# Chapter 1: The ethical basis of RCRH

**The recent course of history in the Western world has been in the direction of greater freedom and self-determination of individuals. A logical result of that has been the movement from paternalism to autonomy in medical care and by extension in medical research. Great impetus to that movement was provided by the atrocities carried out in the name of research by the Nazi German physicians, as described in the reports of the Nuremberg trials. That led directly to the first clear statement of the relationship of research subjects to the investigator and to the research being proposed. ( ). However, a statement of principle, as ethically powerful and persuasive as it was, did not result in uniformly unimpeachable research performance. As a result of considerable consternation over several specific programs of human research in the United States, a national commission was convened under the direction of Kenneth Ryan that issued a report, (The Belmont Report) outlining appropriate research behavior. The commission proposed government control through Institutional Review Boards at research institutions. The report was enacted by Congress to encompass human research carried out under the auspices of a number of Federal agencies, hence The Common Rule. Subsequently the World Health Organization produced the Declaration of Helsinki that supported similar international rules and systems and provided special consideration for the populations of developing countries. That code has been modified and strengthened a number of times.**

## A. Nature of Science

**Science can be thought of as the system of reasoning and communication that has, from the beginning provided our species with increasing control over its environment. Science is derived from the practical knowledge of craftsmanship that has been transferred within and between generations from prehistory. In the last 400 years scientific knowledge has distinguished itself by being observation-driven, cumulative and always tentative. Even its most hallowed theories remain in thrall to the next set of experiments for confirmation or denial. In the past hundred years, the sophistication of experiment and analysis has grown astonishingly deep so that only relatively small numbers of experts really understand the bases for far-reaching explanations of nature including cosmology, quantum mechanics, molecular structure, cellular systems and evolution. We benefit by that sophistication in every electronic gadget we employ, in every recombinant molecule with which we are treated, in new structural materials for medicine and everyday life, in improved weather prediction capacity, and in more efficient and pleasant housing and environs. We know that science works because technology works. We know that evolution is true because of its great explanatory power in all biological fields.**

**The general public remains puzzled by the conditional reasoning and probabilistic thinking that underlie the power of science. Nevertheless, research studies have come underlie legislation, nutritional recommendations environmental assessments and understanding of diesease. To the extent that studies are done scientifically and marketed honestly, they contribute greatly to the general lawfulness and openness to change that characterizes Western Society. Societal dependence on science conveys on scientists a great ethical responsibility to conduct research with integrity. Improving research integrity was the charge of a NAS commission and the following paraphrases parts of the report ( ).**

**A. <u>Research Integrity</u>**

**Research integrity may be defined as active adherence to the ethical principles and professional standards essential for the responsible practice of research.**

**By active adherence we mean adoption of the principles and practices as a personal credo, not simply accepting them as impositions by rulemakers.**

**By ethical principles we mean honesty, the golden rule, trustworthiness, and high regard for the scientific record.**

> **NAS report definition: "For individuals research integrity is an aspect of moral character and experience. It involves above all a commitment to intellectual honesty and personal responsibility for ones actions and to a range of practices that characterize responsible research conduct." These practices include:**
>
> > **"1. Honesty and fairness in proposing, performing, and reporting research;**
> > **2. Accuracy and fairness in representing contributions to research proposals and reports;**
> > **3. Proficiency and fairness in peer review;**
> > **4. Collegiality in scientific interactions, communications and sharing of resources;**
> > **5. Disclosure of conflicts of interest;**
> > **6. Protection of human subjects in the conduct of research;**
> > **7. Humane care of animals in the conduct of research;**
> > **8. Adherence to the mutual responsibilities of mentors and trainees."**

**While science encourages (no, requires) vigorous defense of one's ideas and work, ultimately research integrity means examining the data with objectivity and being guided by the results rather than by preconceived notions.**

**We will return to the importance of preserving the integrity of the scientific record in the section on misconduct.**

## B. Professionalism in Science

**Professionalism in science denotes a pattern of behavior identified with scientific integrity that, in turn provides certain privileges. Like other professionals, scientists are expected to behave with intellectual honesty and excellence in thinking and doing. In many respects they perform their professional activities as a monopoly, licensed by society similar to doctors, nurses, lawyers, hairdressers, accountants, and real estate brokers. Besides providing their expertise, professionals are supposed to behave collegially and teach the skills to others, and put society's needs first in their professional activity. In response, society gives them a great deal of autonomy in conducting their professional lives. With scientists, that means selection of one's own research problems and methods of procedure. They also are given the responsibilities to allocate funding, and review of their output in publications. Like other professions they are given responsibility for discipline in the event of poor performance or malfeasance. When self-regulation fails to sustain honesty and high quality, society imposes rules and laws to maintain its interests in professional quality.**

**Table: Elements of Professionalism**

| |
|---|
| **Intellectual honesty**<br>**Excellence in thinking and doing**<br>**Collegiality and openness**<br>**Autonomy and responsibility**<br>**Self-regulation** |
| |

## C. Practical Elements of Responsible Research Conduct

**1) Conducting and reporting research**
- **Role of the hypothesis**
- **Critical nature of experimental design**
- **The tentativeness of conclusions**
- **Skepticism and humility tempered with conviction**
- **Dealing with surprises - serendipity**
- **Communicating with colleagues**
- **Communicating with the community- media**

**2) Social responsibility of scientists**

**Is it appropriate to consider the broader consequences of the pursuit of a scientific question?**
**"I just make discoveries about nature, others use my discoveries for better or worse (nuclear energy, synthesis of viruses, very toxic compounds)."**

**"I must consider the predictable consequences of my research and decide in advance if I will create serious ethical problems as a result of its outcomes."**

**"It matters not that others might discover what I avoid seeking because of its consequences. I do not have to contribute to the misfortune of humanity in my research."**

**"The true consequences of a research effort are impossible to predict and it is the height of arrogance not to pursue a promising avenue of science just because of qualms about its misuse."**

**"How do I design and interpret my work not to bias the conclusions?"**

**"Do scientists have the responsibility to make every effort to enter their work into the scientific record whether it is positive or negative?"**

**3) Collegiality, sharing**

**This aspect of professional behavior has always been a core value of science. There is an NIH policy on sharing reagents, databases and transgenic animals. Materials Transfer Agreements (MTAs) routinely monitor the transfer of resources between labs and between institutions. On the other hand, science is so competitive that sharing may reduce credit to the lab and diminish the scientific achievement associated with the effort of the trainees in the lab, two of the major signs of research success. How to balance the two mandates is a serious challenge.**

**Patent and licensure are highly desired by research institutions and accrue benefit to investigators as well. They may require secrecy in research and sometimes result in closed laboratories where the trainees cannot discuss their work. This is incompatible with collegiality and sharing.**

**A major element of scientific integrity is the proper assignment of credit for past work of others and current work within the research group. Scrupulous adherence to this practice will help greatly but not eliminate dissatisfaction. Is there a process to ensure understanding and appropriate assignment of authorship and credit?**

**4) Mentorship**

**What is the essence of mentorship? Is it taking on a fiduciary responsibility for the trainee and putting her needs first? That too is one of the practices of research integrity. Questions arise such as, Is it appropriate for a PI to refuse to mentor the trainees in the lab? Is one mentor enough for a trainee or are they better off looking at least for a professional mentor and a research mentor? What are the responsibilities of mentors toward trainees? What are**

**the characteristics of good mentors? What are the responsibilities of trainees toward mentors?**

**5) Reviewing and monitoring research**

**This includes reviewing grants and research reports and serving on Data and Safety Monitoring Boards, Research Ethics Committees (IRBs) and other research oversight committees.**
**In all of these functions the individual involved must:**

- **Provide an objective review**
- **Maintain confidentiality**
- **Avoid conflicts of interest by recusal when appropriate**
- **Avoid taking advantage of inside information**
- **Maintain integrity of the scientific record**

**6) Conflicts of interest and commitment**

**Who is the scientist working for?**
**Definition of a conflict of interest – it's the situation**
**Managing conflicts of interest**

- **Disclosure**
- **Limited financial involvement**
- **Transactional transparency**
- **Oversight – monitoring, auditing,**

**7) Scientific Malfeasance and Misconduct**

**Fabrication Falsification and Plagiarism – definitions and distinction from error**

- **Impact on the research record**
- **Risk of litigation**
- **Whistleblowing**
- **Mandated institutional responses**
- **Bad research manners- interpersonal relations – exploitation of subordinates, exploitation of inside knowledge,**

## CASES Chapter 1

# Immunology Graduate Student, Dubious Data

**Darlene Campion, a PhD candidate in immunology gave her regular presentation of research progress when her PI said that her data looked great and that she should put together an abstract for the spring meeting with herself as first author. After the session Darlene basked in the pleasure of her success. However, nagging doubts about the solidity of her data resurfaced after the next set of experiments. She wanted to do more experiments but the abstract deadline was now only two weeks**

**away and she knew that she would not be able to complete further experiments before the deadline. She went to her PI Gabriella Corral.**

**"Darlene, she was told, you need to go out on a limb a little to be recognized. After all, the system runs on getting credit for doing something first and the innovation can provide recognition for years. Let's put in the abstract and you can keep doing experiments until the meeting. In fact, by then you might have the paper written and submitted. This is a very competitive world, so compete girl, compete!"**

**Darlene, still dubious, sends in the abstract and redoubles her efforts to provide a solid base of experimental evidence to support the novel hypothesis. Meanwhile Dr. Corral heard from the Immunology society that the abstract was selected for a plenary presentation as one of the most significant developments of the year. Elated, she relates the honor to Darlene. Rather than the expected elation, Darlene turns very pale.**

**"As I said before, she states, the data don't seem to be so great to me and I have not been able to substantiate the results."**

**"Well, you still have a little time but if you get no further, we will just present the original material in the abstract," says Dr. Corral.**

**Darlene hurriedly left the room.**

**Questions:**

1. **Is there any questionable behavior here?**
2. **Elaborate on the underlying theme in research ethics?**
3. **What are the options for each of the players if the data remain the same?**

# Case: Transhumans

**It's a short time in the future, say 2020. You have been studying brain processing in hopes of enhancing the cognitive capacities of patients with Alzheimer's disease and those who are mentally retarded. You have just discovered a way of increasing the brain's memory capacity by 100% and it's processing speed two fold using the daily administration of 2 pills. You are overjoyed except for the fact that you know what happened when lesser improvements in cognitive function were introduced early in the 21st century. People started taking them to improve memory even though there was no evidence that they worked in normal persons. It was a reminder of what happened with steroids and growth hormone on physical performance in the 20th century. They became essential for every truly competitive athlete.**

**Your finding is so central to thought that those taking the drug will thoroughly outstrip everyone else that we might consider them to be transhuman. As you think about your discovery, you can visualize a situation in which the transhumans begin to take over the resources of the earth, and ultimately have no use for the "plain humans" they supplanted.**

**Questions:**

1) **What do you think as a scientist of this potential state of affairs?**
2) **Do you have any responsibility as a scientist to consider the consequences of your work when you think of what to do with your findings?**
3) **Science as a discipline deals with major technological developments including:**
    a. **Nuclear power and bombs**
    b. **Recombinant DNA technology**

c. **Totipotential embryonic stem cells**
d. **Reproductive technologies using genetic manipulation**
e. **The Internet**

**Is it appropriate to allow the political process to determine who will make the critical decisions about the use of scientific advances?**

# Case: The Real Thing

**Eckhard and Wimmer demonstrated the complete synthesis from oligonucleotides of the cDNA of poliovirus, from which infectious virus could be produced. They published these results in Science. Cello et al demonstrated that the production of the active virus could be carried out from scratch – one could say that a form of life was created. This received a lot of press play.**

**There was considerable criticism of both the authors and Science for publishing material that might be of use to terrorists. A number of congresspersons filed a resolution criticizing the publication. Although, in this case the virus is tiny and available, the method expensive and unwieldy, and the infectiousness quite limited, there is no doubt that by appropriate genetic manipulation, with enough money, agents like smallpox and anthrax could be produced by scientists and their results published.**

**Scientists have social as well as individual responsibilities.**

**Questions: 1. How can we handle the inevitably increasing capacity to create dangerous life forms?**

**As individual scientists?**

**As a society?**

**As an international scientific community?**

# Case: Sloppy Lab work

**Background: During the first year of graduate school, Tom has been taking courses and doing laboratory rotations. While in Professor Allen's laboratory, Tom makes several exciting observations. Professor Allen tells Tom that the results will be publishable in a major journal.**

**Part 1: When Professor Allen goes to write the manuscript a month later, she finds that Tom did not record in his notebook the incubation medium and times for one group of experiments. Also, the computer files where Tom thinks he saved the information were accidentally erased.**

**Questions:**

**1. Can Professor Allen still write the paper?**
**2. Would it make a difference if Tom said he could remember the details even though he didn't write them down?**
**3. Would it make a difference if a technician working on the project said that he remembered even though Tom could not?**

**Part 2: Professor Allen writes the paper, which is accepted for publication. Tom finishes his first year and returns to Professor Allen's laboratory. He begins where he left off, but in two attempts he cannot repeat the original finding.**

**Questions:**

**1. What should he and Professor Allen do about the paper assuming it has not yet been published?**

**2. What should they do if the paper has been published?**

**Part 3: Professor Allen receives a manuscript to review that contains experiments whose results make clear why Tom has been unable to make further progress with his experiments.**

**Questions:**

**1. Can Professor Alan share this information with Tom?**
**2. What if the information was contained in a grant proposal?**

**Derived from Fred Grinnel**

# Case: Research Integrity

**Jones is a highly successful entrepreneurial academic scientist. He occupies an endowed chair that allows him to avoid teaching. His research team performs brilliantly conceived studies with precision and completeness. His lab has made many important contributions and he is consistently very well funded.**

**A graduate student is considering Jones' lab for his Ph.D. and speaks to the current trainees. They say that Jones is merciless, requiring 15-hour days for months before the annual meeting abstract due date. He assigns projects without regard to the trainee's interests, has trainees compete with each other, unilaterally determines authorship and first authorship in what appears to be an arbitrary manner and deals with staff and trainees in a paternalistic and demeaning manner. He personally spends little time with his trainees and shows little interest in their lives. His usual comment is that research is extremely competitive and they had better learn how to fend for themselves. His trainees almost invariably get excellent positions after completing their degrees with him.**

**QUESTIONS:**

**1. Does the investigator have research integrity? Intellectual honesty? Defend your answer.**

**2. If you were the student, would you select his lab? Defend your answer.**

**3. The department chair and dean know all about this lab chief's behavior and have never discussed it with him. What responsibilities does the administration have in relation to Jones' behavior? Defend your answer.**

## Case: Sharing in the Laboratory Setting

**Al Glantz has recently completed a successful thesis defense and is planning for his move across the country to his new laboratory. He arranged a meeting with his mentor and lab chief, Calvin Jones.**

**Al: I'm really grateful for your support over these five years. I learned a great deal. The lab environment was terrific and your recommendation, I'm sure, was instrumental in my obtaining such a promising post-doctorial fellowship.**

**Prof. Jones: Well, you're one of my best trainees ever and I'm proud of your accomplishments and have great expectations for you as a scientist.**

**Al: That's great. I thought that this would be a good time to review some housekeeping details so that I can use my remaining time in the lab most productively.**

**Prof. Jones: That's a great idea. What do you have in mind?**

**Al: Well, I need to write a new investigator proposal to the NIH and I want to continue the work I've been doing here. I have some new ideas to pursue. In order to do that, I would like to utilize all our unpublished results as background and preliminary results for the fellowship application and get a letter from you supporting me and indicating that I will have access to all the DNA probes and monoclonal antibodies I prepared for our projects here. Then I'll really be able to get a good start. I want to start on the grant right away. When I get that done, I will get back to completing the papers describing our most recent results.**

**Prof. Jones: I'm glad we had this chance to get together on this, because we must make plans for your last three months. I would be happy to write you a good letter with regard to your grant proposal. You have a right to describe anything you personally did as preliminary work but you must not use other unpublished results from the laboratory unless they are accepted for publication and you are a co-author.**

**If I were you, I would write up the papers first because as you know, the data belongs to the lab and when you're gone, if the papers aren't submitted, I'll ask Fred to write them up and he'll be first author.**

**You will be able to take the monoclonals, cell lines and C-DNA probes that we send out but you will not be able to take any irreplaceable materials. Finally, you are going to a competing lab that shares materials poorly, so your ability to receive material from us will depend on reciprocity. We have others here whose careers need to be built, you know.**

**Questions:**

1. **Was Prof. Jones being unfair?**
2. **Was Al expecting too much?**
3. **Was Jones statement consistent with NIH rules on sharing?**
4. **Who owns the data?**

## Case: Genetics of Psychopathic Behavior

**Dr. Brain discovered that a combination of 3 genetic polymorphisms was present in 86% of people who were criminally psychopathic. This combination of traits was present in 6% of the general population. Utilizing PET scanning, he discovered responses to specific scenarios that correlated very highly with criminal behavior. When the data were published, the investigators surmised that the 3 polymorphisms participated in brain development and when they were fully expressed they altered brain structure and function so that distinction of right from wrong was impossible. They thought that the combination of genetic testing and PET to elucidate the expression pattern attributable to the genes might make it possible to determine in advance the chance of recidivism in convicted criminals, that is to predict criminal behavior.**

**Shortly after publication Dr. Brain and team began to receive requests from prosecutors and defense attorneys to work up their clients to prove that they did or did not have the career criminal trait. Judges requested an evaluation before sentencing and parole boards also expressed interest.**

**Faced with fixed budgets, child services organizations wanted to screen troubled youths for the recidivist tendency so they could spend less money on these "incorrigibles" and focus their attention on those they might be able to help.**

**Questions:**

1. **Is there a problem with the research?**
2. **Is there a problem with the reporting of the research?**
3. **The societal responses to the research could have been anticipated. What implications did that have for Dr. Brain and his team?**
4. **What should Dr. Brain do now?**
5. **If there were a medication that could reverse the impetus toward antisocial behavior, would that change the answers to any of these questions?**

**"The use of flawed or incomplete science, and the reliance on scientific predictions beyond what the science is prepared to support, are exactly the kinds of concerns that should be foremost in the public mind when contemplating the potential social impact of predictive technologies or techniques. It is not just in courtrooms that prediction would have an impact, but also in schools, employment, healthcare systems, government investigations, and in other ways that would dwarf usage by the court system. The potential to pigeonhole, to discriminate, and to judge on the basis of test results could result in substantially negative consequences, including the development of a "neuroscientific underclass" denied access to education and other societal benefits on the basis of their neuroscience test results. These concerns parallel the current dialogue around genetics, and some feel the public dialogue around genetics may illuminate some of the promises and pitfalls that could accompany and greater understanding of the brain.**

**Though a host of possible predications might be desirable (e.g. tendency to be honest, willingness to follow authority, etc.), the potential for violence is of particular interest and significance. Prediction of violence has already been the subject of neuroscience research, and it will probably continue to interest science as well as the legal system. It is a predictive measure likely both to have tremendous utility and to carry great risk of misuse; and it is likely to cut both ways in criminal law – in mitigation and in marking someone as being predisposed to violence. While violent behavior will probably never be predicted with complete certainty, the likelihood that techniques will be developed**

**to distinguish those more likely or even very likely to react with violence seems quite enough that those techniques be considered for future research and public discussion."**

**("Neuroscience and the Law," Professional Ethics Report. 2004: 17, p.2)**

# BIBLIOGRAPHY – Chapter 1


Alpert, J. S., K. I. Shine, et al. (2004). "Task Force 1: The ACCF and AHA codes of conduct in human subjects research." Journal of the American College of Cardiology **44**(8): 1724.

A set of guidelines for cardiologist-investigators regarding clinical research.

.Annas, G. J. (2005). "Family Privacy and Death -- Antigone, War, and Medical Research." N Engl J Med 352(5): 501-505.

The article examines the issue of family privacy and death through three distinct cases -- the ban on filming of US casualties in war, Vincent Foster's suicide photos, and Iceland's Health Sector Database. It is applicable to investigators in that it highlights the importance of patient privacy after death. The deceased patient's family rather than the investigator has the right of disclosure if the patient participated in a medical study; this fact makes consent forms and other pre-experiment contracts especially important for research participants.
http://content.nejm.org/cgi/content/extract/352/5/501

Bates, B. R., J. A. Lynch, et al. (2005). "Warranted Concerns, Warranted Outlooks: A Focus Group Study Of Public Understandings Of Genetic Research." Social Science & Medicine **60**(2): 331.

This paper does focus groups on public attitudes toward genetic research and its clinical consequences. It concludes that the public has a reasonable understanding of these in its own terms.
http://www.sciencedirect.com/science/article/B6VBF-4CSYKDG-2/2/5fe206aeb8afd9dcff74ae19fec7ee9f

Beckwith, J. (2001). "On the Social Responsibility of Scientists." Ann Ist Super Sanita. 37(2):189-94

The author deals with the social responsibility of genetic researchers using the discredited eugenics movement in the early 20th century as the model to show that destructive results can be due to scientific developments. Few geneticists are fully aware of the eugenics movement, which led to labeling some humans as genetically inferior. Many geneticists became proponents of eugenics between 1906 and 1915 (scholarly articles and textbook influences). This paper reviews the horrific history and allows us to project the future. It also goes into the ELSI process in the human genome project and the failures of communication between scientists and those involved in the humanities.

Beecher, H. K. (1966). "Ethics and clinical research." Bulletin of the World Health Organization 79(4): 367-72.

This is one of the classics in the field of RCRH in that it points a finger at the unethical aspects of research as carried out at the time.

Benditt, J., et al. (1995). "Conduct in science." Science 268(5218): 1705-18.

This is the introduction to a number of papers on the culture of science and the methods for teaching responsible conduct of research. The whole sequence should be required reading of teachers of RCR.

Berry, R. S. (2003). "Validity and Ethics in Science." Science 300(5624): 1341-.

The author indicates that in science there are experiments and concepts that can be shown to be wrong by further research and experiments and concepts that are fraudulent, and known by their authors to

be so from the beginning. In dealing with misconduct, science is proposed to distinguish between the two poorly, and that is unsatisfactory.
http://www.sciencemag.org/cgi/content/summary/300/5624/1341

Bird, S. J. (1998). "The Role of Professional Societies: Codes of Conduct and Their Enforcement." Sci Eng Ethics 4(3): 315-320.

In discussions of professional standards and ethical values it is reasonable to consider who will develop the codes of conduct and guidelines for behavior that will reflect the standards and values of the community. Also worthy of consideration is whether the standards or guidelines are enforceable, and how and to what extent they will be enforced. The development of guidelines or professional codes of conduct is a responsibility that has been adopted by many professional societies. Useful to this discussion is an examination of the rationale behind the development of ethical codes by professional societies. The Ethics in Science Committee of the Council of Scientific Society Presidents (CSSP) has examined the codes of some of its member societies and some observations regarding them are pertinent. The nature and uses of ethical statements, codes and guidelines developed by professional societies are multiple and diverse. Their enforcement raises both practical and ethical concerns.

Block, S. (2002). "A Not-So-Cheap Stunt." Science 297(5582): 769-70.

This brief paper describes the de novo synthesis of the polio virus, an exercise in the creation of life from precursors. The article generated considerable concern as a potential blueprint for terrorists and raised questions about the social responsibility of scientists regarding publishing material that could be misused in that way.
http://www.sciencemag.org/cgi/content/full/297/5582/769b

Bloom, F. (1995). "Scientific conduct: contrasts on a gray scale." Science 268(5218): 1679.

Intense competition for funding and commercial influences on science have made it more difficult for scientists to live up to ethical standards. This is especially true when subtle ethical choices are involved such as deciding whose name will be listed first on a research report.

Blumenthal, D., E. G. Campbell, et al. (1997). "Withholding research results in academic life science. Evidence from a national survey of faculty." JAMA 277(15): 1224-1228.

This empirical study of scientists' behavior and the consequences for the progress of science focuses attention on secrecy as a mechanism of enhancing a laboratory's relative position and its consequences for society as a whole. A good study.

Bramstedt, K. and K. Kassimatis (2004). "A study of warning letters issued to institutional review boards by the United States Food and Drug Administration." Clin Invest Med 27(6): 316-23.

The author analyzed FDA warning letters to IRBs and found that the most common cause of a letter was failure to follow written procedures as to monitoring research after it was initiated.

Brody, J., D. Scherer, et al. (2003). "Voluntary assent in biomedical research with adolescents: a comparison of parent and adolescent views." Ethics and Behavior **13**(1): 79-95.

This study tests the relationship between perception of risk/aversion between adolescents with asthma and their parents in relation to an asthma protocol set to test agreement. There was about 75% concordance between the two and each felt that they were in control.

Brown, S. K., M. (1998). "Effects of Training in the Responsible Conduct of Research: A Survey of Graduate Students in Experimental Sciences." Sci Eng Ethics 4(4): 487-498.

Do all these courses have an impact? And what is it? Tune in and see.

Campbell, E. G., B. R. Clarridge, et al. (2002). "Data Withholding in Academic Genetics: Evidence From a National Survey." JAMA 287(4): 473-480.

The free and open sharing of information, data, and materials regarding published research is vital to the replication of published results, the efficient advancement of science, and the education of students. Yet in daily practice, the ideal of free sharing is often breached. The authors mailed a survey to geneticists and other life scientists in the 100 US universities that received the most funding from the National

Institutes of Health in 1998 with a response rate of 64%. They compared 1240 geneticists with 600 self-identified nongeneticists. There was substantial withholding of data even after publication and loss of scientific efficiency. Those who withheld had various reasons including further need to publish from the data and lack of resources to comply with requests. This illustrates the weakness of collegiality as a value in certain areas of modern science.
http://jama.ama-assn.org/cgi/content/full/287/4/473

Caplan, A. (2003). "Is Biomedical Research Too Dangerous to Pursue?" Science 303: 1142.
After the problems, often serious associated with biomedical research, the author concludes that it is worthwhile after all. Whew! The arguments in this brief paper are worth a read.
http://www.sciencemag.org/cgi/content/full/303/5661/1142

Chalmers, D. P., P. (1998). "Towards a Consensual Culture in the Ethical Review of Research." Medical Journal of Australia 168(2): 79-82.
The authors point out that research rules commonly follow some kind of ethical crisis and that this may not be the best way to develop and maintain regulations. They suggest an alternative method derived from the notion of consent of the governed. They also deplore the propensity of review organizations to increase the standards and therefore continually make it harder for investigators. As Australians they use Australia as the example.

Chen, D. and B. Worrall (2006). "Practice-based clinical research and ethical decision making--Part I: deciding whether to incorporate practice-based research into your clinical practice." Semin Neurol **26**(1): 131-39.
This paper reviews for neurologist practitioners what clinical research is and the pros and cons of incorporating research into their practices. It also points out, with the expansion of clinical research, that they might have to advise their patients about research participation even if they don't do research themselves.
http://www.thieme-connect.com/DOI/DOI?10.1055/s-2006-933317

Chen, D. and B. Worrall (2006). "Practice-based clinical research and ethical decision making--Part II: deciding whether to host a particular research study in your practice." Semin Neurol **26**(1): 140-7.
The second component of the previous article.

Cohen, J. (1995). "Share and Share Alike Isn't Always the Rule in Science." Science 268(5218): 1715-8.
This is a component of a series of articles on sharing in science, generally asking whether the hallowed principle of collegiality has lost its force and left us in a dog-eat-dog scientific world.

Cohen, J. (1995). "The culture of credit." Science 268(5218): 1706-11.
Scientific ideals call for collaboration and sharing. But in today's competitive scientific enterprise, a tremendous premium is placed on individual credit, setting the stage for conflict.

Cottingham, K. (2001). "University-Industry Collaborations: Whose Data?" Science 11(27).
This ethics case discussion relates to a PhD candidate who participated in a clinical trial as part of her research and found that she could not publish the data as part of her thesis. Because the results were not favorable, she was forbidden to use the data. Three “experts” discussed the scenario.

Cournand, A. (1977). "The Code of the Scientist and Its Relationship to Ethics." Science 198(4318): 699-705.
Scientist's norms (principally honesty, objectivity, tolerance, doubt of certitude, and unselfish engagement) are in danger of serious distortion unless broadened to apply to the relations between scientists and nonscientists. Also needing supplementation is an ethic of development appropriate to a fast-changing society and advanced as an approach to the more effective and humane regulation of cultural and technological development. Taken together, furthermore, they indicate the possibility of a humane world order based on the cooperation of a community of scientists and its public. See the date. This nobelist visualized a world that hasn’t arrived and may never arrive, considering what humans are. This is a classic.

Couzin, J. (2002). "BIOTERRORISM: A Call for Restraint on Biological Data." Science 297(5582): 749-751.

This response to the increasing power of biological sciences suggests that information that might be of use to terrorists not be published in usable form. Others argued that the development of counter weapons depends on knowing what can be done. Needless to say, journals are watching what they print.

Curfman, G. D. and J. M. Drazen (2001). "Too Close to Call." N Engl J Med 345(11): 832.

In response to criticism, the NEJM developed a new process for editorial review of papers derived from their own editorial board.
http://content.nejm.org/cgi/content/extract/345/11/832

Davidoff, F. (2001). "Sponsorship, Authorship, and Accountability." N Engl J Med 345(11): 825-7.
Davidoff, F., C. D. DeAngelis, et al. (2001). "Sponsorship, Authorship, and Accountability." Ann Intern Med 135(6): 463-466.

This article, which was published simultaneously in the agreeing journals began the process of improving the status of articles derived from clinical trials sponsored by pharmaceutical companies by making the listed authors understand they are accountable for the contents and should see the underlying data and actually write the paper. Changes in journal review practices as well as entering clinical trials at the beginning in a database as a criterion for publishability are all derived from the meeting of publishers that led to this paper.
http://jama.ama-assn.org/cgi/content/full/286/10/1232

Davis, L. L., M. S. Little, et al. (1997). "The Art and Angst of the Mentoring Relationship." Acad. Psychiatry 21(2): 61-71.

The authors review the ancient mentoring relationship in Homer's Odyssey and the mentoring discourse of Socrates. These relationships illustrate the art of inspiring a searching quality in the subject and the angst of the struggle that accompanies perplexity and unknowing. The developmental stages of the mentor and resident in psychiatric training are reviewed. A number of teaching interventions are discussed as they might be perceived by the student. Finally, Plato's "Allegory of the Cave" is used as a metaphor for the art of enlightenment and angst of learning and teaching in the mentoring relationship.

Dickenson, D. and J. Ferguson (2005). “Advisory Document for Retained Organs Commission.” University of Birmingham, UK: Centre for Global Ethics.

This document addresses the burning issue of retained organs and the rights of donors. They suggest a modified property rights approach to regulation of the practice.
http://www.globalethics.bham.ac.uk/consultancy/Retained_organs.htm

Easterbrook, G. (1997). "SCIENTIFIC COMMUNITY: Science and God: A Warming Trend?" Science 277(5328): 890-893.

This is a thoughtful discussion of the relationships or the lack thereof between religion and science. Both approaches to the world seek truth in different ways and both exert great power. The question is whether they can be reconciled. Lots of ideas are presented in a vigorous format.

Eastwood, S. D., P; Leash, E; Odrway, S. (1996). "Ethical Issues in Biomedical Research: Perception and Practices of Postdoctoral Research Fellows Responding to a Survey." Sci Eng Ethics 2(1): 89-114.

This empirical study surveyed 1005 trainees and got 1/3 to respond. Their ethics were not very strong and it didn’t matter whether they had taken training in research ethics during their training. This is well worth reading.

Emanuel, E. J., D. Wendler, et al. (2000). "What Makes Clinical Research Ethical?" JAMA 283(20): 2701-2711.

The authors point out that just getting informed consent does not make clinical research ethical. They propose 7 requirements for ethical clinical studies: “(1) value--enhancements of health or knowledge must be derived from the research; (2) scientific validity--the research must be methodologically rigorous; (3) fair subject selection--scientific objectives, not vulnerability or privilege, and the potential for and distribution of risks and benefits, should determine communities selected as study sites and the inclusion

criteria for individual subjects; (4) favorable risk-benefit ratio--within the context of standard clinical practice and the research protocol, risks must be minimized, potential benefits enhanced, and the potential benefits to individuals and knowledge gained for society must outweigh the risks; (5) independent review--unaffiliated individuals must review the research and approve, amend, or terminate it; (6) informed consent--individuals should be informed about the research and provide their voluntary consent; and (7) respect for enrolled subjects--subjects should have their privacy protected, the opportunity to withdraw, and their well-being monitored." They claim that fulfilling all 7 is necessary and sufficient to make clinical research ethical. While studies must be adapted to the environment in which they are conducted, the 7 standards are broad enough to encompass them all. The latter may be questionable but the paper has become an instant classic and clinical research proposals are being evaluated on the basis of the seven points. A must read.
http://jama.ama-assn.org/cgi/content/full/283/20/2701

Endocrine Society. (2005). Ethical Guidelines for Research, found on their web site.

An important guide for understanding the basic requirements of publication in an accredited journal. Also a good source for authors looking for a guide to complying with standards of publication.
www.endocrinesocietyy.org

Evans, M., M. Robling, et al. (2002). "It Doesn't Cost Anything Just To Ask, Does It? The Ethics Of Questionnaire-Based Research." J Med Ethics **28**(1): 41-44.

This paper presents an analysis of potential psychological forms associated with questionnaire research, using as the example a study of attitudes toward breast disease in English women. They point out the possibility of harm both to researchers and to the practicing physicians cooperating in the study.
http://jme.bmjjournals.com/cgi/content/full/28/1/41

Faigman, D. L. (2002). "SCIENCE AND THE LAW: Is Science Different for Lawyers?" Science 297(5580): 339-340.

The author argues that the law is suspicious of the scientific method as a source of expertise. One of the reasons is that in contentious cases the science may not be there, but there is also the underlying theme that probabilistic thinking is difficult for the law. They discuss criteria for credibility of scientific information.

Ferber, D. (2004). "Occupational health. Beset by lawsuits, IBM blocks a study that used its data." Science 304(5673): 937-9.

This article deals with internal IBM data that might show an increased mortality rate in certain IBM work categories. The data were not part of a systematic study and, as they were the subject of numerous torts, they refused to allow the data to be utilized and promised a new, proper study.

Fine, M. K., L. (1993). "Reflections on Determining Authorship Credit and Authorship Order on Faculty-Student Collaborations." American Psychologist 48(11): 1141-1147.

This think piece focusing on psychology, reviews various kinds of trainee-faculty relationships in performing and reporting research. They indicate that beneficence, justice and paternalism should apply in making the decisions.

Flanagin, A., P. B. Fontanarosa, et al. (2002). "Authorship for Research Groups." JAMA 288(24): 3166-3168.

This editorial tries to adopt fair policies for the listing of authors in large multicenter clinical trials. They recognize that it's a tricky matter both to determine who meets authorship criteria and to properly credit those who are not lead authors.
http://jama.ama-assn.org/cgi/content/full/288/24/3166

Francke, U. (1999). Response to National Bioethics Advisory Commission on the Ethical Issues and Policy Concerns Surrounding Research Using Human Biological Materials. H. T. M. Shapiro, Eric. Meslin.

These authors, officers of the Am. Soc. For Human Genetics comment very negatively on the proposals of the NBAC regarding the use of human biological materials. The most powerful objections are

to the absolute requirement for anonymization and for revisiting donors to get permission to use their materials for new projects. They claim it will bring certain types of science to a halt.

Garland, B. (2004). "Neuroscience and the Law." Professional Ethics Report 17(1).

This reports on a conference that eventually became a book relating primarily to 4 questions. How will ability to predict behavior alter the law? How will scientific lie detection affect testifying witnesses? How could new neurological knowledge affect discrimination? What are the risks and benefits of brain modification for enhancement? These questions address key ethical issues including “free will” and responsibility for behavior.

Goodman, Ellen (2001). Medicine needs more "chumps". Boston Globe. Boston, MA. March 1, 2001.

In her way she points out that those who did not benefit financially from their discoveries were, perhaps, better off and more respected than those who struggle to make the last entrepreneurial dollar from their scientific achievements.

Goodwin, F. M., A. (1999). "Scientists in Bunkers: How Appeasement of "Animal Rights" Acitivism Has Failed." The Dana Forum on Brain Science 1(2): 50-62.

These investigators argue that appeasing animal rights activists only encourages them to demand more and more. They will never be satisfied. The suggestion is pushing back.

Gray, M. L. and J. V. Bonventre (2002). "Training PhD researchers to translate science to clinical medicine: Closing the gap from the other side." Nat Med 8(5): 433.

The authors suggest that training basic scientists to have a more practical bent and become interested in translational medicine will more discoveries to the pharmacopiea

Grinnell, F. (1999). "Ambiguity, trust, and the responsible conduct of research." Sci Eng Ethics 5(2): 205-14.

Ambiguity associated with everyday practice of science has made it difficult to reach a consensus on how to define misconduct in science. This essay outlines some of the important ambiguities of practice such as distinguishing data from noise, deciding whether results falsify a hypothesis, and converting research into research publications. The problem of ambiguity is further compounded by the prior intellectual commitments inherent in choosing problems and in dealing with the skepticism of one’s colleagues. To do this responsibly, the underlying theme had to be trust. However, in today’s environment trust had to be earned by being a responsible investigator. This paper raises lots of issues distinguishing the reality of scientific endeavor from the theoretical.

Grunberg, S. M. and W. T. Cefalu (2003). "The Integral Role of Clinical Research in Clinical Care." N Engl J Med 348(14): 1386-1388.

This article analyzes the relationship between clinical care and research in the performance of therapeutic clinical research. They argue that the role of the physician cannot be abrogated during the course of research and that individual subject improvement is the goal. This paper is very well worth reading in the face of contrary arguments indicating that researchers cannot put themselves in the position of clinicians if they are to conduct the research properly.

Gupta, M. (2003). "A Critical Appraisal Of Evidence-Based Medicine: Some Ethical Considerations." Journal of Evaluation in Clinical Practice **9**(2): 111-121.

This paper analyzes the philosophical support for "evidence-based medicine" as the route to better health care, focusing on the intrinsic weaknesses of the data and biases in the research.
http://www.blackwell-synergy.com/doi/abs/10.1046/j.1365-2753.2003.00382.x

Gwynne, P. (1999). "Corporate Collaborations." The Scientist 13(11): 1, 6.

The reporter discusses cases in which a scientist under a confidentiality clause was prevented from reporting on adverse events associated with the research. This occurred under conditions under which the institution did not insist on academic freedom. The importance of writing the right kind of contract with industry was emphasized.

Helmuth, L. (2001). "COGNITIVE NEUROSCIENCE: Moral Reasoning Relies on Emotion." Science 293(5537): 1971a-1972.

This short paper demonstrates that what we consider to be moral reasoning is not fixed in the rational brain but is associated with feeling developed by the manner in which the information is presented to us.

Hensley, S. and L. Abboud (2004). Medical Research Has 'Black Hole.' Negative Results Often Fail to Get Published in Journals; Some blame Drug Industry. Wall St J. New York: B3. June 5, 2004.

This well-written article brings into focus the problems associated with failure to publish negative reports, something that has since gotten a great deal of attention.

Hoeyer, K., L. Dahlager, et al. (2005). "Conflicting notions of research ethics: The mutually challenging traditions of social scientists and medical researchers." Social Science & Medicine **61**(8): 1741.

When anthropologists and sociologists try to study health services in medical institutions, serious problems arise that are proposed in this paper to be due to cultural differences that might be ameliorated by dialogue. Good luck!
http://www.sciencedirect.com/science/article/B6VBF-4G1GFK2-1/2/3b6968c880005504c1256540aafff920

Inouye, S. K. and D. A. Fiellin (2005). "An Evidence-Based Guide to Writing Grant Proposals for Clinical Research." Ann Intern Med 142(4): 274-282.

The competition for research funding is intense. Patient-oriented research lags in support behind that allocated for basic science research. Much of the time that is due to poor experimental design and poor grant-writing, neither of which are taught to M.D.s. This article gives an outline for the grant-writing process for clinical researchers. It focuses on those components of the grant proposal that are most likely to be criticized. They recommend methods to improve the quality of areas commonly cited as deficient. This is a really neat paper for anyone in the early phases of a career who has to write and write in hopes of getting funded.

Institute of Medicine. (2002). Responsible Research: A Systems Approach to Protecting Research Participants.

This book attempts to describe improvements to the entire process of clinical research, emphasizing the protection of vulnerable participants. It makes numerous recommendations to institutions and government to improve the research process and better prepare all the team members for their roles. It should be required reading for those who have institutional responsibility for research.

Kaiser, J. (2005). "SCIENTIFIC PUBLISHING: NIH Wants Public Access to Papers 'As Soon As Possible'." Science 307(5711): 825-.

The NIH has pushed for early online access to research papers and manuscripts in order to increase public awareness and knowledge about science. However, publishers have battled against early release, since giving free access would significantly decrease revenues from scientific journals and reduce funds available to scientific organizations. The article contrasts pressure to make new research studies available with the pressure to produce sufficient revenues to preserve vital scientific organizations. It is significant in addressing both of these issues in an objective way.

Kempner, J., C. S. Perlis, et al. (2005). "ETHICS: Forbidden Knowledge." Science 307(5711): 854-.

A discussion of new social and political constraints placed on certain research subject areas. The article focuses on studies that seek to find out how research limitations affect the performance and opinion of scientists. Although most agreed that social constraints offered important protection for patients, many scientists felt uncomfortable with policy-makers setting limitations on their research. The article addresses the responsibility of investigators to maintain social norms while attempting to produce novel research.

Kennedy, D. (2001). "Editorial: "Accepted Community Standards"." Science 291(5505): 789.

This editorial deals with the concept that readership should have access to all the materials necessary to replicate a paper should they be skilled enough to do it. However, as science has become more proprietary and complex there has been movement away from this standard. He reiterates the standard and discusses exceptions.

Kennedy, D. (2003). "Multiple Authors, Multiple Problems." Science 301(5634): 733.
The author of this editorial deals with the problem of identifying the person among many authors who was responsible for problems in a paper and with the problem of promotion committees deciding whether an author made a critical contribution or otherwise. He suggests that authors be asked to identify their role in each paper.

Korenman, S. G., R. Berk, et al. (1998). "Evaluation of the Research Norms of Scientists and Administrators Responsible for Academic Research Integrity." JAMA 279(1): 41-47.
This study used a sophisticated scenario matrix method with 12 scenarios in four domains of research ethics to examine the professional norms of basic molecular and cellular biologists and institutional representatives to whom the were responsible. There was a 69% response rate. The investigators found that both groups expressed a high degree of research integrity and there was a hierarchy of research malfeasance with fabrication and plagiarism on the top. While scientists and institutional representatives expressed similar normative values, they differed significantly in their approaches to an unethical act.

Leshner, A. I. (2005). "Where Science Meets Society." Science 307(5711): 815-.
This article examines the clash between social/moral value-systems and advances in research. It attempts to examine ethical boundaries to scientific research within the framework of modern society; however, the article does not make a decisive conclusion on the value of ethical limitations on research.

Madsen, S. M., M. R. Mirza, et al. (2002). "Attitudes Towards Clinical Research Amongst Participants And Nonparticipants." Journal of Internal Medicine **251**(2): 156-168.
This Danish study showed that subjects and potential subjects have a positive attitude toward research. Those entering studies do it for both personal and altruistic reasons and those who refuse to participate were concerned about the unknown and about randomization.
http://www.blackwell-synergy.com/doi/abs/10.1046/j.1365-2796.2002.00949.x

Marshall, E. (2002). "DATA SHARING: Clear-Cut Publication Rules Prove Elusive." Science 295(5560): 1625.
This comments on problems associated with producing a uniform code on the ethics of publishing as discovered at a meeting for that purpose. Again it was associated with the issues surrounding data sharing.

May, R. M. (2001). "Science and Society." Science 292(5519): 1021.
He discusses a number of ways in which society is puzzled and disappointed by science, especially since science usually has many voices with different agendas in issues of interest to the public. An example is how to handle bovine spongioform encephalopathy in England.

Merton, R. (1942). "A note on Science and Democracy." J Legal and Political Sociol 1: 115-126.
This little classic laid out the underlying responsibilities of scientists, to seek the truth with objectivity, to share, and to self-govern.

Michels, R. (1999). "Are Research Ethics Bad for Our Mental Health?" N Engl J Med 340(18): 1427-1430.
The author argues that many important mental health studies cannot be done because of the rules requiring informed consent. He points out the importance of studying the most serious psychiatric illnesses and the difficulty getting approval for the research. This continues to be a minority viewpoint.

Miller, F. G. and D. L. Rosenstein (2003). "The Therapeutic Orientation to Clinical Trials." N Engl J Med 348(14): 1383-1386.
Considers the ethical differences between clinical care and clinical research and argues that they should be more separated. Discusses in relation to the “Therapeutic misconception.” Excellent Bibliography.

Miller, F. G., D. L. Rosenstein, et al. (1998). "Professional Integrity in Clinical Research." JAMA 280(16): 1449-1454.

This excellent paper considers the dilemmas inherent in the physician carrying out clinical research. Although it notes the importance of regulation it focuses on the role of professional integrity in both halves of the clinical investigator role. They perform a critical examination of the moral identity of physicians as practitioners and as scientists and points out that they are indeed different. They show that you can't give up your responsibility as a physician completely when you carry out research. Nicely done arguments.

Miller, F. G. (2002). "Ethical Significance of Ethics-Related Empirical Research." J Natl Cancer Inst **94**(24): 1821-1822.

This editorial comments on an empirical study of oncologists' understanding of trials in which they participate. The author supports the idea of empirical ethics research and points out that it too can be excellent on trivial, well or poorly done.

http://jncicancerspectrum.oxfordjournals.org/cgi/content/full/jnci;94/24/1821

Miller, H. I. (2003). "Trickle-Down R&D and the Public Good." The Scientist 17(10): 18.

Curing the public-health ills of less-developed countries might be delivered most efficiently by the work that trickles down from the wealthier countries' high-powered research machines.

Morgan, J. P. (2002). "Lessons From a Horse Named Jim: A Clinical Trials Manual From the Duke Clinical Research Institute." JAMA 288(8): 1017-1018.

This review of Liu and Davis' clinical trials manual indicates that the book is very readable. It gives an excellent history of the sad story that led to today's clinical research environment and provides useful materials for anyone who wants to engage in clinical investigation.

N.I.H. (2003). Final NIH Statement on Sharing Research Data. N.I.H.

The NIH comes down on the side of data sharing and has the capability to make it happen.

Nathan, D. G. (2002). "Careers in translational clinical research-historical perspectives, future challenges." JAMA 287(18): 2424-7.

The author lays out the problems with developing a career in translational research under the funding mechanisms as they exist and the promotion policies of academic medical centers.

Petrelli, N. J. (2002). "Clinical Trials Are Mandatory for Improving Surgical Cancer Care." JAMA 287(3): 377-378.

The author notes that many advances in surgery have not gone through a formal clinical research process to their detriment. He argues that formal clinical trials are needed in surgical oncology.

Phillips, R. L., C. Jim, et al. (2004). "Intellectual Property Rights and the Public Good. Universities have Obligations To Developing Countries." The Scientist 18(14): 8.

Is there a fiduciary responsibility of academic institutions to provide patented materials to poor countries? They use the example of Golden rice, which would save many from blindness but is hung up in private hands and beyond the ability of the poor to pay.

Porter, R. and V. Tech (2003). "Facilitating Proposal Development: Helping Faculty Avoid Common Pitfalls." The Journal of Research Administration XXXIV(1): 28-32.

With increasing pressure to obtain extramural funding, success in proposal writing becomes ever more important to colleges and universities. Though the characteristics of good proposal writing are well understood, success ratios remain low and most proposals are rejected on first reading. This paper discusses the dimensions of the problems, identifies some common proposal errors and pitfalls, and suggests techniques to avert them. It concludes that grants specialists can employ intervention strategies centered around internal competitors, early career award workshops, funding search workshops and acceptance of pre-proposals to help faculty improve their grant writing skills.

Price, J., J. Dake, et al. (2001). "Selected ethical issues in research and publication: perceptions of health education faculty." Health Education & Behavior 28(1): 51-64.

This paper surveys a random sample of health education faculty with regard to their perceptions of ethical issues in research and publishing. Most of the respondents were academically mature. They were asked to rate whether each of 21 scenarios was ethical, unethical, questionable or not an ethical issue. The responses were overall quite variable but this did not relate to rank, gender or other demographic factors..

Reinhardt, U. E. (2004). "MEDICINE: Health Care in the Service of Science?" Science 303(5664): 1613-1614.

This review of Daniel Callahan's book "What Price Better Health", that argues that hell- bent scientific development is not the most effective way to optimize health in the population. He feels that scientists have a social responsibility to direct their research where they could reasonably think it will do the most medical good. Reinhardt believes that the way we do medicine reflects societal values and that Callahan is a little off track. Very good reading.

Rennie, D. (2004). "Trial Registration: A Great Idea Switches From Ignored to Irresistible." JAMA 292(11): 1359-1362.

The author reviews the recent history leading to clinical trial registration. Required reading.

Rensberger, B. (2000). "ESSAYS ON SCIENCE AND SOCIETY: The Nature of Evidence." Science 289(5476): 6.

The author, a science writer, responds to criticisms of his profession that they do not teach Americans about science and that opposition to science is based on their giving equal space to quacks as to real science, by indicating that the quality of scientific evidence is often very weak, generating doubt on its own. A very good short paper about the weakness of scientific communication.

Roberts, L. W., T. Warner, et al. (2003). "What is ethically important in clinical research? A preliminary study of attitudes of 73 psychiatric faculty and residents." Schizophrenia Bulletin **29**(3): 607-13.

This survey of psychiatric faculty and residents at one facility identified scientific quality and safeguards followed by trust in the integrity of the PI as the most important ethical aspects of clinical research. As might be expected, the residents are more ethically sensitive than the faculty.

Rodbard, D., P. O'Shea, et al. (2003). Survey of Research Integrity Measures Utilized in Biomedical Research Laboratories. American Institutes for Research.

This private survery conducted for the NIH identified methods that scientists think preserve research integrity and the kinds and duration of training activity in research integrity.

Rosenberg, L. E. (1999). "Physician-Scientist- Endangered and Essential." Science 283: 331-332.

The author raises the alarm about the declining number of physicians preparing themselves as scientists and doing clinically related research. This argument was heard, finally in 2006.

Sa Couto Md, J. (2003). "An Objectivist's View On The Ethics Of Evidence-Based Medicine: Commentary On 'A Critical Appraisal Of Evidence-Based Medicine: Some Ethical Considerations' (Gupta 2003; Journal of Evaluation in Clinical Practice 9, 111-121)." Journal of Evaluation in Clinical Practice **9**(2): 137-139.

The author constructs a strong argument that "evidence-based medicine" and reason based on medical theory are incompatible. This "evidence based medicine" is opposed to objective reason. http://www.blackwell-synergy.com/doi/abs/10.1046/j.1365-2753.2003.00401.x

Saletan, W. (2001) The Ethicist's New Clothes. Slate Volume, DOI:

This article points out that drug and device companies were hiring ethicists as consultants, and compromising them. The ethicists seemed to them to be blind to how bad their conflicts of interests were in their field of endeavor.

Schacter, B. (2002). "Partners in Research, Competitors in Pay." The Scientist (March 4, 2002): 44-45.

The author sheds light on the fact that while scientists collaborate broadly in research, they are really competitors for the same relatively few good positions and pay. He points out the irony in this. But, is this so different from the real world where leadership teams both collaborate and compete?

Sideris, L., C. McCarthy, et al. (1999). "Roots of Concern with Nonhuman Animals in Biomedical Ethics." ILAR Journal 40(1): 3-14.

This paper reviews the history of concern for research animals and the impact of passionate anti animal research groups in getting more humane treatment of research animals on the regulatory agenda.

Silbergeld, E., S. Lerman, et al. (2004). "ETHICS: Human Health Research Ethics." Science 305(5686): 949-.

This is a strong argument for the use the "common rule" in designing and carrying out studies related to environmental protection. Distinctions between internal EPA studies and non-governmental studies that exist are proposed for change.

Steinbrook, R. (2000). "Medical Journals and Medical Reporting." N Engl J Med 342(22): 1668-167.

The author defends the role of the NEJM in reporting materials to the media. They claim purity because they only send out an advance copy of each issue to the press. Of course, we subscribers believe we are paying for the first look at the information. A very self-serving article, I think.

Steinbrook, R. (2004). "Public Registration of Clinical Trials." N Engl J Med 351(4): 315-317.

This is one of the articles from leading journals that publish clinical trials arguing the importance of registration. Subsequently, registration has become essentially required.

Swazey, J. P., M. S. Anderson, et al. (1993). "Ethical Problems in Academic Research: A survey of doctoral candidates and faculty raises important questions about the ethical environment of graduate education and research." American Scientist 81: 542-553.

This empirical study of faculty and trainees indicated that ethical lapses were both commonly admitted and commonly noted in others. The authors argued for better ethical education.

Tunis, S. R., D. B. Stryer, et al. (2003). "Practical Clinical Trials: Increasing the Value of Clinical Research for Decision Making in Clinical and Health Policy." JAMA **290**(12): 1624-1632.

This policy proposal argues that we need much greater emphasis in research on practical clinical trials to help medical decisions makers make rational choices or offer rational choices to their patients. Almost all current clinical trials are designed for different purposes and are not helpful in real decisions http://jama.ama-assn.org/cgi/content/full/290/12/1624

Vandenbroucke, J. P. (2001). "In Defense of Case Reports and Case Series." Ann Intern Med 134(4): 330-334.

The author argues that case reports and case series have their own role in the progress of medical science. They permit reporting of new diseases and unexpected effects (adverse or beneficial) as well as the study of mechanisms, and they play an important role in medical education. He claims that case reports and series have a high sensitivity for detecting novelty and therefore remain one of the cornerstones of medical progress. Good case reporting demands a clear focus to make explicit to the audience why a particular observation is important in the context of existing knowledge.

Varki, A. and L. E. Rosenberg (2002). "Emerging opportunities and career paths for the young physician-scientist." Nat Med 8(5): 437.

The authors trumpet careers in translational medicine for scientifically trained physicians.

Wallerstein, M. B. (2002). "Science in an Age of Terrorism." Science 297(5590): 2169.

The author suggests that to thwart the use of biological agents by terrorists, we have to be careful in specific sensitive areas and try to teach our foreign students and other trainees to use what they learned for good. Sounds good but …

Wenger, N. S., S. Korenman, et al. (1997). "The ethics of scientific research: an analysis of focus groups of scientists and institutional representatives." J Investigative Med 45(6): 371-80.

The authors report on the range and depth of perceptions of scientists and institutional representatives on what is unethical in science.

Wolpert, L. (1989). "The social responsibility of scientists: moonshine and morals." BMJ 298(6678): 941-3.

A very compelling article that contrasts research for the Manhattan project with the eugenics movement leading to 1930s Nazi policy of discrimination and genocide. While the designers of the atomic bomb are praised for their insight, the eugenics movement is now seen as one of science's greatest evils. The author concludes that scientists must have the capacity to research all fields, but also bear the responsibility of disclosing the ramifications of their research.

Yarborough, M. and R. Sharp (2002). "Restoring and preserving trust in biomedical research." Acad Med 77(1): 8-14.

This significant position paper describes the diminution of trust in clinical research associated with recent events and the media characterization of them. The authors argue that if these institutions are to preserve the trust that the public has historically bestowed upon them, they must go beyond mere compliance with regulatory mandates. Several steps are suggested that the authors believe will bolster the public's confidence in academic research institutions. These steps grow out of the authors' analysis of three key components of institutional trustworthiness: (1) shared goals between research institutions and the communities they serve, (2) robust institutional oversight of research activities, and (3) training programs that build professional character. The authors' recommendations include the use of research advisory councils to assure the public that research goals reflect community interests, more collaborative relationships between institutional review boards and members of investigative teams, and educational programs that emphasize the importance of professional integrity in biomedical research.

Zigmond, M. (1999). "Promoting responsible conduct: striving for change rather than consensus. Commentary on "Ambiguity, trust, and the responsible conduct of research" (F. Grinnell)." Sci Eng Ethics 5(2): 219-28.

In this paper the author duels with Fred Grinnel about promoting the responsible conduct of research. He points out that "aspirational codes depend too much on the individual. He thinks that discussion and controversy play a role in buy in and clarification of issues and , unlike Grinnel, the scientific societies and investigators should play an important role in defining the rules of behavior. This is a very worthwhile read for those interested in teaching the responsible conduct of research.