operate. Not only can we try to manufacture the reward just mentioned, and not only can we try to introduce penalties for the false negative, we can also attempt to reduce the dimensions of the penalty that threatens any false positive, or any apparently false positive, decision. We can look at ways of protecting the members of ethics committees from media exposure and from litigation. I am unclear about how this end may be best achieved but I have no doubt that the goal is important. So long as ethics committee members remain vulnerable to exposure and litigation, they cannot be expected to pursue the task of ethical review in the responsible manner we would desire.

These three measures would help to cope with the problems generated by the context within which ethics committees operate. But what about problems generated by the character of ethics committees: generated, in particular, by their tendency to be self-assertive and self-righteous? Reflection on these problems motivates a number of further proposals.

First, I think it is important that ethical guidelines for the practice of each sort of human research should be established on a national or, even better, an international basis. These guidelines should be proposed by the researchers in each area but should be approved by bodies that involve not just professionals but also the representatives of other groups. There should be representatives from ethics committees; there should be representatives from consumer groups; and there should be representatives from governments. If such guidelines are in place then ethics committees are more likely to be well directed in their judgment of individual cases. They are more likely to see themselves as doing something more than rubber-stamping, even when they approve. And they are more likely to resist the self-righteous impulse.

Second, I think it is important that members of consumer move-

ments, and perhaps representatives of government, be appointed to ethics committees. At the moment we have professional researchers on those committees who certainly will be sensitive to the potential aggregative benefits of research. But those professionals are set too starkly in contrast with the lay members of the committees, members who may tend to identify with individual subjects and be neglectful of potential aggregative effects. Professional researchers may not be persuasive in arguing for the benefits of research, as they can easily be cast as self-interested. The representatives of consumer movements and of government are likely to share an interest in aggregative effects, while lacking the self-interest of the professional researcher. They would help to temper any inclination on the part of lay members to over-identify with individual subjects, in righteous mode, and to prevent potentially important research.

Third, in order to guard against the self-assertiveness I described, I think it is important that ethics committees come to be concerned only with research projects that raise genuine difficulties. This being so, I think it is important that in each institution, perhaps on a national or international model, we should identify those sorts of research on humans that need not come before the committee. Peter Singer has suggested that we might describe such research as follows:

Research that does not involve significant risk of harm to the subjects, and is carried out on the basis of informed consent, where researcher and research subject are in a position of equality.²³

I do not say that that characterisation of exempted research is necessarily appropriate. But I do think that we should look for exemption on some such basis.

Finally, a simple measure that may be difficult to implement. It is often said that the only trustworthy politician is the reluctant politician. There may be something in the thought that the less inclined someone is to take a place on an ethics committee, the more inclined we should be to find a place for them. I think that it is important that we guard against the appointment of moral enthusiasts – or, for that matter, professional enthusiasts – on such committees. There is no end to the difficulties that such a busybody can cause. How to guard against this sort of appointee? There is no mechanical procedure that is sure to give the right result but it is important, at the least, that nominations for an institutional ethics committee are discussed by some body representing the different interests

²³ Singer, 'Rats, patients and people: issues in the ethical regulation of research', p. 22.

involved; it is important that nominations, in particular self-nominations, do not go through on the nod of an executive.

If the different measures I have mentioned were introduced, then I think that the future for research on human beings would look brighter than it does just now. But I also think that the future for a thriving research ethic would look better too. There would be less reason to fear the alienation and demoralisation of researchers that I mentioned earlier.

The two sets of recommendations presented so far bear on ethics committees themselves; they involve reshaping their context of operation and their inherent character. But it is important, not just that we reshape the context and the character of ethics committees; it is important also that we nurture a culture of research ethics that is independent of ethics committees. This is important, not just to contain the committees – not just to deprive them of a monopoly in the area of ethics – but also to nurture a reliable ethic of research and to reassure the community at large about the responsible attitudes of researchers. I see three measures that ought to be introduced.

First, all students of a behavioural or biomedical discipline ought to be educated in the ethics of research, and educated in particular by experts in their discipline, not just by outsiders. Philosophers might play a part in conducting appropriate ethics courses for students but I stress that members of the discipline itself ought to be involved in such a process of education. The students ought to be exposed to a discussion by professionals of the sorts of cases that they are likely to confront in research. They ought to be made aware of what, by current professional consensus, is acceptable behaviour.

Second, I believe it is important in each profession that there is a continuing discussion of the code that ought to bind researchers in the area and of the difficult kinds of cases which researchers confront. For example, there might be a special session at annual conferences, in which people raise difficult questions that have confronted them and discuss with their peers the sorts of response they ought to have taken.²⁴

Finally, I think that each profession ought to establish procedures under which complaints may be heard against members of the profession and, if necessary, disciplinary action taken. If researchers in any area are to show that they take their own work seriously, then they must begin to institute such procedures.

In the earlier parts of this paper I described a reactive dynamic

²⁴ See in this connection Joan Cassell and Sue-Ellen Jacobs, eds. *Handbook on Ethical Issues in Anthropology*, American Anthropological Association, Washington, 1987.

which has taken us to the present stage in the ethical review of human research and which, if left alone, is likely to carry us along a degenerating trajectory. In this section I have mentioned a number of measures that must be taken if that dynamic is to be contained, and if ethical review is to be conducted in a profitable manner. Unfortunately, no automatic mechanism will ensure that the measures I have described will be taken. Here we can only look to the professionals in the area, in particular the professional associations, to begin to think about what should be done. The point, for them, is not just to understand the world; the point is to begin to change it.²⁵

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²⁵ I have made use of suggestions received from John Braithwaite and Geoffrey Brennan and I am very grateful for their advice.