Research Ethics

Edited by

Kenneth D. Pimple

Indiana University Bloomington, USA

ASHGATE

Published by
Ashgate Publishing Limited
Gower House
Croft Road
Aldershot
Hampshire GU11 3HR
England

Ashgate Publishing Company
Suite 420
101 Cherry Street
Burlington, VT 05401-4405
USA

Ashgate website: http://www.ashgate.com

British Library Cataloguing in Publication Data
Research Ethics. – (The international library of essays in public and professional ethics)
1. Research – Moral and ethical aspects 2. Research – Methodology 3. Science – Moral and ethical aspects
I. Pimple, Kenneth D.
174.9’5

Library of Congress Cataloging-in-Publication Data - Corrected version to follow
Research Ethics / edited by Kenneth D. Pimple.
p. cm. – (The international library of essays in public and professional ethics)
Includes index.
ISBN 978–0–7546–2621–3 (alk paper)
1. Research–Moral and ethical aspects. 2. Research–Methodology. 3. Science–Moral and ethical aspects. I. Pimple, Kenneth D.
Q180.55.M67R43 2008
174.9'5–dc22

2007037406

ISBN: 978–0–7546–2621–3

Printed and bound in Great Britain by
TJ International Ltd, Padstow, Cornwall

Contents

PART III BIOMEDICAL RESEARCH

PART IV CONTEXTS OF SCIENCE

PART VIII ANIMALS IN RESEARCH

PART IX FINANCIAL CONFLICTS OF INTEREST

Acknowledgements

The editor and publishers wish to thank the following for permission to use copyright material.

AAAS for the essays: From William J. Broad (1981), 'Fraud and the Structure of Science', *Science*, **212**, pp. 137– 41. Reprinted with permission from AAAS; Gerard Piel (1986), 'The Social Process of Science', *Science*, **231**, p. 201. Reprinted with permission from AAAS; Bertrand Russell (1960), 'The Social Responsibilities of Scientists', *Science*, **131**, pp. 391–92. Reprinted with permission from AAAS.

American Institute of Physics for the essay: Caroline Whitbeck (2004), 'Trust and the Future of Research', *Physics Today*, **57**, pp. 48–53. Copyright © 2004 American Institute of Physics.

American Medical Association for the essays: William J. Curran and Henry K. Beecher (1969), 'Experimentation in Children: A Reexamination of Legal Ethical Principles', *Journal of the American Medical Association*, **210**, pp. 77–83; Ezekiel J. Emanuel, David Wendler and Christine Grady (2000), 'What Makes Clinical Research Ethical?', *Journal of the American Medical Association*, **283**, pp. 2701–11; Drummond Rennie, Annette Flanagin and Veronica Yank (2000), 'The Contributions of Authors', *Journal of the American Medical Association*, **284**, pp. 89–91.

American Psychological Association for the essays: Diana Baumrind (1964), 'Psychology in Action: Some Thoughts on the Ethics of Research: after Reading Milgram's "Behavioral Study of Obedience"', *American Psychologist*, **19**, pp. 421–23; Mark A. Fine and Lawrence A. Kurdek (1993), 'Reflections on Determining Authorship Credit and Authorship Order on Faculty–Student Collaborations', *American Psychologist*, **48**, pp. 1141–47; Harold A. Herzog Jr (1988), 'The Moral Status of Mice', *American Psychologist*, **43**, pp. 473–74.

Blackwell Publishing for the essay: Fred Gifford (1995), 'Community Equipoise and the Ethics of the Randomized Clinical Trials', *Bioethics*, **9**, pp. 127–48.

Copyright Clearance Center for the essays: Patricia Woolf (1988), 'Deception in Scientific Research', *Jurimetrics Journal*, **29**, pp. 68–95; Kenneth J. Ryan (1999), 'Research Integrity', *Professional Ethics*, **7**, pp. 33–43; Michael Davis (1991), 'University Research and the Wages of Commerce', *Journal of College and University Law*, **18**, pp. 29–38.

Elsevier Ltd for the essays: Elizabeth J. Susman, Lorah D. Dorn and John C. Fletcher (1992), 'Participation in Biomedical Research: The Consent Process as Viewed by Children, Adolescents, Young Adults, and Physicians', *Journal of Pediatrics*, **121**, pp. 547–52; Philip G. Zimbardo (1973), 'On the Ethics of Intervention in Human Psychological Research: With Special Reference to the Stanford Prison Experiment', *Cognition*, **2**, pp. 243–56.

Society for Experimental Biology and Medicine for the essay: Mark S. Frankel (2000), 'Scientific Societies as Sentinels of Responsible Research Conduct', *Proceedings of the Society for Experimental Biology and Medicine*, **224**, pp. 216–19.

Hastings Center for the essays: Robert J. Levine (1979), 'Clarifying the Concepts of Research Ethics', *Hastings Center Report*, **9**, pp. 21–26; Paul S. Appelbaum, Loren H. Roth, Charles W. Lidz, Paul Benson and William Winslade (1987), 'False Hopes and Best Data: Consent to Research and the Therapeutic Misconception', *Hastings Center Report*, **17**, pp. 20–24; Thomas H. Murray (1980), 'Learning to Deceive: The Education of a Social Psychologist', *Hastings Center Report*, **10**, pp. 11–14; Jerrold Tannenbaum and Andrew N. Rowan (1985), 'Rethinking the Morality of Animal Research', *Hastings Center Report*, **15**, pp. 32–43.

Massachusetts Medical Society for the essays: Robert L. Engler, James C. Covell, Paul J. Friedman, Philip S. Kitcher and Richard M. Peters (1987), 'Misrepresentation and Responsibility in Medical Research', *New England Journal of Medicine*, **317**, pp. 1383–89. Copyright © 1987 Massachusetts Medical Society; Dennis F. Thompson (1993), 'Understanding Financial Conflicts of Interest', *New England Journal of Medicine*, **329**, pp. 573–76. Copyright © 1993 Massachusetts Medical Society; Marcia Angell (2000), 'Is Academic Medicine For Sale?', *New England Journal of Medicine*, **342**, pp. 1516–18. Copyright © 2000 Massachusetts Medical Society; Lewis Thomas (1977), 'Notes of a Biology Watcher: The Hazards of Science', *New England Journal of Medicine*, **296**, pp. 324–28. Copyright © 1977 Massachusetts Medical Society; John Concato, Nirav Shah and Ralph I. Horwitz (2000), 'Randomized, Controlled Trials, Observational Studies, and the Hierarchy of Research Designs', *New England Journal of Medicine*, **342**, pp. 1887–92. Copyright © 2000 Massachusetts Medical Society; Kjell Benson and Arthur J. Hartz (2000), 'A Comparison of Observational Studies and Randomized, Controlled Trials', *New England Journal of Medicine*, **342**, pp. 1878–86. Copyright © 2000 Massachusetts Medical Society; Carl Cohen (1986), 'The Case for the Use of Animals in Biomedical Research', *New England Journal of Medicine*, **315**, pp. 865–70. Copyright © 1986 Massachusetts Medical Society; Henry K. Beecher (1966), 'Ethics and Clinical Research', *New England Journal of Medicine*, **274**, pp. 1354–60. Copyright © 1966 Massachusetts Medical Society; Benjamin Freedman (1987), 'Equipoise and the Ethics of Clinical Research', *New England Journal of Medicine*, **317**, pp. 141–45. Copyright © 1987 Massachusetts Medical Society; Samuel Hellman and Deborah S. Hellman (1991), 'Of Mice But Not Men: Problems of the Randomized Clinical Trial', *New England Journal of Medicine*, **324**, pp. 1585–89. Copyright © 1991 Massachusetts Medical Society.

MIT Press Journals for the essay: Hans Jonas (1969), 'Philosophical Reflections on Experimenting with Human Subjects', *Daedalus*, **98**, pp. 219–47. Copyright © 1969 American Academy of Arts and Sciences.

Springer Science and Business Media for the essays: C.K. Gunsalus (1998), 'How to Blow the Whistle and Still Have a Career Afterwards', *Science and Engineering Ethics*, **4**, pp. 51–64. Rperinted with kind permission from Springer Science and Business Media; Margot Iverson, Mark S. Frankel and Sanyin Siang (2003), 'Scientific Societies and Research Integrity: What Are They Doing and How Well Are They Doing It?', *Science and Engineering Ethics*, **9**, pp.

141–58. Reprinted with kind permission from Springer Science and Business Media; David L. DeMets (1999), 'Statistics and Ethics in Medical Research', *Science and Engineering Ethics*, **5**, pp. 97–117. Reprinted with kind permission from Springer Science and Business Media; Mary Frank Fox (1990), 'Fraud, Ethics, and the Disciplinary Contexts of Science and Scholarship', *American Sociologist*, **21**, pp. 67–71. Reprinted with kind permission from Springer Science and Business Media; Steven J. Taylor (1987), 'Observing Abuse: Professional Ethics and Personal Morality in Field Research', *Qualitative Sociology*, **10**, pp. 288–302. Reprinted with kind permission from Springer Science and Business Media.

Taylor and Francis for the essays: David B. Resnik (2003), 'From Baltimore to Bell Labs: Reflections on Two Decades of Debate about Scientific Misconduct', *Accountability in Research*, **10**, pp. 123–35; Mark S. Davis (2003), 'The Role of Culture in Research Misconduct', *Accountability in Research*, **10**, pp. 189–201; Tom Regan (1997), 'The Rights of Humans and Other Animals', *Ethics and Behavior*, **7**, pp. 103–11; John P. Gluck (1997), 'Harry F. Harlow and Animal Research: Reflection on the Ethical Paradox', *Ethics and Behavior*, **7**, pp. 149–61.

Wolters Kluwer for the essays: Kay L. Fields and Alan R. Price (1993), 'Problems in Research Integrity Arising from Misconceptions about the Ownership of Research', *Academic Medicine*, **68**, pp. S60–S64; Mark S. Frankel (1996), 'Perception, Reality, and the Political Context of Conflict of Interest in University–Industry Relationships', *Academic Medicine*, **71**, pp. 1297–304.

John Wiley and Sons for the essay: Drummond Rennie (2001), 'Who Did What? Authorship and Contribution in 2001', *Muscle & Nerve*, **24**, pp. 1274–77. Copyright © 2001. Reprinted with the permission of John Wiley and Sons, Inc.

The following essay is in the public domain: Ezekiel J.Emanuel, David Wendler, Jack Killen and Christine Grady (2004), 'What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research', *Journal of Infectious Diseases*, **189**, pp. 930–37.

Every effort has been made to trace all the copyright holders, but if any have been inadvertently overlooked the publishers will be pleased to make the necessary arrangement at the first opportunity.

Introduction

This volume explores the key issues in the ethics of research. 'Research' is here understood as the systematic and rigorous collection and/or generation of empirical data combined with the analysis and publication of that data, regardless of method or discipline.

The essays gathered here cover a wide range of issues in research ethics. I have chosen from among scores of essays those that I consider to have been most influential, as well as some that I believe deserve more attention. Most of the essays focus on research in the United States, which enjoys a dominant position in scientific research, but has an unenviable history of violating ethical norms in science, as well as a more laudable – if not entirely successful – track record of trying to correct and prevent such violations.

Any extensive treatment of research ethics is bound to be dominated by the ethical issues involved in biomedical research with human subjects, for at least two reasons. First, the moral stakes are generally highest when human life and welfare are directly implicated, and research involving ill or dying humans obviously always entails palpable risks. Second, most of the worst abuses of research ethics have involved biomedical research. These two considerations presumably also explain why the regulatory bodies that review and oversee research with human subjects are often called 'Research Ethics Committees', which in turn naturally leads to the use of the term 'research ethics' as a synonym for the relatively narrow subset of ethical issues associated with the protection of human subjects of research.

While the ethical issues of research with human subjects are important and are conspicuous in the essays gathered here, they do not exhaust the realm of research ethics, and other issues are represented as well.

Not surprisingly, one of the earliest documented statements of concern over the ethics of research concerns experimental medicine. Thomas Percival's Code (1803) specified that 'the physician may try experimental treatments when all else fails, and when it can serve the public good' (Berdon, 2002).[1] Thereafter, this moral foundation was built upon fairly regularly.

- 1833 – William Beaumont's code reiterated Percival's Code, but placed a new emphasis on the importance of the voluntary, informed consent of the research subject.
- 1865 – Claude Bernard insisted that experiments that might harm the subject should never be performed, that harmless experiments are acceptable, and that experiments that might do good are morally required.
- 1898 – Walter Reed, to improve understanding and accountability, created and used an informed consent contract with the human subjects of his research on the transmission of yellow fever.
- 1900 – The Berlin Code or Prussian Code 'emphasizes when one ought not perform medical "interventions for other than diagnostic, healing, and immunization". For

[1] For this brief review of early statements on research ethics, I rely on an impressive list of codes of ethics compiled by my former graduate assistant, Victoria Berdon (Berdon 2002).

example, it excludes minors or those otherwise not competent and argues against medical "interventions" in the absence of unambiguous consent or properly explained information given to the subject.' (Berdon, 2002).

- 1931 – The Reich Circular also emphasizes the importance of informed consent to medical research.

Anyone familiar with the history of medical and experimental ethics is likely to taste a bitter irony that two of the items on the short list above originated in Germany, where, under Nazi rule, concentration camp prisoners were tortured and murdered under the guise of scientific research (Annas, 1992). Following the Nuremberg Trials, the Nuremberg Code was published in 1947, the first line of which is: 'The voluntary consent of the human subject is absolutely essential.'

The Nuremberg Code was probably the first major internationally influential code of research ethics, but was followed by others, notably the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (1964)[2] and the Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects (1982).[3]

The ethics of biomedical research is covered in Part III of this volume.

In this same period, the only significant document of which I am aware that treats the ethics of research aside from human subjects research appears in Charles Babbage's *Reflections on the Decline of Science in England, and on Some of its Causes* (1830). Chapter 5 ('Of Observations') Section 3 ('On the Frauds of Observers') describes four classes of 'fraud':

- hoaxing – creating a fictional account of scientific findings with the intention of temporarily fooling (and ridiculing) other scientists and/or the public
- forging – claiming as true observations or findings that are actually fictitious; this deception, unlike hoaxing, is intended not to be uncovered
- trimming – 'clipping off little bits here and there from those observations which differ most in excess from the mean, and … sticking them on to those which are too small'
- cooking – the selective use of data or methods to obtain an impressive result, such as making a very large number of observations but publishing only the few that agree with each other most closely

The issues raised by Babbage (and others) are covered in Part II of this volume.

The essays compiled here were all originally published long after Babbage's observations, during the 'ethics movement in biological and health sciences', identified by Stanley Joel Reiser as beginning in 1945 (Reiser, 2002). They are divided into nine parts; within each part, essays are organized in chronological order with a few exceptions when I felt that a thematic or logical flow was more appropriate.

---

[2] Revised 1975, 1983, 1989, 1996, 2000, 2002 and 2004; available online at: http://www.wma.net/e/policy/b3.htm (accessed 30 July 2007).

[3] Revised 1993 and 2002; available online at: http://www.cioms.ch/frame_guidelines_nov_2002.htm (accessed 30 July 2007).

Foundations

Perhaps the second most notorious case of unethical research, after the Nazi experiments, came to light in 1972 when the PHS Syphilis Study at Tuskegee[4] became widely known (Jones, 1993; Reverby, 2000). During the 40-year study (1932 to 1972), the natural history of syphilis was followed in 399 poor black sharecroppers (all men) in Macon County, Alabama. The subjects did not know that they were involved in research, nor were they told the nature of their disease. Researchers actively led the men to believe that they were being treated for their symptoms – described as 'bad blood' – when in fact the research team took pains to ensure that their subjects received no therapy for syphilis, even when penicillin became the accepted treatment in 1945.

The PHS Study had never been secret – results were published openly on several occasions – but neither was it common knowledge. Widespread publicity in 1972 was met with outrage and instigated a great deal of soul-searching and a prolonged, intensive process to ensure the protection of human subjects in research in the United States.

The four essays in Part I all concern fundamental issues in biomedical research with human subjects, and three were published before the PHS Study was publicized. Compared to the essays found in Part III on biomedical research, these earlier essays are more general overviews describing and defining problems and concepts broadly.

The contemporary concern over ethics in research arguably began with Henry K. Beecher's 1966 essay, 'Ethics and Clinical Research' (Chapter 1 herein). Beecher provides synopses of 22 published studies (out of 50 that he had collected) which he classifies as '*experimentation on a patient not for his benefit but for that, at least in theory, of patients in general*' (p. 3, emphasis in original). The studies are arguably unethical for a variety of reasons, most of them having as their subjects patients who did not have adequate understanding of the risks involved in the study. Beecher bemoans this lack of informed consent as widespread. Like the later exposé of the PHS Study, Beecher's essay served as a wake-up call to medical researchers – a call that met an inadequate response. One assumes that the PHS Study would have been included if Beecher had known of it.

In 1969, Beecher co-authored an important essay with William J. Curran (Chapter 2) which clarified ethical and legal principles with regard to experimentation in children, including the circumstances under which minors can ethically and legally be allowed to donate tissue for experimental procedures. They discuss the complex interplay of considerations regarding the child's age, the degree and kind of risks and benefits imposed by participation in specific circumstances, and the issue of parental permission.

The first heart transplant (performed by Christiaan Barnard in 1967), among other events, heightened concerns among researchers and the general public about the ethics of experimentation on humans. These concerns led to a special issue of *Daedalus* on 'Ethical Aspects of Experimentation with Human Subjects', including an essay by philosopher Hans Jonas that laid the groundwork for justifying – and limiting – research with human subjects (see Chapter 3).

---

[4] The PHS Syphilis Study at Tuskegee was conducted at the Tuskegee Institute in Tuskegee, Alabama, and is commonly referred to as the Tuskegee Syphilis Study. This is misleading because it implies that the Tuskegee Institute was responsible for the study, which was in fact instigated, supported and led by the US Public Health Service (PHS).

As mentioned above, the public reaction to the PHS Syphilis Study at Tuskegee led to the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was chaired by Kenneth J. Ryan. The National Commission published several well-regarded reports which provided the foundation for restructuring human subject research in the United States. Perhaps the most important of these reports is the short and highly-readable *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (National Commission, 1979), which was clearly influenced by Jonas's essay. Robert J. Levine's essay (Chapter 4) clarifies key aspects of several of the National Commission's reports.

Integrity and Misconduct

The 1970s and 1980s also saw a number of cases in which scientists falsified or fabricated data or plagiarized the work of other scientists (four major cases in the summer of 1980 alone – see Chapter 7). The scientific community responded to reports of 'scientific fraud' (as it was often called) by asserting that such cases are rare and that neither errors nor deception can be hidden for long because of science's self-correcting nature – between peer review, replication of published experiments and the process of building on earlier work, the argument goes, bad science will be discovered eventually.

William Broad (Chapter 5) writing in the journal *Science*, as the US House of Representatives Science and Technology subcommittee on investigations and oversight prepared to hold meetings on falsification of data (p. 57), observes that cheating in science was nothing new. However, for the most part dishonesty in science had been handled as an internal affair, among scientists and colleagues, and was therefore not widely known. With the dramatic increase in federal and other public funding of science following the Second World War, non-scientists have had an increasing interest in the integrity of research results and the behaviour of scientists. The federal government began putting pressure on research institutions, such as universities, to oversee research more effectively and to investigate allegations of cheating. Furthermore, Broad cites a review of publicized cases of cheating showing that 'the failure to duplicate experiments plays a relatively minor role in uncovering fraud' (p. 60) – science's self-correcting mechanisms do not work as well as some believe.

Robert Engler and colleagues (Chapter 6) provide an overview of their investigations into Robert A. Slutsky's seven-year career of falsification and fabrication, and reflect on motivations for misrepresentation, how fraud is uncovered and on the victims of fraud. They suggest that Slutsky was inadequately supervised, that having many co-authors (some of whom received the authorship as a 'gift' from Slutsky, others of whom were listed as co-author without their knowledge or permission) provided him with cover, and that Slutsky's ability to hide his data from other researchers, including his co-authors, protected him from discovery. Journals that published Slutsky's work might have been able to detect his fabrications but most did not, and several of his colleagues who suspected him of cheating did not speak up. The authors conclude that fraud in science is 'probably rare in proportion to the large numbers of scientific publications' (p. 68), but it does happen, and mechanisms are needed to prevent, detect and investigate allegations of fraud.

In her excellent broad overview of issues related to deceptive science, Patricia Woolf (Chapter 7) notes that 'the boundaries between egregious self-deception, culpable carelessness, fraud,

and just plain error, can be very blurred indeed' (p. 80). This proves to be a major obstacle to identifying the causes and prevalence of research fraud, as does the lack of uniform reporting requirements and standards. Woolf surveys major federal agencies to estimate prevalence of 'research fraud', concluding that 'there is no evidence of an epidemic of fraudulent science', but there is 'a persistent and growing concern' (p. 78). She also analyses 40 publicly-reported cases of alleged misconduct (1950–87), finding that the majority of cases were related to research in medicine and many of the perpetrators worked at or received their degrees from prestigious universities. It also appears that peer review, described by Woolf as including 'all the evaluative processes of collegial interaction – from lab seminars to public professional meetings, from reading a paper for a friend to assessing it for grant support … has in fact been one of the most effective methods for detecting fraud', but efforts to replicate experiments also play a role (p. 85). Woolf emphasizes that, while 'professionals have an obligation to maintain [professional] standards … [i]nterfering with collegial trust can be perilous for science and should be undertaken only when there is a compelling reason' (p. 86), echoing an often repeated concern that efforts to control misconduct might 'harm … the very activities they seek to preserve' (p. 87). She observes that the lack of a 'clear consensus about responsibility and due process' had led to 'a great deal of denial and confused and counterproductive behavior' (p. 87). Woolf also analyses institutional and funding agency responses to misconduct, the different standards of evidence and proof prevalent in law and in science, the role of the media, consequences of fraud and misconduct, and methods to deter dishonest science.

The growing publicity around cheating in science and the clear need for improved standards led the United States Public Health Service (PHS, 1989) and the National Science Foundation (NSF, 1991) to adopt and publish similar definitions of misconduct in science. The core of both definitions was fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted in the scientific community. By this time, the phrase 'misconduct in science' or 'scientific misconduct' had replaced 'scientific fraud' because 'most legal interpretations of the term 'fraud' require evidence not only of intentional deception but also of injury or damage to victims, … [and] this evidentiary standard seemed poorly suited to the methods of scientific research' (COSEPUP, 1992, p. 25). These definitions, especially the 'other deviations' clauses, evoked immediate and ongoing resistance from the research community.

In 1993, the United States Congress formed the Commission on Research Integrity (CRI), which, like the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, was chaired by Kenneth J. Ryan, to 'advise the Secretary of Health and Human Services and Congress about ways to improve the Public Health Service (PHS) response to misconduct in biomedical and behavioral research receiving PHS funding' (CRI, 1995, p. vii). In 1995, the CRI (sometimes called the Ryan Commission after its chair) made some 33 recommendations, of which 23 – not including a proposed new definition of misconduct – were endorsed by PHS (IGRIM, 1996, p. 8).

It is important to note that 'research misconduct' is primarily a regulatory concept and only secondarily concerned with ethics.[5] The issue at hand in defining research misconduct has

[5] The long-standing and contentious debate over governmental oversight of research has colored and skewed almost all discussions of research ethics. My attempt to disentangle the issues can be found in Pimple (2002).

always been to delineate the research-related practices that merit intervention by the federal government – the federal offences of unethical research. Many ethical issues do not fall under this umbrella.

In 1999, Kenneth J. Ryan (Chapter 8) revisited the issue of integrity in science, emphasizing that the pursuit of the 'internal goods' of science – 'obtaining knowledge by solving problems and answering questions' – 'is unlikely to corrupt the objective process of looking for and gathering knowledge since they are one and the same' (p. 100). The pursuit of 'external goods', such as prestige, promotion and financial rewards, however, can have a corrupting effect if it is not adequately restrained by respect for science's internal goods. Ryan briefly reviews the history of misconduct and its regulation, and critiques governmental responses, which, in his view, fall short compared to analyses by sociologists, historians and philosophers of science. He notes that some progress in addressing misconduct has been made, but not as much as he would like.

After two decades of efforts to define misconduct in science, the issue is still alive. David B. Resnik (Chapter 9) describes five goals that such definitions can be expected to uphold, and concludes that the most important goal is 'promoting education in … responsible [or ethical] conduct in scientific research' (p. 117) because 'the point of having ethical rules and definitions is to promote ethical conduct, and ethical conduct is not likely to occur without effective education' (p. 120). He also favours two 'less important' goals: 'the government's interest in holding researchers and educators accountable for the use of government funds' and 'having a definition that is enforceable' (p. 120). He offers a new definition that he believes meets these three goals.

Caroline Whitbeck (Chapter 10) looks back at the recent history of cheating in science for lessons about the future of science. Cheating by scientists has eroded trust in research both among members of the general public and in the research community. Researchers working in an atmosphere of suspicion suffer from low morale; distrust of the fairness of the research process – including, for example, peer review – can lead to compromised research practices. The realization that 'charges of misconduct are prone to arise in settings where other instances of wrongdoing, abuse, or conflict have been left unresolved' (p. 128) has fostered a shift in attention from the federal offences (falsification, fabrication, plagiarism) to the whole research setting. Trust in research and between researchers has to be re-established and maintained for the research enterprise to thrive.

At times when one researcher believes that he or she has observed another engaging in research misconduct it is necessary to report the apparent misconduct to someone in authority – that is, to 'blow the whistle'. Although everyone agrees that serious wrongdoing should be reported, whistle-blowers often face retaliation and recrimination. C.K. Gunsalus (Chapter 11), who has led or assisted many investigations into research misconduct, offers priceless practical advice for anyone who finds him- or herself in this morally fraught and perilous situation.

Biomedical Research

Thanks to biomedical research, improvements in medical treatments have increased dramatically over the last century or so, and the pace of improvement continues to increase. At times, the drive for improved treatments runs foul of well-established ethical principles.

In the practice of medicine, the therapeutic obligation of the physician to the patient has been fundamental since the days of Hippocrates: when treating a patient, the physician is to take into account the patient's own needs above all other considerations. In the practice of biomedical research, the production of the best, most reliable knowledge is fundamental, and arguably the best method for doing so is the randomized, placebo-controlled clinical trial (RCT).[6] Fred Gifford (Chapter 12) discusses the intrinsic conflict between these two values. In order for physicians to live up to the therapeutic obligation, they must be free to exercise their best clinical judgement. In order for researchers to execute an effective RCT, they must accept strict constraints on clinical practice to conform to the RCT, which in some cases must mean compromising their ability to meet the therapeutic obligation. Gifford explores attempts to avoid this dilemma, ways to minimize harm and justifications for violating the therapeutic obligation, none of which prove to be completely satisfactory.

Invoking the therapeutic obligation, but using the term 'personal care', Paul S. Appelbaum and colleagues (Chapter 13) note that 'the scientific method is often incompatible with one of the first principles of clinical treatment [personal care]' (p. 167). Their concern is with the therapeutic misconception – that is, the belief held by a research subject that 'every aspect of the research project to which he had consented was designed to benefit him directly' (p. 167). If a person does not understand that he or she may receive a placebo, how can the consent be considered 'informed?' Appelbaum *et al*. share data showing that the therapeutic misconception is very common, but that its impact can be reduced by fairly simple interventions; they do not show, however, that it can be eliminated.

At the time he wrote his essay, Benjamin Freedman (Chapter 14) perceived a 'crisis of confidence in the ethics of clinical trials' (p. 177) associated with the ethical requirement that 'each clinical trial begin with an honest null hypothesis' (p. 173). Freedman calls this requirement 'equipoise' – the physician-researcher's honest uncertainty about which of the treatments to be tested against each other is superior. When conceived as stated, equipoise is very fragile, for the physician-researcher needs only to get a hint that one treatment is better than another for equipoise to be disturbed, in which case the therapeutic obligation kicks in and the research must be ended. Freedman argues that a more appropriate concept of equipoise, 'clinical equipoise', is both more robust (requiring more evidence to be disturbed) and more likely to result in high-quality, useful and ethical research. Clinical equipoise depends not on the individual researcher's beliefs about the comparative merits of treatments to be tested, but on the beliefs and practices of the relevant medical community.

Fred Gifford (Chapter 15) raises a number of serious objections to Freedman's conclusion that the concept of clinical equipoise saves randomized clinical trials and the therapeutic obligation. These include: ambiguities in the clinical equipoise standard, the idea that medical knowledge is embodied in the medical community, and ambiguities that arise from the multiple possible purposes of performing trials. Gifford concludes that 'a policy of carrying out RCTs may well require reference to utilitarian trade-offs [between the therapeutic obligation and the high quality of information produced by RCTs] after all' (p. 200).

Samuel Hellman and Deborah S. Hellman (Chapter 16) strongly resist utilitarian trade-offs at the expense of the therapeutic obligation: 'Randomized trials often place physicians in the ethically intolerable position of choosing between the good of the patient and that of

---

[6] For an early statistical treatment of the ethics of the RCT, see Zelen (1969).

society. We urge that such situations be avoided and that other techniques of acquiring clinical information be adopted' (p. 204).

Another challenge to the supremacy of the RCT comes from meta-analyses of observational studies, long disparaged as inferior. In separate studies, John Concato *et al*. (Chapter 17) and Kjell Benson and Arthur J. Hartz (Chapter 18) found that 'observational studies usually do provide valid information' (p. 219). Concato *et al*. emphasize the importance of using a variety of methods in biomedical research. Although observational studies have their shortcomings, they tend not to violate the therapeutic obligation, unlike RCTs.

While the moral importance of attaining informed consent from potential subjects before they are enrolled into a research study has been explicitly recognized since at least 1833, empirical studies into the effectiveness of informed consent processes appear to have been undertaken only much more recently. The article by Elizabeth J. Susman and colleagues (Chapter 19) may be the first such study involving children (age 7 to 20) as subjects in biomedical research. Perhaps the most interesting finding is the lack of significant difference between age groups (7 to 13 and 14 to 20 years) in issues associated with the purpose of the research: benefit to self, freedom to withdraw and so on (p. 226). Understanding was found to be high for items 'relating to concrete experiences in the lives of [the] subjects', such as the freedom to ask questions, to which they had been socialized in school. Understanding was found to be low for items 'relating to abstract issues', such as the purpose of the research, comprehension of which 'depends on the intellectual capability of abstract reasoning, an ability that emerges during early to mid adolescence' (pp. 226–27). When considered in the light of the therapeutic misconception, the finding that 'the majority of the study subjects mentioned [as the purpose of the study] the therapeutic purpose of the treatment ("to get better" or "to be cured")' is somewhat unsettling (p. 227).

In two related essays, Ezekiel J. Emanuel and colleagues delineate eight ethical principles for ethical clinical research. In Chapter 20 they explain seven of the principles and trace their roots to a large number of influential codes and statements on ethical biomedical research. In Chapter 21 they add an eighth principle, collaboration, to make more explicit the relevance of their schema to research in developing countries. This eighth principle is largely implicit in the other seven. The second essay also provides '31 benchmarks that systematically specify practical measures to determine the extent to which the research satisfies the principles' (p. 241). The benchmarks are applicable to any cross-cultural research, whether between two countries or between a scientifically sophisticated research team and a non-scientific, poorly educated population in the same country.

Contexts of Science

Science generally has an objective, timeless air, consisting of discoveries of pre-existing phenomena. However, the practice of science is always context-bound, a fact that is sometimes overlooked in discussions of research ethics.

In his short editorial, Gerard Piel (Chapter 22) describes the tension between the private and public faces of science as well as the core values of science – 'reason, openness, tolerance, and respect for the autonomy of the individual' – and claims that 'the social process of science brings along the means to realize its values' (p. 251). In other words, as science becomes more accepted and dominant in a society, that society increasingly adopts those same core values

in all spheres. If he is correct, the practice of science has deep implications beyond the mere findings of science.

Edward J. Hackett (Chapter 23) documents and analyses major changes in the culture of academic science as the last decade of the twentieth century loomed. While some of the data and references are dated, his core points are still applicable and the tensions he describes have not been resolved; rather, they have largely become accepted as part of the terrain. Academic science must accommodate the values of science and of the academy; this tension is increased as both academe and science rely more and more heavily on outside sources of funding, both private and public. The values of academic science can be significantly deformed as they are forced into this Procrustean bed, as he illustrates with many examples.

Mary Frank Fox (Chapter 24) makes several useful observations on how illegitimate activity in science differs based on discipline – which is here used broadly to differentiate between hard[7] ('natural and biological – principally, biomedical') science and social science (p. 294). While reported (or, as Fox puts it, 'surfaced') misconduct is more common in hard science, it is possible that actual misconduct is as common in social science but is less likely to come to the surface for a variety of reasons, including the generally lower stakes of social science research and its lower rate of co-authorship. Fox speculates that fabrication and falsification of data is likely to occur more often in hard science because 'in [hard] science, the research is the creative act', and plagiarism is likely to occur more often in the social sciences because in 'social sciences … the publication itself is a creative act' (p. 295). She calls for the research community to 'acknowledge deception … as an explanation of [some] violations' and to 'institutionalize means of addressing and redressing fraud' (p. 296).

Fox and John M. Braxton, in a concluding essay to an issue on 'Perspectives on Research Misconduct' published in the *Journal of Higher Education* (Chapter 25), summarize other essays on the issue and explore mechanisms for the social control of science. They examine in turn the federal government, universities, journals and individuals, outlining incentives and disincentives influencing each to deal with research misconduct, sanctions they can impose, and limits on the scope of their ability to address problems. Their discussion makes it clear that there is no single path to preventing or responding to misconduct in science.

Of the many factors that might influence ethical behaviour in science, one that is seldom articulated is native culture. Mark S. Davis (Chapter 26) correctly points out that linking research misconduct with national or ethnic culture is sensitive and open to charges of prejudice,[8] but holds nonetheless that it is a logical and reasonable question to pursue. He presents data – admittedly inadequate, but probably the best available – suggesting that a disproportionate number of persons found guilty of research misconduct in 1994–2002 by the US Office of Research Integrity may have been foreign nationals (p. 317). He suggests that training in research ethics for foreign nationals and training in cultural diversity for natives might help to alleviate this problem.

---

[7] Fox does not use the term 'hard science', but refers to the natural and biological sciences simply as 'science'.

[8] Another reason for the near-silence on this issue that Davis does not mention is the assumption that adequate training in science anywhere will instil the values of science. It seems likely that any science education worthy of the name would make clear that fabrication and falsification of data are totally at odds with the practice of science; however, it seems possible that plagiarism might be interpreted differently in different settings, including cultural settings.

Scientific societies have a special role to play in fostering research integrity. Mark S. Frankel (Chapter 27), long-time director of the Scientific Freedom, Responsibility, and Law Program of the American Association for the Advancement of Science (AAAS), argues that 'Rules and regulations proscribe rather than prescribe expected behavior. That is, they tell us what we cannot do – not what we ought to do. … The scientific community should embrace a commitment to promote actively ethical research practices' (p. 325). Scientific societies can play an important role by acting as 'custodian of a discipline's core values and distinct traditions' (p. 326), by articulating standards, offering guidance and providing other activities that support research integrity.

Margot Iverson and colleagues (including Frankel) (Chapter 28) report the findings of a survey of scientific societies and their role in promoting research integrity. They find that societies have taken an active role in articulating standards and codes of conduct, as well as providing activities and resources for promoting research integrity. However, efforts to evaluate the effectiveness of the standards and activities are mostly absent: 'The data also paint a picture of a group of societies expending little effort to determine what works and what does not' (p. 339).

Social Research

The social sciences, especially social psychology, sometimes raise troubling ethical issues about research design and balancing the rights of individual research subjects against the possible social benefits of research. Stanley Milgram wanted to understand how ordinary Germans could be persuaded to take part in Nazi atrocities, but his research on obedience was seen by many as unethical. Diana Baumrind (Chapter 29) summarizes Milgram's 'Behavioral Study of Obedience' (Milgram, 1963; see also Milgram, 1965) and offers a powerful critique of the experimental design as well as the disrespect shown and possible harm done to subjects in the study. Her critique holds lessons for other kinds of experimental social and psychological research, particularly in regard to balancing – if such a thing is possible – the harm incurred by subjects with the benefit derived by science and society.

Similarly, Philip G. Zimbardo's so-called Stanford prison experiment was undertaken with an admirable social goal, but admittedly went wrong. In his response to an essay critical of the ethics of the study, Zimbardo himself (Chapter 30) provides an insightful analysis of the ethical issues involved in research that addresses an important and practical social problem (the brutality of prison life) but also has a real potential of harming the subjects involved. Zimbardo is defensive – even arch – in a few passages, and his interests must be taken into account when evaluating his arguments and conclusions. Even so, his essay deserves serious consideration and raises important and difficult issues.[9]

Much research in social psychology has involved deceiving subjects about the intention of the research, as in Milgram's study, but not in Zimbardo's. Thomas H. Murray (Chapter 31) paints a picture of social psychology as self-contradictory: in the 1960s, at least, it was dedicated to the study of 'a multitude of topics that seemed to penetrate to the heart of war, injustice, and other evils', but led researchers 'routinely to frighten, provoke, insult, depress,

[9] Zimbardo has made available a chilling slideshow on the study at: http://www.prisonexp.org/ (accessed 30 July 2007).

and generally lie to the subjects of their experiments' (p. 367). Murray describes his own training as a social psychologist and provides a keen critique of the ethics and the scientific validity of deceptive research of this sort.

Steven J. Taylor (Chapter 32) also provides an insightful account and analysis of his own experience as a graduate student performing observational research in a ward for the mentally retarded where he observed the staff routinely abuse the inmates. The standards of social science required him to be an objective observer, to gather data and not to interfere; his personal morality made his experience quite uncomfortable. He describes four possible responses to observing abuse (intervene, leave the field, blow the whistle, or continue the study) and weighs their moral and practical value. He also offers well-considered suggestions on how researchers should act 'in the face of immoral acts [observed] in the field' (p. 380).

Social Responsibility

Science is, in the first instance, the search for understanding of the natural world – for what might be called pure knowledge. That search, however, has always taken place within cultural and social contexts, and the findings of science frequently alter and even transform cultures and societies. Many scientists have argued that they are not responsible for the uses to which scientific knowledge is put: politicians and industrialists bear that burden. At least since the Second World War, the pace of discovery in science and the practical implications of scientific findings have increased so dramatically that such an ivory-tower attitude is hardly tenable.

The distinguished mathematician and philosopher of science Bertrand Russell (Chapter 33) eloquently argues that scientists cannot shirk the responsibility that comes with the development of life-threatening theories and their practical application – his case in point is the atomic bomb. At the very least, scientists have a duty to make sure that the public understands the implications of scientific findings so that they can, in turn, hold politicians responsible for their use.

Concerning the realm of biology rather than physics, and dealing with a putative, rather than demonstrated, danger (recombinant DNA), the great essayist and medical researcher Lewis Thomas (Chapter 34) argues, in effect, that applications of knowledge are relatively easy to control, but that the search for knowledge should be unfettered. To Thomas, curiosity and the drive to slake it are characteristically human, and to restrain scientific inquiry would be a greater offence than to pursue it, however dangerous its application may be.

John T. Edsall (Chapter 35) distinguishes between two kinds of scientific responsibility, 'the pattern of responsible behavior that is associated with basic research and the communication of the results' (p. 397), which might also be called research integrity, and social responsibility. In his discussion of the former, Edsall touches on issues of possible social consequence, such as secrecy among and competition between scientists. In his discussion of the latter, Edsall describes the impact of Rachel Carson's book, *Silent Spring* (1962), with its warnings about the over-use of pesticides, and outlines some of the difficulties scientists face when entering the public arena. Along the same lines, Edsall defends scientists and engineers who go over the heads of their employers to report publicly flawed research and dangerous technologies.

Authorship and Data

Without data and data analysis there is no science. As a key tool of science, statistical methods of data analysis turn out also to be a key tool of perpetrating, and detecting, unethical practices in science. Biostatistician David L. DeMets (Chapter 36) provides a number of examples drawn from actual cases, some from his own experience, of ways in which statistical methods can be misleading, whether through bad research design (such as the inappropriate use of surrogate outcome measures) or illegitimate statistical analysis (such as fishing or dredging data – doing so many analyses that a statistically significant result is bound to pop up). Statisticians sometimes inadvertently discover flawed analyses, from the relatively honest problem of bias in patient evaluation to outright fabrication of data, and they 'bear an important responsibility for using these research tools ethically as well as correctly. They must resist temptations or pressures to violate the principles upon which the validity of these methods are based' (p. 404).

Authorship has been called the 'coin of the realm' (Wilcox, 1998) in research because all other goods – promotion, tenure, prestige, and so on – flow from successful and prolific publication. In recent decades, collaborative research and multiple-authored publications have proliferated. Not surprisingly, conflicts over credit often arise between collaborators. Kay L. Fields and Alan R. Price (Chapter 37), of the US Office of Research Integrity, examine and correct many misconceptions regarding who 'owns' data and research findings and briefly describe a number of actual cases in which misunderstandings have led to allegations of research misconduct. In science, the 'ownership' of an idea or product sometimes depends on matters other than who had the insight or did the work, including who secured funding for the project. The relevant considerations discussed by Fields and Price are not intuitively obvious, but are grounded in practical realities of research today.

Until recently, the only indication of the contributions of authors to a co-authored publication was encoded in the order of authors, and this holds in most publications today. In some fields, the first author is considered most important; in others, the last. Sometimes, unfortunately, the code is interpreted differently by various individuals. As Drummond Rennie and colleagues (Chapter 38) describe, various abuses of authorship, including 'gift' or 'honorary' authorship, along with disputes over who should be held responsible if misconduct is alleged in a multi-authored publication, has led a number of prestigious journals to require explicit information about what each author contributed to the study. In a later essay, Rennie (Chapter 39) describes in greater detail the problems that led to these policy changes.

Decisions about determining authorship credit and order are eased, but not solved, by explicit guidelines. Making such decisions is often complicated when the research team is characterized by power differentials, such as when students and faculty members work together. The duties, interests and contributions of a faculty advisor and a thesis-writing student are sometimes at cross-purposes. Mark A. Fine and Lawrence A. Kurdek (Chapter 40) offer examples and guidance on making these decisions.

Animals in Research

The use of animal models in research has long been controversial, with active and vocal criticism of animal abuse going back at least to the antivivisection movements of the

nineteenth century (French, 1975). Perhaps the most influential work of recent years is Peter Singer's *Animal Liberation* (1975), which uses a utilitarian framework to argue against the exploitation of non-human animals in all realms, not just research. Utilitarianism holds that pain and pleasure are morally significant, and that the infliction of pain or suffering is morally unacceptable.

Another argument against the use of animals for human needs comes from Tom Regan (Chapter 41), who argues forcefully, both in this essay and in his book (Regan, 1983), that non-human animals are possessed of moral rights that should protect them from exploitation in scientific research.

Carl Cohen (Chapter 42) provides a much-cited defence of the use of animals in biomedical research by, first, arguing, *contra* Regan, that non-human animals have no moral rights because they are not 'capable of self-restricting moral judgments'. This is not to say that humans are morally free to treat animals in any way we choose; despite *their* lack of moral rights, *we* are obliged, at least, 'to treat them with the decency and concern that we owe, as sensitive human beings, to other sentient creatures' (p. 460). Cohen then proceeds to dismantle the key utilitarian argument against using animals in research: 'We ought to desist from the imposition of pain insofar as we can. Since all or nearly all experimentation on animals does impose pain and could be readily foregone, say these critics, it should be stopped' (p. 461). From a utilitarian standpoint, however, the premise that such research 'could be readily foregone' is untrue, for the 'sum of the benefit of their use is utterly beyond quantification' (p. 462). Indeed, Cohen argues, utilitarianism *demands* the use of animals in certain kinds of research. While strong, his arguments have obviously not been conclusive, for the controversy continues.

Jerrold Tannenbaum and Andrew N. Rowan (Chapter 43) provide an excellent overview of critical ethical issues in animal research. They describe eight major ethical positions, ranging from those that would not pose any restrictions on animal research to those that would ban it altogether. They also elucidate the most important considerations that must be brought to bear in any debate on the topic and the key justifications for animal research. While they do not take a stand, they make it clear that either justifying or condemning animal research would require careful thought based in a sound empirical understanding of the capabilities and qualities of the animals in question.

In perhaps the most memorable and shortest essay on the subject, Harold A. Herzog Jr (Chapter 44) offers a typology of mice in a typical research facility. There, the 'moral status' of a mouse is not intrinsic; rather, it depends on the mouse's role and how it is labelled, with experimental mice ('the good mice') being treated a good deal better than pest mice ('the bad mice') and those used to feed snakes, lizards and other animals in the facility ('feeders'). Herzog illustrates that 'because ethical judgments are inextricably bound in a complex matrix of emotion, logic, and self-interest, a better understanding of the *psychology* of how humans arrive at moral decisions will be critical to progress in the area of animal welfare' (p. 478, emphasis in original).

John P. Gluck (Chapter 45) provides insights that can be applied to research beyond that which uses animal subjects. He describes Harry F. Harlow's distinguished career and important findings as well as the atrocious experiments underlying his accomplishments. Many careers include contradictory elements, but Harlow's key contradiction is exceptionally pointed: his experiments, in which monkeys were subjected to what can reasonably be termed torture, demonstrated the importance of early attachment so vividly that the application to humans

was undeniable; his cruelty underscored the necessity of kindness. Gluck provides several 'factors that limited ethical analysis' (p. 486) of Harlow's work, none of which are unique to animal research, as well as three important considerations for ensuring responsible research.

Financial Conflicts of Interest

For centuries, the greatest extrinsic reward for scientists came in the form of prestige, especially in the eyes of scientific peers. By the end of the twentieth century, however, science's commercial possibilities had increased to the extent that many industries are now dependent on advanced science and ongoing scientific research. Working relationships between academic researchers and industry are now common, as are concerns that commercial interests may hamper the objectivity of scientists and distort the trajectory of scientific progress. Michael Davis (Chapter 46) analyses this problem, informed by his experience in studying practical ethics as well as informal interviews with businesspeople and university researchers. He identifies several legitimate reasons why business seeks out academic researchers and vice versa, none of which seem deeply ethically problematic. Davis concludes that some dangers from such relationships do exist, but that the relationships themselves are productive (not merely profitable) for academic science, industry and society and that they should be managed, not banned.

In professional life, conflicts of interest, in which a primary professional duty (such as scientific research) is unduly influenced by a secondary interest (such as promoting a friend's career), are endemic. As Dennis F. Thompson explains in Chapter 47, financial conflicts of interest – in which the secondary interest is money – are easier to identify objectively and to manage effectively than most other forms of conflict, and they are more likely to raise suspicion. Sometimes the most effective way to manage a financial conflict of interest is merely to disclose it. Thompson clarifies the broad outlines and sometimes subtle distinctions involved in understanding financial conflicts of interest, defends the necessity of policies to regulate such conflicts, and provides a brief overview of ways in which these conflicts have been managed.

Mark S. Frankel (Chapter 48) recounts the political climate and the social context of science in the late 1980s when the National Institutes of Health felt obliged to formulate policies regulating conflicts of interest among NIH-funded researchers. In 1989 the proposed draft policy was withdrawn after three months due to considerable controversy. After a great deal of further work, a policy that was more acceptable to the research community was adopted in 1995. The difficulty chiefly lay in developing a policy that would stave off the appearance of conflict of interest (as well as, one hopes, the reality of conflicts that mar objectivity) without being overly burdensome for researchers and research institutions.[10]

Marcia Angell (Chapter 49) describes the amazing extent and variety of ties between academic biomedical research and industry. As she points out, cash-poor medical schools welcome such relationships as much as individual researchers. Angell argues that, in addition

[10] The policy discussed by Frankel covered extramural research – research funded by NIH but carried out in separate institutions, including universities. A few years later a similar level of public concern arose regarding intramural NIH research (research carried out at the NIH institutes themselves), a similar series of policy drafting and objections ensued, and a policy was adopted in 2005.

to the concern over objectivity, relatively easy money from industry may threaten academic biomedical research by skewing the kind of research undertaken. Industry is not as interested in basic science as academic research has traditionally been, and science could suffer if applied research – especially research driven by financial profit rather than human need or scientific importance – becomes overly dominant.

Conclusion

The importance of research in today's world can hardly be overstated. It is hard to identify a significant aspect of social life that does not owe its current form to a long history of research and that does not depend on research for its continued functioning, including medicine, agriculture, transportation, communication, defence, education and government. Science, once a hobby of distinguished and somewhat eccentric ladies and gentlemen, is now the keystone of everyday life.

In 2001, I wrote:

> In all, I think that researchers and research administrators have endured a difficult political adolescence these last few years. The naïveté of science's political childhood during the Cold War's Golden Age of Science has come to a close. Scientists are less likely to think that they should be able to work with public funds but no public oversight ('interference', they would have called it). They are more likely to admit that not all good scientists are morally impeccable. 'Disinterestedness' is mostly recognized as more of an ideal than a reality. And perhaps most significantly, I believe researchers and those who oversee research, both in the government and in the universities, have very nearly buried their hatchets and agreed to work together. (Pimple, 2001, p. 21)

Back then, I felt that it was 'still an open question whether science [had] reached its full political maturity and [was] thoroughly willing and ready to live up to all of its responsibilities, including the unpleasant ones associated with cleaning house' (p. 21). Today I believe it has made undeniable progress; although ethical lapses – some of them spectacular – continue to surface, the earlier reflex towards denial has diminished.

Science will continue to mature and to adapt, as do all human endeavours that do not disappear; and it will continue to have its shortcomings, including moral ones. Reflection on where we have been and the mistakes we have made will help in this process, and I hope this volume will make some contribution to ethical research.

Acknowledgements

I am grateful to Tom Campbell for inviting me to edit this volume, and for his patience as I missed one deadline after another when medical and other conflicts arose.

During the course of my career, I have met and learned from scores of researchers, ethicists, research administrators, and others too numerous to mention, but I am pleased to have this opportunity to acknowledge my debt to David H. Smith, Brian E. Schrag, Karen M.T. Muskavitch, Julia A. Pedroni, and Richard B. Miller, all of whom I have had the privilege and pleasure of working with over an extended period of time at the Poynter Center for the Study of Ethics and American Institutions at Indiana University at Bloomington.

No career would be endurable without the support of Jennifer, Gwendolyn and Vivian Livesay; I am also indebted to Jennifer for her critical insight and copy-editing skills.

References

Annas, George J. (1992), *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation*, New York: Oxford University Press.

Babbage, Charles (1830), *Reflections on the Decline of Science in England, and on Some of its Causes*, London: Fellowes.

Berdon, Victoria (2002), 'Codes of Medical and Human Experimentation Ethics', Bloomington: Poynter Center. Available online at: http://wisdomtools.com/poynter/codes.html (accessed 30 July 2007).

Carson, Rachel (1962), *Silent Spring*, Boston, MA: Houghton Mifflin.

COSEPUP (Committee on Science, Engineering, and Public Policy), National Academy of Sciences (1992), *Responsible Science: Ensuring the Integrity of the Research Process*, Vol. 1, Washington, DC: National Academy Press.

CRI (Committee on Research Integrity) (1995), *Integrity and Misconduct in Research: Report of the Commission on Research Integrity*, Washington, DC: US Department of Health and Human Services. Available online at: http://ori.dhhs.gov/documents/report_commission.pdf (accessed 30 July 2007).

French, Richard D. (1975), *Antivivisection and Medical Science in Victorian Society*, Princeton, NJ: Princeton University Press.

IGRIM (Implementation Group on Research Integrity and Misconduct) (1996), 'Implementation Proposals on Recommendations by the Commission on Research Integrity', unpublished report. Available online at http://chronicle.com/che-data/focus.dir/xtra4242.dir/ori.htm (accessed 30 July 2007).

Jones, James H. (1993), *Bad Blood: The Tuskegee Syphilis Experiment*, New York: The Free Press.

Milgram, Stanley (1963), 'Behavioral Study of Obedience', *Journal of Abnormal and Social Psychology*, **67**(4), pp. 371–78.

Milgram, Stanley (1965), 'Some Conditions of Obedience and Disobedience to Authority', *Human Relations*, **18**(1), pp. 57–76.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979), *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, Washington, DC: Office of the Secretary of the Department of Health, Education, and Welfare. Available online at: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm (accessed 30 July 2007).

NSF (National Science Foundation) (1991), 'Misconduct in Science and Engineering', *Federal Register*, **56** (14 May), pp. 22286–90.

PHS (Public Health Service) (1989), 'Responsibilities of Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science', *Federal Register*, **54** (8 August), pp. 32446–51. Available online at: http://ori.dhhs.gov/misconduct/reg_subpart_a.shtml (accessed 30 July 2007).

Pimple, Kenneth D. (2001), 'The Moral Climate of Research in the United States Today', paper prepared for the Institute of Medicine Committee on Assessing Integrity in Research Environments. It can be obtained from the National Academies Public Access Files, 2101 Constitution Avenue NW, Washington DC 20418; (202) 334–3543. Available online at: http://mypage.iu.edu/~pimple/iom2.pdf (accessed 30 July 2007).

Pimple, Kenneth D. (2002), 'Six Domains of Research Ethics: A Heuristic Framework for the Responsible Conduct of Research', *Science and Engineering Ethics*, **8**(2), pp. 191–205.

Regan, Tom (1983), *The Case for Animal Rights*, Berkeley: University of California Press.

Reiser, Stanley Joel (2002), 'The Ethics Movement in the Biological and Health Sciences: A New Voyage of Discovery', in Ruth Ellen Bulger, Elizabeth Heitman and Stanley Joel Reiser (eds), *The Ethical Dimensions of the Biological and Health Sciences*, Cambridge: Cambridge University Press, pp. 3–18.

Reverby, Susan M. (ed.) (2000), *Tuskegee's Truth: Rethinking the Tuskegee Syphilis Study* (new and expanded edition), Chapel Hill: University of North Carolina Press.

Singer, Peter (1975), *Animal Liberation: A New Ethics for Our Treatment of Animals*, New York: Random House.

Wilcox, Linda J. (1998), 'Authorship: The Coin of the Realm, the Source of Complaints', *Journal of the American Medical Association*, **280**(3), pp. 216–17.

Zelen, M. (1969), 'Play the Winner Rule and the Controlled Clinical Trial', *American Statistical Association Journal*, **64**(325), pp. 131–46.