ETHICS

A Case Study from Fluency

Edited by
Robert Goldfarb, Ph.D.

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CHAPTER

9

RETROACTIVE ETHICAL JUDGMENTS AND HUMAN SUBJECTS RESEARCH

The 1939 Tudor Study in Context[1]

Nicholas Johnson

However significant speech pathology research may be, its publication is seldom the focus of the kind of national media attention that the Tudor study received during the summer of 2001.

That the media's spotlight was focused, not on a new discovery, but on ethical judgments regarding Mary Tudor's then 62-year-old little masters thesis about speech disfluency (Tudor, 1939) should have made university and association administrators, speech pathologists, and journalists a little skeptical as to why this was considered "news." Some were.

Indeed, as will be seen, the ethical issues surrounding the study turn out to involve the ethics of journalism and administration as much or more than the ethics of human subjects research.

The barrage of ethical and moral accusations hurled at the surviving researcher, and her then-36-years-dead supervisor, Dr. Wendell Johnson, were driven by a couple of articles by Jim Dyer in the *San Jose Mercury News* (Dyer, 2001).[2] The articles were treated as a major exposé, widely distributed by the *Mercury News*, and reprinted all across the country.

There is a noteworthy contrast between the 2001 coverage of the 1939 study by the *Mercury News*, and the 2001 coverage of a 2001 study by the *Baltimore Sun* (Siegel & Sugg, 2001). The former study involved no physical contact with subjects, no use of harmful substances, and, the best evidence suggests, no permanent harm. It was conducted by a young masters student with a handful of subjects 62 years earlier. The 2001 study involved subjects' ingestion of harmful substances, produced a possibly predictable *death* of a subject, and occurred at the hands of professional researchers at one of the nation's most prestigious institutions that very year.

The *Mercury News* reporter ignored the more dramatic late 20th century ethical lapses resulting in serious harm to human subjects. He chose instead to cast moral aspersions on what he charged a masters student and her supervisor had done 62 years earlier.

The *Sun*'s series of stories, by contrast, skipped the Tudor study and avoided emotion-laden charges. They profiled the Hopkins researcher and provided an explanation both of the need for oversight and the harm that comes from overreaction. They explored the most appropriate public relations stance for an institution in this position and some of the conflict of interest issues that arise when academic research is funded by corporations impacted by the results. In short, by putting the story in context, the *Sun* was able to explore some of the broader issues for its readers and, in this writer's opinion, use its editorial page responsibly.

Why the *Mercury News* reporter was motivated to do what he did remains unknown. What *is* known is that he "resigned" shortly after his stories appeared and his own ethical lapses were revealed (see section VII. D., below).

Sadly, however, the damage had already been done. The advice attributed to Mark Twain, "never pick a fight with someone who buys printer's ink by the barrel," is still applicable. Media damage, once done, can almost never be fully repaired; truth is a notoriously slow runner in its race with defamation.

Responses to the ethical charges leveled at the researcher and her supervisor can be summarized as follows:

1. **If harm was neither intended nor done, that really ought to be the end of the matter.** If some of the critics of the *sub-*

stance of the Tudor study are correct (i.e., that she drew unwarranted conclusions from her data), Tudor not only could not have, and did not, produce "stuttering" in her subjects, neither did she do them any other permanent harm. Moreover, say the critics, there is no evidence that she or her supervisor *intended* to do any permanent harm.

Human subjects researcher Dr. Michael Flaum wrote a response to his local college paper's editorial criticizing Tudor's ethics. After reviewing the evidence he wrote, "That really ought to be the end of the matter. If harm was neither intended nor done, what's the problem? Where's the 'lack of ethics' your editorial headlined?" (Flaum, 2002, p. 8A)

2. **Measured by the standards of its time.** Assume permanent harm *was* done to some subjects, even though the best evidence suggests none occurred. But even were that true, scholarly thoroughness and basic fairness require that Tudor's procedures be judged by the human subjects research standards of 1939 (when the study was done) not those of 2001 (when the criticisms were leveled).

   Indeed, why would anyone even *want* to be morally judgmental (as distinguished from descriptive or analytic)? Why would anyone *want* to judge the research procedures of a 1939 study by the human subjects ethical standards of 2001, 62 years later? That is as inappropriate as it would be to use the ethical standards of 2063 to look back upon our behavior in 2001.

   In any event, as a former university vice president for research has said of the ethics of the Tudor study, "it was fully within the norms of the time" (Dyer, 2001).[3]

3. **Measured by today's standards.** Now make *two* false assumptions: that harm *was* done, *and* that the most appropriate baseline for evaluating the Tudor study's ethics are the human subjects standards of 2001. At a minimum, the procedures used by Tudor compare very favorably with those used by some researchers in prestigious U.S. institutions since 1939, even some since 1995.

4. **Indictment or itemization?** Given the abuses in post-World War II human subjects research, if one is interested in

exploring and improving the ethical standards applicable to twenty-first century research the Tudor study seems a trivial, dated, and unproductive example to choose.

If one wishes to examine it anyway, the only responsible approach is to itemize the qualities and procedures of that study one at a time. What *specifically* is it about the Tudor study that is thought to be unethical? When the analysis is approached in that way there are few, if any, aspects of the study one can fairly criticize.

5. **Administrative ethics.** Responses to the Tudor study provide insights not only into journalistic ethics, and human subjects research ethics, but administrative ethics as well.

   Following the *Mercury News* stories, the reaction by some university and association administrators and speech pathologists was a prompt and forceful indictment of the ethics of the researcher and her supervisor. This response bore a stark contrast to their response, and that of their predecessors, to the publicity involving harm to human subjects for which *they* bore some responsibility. From the post-World War II abuses through the post-1995 scandals, human subjects research abuses often provoked no response whatsoever from responsible administrators—until those abuses were publicized. Even then, all too often, the response of administrators and researchers in industry, research institutions and the academy was one of defensiveness rather than apologies and calls for reform.[4]

   Such responses understandably leave the impression, whether fairly or not, that researchers' and administrators' primary concern may be public relations and continued funding. The welfare of their human subjects and the harm done to them seldom produce even comment, let alone action.

   Given this history, one can only speculate as to why administrators were so quick to chastise Tudor. Perhaps it was their confidence that ethical rectitude regarding 62-year-old studies could only enhance, rather than threaten, their research budgets.

6. **Scholarship, scandals, and the ethics of ethical criticism.** An evaluation of the *substance* of the Tudor study—the adequacy of its design, reliability of the data, and soundness of

the conclusions—is beyond the scope of this chapter. It is the subject of other chapters. But the writer shares the view that if the Tudor study's data are subject to a more accurate analysis today than when first gathered, that analysis should be done, reported, and published, as it has been (Ambrose & Yairi, 2002).

Similarly, the ethical issues surrounding the study also can be explored in a dispassionate, analytical, and scholarly way.

The writer's primary objection relates to those criticisms of the study's ethics that have been as full of emotionalism as they have been empty of factual analysis and serious reflection, such as the headlined characterization of it as "the monster study."[5] Such criticisms are similar to the thoughtless repetition of harmful, inaccurate, and uncorroborated gossip that sometimes creates legal liability for defamation. There *should be*, in short, an ethics of ethical criticism.

7. **Journalist, Heal Thyself.** Finally, and central to the chapter, is journalistic ethics.

   In 1939 the research community had not yet written and agreed to the international human subjects research standards that would only come decades later. The University of Iowa had in place neither standards nor a process for reviewing their compliance. Thus, none could have been violated. Moreover, the Tudor study complied with most of those that have evolved since. The best evidence is that no permanent harm appears to have been done to any of Tudor's subjects.

   By contrast, there *were* applicable journalistic ethical standards in 2001. They *were* violated. And those violations *have* caused harm (see section VII. D., below).

I. Neither Harm nor Intention to Harm

Nicoline Grinager Ambrose and Ehud Yairi are critical of the conclusions that Mary Tudor drew from her data. When they reanalyzed her original data they concluded there were no significant changes in disfluency of *any* type in *any* of the four groups tested. As is fully explained elsewhere in this book, there was certainly no direct evidence of "stuttering" based on changes in the speech of participants.[6]

Given that they are severe critics of the study and not its apologists, it is the more credible and commendable that they are able to bring such scholarly balance and dispassion to their analysis of Tudor's ethics. They report their belief that no harm was done to the subjects, in the sense of "instilling chronic stuttering," and that there was no intention to do harm.[7]

II. Compared to What?

A. What Is Human Subjects Research?

"Human subjects research," as the phrase suggests, is research for which the laboratory test tube and animal studies are inadequate. It must involve humans if it is to be done at all. A common example would be the testing of a new pharmaceutical product. In 2001, before a new drug could be sold to the public the manufacturer had to demonstrate that it would not do serious harm, that it would alleviate whatever condition it is designed to cure, and that its side effects are known and communicated (FDA, 1962).

This process usually requires that the drug be tested on humans during "clinical trials," often conducted by researchers in academic institutions. Those who participate in those trials are called human subjects.

B. The Evolution of Human Subjects Research Ethics

Over time, thinking has shifted regarding the ethical issues raised by human subjects research. The standards of the nineteenth century are different from those in 1939, 2001, and what those standards will evolve to become by 2063. For example, in 2001 there was greater sensitivity regarding the use of prisoners and institutionalized children as subjects than there was during the 19th and early 20th centuries.

Similarly, in the 20th century there was a stark disparity in the ethical standards applied by American researchers to human subjects in North America compared to their subjects in developing countries.[8] This practice, seldom even questioned let alone

criticized at the time, may come to be viewed by mid-21st century critics as having been highly unethical.

During the last half of the 20th century, there was much progress in the thinking regarding ethics in human subjects research. Many more regulations and opportunities for review were put in place. It is still possible for harm to occur. It is still probable that future ethicists will look backward, condemning with the standards of their day practices widely accepted in 2001. But either is much less likely than a century, half-century, or even decade before 2001.

The research community can be rightfully proud of that progress. At the same time, two things must be said.

1. Ethical violations causing harm to human subjects will still occur, whether measured by the articulated standards of 2001 or the standards that will evolve.
2. Pendulums have a tendency to swing beyond the midpoint. This may have happened with human subjects research ethical standards. That is, some of the early twenty-first century standards may be inhibiting needed research while producing little benefit.[9]

C. The Four Phases of Ethical Evolution

In evaluating the evolution of human subjects research ethics it is useful to identify, albeit somewhat arbitrarily, four phases of ethical evolution.

Phase I includes roughly the 19th and first half of the 20th centuries. During this phase, there were "ethics" in general, and even occasional comments about human subjects research in particular, but few if any officially promulgated and universally agreed-on human subjects research standards. The ethical standards, like the research designs, were left almost entirely to individual researchers.

Phase II, the primary focus of this historical section of the chapter, is the period from World War II through the 1970s. This is the time when abuses came to public attention, consciousness was raised, and international ethical standards evolved, were drafted, adopted, and published.

Phase III is the 1980s and 1990s, when new standards were finally in place and applied.

Phase IV is the last five years of the 20th century, a period when concerns and procedures were at their most intricate, intense, and some would say self-defeating stage so far (e.g., Shea, 2000).

Phases I, III, and IV are dealt with only in passing. The illustrations selected from Phase II, described below, will be referred to throughout the remainder of the chapter.

D. From World War II Through the 1970s[10]

Following World War II a review of experiments conducted by German researchers resulted in what came to be called the Nuremberg Code of 1948.[11] It provided that human subjects research should involve only subjects who give informed consent and volunteer to participate.

The code is significant because it marks the beginning of Phase II. The first time such standards were ever set forth in an international agreement was 1948, nine years *after* the 1939 Tudor study. This was followed by the World Medical Association's Declaration of Helsinki, adopted a quarter century after Tudor, and most recently revised in 2000.[12] It spells out some additional requirements, such as the suggestion that laboratory and animal research should precede human subjects research.

It is worth noting, however, that even these most rigorous standards do not forbid the taking of risks in human subjects research. The necessary finding is simply that "risks to subjects are reasonable relative to anticipated benefits . . . and the importance of the knowledge that may reasonably be expected to result."[13]

The reader should also bear in mind that none of the experiments described below were done by a lone researcher in a secret laboratory outside the control of reputable research institutions and other controls. These are studies done by well-educated, accomplished, and respected professionals. Most were reviewed and funded by additional professionals and institutions. They were often published in peer-reviewed academic journals. Few or no questions of their propriety appear to have been raised about them by anyone at any stage.

Note also that, unlike the 1939 Tudor study, all were done *after* ethical standards and regulations were in place, standards that would seem to have been violated by one or more aspects of the studies.

1. The Tuskegee Syphilis Study

One of the most often-cited illustrations of the ethical problems in human subjects research is the Tuskegee syphilis study. Like other human subjects research studies of the time, it was designed and conducted by highly educated, professional physicians, in this instance those with the U.S. Public Health Service (PHS).

Over 400 African-Americans with syphilis were recruited. Not only did the subjects not provide informed consent to their participation, they were affirmatively *misinformed* that they would receive "special free treatment." They were not informed of the nature of their disease or that the research would offer them no therapeutic benefit.

Their complications got worse. Their death rate became twice that of the control subjects. Yet the study continued. Even after penicillin became available, and was known to be effective in the treatment of syphilis, the men were neither informed of this nor treated. When outside doctors diagnosed a subject as having the disease researchers intervened to *prevent* treatment.

In 2001, research professionals and even many members of the public were aware of this study. What was not so widely known was that the Tuskegee study *continued from 1932 until 1973*, long after the Nuremberg Code and Helsinki Declaration were in existence and well known.

How could this be? Was it because the study continued for too brief a time, or was unknown to the research community? No, it continued over a period of 40 years and was widely reported in medical journals.

One of today's administrative protections of subjects' rights is the oversight of human subjects research by an institutional review board, or IRB. A researcher's colleagues must review and approve each study and find that it complies with current administrative regulations, institutional procedures, and ethical standards.

Were there no IRBs at that time? No, that cannot be the answer either. Earlier versions of an IRB were in place. The

Tuskegee study was periodically reviewed and approved by Public Health Service officials and medical societies. As a federally funded agency, there may have been Congressional oversight as well.

Today, such agencies and institutions would have detailed regulations in place. Were there no regulations at the PHS at that time? No, that can't be it. The *Public Health Service Policy for the Protection of Human Subjects* became effective six or more years before the study was stopped.

Can one say that the Tuskegee study is merely one unfortunate aberration in an otherwise stellar history of ethical sensitivity and compliance by research institutions? No, unfortunately, the following studies suggest that's not the answer either.

2. Radiation at the "Science Club"

From 1946 to 1956 19 boys who thought they were part of a "science club" were, without their consent or knowledge, drinking radioactive milk provided them by researchers from Harvard and MIT.

3. Calculated Risks from Atomic Bomb Testing

Radiated milk is one thing. But in 1949 the Atomic Energy Commission wanted to know whether the fallout from its atomic bomb tests could threaten the viability of all life on earth. Apparently, knowing the seriousness of the risk, the agency thought it one worth taking. The tests continued, including those it conceded posed a "calculated risk" of radiation exposure to populations living downwind from the tests.

4. Doctors' Patients as Human Research Subjects

Until the 1960s, pharmaceutical companies paid doctors willing to use uninformed patients for human subjects research. Participating doctors were provided free samples by the drug companies, required to keep records of patients' reactions, and then provide those results to the companies. The acceptance of the practice was so widespread that few thought it worthy of comment.

In the 1960s there was no law that required drugs be tested before marketing. Companies did not have to show their prod-

ucts were even safe, let alone useful for the conditions for which they were prescribed.

At that point in the history of human subjects research ethics, America was an entire nation of uninformed, nonconsenting human subjects. The profits from the system went to the pharmaceutical companies and doctors. The losses were borne by their human subjects in the form of occasional injury, disease, and even death.

By 2001, the testing took the form of what were called "clinical trials," often in academic medical centers. Most subjects provided some form of informed consent, thereby relieving the institutions of potential legal liability. But the medicines were still free, the doctors were still compensated by the pharmaceutical companies in a variety of ways, and the health and financial risks still fell upon the subjects.

For example, in August 2001 it was reported that some 81 persons using cholesterol-lowering drugs had died from muscle cell degeneration. Hilts reported that doctors often ignored warnings regarding usage and side effects. As few as 5% of the participating doctors were found to be conducting the essential monthly liver tests of their patients (Hilts, 2001).

5. The Thalidomide Babies

One of the human subjects tests of pharmaceuticals in the 1950s involved a sedative from Germany called thalidomide. It was given to pregnant women to control sleep and nausea. Unfortunately, however useful as a sedative, one of thalidomide's nasty side effects is that it causes missing or deformed limbs and other severe deformities in fetuses. As a result, the human subjects in this research project, almost all of whom were in Europe, gave birth to some 12,000 deformed "thalidomide babies."

These results were so dramatic, widely reported, and accompanied by gruesome photographs, that they led to public and official questioning of the lucrative relationship between doctors and pharmaceutical companies.

6. The Army's Exclusion

In 1962, the U.S. Army addressed human subjects research ethical issues with regard to its experiments on soldiers and others.

The Army wanted data regarding the human impact of weapons of mass destruction (agents used in atomic, chemical, and biological warfare). But with the urging of nonmilitary consultants it expressly *excluded* from its ethical standards "clinical research" involving military personnel.

By 2002, the Defense Department released more than two dozen reports of previously classified exercises from 1962 through 1973. These exercises involved the deliberate exposure of U.S. troops to agents in chemical and biological weapons without the consent, or even knowledge, of the subjects. The agents, "some of the most poisonous in the arsenal," included VX, sarin, soman, tabun, and *Bacillus globigii* (related to anthrax). As of 2002, the Department was trying to track down some 5,500 known subjects (*New York Times*, October 10, 2002).

7. *Injecting Cancer*

As late as 1963, doctors in a New York hospital were deliberately injecting live cancer cells into subjects. The chief investigator was a physician from the Sloan-Kettering Cancer Research Institute. The study was reviewed and approved by the hospital's medical director. There was no documentation of the subjects' consent, nor were they informed what was being done to them.

Following the disclosure of the study and its procedures there were no immediate repercussions for the hospital, Sloan-Kettering, the university involved, or the U.S. Public Health Service.

8. *The Chimpanzee's Kidney Experiment*

The same year (1963), a Tulane University doctor performed an unsuccessful transplant of a kidney from a chimpanzee into a human being. The procedure promised no benefit to the recipient or new scientific knowledge. It was funded by the National Institutes of Health after repeated approval as the proposal passed through various levels of review.

9. *Giving Hepatitis to the Mentally Retarded*

From 1956 to 1972, a New York University doctor led a hepatitis study team at the Willowbrook State School for the Retarded in

New York. The subjects, all of whom were children, were fed extracts of stools from individuals infected with hepatitis.

Did their parents consent? In theory, yes, because there was a "consent form." In reality, no, because the form seemed to suggest that the children were going to receive a vaccine to *protect against* the virus rather than be *deliberately infected*. Moreover, Willowbrook administrators told parents it was overcrowded and unable to take more residents. More precisely, children would not be admitted *unless the parents would first consent* to their children becoming a part of the study, in which case there was plenty of room.

Note that the study very likely could have been done with children who already had the disease, rather than infecting those who did not. Once again, this was not an example of the research of an unsupervised loner. The study was reviewed, approved and funded by the Armed Forces Epidemiological Board. It was further reviewed and approved by the executive faculty of the NYU School of Medicine.

10. NASA's Exception

It was 1968 before NASA came up with an informed consent policy. However, even then the policy provided that the requirement could be waived in a number of circumstances, including when the research *"would be seriously hampered" if consent had to be obtained*.

11. LSD from the CIA

It was not until *1975* that Congressional hearings brought to public attention some of the more questionable human subjects research projects of the CIA and Defense Department. The agencies wanted to know the extent to which it was possible to control human behavior through the use of radiation, psychologic means, psychoactive drugs, such as LSD and mescaline, and other chemical and biological substances. The subjects used in these experiments had not given informed consent, and some died.

The secret project's code name was MKULTRA. It involved at least 150 individually reviewed, approved, and funded projects conducted by presumably reputable research scientists. The CIA director ordered all records of the studies destroyed in 1973.

12. 2005: The Deaths Continue

There is no shortage of such examples—up to and including the present day. To illustrate the point, and conclude this listing, as the book was going to press there were another couple of Associated Press reports of deaths in human subjects research studies. One was a May 5, 2005, story about a then-current NIH study that utilized foster children with AIDS (Associated Press, 2005a). Many of these often poor and minority children were not provided the required child advocates researchers had promised, and some suffered side effects, including increased death rates, as a result of otherwise untested dosages. The story led to a congressional investigation which revealed variations in practices from state-to-state (Associated Press, 2005c). The other was a May 18, 2005, story regarding two deaths and "life-threatening complications in an alarming number of others" resulting from a breast cancer study of the combined effects of two drugs, docetaxel and doxorubicin (Associated Press, 2005b).

III. Administrative Ethics, Complacency, and Opposition to Reform

The relevance of these 12 illustrations are the contrasts between them and the Tudor study in terms of (a) the degree of permanent harm done, (b) the existence of applicable, published ethical standards, (c) the willingness to apply the ethical standards of the day to studies done over half a century earlier, (d) the availability of institutional resources and participation of professionals, and (e) the criticism subsequently leveled at the researcher.

A. The Tuskegee Syphilis Study

What finally stopped the Tuskegee study? It does not appear to have been the ethical concerns of a research community clearly willing to continue for 40 years procedures that violated known ethical standards.

It seems to have been an outraged public that finally prodded Congress into holding hearings on the ethical and legal stan-

dards for human subjects research. Even then, *after* all the revelations, Senator Ted Kennedy's bill to create a National Human Experimentation Board, *as recommended by the Tuskegee Syphilis Study Ad Hoc Panel*, was defeated. The hope for oversight of all federally funded research was lost as a result of the efforts of lobbyists for the research community and their corporate sponsors.

Even the compromise, the National Research Act of 1974, was cut back so that the regulations would govern only the Department of Health, Education and Welfare. And those compromised regulations were further watered down, leaving the grantee institutions free to regulate themselves through their self-appointed institutional review boards.

The subsequent *Belmont Report*, spelling out more ethical standards ("respect, beneficence, and justice"), did not appear until 1979 (National Committee for the Protection of Human Subjects, *The Belmont Report*, 1979). The Department of Health and Human Services (DHHS) regulations based on that report became available in 1981. Other governmental agencies did not sign on until 10 years after even that. The DHHS regulations were formally adopted by over a dozen agencies in 1991, 52 years after the Tudor study, and are now referred to as the "Common Rule." And even this set of rules provides for six categories of exemptions.

B. The Thalidomide Babies

The deformities in 12,000 thalidomide babies were one of the most dramatic of human subjects research failures. However, even they were not enough to produce reform. It was only after those deaths had attracted a good deal of *media attention* that Congressional hearings were scheduled and held.

Moreover, notwithstanding the dramatic events, media attention, and hearings, the industry and research community were still able to weaken the legislation. In the end, "informed consent" would be required, but "the best judgment of the doctors involved" would control whether consent was "feasible" or "in the best interests of the patient."

With little or no thanks to the pharmaceutical industry or medical profession, by 2001 the law authorized the Food and Drug Administration (FDA) to insist on the safety and efficacy of

new drugs. At that time, the law was still attacked by industry on grounds that it delayed getting drugs to patients. Meanwhile, experiments with thalidomide continue, although hopefully not on pregnant women.

C. Injecting Cancer

As noted above, even after it was revealed that the Sloan-Kettering researchers had been deliberately injecting cancer into human subjects, there were no immediate repercussions for the hospital, Sloan-Kettering, the university involved, or the U.S. Public Health Service. Such professional concern as did exist focused not so much on the ethics of the researchers, and harm to the subjects, as on the possible adverse impact of public knowledge on the continued funding of such research and the possibilities of legal liability.[14]

D. The Chimpanzee's Kidney Experiment

Following revelations of the chimpanzee's kidney experiment, there was a thorough NIH review of "research protocols and procedures." However, the ultimate recommendation was for no changes whatsoever. The agency was concerned that if it promulgated standards they might "inhibit, delay or distort the carrying out of clinical research." One of the nation's primary sources of funding for human subjects research was simply "not in a position to shape the educational foundations of medical ethics."

E. Deaths in Developing Countries

The dual ethical standards applied by American researchers to their human subjects in the U.S. and in developing countries are illustrated by Paul M. McNeill's report (McNeill, 1998). For example, in a Uganda AIDS study, partners of AIDS-infected subjects were not informed and 90 of them (22%) subsequently died.

What was the response of ethical professionals? *AllAfrica Global Media* reported that "The Rakai study was approved by

scientific and ethics boards in Uganda and the United States. After the controversy broke out, UNAIDS, the United Nations office that coordinates the international response to the epidemic, found no ethical violations" (AllAfrica Global Media, 2001). For a fictional account of a pharmaceutical company's unethical human subjects research on Africans (said to be based on a true story), see John LeCarré, *The Constant Gardener* (2001). The movie version of the same name, starring Ralph Fiennes and Rachel Weisz, was released and playing in theaters as this book went to press in 2005.

F. The Beecher Report

One person who *did* try to bring attention to some of the earlier questionable studies was a researcher named Henry Beecher. He spoke at a convention of science journalists in 1965. He cited 22 examples of research with potentially serious ethical violations that he had found in published reports in medical journals.

How could this be? Were the authors and editors of these 22 papers unaware of the applicable ethical standards? Aware but uncaring? Or was there some less disturbing explanation? Rather than distance himself from such questions about abuses, Beecher was candid enough to acknowledge that "in years gone by work in my laboratory could have been criticized."

His paper was rejected for publication by the *Journal of the American Medical Association* (JAMA).

IV. Ethical Analysis of the Tudor Study: Indictment or Itemization?

The more one knows of the human subjects research ethical violations described above, and administrators' responses to them *after* standards were in place, the more difficult it becomes to fault the Tudor study. One becomes ever more questioning of why anyone would even think about its ethics 62 years later, let alone make it the poster child for a national media blitz.

Moreover, in doing so, to phrase an ethical inquiry into the Tudor study as a question of "whether it was ethical or unethical"

is to reveal one's lack of analysis before the inquiry even begins. The inquiry should not be focused on the study as a whole, but rather on specific aspects of the study's ethics. What *precisely* was it about the study that was or was not ethical? Some of those aspects are listed below. As will be seen, when examined in this way the 1939 Tudor study, conducted at a time when no applicable ethical standards had yet been promulgated, compares very favorably with studies done *after* the existence of those standards.

A. Was There Anything Unethical About the Involvement of Children as Human Subjects?

Although the 2001 standards were quite strict, they still permitted child subjects. Indeed, as Eberlein notes, as many as 95% of children with cancer are today involved in clinical trials (Eberlein, 2000).

Clearly children continued to be a part of many studies during Phase II. Consider, for example, the boys served radioactive milk, the children infected with hepatitis, and the foster children used as subjects in tests of AIDS drugs in 2005.

Because the Tudor study involved a test of a hypothesis about the onset of disfluency in *children*, it was necessary that children be involved if the study was to be done at all. This would not appear to have been the case with the later Phase II experiments, approved as appropriate at the time, such as those involving children's reaction to radioactive foods or hepatitis. Those studies possibly could have used adults.

So the mere fact that children were involved in the Tudor study is not, alone, basis for adverse ethical or moral judgment.

B. Was There Anything Unethical About the Use of Residents of an Institution?

Participation by institutionalized individuals was approved even after standards were in place during Phase II. For example, the Willowbrook hepatitis study was proposed by a qualified research scientist and approved by the faculty of the NYU School of Medicine, among others. It involved institutionalized children who

were mentally retarded. At least the children used in the Tudor study were of normal intelligence. The study involving the injection of cancer cells used institutionalized adults.

Moreover, in 1939, it was totally acceptable to use the very institution used in the Tudor study: the Iowa Soldiers' Orphans' Home. Many other University of Iowa professors and graduate students used the facility in this way. In fact, one of the stuttering study participants is quoted as saying, referring to other studies, "Every week somebody else from the university would come and start testing us for God knows what" (Dyer, 2001).

The Iowa State Board of Control, which oversaw the orphanage, encouraged this research, as did, presumably, the university. So far as is known the Iowa Legislature found nothing in this use of the orphanage to which to object. Permission from the orphanage was required, and was obtained.[15]

All considered, it is hard to fault the study because it involved institutionalized subjects even under today's standards, let alone the standards of its time.

C. Was Informed Consent Not Provided?

After standards were in place, the Atomic Energy Commission did not get informed consent before risking radiation for large populations, nor did the Army or CIA. The 1968 NASA standards *expressly permit* the waiver of informed consent requirements when obtaining consent would interfere with the research.[16] Doctors did not always get the consent of their patients when testing new drugs on them. The Sloan-Kettering doctor did not get the consent of those he injected with cancer.

If "informed consent" had always been required much of the early research in social psychology could not have been done. To measure the impact of group pressure on an unknowing individual necessarily requires *some* deception of the uninformed human subject.[17] Indeed, one can question the extent to which, in 2001, college undergraduates enrolled in psychology classes provided "informed consent" to their participation in graduate students' experiments when their participation was made a condition of undergraduates' credit.

Of course, the 1939 experiment was not a NASA study. But it may very well have met NASA's 1968 standard. That is, like

the social psychology studies, Tudor's study would have been very difficult if not impossible if the subjects had been told of its nature.Thus, it is not clear that the Phase I Tudor study, even if judged by the standards of Phase II, would necessarily have been unethical if *no* consent had been obtained.

However, there is reason to believe informed consent *was* provided. It would have been unethical to attempt to obtain the consent of children by negotiating with them directly. An adult needed to be involved. But, by definition, no researcher could obtain the consent of the parents of orphans. The only adult who legally could have given consent on behalf of an institutionalized orphan would have been the administrator of the orphanage. And all indications are that he *did* consent.[18] Thus, for a variety of reasons, it seems inappropriate to criticize the study for a failure to obtain the subjects' consent.

D. Did the Researcher Deliberately Do Permanent Harm?

Ambrose and Yairi, otherwise critical of Tudor's conclusions, assert that Dr. Wendell Johnson and Mary Tudor neither did nor intended any permanent harm.[19] They conclude the procedures used did not, and could not have, caused "stuttering."

Injecting cancer or hepatitis into subjects is deliberately doing known harm. Using LSD on unsuspecting subjects to test its possible utility as a military or intelligence weapon is deliberately doing harm. The Johns Hopkins' human subject's death in 2001 resulted from deliberately doing harm. In 2001, testing the efficacy of new drugs on diseased human subjects by deliberately withholding the remedy from the proportion of them getting placebos risked a measure of harm. In the case of young children in Thailand it was the harm we call AIDS (McNeill, 1998).

If it could be documented that Mary Tudor and Dr. Wendell Johnson knew to a certainty that the study would turn normal speakers into lifelong persons who stutter, an ethical inquiry into their judgment might be warranted. But that is not known. And available evidence compels the opposite conclusion.

The 1939 Tudor study involved speaking to children in a manner and with words still used in 2001 by millions of well-

meaning parents who want nothing more than to "improve" their child's disfluency.

The hypothesis being tested was that these well-meaning parents' speech is actually increasing, rather than decreasing, their child's disfluency. But Tudor reasonably could have presumed that whatever conditions might be produced from her four months of intermittent contact would be, if anything, only temporary. At worst, they would be conditions that would promptly respond to therapy.

Dr. Wendell Johnson suffered from his own severe stuttering in 1939, and had a reputation among those who knew him for great kindness and sensitivity, especially with children.[20] He personally experienced every day the emotional pain and frustration of stuttering. He single-mindedly devoted his life to improving his own speech and that of other persons who stutter. It is inconceivable that this man would have permitted any study for which there was even a known *risk* to subjects, let alone a *probability*, of producing lifelong persons who stutter.

Compare this experiment with those Dr. Wendell Johnson, who described himself as "a professional white rat," was subjected to by his professors. As one journalist describes it, he "was hypnotized, psychoanalyzed, prodded with electrodes, and told to sit in cold water to have his tremors recorded. Like Demosthenes, the ancient Greek stutterer, he placed pebbles in his mouth [and] had his dominant arm, the right, placed in a cast to help prove his professor's controversial 'cerebral dominance' theory . . . " (Dyer, 2001).[21]

The passage makes three points. It provides a perspective as to the acceptable range of human subject experimentation in Phase I. It shows Dr. Wendell Johnson's commitment to science and the passion he brought to a lifetime of stuttering research. It also demonstrates the rather dramatic contrast between what he was quite willing to endure himself and what was being tested with Mary Tudor's study.

Finally, note that this 1939 study of the impact of speaking to children involved none of the *approved* physical contact, nuclear radiation, drug-induced behavior modification, exposure to disease, untested pharmaceuticals, or other invasive techniques sometimes used in human subject research *after* ethical standards were in place.

E. How Much Permanent Harm Came from This Brief Experiment?

Were the subjects permanently harmed? All that is available are a journalist's repetition of quotes from the subjects, one of whom was hoping to sue the University of Iowa for a substantial sum of money. And even she acknowledged, at the same time she was working with lawyers to build her case, that she did not stutter during the 45 years of her marriage.

And, of course, "a correlation is not a cause." The subjects undoubtedly had many adverse conditions to deal with before, during, and after their stay in the orphanage. Some had become persons who stutter before the study began. Thus, even if a subject did suffer a speech-related problem as an adult, that alone would not indicate it could be traced in any *causal* way to the study. Moreover, the subject the journalist selected to highlight was one whose fluency actually *improved* during the course of the study.[22]

Accept for the sake of argument two false assumptions (false because the evidence strongly suggests the opposite): (a) there was harm, and (b) a causal relation could be shown between the study's procedures and that harm. Even if both were found to be true, if one is to pass moral judgment on the researcher, one must first confront a considerable additional question, which the passage of time prevents answering: How deliberate or predictable was any of this harm?

This was original research. As discussed above, there was a substantial probability there would be no effect whatsoever on the subjects. The hypothesis, however interesting, might have proven to be totally invalid, as have so many research scientists' hypotheses before and since (and as its critics suggest was the case with the Tudor study).

There is reason to know that the injection of cancer or hepatitis is going to cause temporary or permanent harm. There was no reason to believe that even troublesome temporary, let alone permanent, harm would result from speaking to children in the ways parents do.

It would have been reasonable for the researcher to believe, knowing what was then known, that any disfluencies created in

the six subjects' speech during this brief, four-month experiment would quickly disappear.

If in fact disfluencies occurred, and did not disappear in all subjects, it is certainly regrettable. But it does not automatically follow that it represents a reprehensible moral and ethical lapse on the part of the researcher. This is true regardless of whether one evaluates it by the norms of Phase I, when it occurred, or by comparing it with numerous studies done *after* ethical standards were in place during Phase II.

Even had there been known risks, recall today's standard with regard to risks from human subjects research. The standard is not that no risks may be taken. It is, according to the NIH, that risks *not* be taken *unless* "risks to subjects are reasonable relative to . . . the importance of the knowledge that may reasonably be expected to result."

Given the millions of persons who stutter who have benefited from stuttering research, and the millions of children who have *not* become persons who stutter because the findings have been communicated to parents, even if permanent harm could be shown (and apparently it cannot) one could still argue that the NIH standard of permissible risk was met.

As one person who stutters puts the question, and then answers it: "Were the experiments justified? Was their potential benefit to society greater than the potential harm to the subjects? Speaking as a stutterer myself, I think 'yes.' Johnson's results showed that stuttering is learned behavior that can be modified, not a congenital curse that has to be accepted as given. Johnson gave hope and opportunity to the thousands of us who are afflicted with stuttering" (Hedges, 2001, p. 4).

F. Was There a Way of Testing the Tudor Study's Hypothesis Without Involving Children?

Tudor did not have the option of using laboratory or animal studies. Obviously, animal studies are of no use when studying *human* communication. And if the focus of a study is on disfluency in young children, as it was, the participation of young children is required.

The conclusion may be that human subjects research ethics preclude anyone ever finding out what the Tudor study sought to explore. If so, that is a very heavy price to pay. But even that conclusion makes the point. Whatever other ethical criticism is made of the Tudor study, it cannot be faulted for its failure to use an obvious alternative methodology. There simply was none.

G. Were a Large Number of Subjects Affected?

It is regrettable if even one human subject is harmed by a research project. But the fact is that very few subjects were involved in any way in the 1939 Tudor study, especially when compared with the numbers in the Phase II studies. Tens of thousands were potentially involved in the atomic bomb tests. Twelve thousand babies were harmed by thalidomide.

Only two or three of the stuttering research subjects were even *alleged* to have been adversely affected, and that was in support of their quest for legal damages. As discussed above, re-examination of Tudor's data suggests that, not only were no subjects permanently harmed, but given the nature of the experimental design they could not have been.

H. Did the Experiment Continue After the Results Were Known?

The disfluency experiment was a short-lived four-month study. Once the hypothesis was tested and thought to have been strengthened, the study ceased. Compare this ethical response with what was done in the Tuskegee study over the course of not 4 months but 40 years.

Clearly the study cannot be faulted on grounds there was a purposeful, continuing, callous abuse of anyone.

I. Was There Any After-Study Concern for the Subjects?

An effort was made to provide poststudy recuperative therapy for any Tudor subject who might benefit from it. Even Tudor

ethics critic Jim Dyer acknowledges that "Johnson asked Tudor to evaluate the children and try to reverse the effects of the experiment using positive therapy" (Dyer, 2001). Judging by the number of subjects who have told the media they suffered no long-term consequences the therapy may well have been helpful.

But this was the dawn of human understanding of speech disfluency and persons who stutter. Therapies that were routine in 2001 were simply unknown at the time. It is not clear that there was anything more that could have been done in 1939. In hindsight, a critic could argue that additional recuperative therapy should have been provided anyway, if for no other reason than to remove any possible question regarding the researcher's desire to be helpful.

The very least that must be credited, however, is that there was far more after-study concern and care of the Tudor subjects than was provided in many human subjects experiments thereafter.

J. Were the Results Not Published and the Data Destroyed?

Some media reported that the results of the Tudor study were never published. Standing alone this is so misleading as to be false.

As with all masters theses at the University of Iowa at the time, the Tudor thesis was bound, given to the University's library, cataloged, and made available to the public. It was often checked out. There was no effort to suppress it.

Few masters theses are commercially published or reprinted in academic journals.[23] They are shelved in academic libraries. That is what was done with this one. It is apparently true that the study was not cited very often in subsequent academic articles.[24] But that is also the fate of much scholarship.

It is not customary to save all the research data associated with a masters thesis. But it is certainly inaccurate to suggest that the data in this study was "destroyed." Not only is it contained within the thesis itself, but some media reports indicate that much if not all of the raw notes were saved, in this instance by the student who did the study.

Making the study available and saving the research data, especially if the researcher and supervisor had any concerns regarding the results, compares very well with, say, the 1973 actions of the CIA director who deliberately destroyed records of the agency's 150 LSD studies.

A responsible, sober analysis of the *elements* of human subjects research ethics, rather than a sensationalist broadside accusation, requires that one ask, "What is it *exactly* about the Tudor study that was unethical?" From that perspective, at a minimum it compares very favorably with an element-by-element analysis of later Phase II studies.

V. Measured by the Standards of Its Time

Given that the Nuremberg Code did not come into existence until 1948, the fact is that there were no international, federal, or state laws, regulations, or other standards applicable to the Tudor study in 1939. As noted earlier, the procedures and ethical standards of the Tudor study researcher were "well within the norms of the time."

The most rational and fair approach is to judge the ethics of the study by the research standards of the time, nationally, in Iowa, at the University of Iowa, and at the institution where the subjects lived. By those standards it seems somewhere between very difficult and impossible to come to any critical ethical judgment.

Indeed, what is particularly striking, given the absence of standards, is the sensitivity both the researcher and supervisor brought to the subjects of the study, self-imposed standards that compare very favorably with those of 2001.

VI. Measured by the Standards of 2001

As mentioned above, it seems no more appropriate to judge the ethics of actions in 1939 by the standards of 2001 than to later pass ethical judgment on our 2001 behavior from the vantage point of the ethical standards of 2063.[25]

Many of the Tudor study's critics have fallen into a trap well known to general semanticists.[26] These critics think and speak as if "ethics is ethics." General semanticists use what they call "dates and indexes." They are never surprised to find, indeed they rather expect, that "ethics1939" is not at all like "ethics2001."

As the previous section has demonstrated, however, even if one uses the totally inappropriate standards of 2001, the Phase I Tudor study still appears more ethical than many of the studies going on in Phase IV, not to mention Phases II and III.

It may turn out that no one has yet earned the right to cast moral aspersions on those whose pioneering work was done 62 years earlier. After all the pious proclamations from the Tudor study's self-righteous critics, and their insistence the human species has evolved into creatures with a much heightened ethical and moral sense, things still are far from perfect in research land.

The evolution of human morality and ethics with regard to any aspect of human behavior is usually a very slow process.[27] Moreover, even with standards in place the mere existence of institutions, regulations, and ethical standards seldom proves to be enough to protect the rights of human subjects, as the following examples demonstrate.

A 1994 Department of Energy advisory committee report contains an historical account of Public Health Service employees' site visits to research institutions. Those visits "revealed a wide range of compliance . . . confusion about how to assess risks and benefits, refusal by some researchers to cooperate with the [PHS] policy, and in many cases, indifference by those charged with administering research and its rules at local institutions."

As late as the post-1998 period the NIH shut down research programs at eight prestigious institutions for a variety of ethical violations. They included the September 1999 death of a human subject in a gene therapy study who, it is alleged, was not adequately informed of the risks.

Consider the April 2000 report of the DHHS Office of Inspector General, "Protecting Human Research Subjects." The report notes the office's concerns two years earlier: a "call for widespread reform," "a sense of urgency," "disturbing inadequacies in IRB oversight of clinical trials," up to and including

"the death of a teenager participating in a gene transfer clinical trial funded by NIH."

Presumably death could be considered a kind of "permanent harm" at least the equivalent of children's speech disfluency.

Notwithstanding these concerns, the report noted, "few of [the office's] recommended reforms have been enacted." IRBs are focusing "on review responsibilities of questionable protective value" while giving low priority to protecting human subjects. Many IRBs give reviews insufficient attention, and subsequently "know little of what actually occurs." Many researchers are untrained in human subjects research standards because "No educational requirements have been enacted." Increased commercialization in studies was a concern because it "heightens the potential for conflicts of interest in clinical research."

As late as October 2000 the NIH was still sufficiently concerned about researchers' lack of knowledge, understanding, and compliance with human research standards that it began to require proof of the education of researchers regarding those standards before studies are funded and undertaken.

Some of the ethical practices used by U.S. institutions with their research in developing countries could well be subject to serious criticism. One example may be enough to make the point.

A major academic journal reported in March 2000 a study reminiscent of the Tuskegee syphilis study (Quinn, 2000). It was done by researchers from no less prestigious a research institution than Johns Hopkins. In the Rakai region of Uganda they monitored 415 couples, of which only one partner was infected with HIV. The researchers did not inform the AIDS-free partners. Thirty months later 90 of the formerly healthy spouses had become infected. The journal's editor noted that the study was unethical by U.S. standards.

In July 2001 there were news reports that the federal Office for Human Research Protections had shut down human subjects research at Johns Hopkins. This was huge; all Hopkins medical institutions combined received $419 million in research funds from the NIH alone in 2000, the most of any such institution. The cited reason? "This is about protecting people's lives." The precipitating cause? The death of yet another human subject.[28]

The contrast between the media's coverage of this 2001 death at one of the nation's largest research institutions and the

coverage of the little 1939 Tudor study is striking. The word "hypocrisy" may or may not be misplaced, but "disparity" certainly is not.

There were no editorials passing moral judgment on the Hopkins researchers and their institution. No characterization of their work as a "monster study." No calls for punishment, or for removing names from buildings. Indeed, there was not even an editorial demand for apologies to the family members of the dead subject, let alone proposals that they be paid damages, all of which at least some editors thought appropriate for the 1939 study. There were no known media mentions of expressions of sympathy or sorrow for the deceased's survivors, though surely there must have been some. Table 9-1 compares the two studies.

Table 9–1. The 1939 Tudor Masters Thesis Versus The 2001 Hopkins Study

The 1939 Tudor Masters Thesis	The 2001 Johns Hopkins Study
The 1939 study was conducted before any ethical standards were in place; before even the Nuremberg and Helsinki statements. All possible standards were violated. No approvals were obtained.	The 2001 study was conducted after decades of evolution of detailed, written ethical standards. Those standards were violated. Yet the relevant IRB approved the study.
The 1939 study involved a young masters degree student with little or no funding, staff, or research experience.	The Johns Hopkins study involved respected professionals in the largest medical research institution in the country (the recipient of $419 million for taxpayer-supported research).
The 1939 study was conducted before there was any way of knowing what impact it would have upon the subjects, and every reason to believe any adverse effects easily could be reversed. It was original research; by definition there was no prior literature.	The Hopkins study involved the use of hexamethonium, a chemical about which much was known and published. It was known to cause lung damage, which was why it was used. It was given in amounts characterized as "extraordinarily large"; amounts the FDA would not have approved had it been asked.

Continued

Table 9–1. *Continued*

The 1939 Tudor Masters Thesis	The 2001 Johns Hopkins Study
The 1939 study involved the maximum informed consent possible (that of the adult administrator of the children's institution). No objections were raised to the study from the university, the institution, or the state agency with oversight responsibility. The researcher complied fully with the informed consent required by the ethical standards of the time.	The 2001 study's subjects provided a measure of consent, but it was not fully informed, as required. They were unaware of the full extent of the risks to which they were being subjected—such as death from the total destruction of their lungs. What they were told was a "medication"—was in fact a lung irritant, not an asthma remedy. The chemical had lost FDA approval for its original purpose in 1972, was not FDA-approved for this study, was used experimentally, in excessive amounts, and had never been approved in an inhaled form.
The 1939 study is criticized because the researcher's speaking to the subjects in ways millions of parents did in 2001 did not involve the evaluation of a *cure* for stuttering.There were no "cures" for stuttering to be tested in 1939.	There *were* possible cures for asthma in 2001. Yet in researching asthma the Hopkins researcher deliberately used a chemical he knew would *worsen* the subjects' lung condition. The study was in no sense a search for a "cure."
The 1939 study is criticized (falsely according to the best data) for causing permanent disfluency in the subjects.	The 2001 study caused a death, surely a kind of permanent harm the full equivalent of disfluency, even if not in the minds of many journalists and editorial writers.
The very least that can be said is that the 1939 researcher did not knowingly and deliberately do permanent harm to the subjects.	The 2001 researcher either knew, or ought to have known (based on the required literature search), that his deliberate actions risked permanent harm, including death, to his subjects. Indeed, his description of the study said its purpose was "to find out how the tubes that carry air into the lungs can stay open even when we breathe all types of irritating chemicals." This was, by any definition, knowingly and deliberately doing harm.

Whatever may be said by way of criticism of the ethics of the Tudor study, any fair critic would have to concede that, even applying the ethical standards of 2001, it compares very favorably to the studies to which those ethical standards clearly *do* apply.

VII. Scholarship and Scandals

A. Why Select the Tudor Study for Ethical Analysis?

There is a legitimate academic interest in the theories being tested by the Tudor study and the impact of those theories, and Tudor's evidence, on the history of stuttering research and therapy which followed. That is the focus of much of this book.

Moreover, human subjects research ethics, and the evolution of the standards reflecting those moral principles and ethical practices, are also clearly important subjects worthy of academic, and even journalistic, attention.

But *if* one is going to pursue an inquiry into human subjects research generally, there is a very large, and as yet unanswered, question as to why the Tudor study would play *any* role. Singling out Tudor as *the* case study in such an inquiry is, at best, a little bizarre.

Reflect on the thousands of studies that have been conceived, reviewed, approved, funded, and carried out by academic research institutions during the last half of the twentieth century, some of which are detailed in section II. D., above. Obviously, many prominent and reputable academic researchers, institutions, and granting agencies believed that those studies were defensible *after* ethical standards were in place.

By what logic would one ignore *those* studies? Why would one stretch to single out for moral judgment a little 1939 masters thesis, conceived and carried out long before any such standards existed?

B. Why Would University and Association Officers Join in the Critical Chorus?

Why would an officer of a professional association that includes speech-language pathologists want to say, not incidentally of a

person involved in the early years of that association, that the Tudor research "cannot be justified on theoretical, moral or ethical grounds and represented a serious error of judgment" (Bernthal, 2001)?

Why would a current university administrator at Dr. Wendell Johnson's institution want to be quoted as saying, "This is not a study that should ever be considered defensible in any era. In no way would I ever think of defending this study. In no way. It's more than unfortunate" (Ratliff, 2001)?[29]

It may be "more than unfortunate" that the mass media brought the Tudor study to national attention. But if it was so indefensible, if castigation and apologies are so necessary, why was none of this said and done when the study was spread across a local newspaper in that university's town years ago, described in an academic journal years before that, and subsequently found its way into a novel?[30]

The university administrator and association officer quoted above were unwavering in their rectitude. "The University of Iowa today has in place a strict policy and procedures [so that] experiments of this nature [the Tudor study] cannot happen again," says one (Jacobson, 2001, p. 1A).[31] "Such research is strictly prohibited under [the association's] Code of Ethics," says the other (Bernthal, 2001).

They thereby built themselves a very high pulpit from which to cast moral judgments on their predecessors below. Unfortunately, it sat atop a shaky scaffolding from which their fall from grace proved to be as prompt as it was painful. Not only were there the numerous examples of unethical practices throughout the research community in 2001, detailed in section V., above, but the University of Iowa in particular found itself criticized for its own violations less than a week after the Hopkins death was reported.[32]

Is this but one more example of a professional association and research institution primarily responding to the public relations demands[33] of a negative national media blitz? Or is there evidence of genuine concern for the subjects and the ethical issues involved?

C. The Ethical Failures of the Ethical Criticism

Such moral castigation, and the tabloid-style journalism that preceded and provoked it, have the effect of removing the Tudor study from meaningful perspective.

They fail to place the Tudor study within a context of the decades-long body of speech pathology research; to describe for persons who stutter, and the parents of those to come, the array of available assistance[34]; or the historical evolution of human subjects research ethics, which cannot be explained with sound bites and knee-jerk moral judgments. And they fail to recognize the place of the Tudor study in the lifetime body of stuttering research at the University of Iowa in general and of Dr. Wendell Johnson in particular (Johnson, 1930; Johnson, 1946; Johnson, 1955; Johnson, 1959; Moeller, 1975).[35]

It might be worth the price of tarnishing the reputation of a highly respected scientist, even a deceased giant from one's own institution, if it could contribute to a substantial improvement in public policy.

But comments and articles about the Tudor study are unlikely to have much, if any, impact on evolving human subjects research ethical standards and their administration.[36] Indeed, it truly would be shocking if a 62-year-old, Phase I masters thesis could raise ethical issues that had been neither recognized nor addressed in the detailed Phase IV regulations in place by 2001.

It also might be worth harming a reputation if the revelations would help millions, thousands, hundreds, or even dozens of people. There are numerous examples in which that is the case, involving everything from information about tobacco, asbestos, and pharmaceuticals' side effects to silicone breast implants and environmental lead and mercury.

It is not clear whether *any* of the Tudor subjects were harmed by the study in any way. Worst case, which requires that the assertions of litigants and their lawyers be treated as fact rather than negotiating gambits, there were one or two individuals whose disfluency increased.

The question is not whether a mere two people matter. Of course they do. The question is whether the publication of these articles and administrators' comments in 2001 did not do even *them* more harm than good.

D. Journalist Heal Thyself

It is pointless to speculate as to a journalist's motives. It does appear that there was a deliberate dramatization of a 62-year-old

masters thesis into a national story discrediting the reputations of the researcher and a supervisor 36-years dead.

This is the stuff for which the law provides remedies, such as defamation or false light. They involve a defendant's use of a fact here and there to present a false and damaging impression of someone.

The author of the newspaper stories in question was quick to cast moral opprobrium on the researcher and supervisor of the Tudor study. He was considerably slower in coming to an examination of his own ethical lapses. In fact, it appears he never bothered to consider them at all.

Journalistic ethics is not the oxymoron some may believe it to be.[37] There is a Society of Professional Journalists, which has created a "Code of Ethics." By 2001 the most recent version of the Code was the one adopted in September 1996 (Society of Professional Journalists, 1996). There are a number of provisions in this Code that raise issues with regard to the ethics of the reporter's and newspaper's handling and promotion of their stories about the Tudor study.

The Code speaks of goals such as "public enlightenment" from journalism. It says that journalists have a "duty" to "further those ends by . . . providing a fair and comprehensive account of . . . issues . . . [and] to serve the public with thoroughness and honesty." They "should . . . examine their own cultural values and avoid imposing those values on others."

Journalists should "show compassion to those who may be affected adversely by news coverage . . . recognize that gathering and reporting information may cause harm or discomfort . . . [and] that private people have a greater right to control information about themselves than do public officials. . . . Only an overriding public need can justify intrusion into anyone's privacy."

Finally, in a Code provision perhaps more applicable to editors than reporters, "Journalists should . . . make certain that headlines, news teases and promotional material, photos, video, audio, graphics, sound bites and quotations do not misrepresent. They should not oversimplify or highlight incidents out of context."

Consider the actions of Dyer and the *Mercury News* when measured by the standards of these admonitions.

The *Mercury News'* stories detracted from, rather than added to, "public enlightenment" about ethics in human subjects

research in general and the ethics of the Tudor study in particular. Their account of the issues was neither "fair and comprehensive" nor presented with "thoroughness and honesty."

One of the more serious indictments of the journalist's professional ethics and abilities is that the very human subject he selected to highlight was one whose fluency actually *improved* during the course of the study.[38] Whatever this may indicate regarding the validity of the theory drawn from the data by the researcher, it certainly seriously undercuts the journalist's efforts to trash the reputations of Dr. Wendell Johnson and Mary Tudor because of the harm he alleges they did to the subjects. One would think that a "fair" account, presented with "honesty" would require, at a minimum, a measure of factual accuracy. The journalist may have been unaware of his ethical transgression. Perhaps he did it deliberately. Or maybe it was simply a sloppy job of research and writing. And which would be worse?

The journalist failed to heed the ethical requirement that he "avoid imposing [his cultural] values on others;" moreover, in this case others who lived and acted in a different time and place, 62 years before the story was written. He failed to "show compassion to those who may be affected adversely by news coverage." There was no demonstration of compassion, and total indifference to "information [that] may cause harm or discomfort" to the named subjects, the researcher, and the family survivors of the supervisor of the study.

There was no apparent "overriding public need [to] justify intrusion into anyone's privacy." In order to avoid invasions of privacy at least the researcher had exercised enough sensitivity to refer to the subjects only by number rather than by name. Unfortunately, the journalist chose to ignore both the *researcher's* sense of decency and *his* ethical responsibilities.

The journalists' Code of Ethics also provides that, "Journalists should . . . avoid undercover or other surreptitious methods of gathering information except when traditional open methods will not yield information vital to the public. Use of such methods should be explained as part of the story."

On July 25, 2001, the journalist's executive editor felt obliged to run an editorial revealing that the journalist had violated the paper's own ethical standards regarding "surreptitious methods" (a provision equivalent to that quoted above).[39] The journalist had gained entry to a State of Iowa archive that is

closed to journalists. He had misrepresented that his role was that of an academic researcher. The editor failed to mention any of the reporter's other ethical violations, including the violation of the privacy rights of the subjects, which was one of the reasons for excluding journalists from the archives.

As for the ethics of the promotional material, consider this promo in the journalist's paper a couple days before the series was scheduled to run. The headline blared:

> ***"San Jose Mercury News Uncovers Secret Experiment to Make Orphans Stutter; Traces Living Legacy of Tormented Children and Haunted Researcher"***

The promo began, "In a chilling investigative series beginning Sunday, the Mercury News reveals for the first time the complete story of a secret experiment conducted 60 years ago to induce a group of orphans to stutter. The study [was] designed and concealed by Wendell Johnson . . . "[40]

Consider the inaccuracies and exaggerations. The researcher did not "torment" the subjects. A "haunted" researcher? A "chilling" series? There was nothing to "uncover." The study was not "revealed for the first time." It had been written about by others, including Dyer himself nine years earlier.[41] It was not "a secret experiment." It was not "conducted . . . to induce a group of orphans to stutter." It was not "concealed."

Compare this promotion with the ethical standard. Are these "headlines, news teases and promotional material [that] do not misrepresent; [that do] not oversimplify or highlight incidents out of context"? Or do they (and the series itself) have more in common with sensationalist, tabloid, supermarket scandal sheets?

The journalist's ethical violations ultimately led to his "resignation" (Associated Press, 2001).

It is beyond the scope of this chapter to explore whether he also may have been guilty of defamation or false light. It is enough to note that he is in a very weak position when questioning the ethics of others, especially when he is doing so in the emotionally laden vocabulary of the tabloids. After all, those he criticized acted *before* the existence of relevant ethical standards for human subjects research. He was writing *after* the journalis-

tic ethical standards he violated were in place and applicable to his journalism.

One need not look back on his actions with the benefit of hindsight and judge him by the standards of journalistic ethics 62 years later, in 2063. It is enough to judge him by the standards in place at the time he wrote, standards that presumably were, or ought to have been, well known to him.

VIII. Conclusion

Whatever the Tudor study's *substantive* faults may be, its ethics compare very favorably not only to the standards of its own time, in 1939, but to those of 2001 as well.

If its substantive critics are right, no harm was done or intended, either by Dr. Wendell Johnson or by Mary Tudor. The study could not, and did not, "cause stuttering."

Even if those critics are wrong, and contrary to the best evidence the subjects *did* experience increased disfluency in later life, there is no indication it was *caused* by anything done by Mary Tudor, as distinguished from the subjects' experiences before, during, or after their stay in the institution.

Make three *false* assumptions. Critics of the Tudor study's substance are wrong. The subjects have suffered permanent harm. There is proof beyond a shadow of a doubt that the sole cause of that harm was the Tudor study. Even if each of those false assumptions were true, there still would have been no violations of international or other ethical standards for human subjects research applicable to the Tudor study in 1939. There simply were none in existence at the time.

Even if *all* the above were true, *and* it were to be irrationally and unfairly decided that the study's ethics should be judged by the standards of 2001, it would still be difficult to find serious ethical violations.

One cannot judge the ethics of "the study," only the *specific* ethical standards that are alleged to have been violated. Few, if any, can be found.

Finally, insofar as there might be found to be any specific violations, there are many more, of much greater seriousness, going on today that have *not* brought forth anything like the

moral castigation hurled at Dr. Wendell Johnson and Mary Tudor.

So why were the ethics of the Tudor study attacked? This review of the ethics of administration, journalism, and human subjects research provides no answer. And speculation regarding the motives of others is a task even less rewarding than looking for ethical needles in a 62-year-old haystack.

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Endnotes

1. This chapter is supported by a Web site at http://www.nicholasjohnson.org. Many of the chapter's citations are to on-line material. Although the URL links were working when the book went to press, in the future some may no longer function. Thus, the Web site provides updated URLs. It also contains links to the original version of this chapter presented as a paper, additional references beyond those listed here, the Wendell A.L. Johnson Memorial Home Page, and additional information about the author.

This chapter only addresses the ethical issues surrounding the Tudor study. It leaves to research scientists' other chapters the analysis of the Tudor study data and conclusions. It presumes the reader has at least some awareness of stuttering research in general, the research of Dr. Wendell Johnson in particular, and most especially a 1939 masters thesis by one of his graduate students, Mary Tudor.

2. The emotionally-loaded quality of the reporting is illustrated by the language used in the accompanying promotion:

> [In the] 'Monster Study' in 1939, an ambitious professor conducted a secret experiment on a group of orphans to test a new theory on stuttering. The results helped gain renown for the professor, but many of the children were psychologically harmed for life. The study was covered up, even from the orphans—until now.

Aside from the obvious difficulties one would confront in an effort to "gain renown" from a "secret experiment" that was "covered up . . . until now"—even one known to be a "monster study"—the numerous violations of journalistic ethics represented by the newspaper's stories and promotional announcements are detailed in section VII. D., in the text.

There is no evidence for the assertions that the study, often examined by researchers and referenced in print (including an earlier story by this very reporter), was "covered up . . . until now," that it involved "stuttering" rather than "disfluency," or that "many of the children were psychologically harmed for life."

Part Two was published by the same newspaper June 11, 2001, also on page 1A. Its promotional material included this quote: "An experiment leaves a lifetime of anguish [as] the study's young victims were left in ignorance, to cope alone. Experts debate whether the benefits justified the harm."

3. "For [former University of Iowa Vice President for Research] Duane Spriestersbach . . . [the] experiment was both justified and ethical. 'It was a different time and the values were different. . . . Today we might disagree with what he did, but in those days it was fully within the norms of the time.'" Jim Dyer, "Ethics and Orphans: The Monster Study," Part Two of a Mercury News Special Report, *San Jose* [CA] *Mercury News*, June 11, 2001, p. 1A. Others agree. "The University of Iowa's stuttering experiment six decades ago . . . wouldn't have been considered so unusual at the time, according to experts." Colleen Krantz, "Orphans Targteted for Tests," *Des Moines Register*, July 9, 2001, p. 1. As then-University of Iowa President Mary Sue Coleman put it, "It was a different time and place." Jim Jacobson, "UI Denounces Experiment," *Iowa City Gazette*, June 13, 2001, p. 1A. The University's Human Subjects Office director, Trish Wasek, said, "It was a different time and a different set of mores in existence at the time." Colleen Krantz, "U of I Rues Experiment on Stutterers," *Des Moines Register*, June 14, 2001, p. 1.

4. That this is not always the case, that there are mature adult responses occasionally, is illustrated by the *Baltimore Sun*'s noting the contrast between the responses of Johns Hopkins and Rochester researchers after the death of a human subject. "In Rochester in 1996 [following the death of a human subject], doctors disclosed as many details as they could, at the risk of embarrassing themselves and complicating their legal position . . . . In Baltimore in the past few weeks, Hopkins leaders initially chose to reveal little, at the risk of appearing to have something to hide." Eric Siegel and Diana K. Sugg, "Management of Crisis Key to Public Trust," *The Baltimore Sun*, June 24, 2001.

5. Aside from the obvious use of the label "monster study" as a pejorative to besmirch the reputations of the researcher and her supervisor, it is not otherwise totally clear what "monster study" is intended to convey. Is it that the researcher was a "monster" ("a cruel, wicked and inhuman person")? Is it that the study *produced* "monsters" ("a grossly malformed and usually nonviable fetus")? That the study actually made the subjects stronger ("someone or something that is abnormally large and powerful")? Certainly those who so describe the study do not mean to suggest that the study was a big hit in speech communication research, as in "a monster hit at the box office." (Quoted definitions from http://dictionary.com) Whichever of these meanings is intended by the use of "monster study" it is so totally devoid of factual basis as to leave it as little more than a purposeful attack on reputation.

6. The president of the Stuttering Foundation of America has also noted, "In the 60 intervening years, no other researcher [than Mary

Tudor] has demonstrated that labeling someone a stutterer or criticizing his speech alone leads to the development of stuttering." Jane Fraser, *The Fresno Bee*, July 10, 2001, p. B6.

7. "Inasmuch as there is willingness to recognize differences in standards that existed 60 years ago, the remaining major concern in the case of the Tudor study is whether or not the experimenter and her mentor intended to cause harm by turning normally speaking children into children who stutter. Our review of the study reveals no such apparent intent. The study investigated whether the level of disfluency could be changed as a result of labeling. It was not to create stutterers. Even if there was an unstated goal to increase disfluency to a level perceived as stuttered speech, there is no indication that Tudor or Johnson believed that, if successful, this would make the children chronic stutterers. This, in our opinion is a critical point in judging the ethics of those involved in the conduct of the study."

They conclude, "Our assessment of the ethical issues suggests that the study should be viewed within the common standards of the period, that there is no evidence of intent to harm, and that the objective of increasing disfluent speech should not be confused with instilling chronic stuttering in normally fluent children." (Ambrose & Yairi, 2002, p. 201)

8. The World Health Organization (WHO) is involved in evaluating the ethics of a number of aspects of medical care in developing countries. U.S. pharmaceutical companies have sometimes sold drugs in developing countries that have been rejected by the FDA for sale in the United States. Among the WHO's concerns are the ethical issues raised by the use of human subjects from developing countries in studies conducted by corporations and their researchers from the developed world. Concern for human subjects research ethics when the subjects are Americans tend to evaporate beyond our borders. As one author has put it, researchers are "changing their ethics 'at the customs desk.'" Paul M. McNeill (1998), "Should Research Ethics Change at the Border?" *The Medical Journal of Australia*, *169*, 509–510, http://www.mja.com.au/public/issues/nov16/mcneill/mcneill.html

The WHO has an ethics page on the Web, http://www.who.int/ethics/en. One of its publications refers to "current ethical controversies as experienced in Argentina, Brazil, Canada, Colombia, Chile, Spain, the United States, Mexico and Peru."

The Centers for Disease Control and Prevention has a "Human Subjects Research" page (http://www.cdc.gov/od/ads/hsr2.htm) and provides

the text of the Council for International Organizations of Medical Sciences (CIOMS), "International Guidelines for Ethical Review of Epidemiological Studies" (Geneva, 1991), http://www.cdc.gov/od/ads/intlgui3.htm

In March 2000, the *New England Journal of Medicine* reported a study reminiscent of Tuskegee (discussed in section II. D. 1., in the text) done by researchers from no less prestigious a research institution than Johns Hopkins. In the Rakai region of Uganda they monitored 415 couples of whom only one partner was infected with HIV. The researchers did not inform the AIDS-free partners. Thirty months later 90 of the formerly healthy spouses had become infected. The journal's editor charged that the study was unethical by U.S. standards. "Ethics of Medical Research in the Third World," *AllAfrica Global Media*, February 2, 2001, http://allafrica.com/stories/200102020128.html (subscription required). Five people died in a South African clinical trial of anti-AIDS drugs at the Kalafong hospital where participants "claimed they were ill-informed about their rights when they signed consent forms." Ibid.

Paul M. McNeill, cited above, reports that as a result of providing HIV-infected mothers with placebos as a part of studies in Thailand, Africa, and the Caribbean, their children were unnecessarily, and deliberately, permitted to develop AIDS.

9. That supersensitivity about human subject research ethics is both preventing research that needs to be done, and producing unfair moral judgments about that which has gone before, is supported by a couple of articles: Christopher Shea, "Don't Talk to the Humans," *Linquafranca*, 10(6), September 2000, and John R. Stanley, "Ethical Accusations: The Loss of Common Sense," *Archives of Dermatology*, *136*(2), 268–269, February 2000, http://archderm.ama-assn.org/cgi/content/extract/136/2/268-a (extract only with link to subscription-based full text).

Shea discusses examples of IRBs interfering with research in anthropology, history, journalism, public policy (researchers' interviews with government officials), and urban ethnography. He cites the case of a history Ph.D. candidate who also works as a newspaper editor. "So during the day, when he's working on his dissertation, he is supposed to get permission from an IRB before he talks to a retired governor or columnist. . . . At night, he can call up anyone he wants and grill them."

Shea draws a stark contrast between the punctilious attention given by some to relatively harmless practices on the one hand (what he characterizes as the ethical equivalent of "run[ning] a red light on a deserted

street at 3:00 AM."), and the somewhat less attention paid to much more serious ongoing ethical violations:

> You would not get the impression that human-subject committees are overly aggressive from reading the newspapers. In September 1999 a young man died while undergoing experimental gene therapy at the University of Pennsylvania, and his father subsequently claimed that no one had fully explained the risks involved in the treatment. Since the fall of 1998 the National Institutes of Health (NIH) have shut down research programs at eight institutions, including Duke University Medical Center, the University of Illinois at Chicago, and Virginia Commonwealth University. The NIH cited violations that ranged from inadequate record-keeping to a failure to review projects that should have been vetted.

One of the WHO ethics publications asserts that there is, "a growing perception that research involving human subjects is beneficial rather than threatening and that vulnerable groups, such as women, children, the elderly, and prisoners, should not be deprived arbitrarily of the opportunity to benefit from investigational drugs, vaccines or devices."

10. Much of the research regarding studies described in this section came from the Department of Energy's Advisory Committee on Human Radiation Experiments Report, DOE Openness: Human Radiation Experiments, http://tis.eh.doe.gov/ohre/roadmap/achre/ The Committee was established by the President in 1994. See especially "Part I. Ethics of Human Subjects Research: A Historical Perspective," http://tis.eh.doe.gov/ohre/roadmap/achre/overpt1.html

The U.S. Department of Health and Human Services' Office for Human Research Protections is a prime site for links to many of the basic documents both historical and current, http://www.hhs.gov/ohrp/ One of its pages provides links to educational material for researchers about human subjects ethics, http://www.hhs.gov/ohrp/education/index.html#materials

The Virginia Commonwealth University's site, "Ethics of Research Involving Human Participation," contains useful links: http://www.vcu.edu/hasweb/psy/faculty/fors/ethics.htm Professor Lawrence M. Hinman at the University of San Diego maintains an "Ethics Update" site, http://ethics.acusd.edu/

The National Library of Medicine's "Current Bibliographies in Medicine" series includes 5000 references in "Ethical Issues in Research Involving Human Participants," Current Bibliographies in Medicine 99–3, http://www.nlm.nih.gov/pubs/cbm/hum_exp.html The Introduction notes the significance of the President's 1997 apology to the

survivors of the Tuskegee Syphilis study and the reforms that followed. It says, "Contemporary safeguards such as [IRBs] are important, but by themselves are insufficient. Educating researchers and the public about research ethics is critical for the full protection of research participants." This bibliography is itself a consequence of that finding, and the work of the Bioethics Education Materials and Resources Subcommittee of the National Bioethics Advisory Commission.

11. The Nuremberg Code (1948) is a basic document available from numerous sources and Web sites. One is, "Nuremberg Code: Directives for Human Experimentation," Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2, pp. 181–182. Washington, DC: U.S. Government Printing Office, 1949, http://ohsr.od.nih.gov/nuremberg.php3

12. World Medical Association, "World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects" ("Declaration of Helsinki") (Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and amended by the 29th World Medical Assembly, Tokyo, Japan, October, 1975, 35th World Medical Assembly, Venice, Italy, October 1983, 41st World Medical Assembly, Hong Kong, September 1989, 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996, and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000), http://www.nihtraining.com/ohsrsite/guidelines/helsinki.html

And see Glen Drew, "Side-by-Side Comparison of 1996 and 2000 Declaration of Helsinki," http://www.hhs.gov/ohrp/nhrpac/mtg12-00/h1996-2000.pdf

13. See, for example., NIH, Office of Human Subjects Research, "Criteria for Institutional Review Board (IRB) Approval of Research Involving Human Subjects," http://www.nihtraining.com/ohsrsite/info/sheet3.html Criterion 2 provides, "An IRB may approve research only after it has determined that all of the following requirements are satisfied: . . . (b) Risks to subjects are reasonable relative to (1) anticipated benefits, if any, to subjects, and (2) the importance of the knowledge that may reasonably be expected to result."

14. This common defensive, and seemingly uncaring, reaction continues to this day. Following the death of a subject during a 2001 Johns Hopkins study there was an expression of considerable outrage by Johns Hopkins' doctors over the government's closing down their research ("unwarranted, unnecessary, paralyzing and precipitous").

There was after all, they pointed out, only one dead subject. You would think it was they who were the victims rather than their dead human subject and her family members.

Nor was concern about loss of funding limited to Hopkins. The University of Iowa contributed to a local news story by Jim Jacobson, headlined "UI Funding Unaffected by Halt in Johns Hopkins Cancer Study," *Iowa City Gazette*, July 21, 2001, p. 1. Apparently Hopkins, rather than the government, subcontracts to the university $700,000 a year for one study and $11,000 for another. Iowa City residents were no doubt reassured to learn that the local research "likely will not be affected." There was no mention of the death, nor of expressions of concern by university administrators.

15. Even *Mercury News* reporter Jim Dyer later acknowledged, during an NPR interview, that "[Johnson] went to the . . . place that the University of Iowa . . . had used for several studies and research projects, and received permission . . . for this particular project." NPR, "Weekly Edition," June 23, 2001. He wrote, "In fact, in its 1936 biennial report, the Iowa State Board of Control, which oversaw all state institutions, openly encouraged and reported on cooperation with the University of Iowa in conducting research using children in various institutions." Jim Dyer, "Ethics and Orphans: The 'Monster Study,'" *San Jose Mercury News*, June 11, 2001. And see Colleen Krantz, "Orphans Targeted for Tests," *Des Moines Register*, July 9, 2001, p. 1. James Holmes, superintendent of the institution during the 1950s and 1960s has said of the Tudor study, "The state must have known about it" (Dyer, above).

16. References to the full text of the NASA standards, and their historical evolution, are a part of the Advisory Committee on Human Radiation Experiments Report; see Part I, Chapter 3, NASA Policy, http://www.eh.doe.gov/ohre/roadmap/achre/chap3_3.html

17. "The history of psychology . . . is studded with experiments whose designers gave too little thought to the well-being of their subjects . . . . [I]n the early 1960s the young Theodore Kaczynski—the future Unabomber—was among a group of Harvard students garlanded with electrodes and confronted by skilled lawyers who ridiculed and demolished what the students avowed were their most deeply held beliefs. No one explained the experiment in advance, the psychologists wanted to see how the students would handle the stress." Christopher Shea, "Don't Talk to the Humans: The Crackdown on Social Science Research," *Linguafranca*, *10*(6), September 2000. For

additional references see, Nicholas Johnson, "Psychology's Special Problems," in "Cites, Sites, Sources and Notes," linked from http://www.nicholasjohnson.org

18. Even Tudor ethics critic Jim Dyer expressly acknowledges, "In the autumn of 1938, Johnson received permission from orphanage officials to begin his experiment." Jim Dyer, "Ethics and Orphans: The 'Monster Study,'" *San Jose Mercury News*, June 10, 2001. He continues, "The university had already conducted numerous research projects . . . there, among them a decades-long study to see if developmental retardation would be more common among children who remained in the overcrowded and unstimulating orphanage than among children placed in a special new preschool."

19. Retired Marquette speech pathology professor Bill Trotter agrees: "I know Wendell Johnson was an extremely ethical and moral person, and if something happened to those children it was because of something he did not foresee." Jim Dyer, "Ethics and Orphans: the 'Monster Study,'" *San Jose Mercury News*, June 11, 2001.

20. For any readers totally unaware of the reputation of Dr. Wendell Johnson for ethical, kindly and thoughtful behavior toward others, a few quotes and a Web site link may provide some insight.

Shortly after the *Mercury News* articles the former director of the Indiana University Speech, Language and Hearing Clinics wrote, "Johnson . . . completed a formidable body of scientific research that gave hope to millions. Johnson was a remarkable personality who got along well with everyone. His stuttering clients, their families, university students, etc. all loved him. He was such a kind man. There was nothing that he would ever have done intentionally to harm anyone." Robert L. Milisen, "Johnson Was a Great Man," *Iowa City Press-Citizen*, June 27, 2001, p. 11A.

Former colleague Dr. D. C. Spriestersbach told Jim Dyer, "Wendell Johnson was a most revered and universally loved man." Jim Dyer, "Ethics and Orphans: The 'Monster Study,'" *San Jose Mercury News*, June 11, 2001.

Five speech pathologists wrote, "Recently have come comparisons of Dr. Wendell Johnson to Timothy McVeigh and Adolf Hitler. This has made us so angry. Johnson has no similarities to such individuals. He was a fine man, dedicated to helping solve the problems of stuttering, not only in the United States but also in the world. All that has been accomplished in this emotion-laden journalism is the trashing of a well-earned reputation of one of the most decent men who ever lived."

Judith Knabe, Peggy Gingerich, Nancy Fesenmeyer, Jill Lorack, and Becky Hubbard, "Wendell Johnson was a Fine Man: Judge Him in Light of the Times," *Iowa City Gazette*, July 5, 2001, p. 7A.

Even while issuing the University's apology to surviving subjects of the Tudor study, the University's Vice President for Research, David Skorton, who was very critical of the study's ethics, added, "In no way does this statement denigrate Wendell Johnson's very important and contributory career. He was a huge, positive factor in the field of speech pathology and in the lives of many, many patients with speech disorders." Kathryn Ratliff, "UI Apologizes for Research on Stuttering," *Iowa City Press-Citizen*, June 14, 2001, p. 1A.

A former student and colleague wrote of him after his death, "He was much beloved, even by those in Iowa City who knew little of his international recognition and awards. To them he was a neighbor, a great public speaker, teller of stories, composer of songs and limericks, personal counselor and active member of civic organizations. When he died, in addition to the stories in national news magazines and newspapers, the family was flooded with thousands of letters from individuals around the world, formerly unknown to them, who had been touched in some way by his life and love of humankind." Dean Williams, "Remembering Wendell Johnson," *Et cetera*, Winter 1992–93, p. 433, reprinted from the *Daily Iowan*, May 4, 1992.

> The man I knew seemed exceedingly gentle and incapable of angering. His disposition had a very calming effect in otherwise trying times . . . . A few days before he died in August 1965, I received a very long letter with remarks on his health status, general philosophizing, and the wish that he could be 50 white rats so his physicians could do the kind of research on his condition that could provide some answers, a typically Johnsonian approach to life. . . . To sum up the Johnson I knew, my best memories are of a pleasant, jovial, dedicated man whose love of life and of people was evidenced in his every act. (Joseph L. Stewart, "Wendell Johnson: A Memoir," *Et cetera*, Winter 1992–1993, p. 424.)

See generally, "Wendell A. L. Johnson Memorial Home Page." Available as a link from: http://www.nicholasjohnson.org

21. See also Dorothy Moeller, *Speech Pathology and Audiology: Iowa Origins of a Discipline* (Iowa City: University of Iowa, 1975), pp. 61–62.

22. "As you can see, the woman 'featured' in Dyer's articles actually got more fluent over the four months." Dr. Robert W. Quesal, E-mail to author, June 21, 2001, with accompanying supporting analysis of the Tudor study data.

23. Dr. Wendell Johnson's masters thesis, *Because I Stutter* (Appleton, 1930), was one of the very few masters theses to be commercially published. Although out of print, it is available on the Web as a link from http://www.nicholasjohnson.org/wjohnson

24. The masters thesis is a very thin document consisting of no more than a handful of pages of commentary and conclusions along with a reproduction of the data. Moreover, twenty-first century critics of the study argue that the data it contains simply do not support its few conclusions. Few masters theses in any field are likely to receive much attention and subsequent citation, so it is not remarkable that the Tudor study did not. However, in this case it is at least possible that an additional reason for the little attention it received over the years is that earlier researchers saw in it the same flaws seen by its critics a half-century later. In any event, given that it was cataloged in the University of Iowa Library, as accessible as any other masters thesis over the years, and checked out many times, this seems a much more probable explanation than that it was "suppressed."

25. Standards change over time with regard to many aspects of human behavior. Language widely used without formal objection at one time, say, the way some men talked about women during the 1950s, may become the basis for everything from social shunning to law suits for sexual harassment decades later.

The writer was a human subject in a University of Iowa clinical trial of a new drug. It is apparently standard practice to require human subjects, who are taking at least some risk for no pay in a project from which everyone else is profiting, to sign a couple of waivers. One absolves the institution not only from any liability for harm, but even liability for negligence. The other seems especially uncaring. The testing institution, a major research hospital, expressly leaves human subjects harmed by the study entirely on their own in their search, and ability to pay, for restorative medical care. Is this ethical? Under 2001 standards apparently it is. Will there be another view of the matter in the future? One would hope so. And, if so, will moral outrage then be expressed regarding those who utilized such overreaching waiver language today? One would hope not.

By mid-twenty-first century a majority of the world's population may conclude that today's animal rights activists were right all along. Those not vegetarians in 2001 may find their eating habits subsequently described as "barbaric" some 62 years later because of their earlier willingness to slaughter animals and eat their flesh. They may even

become named defendants in mock trials for their participation in this animal genocide. PETA (People for the Ethical Treatment of Animals) has for years objected to the use of animals in research, http://www.peta.org and see especially, "Cruel Science," http://www.peta.org/cmp/sci.html and "Stop Animal Tests," http://www.stopanimal tests.com

The citizens of many countries already regard Americans as barbarians because we continue the death penalty, a practice they believe violates the United Nation's Universal Declaration of Human Rights (1948), http://www.un.orgt/Overview/rights.html, as President George W. Bush discovered during his 2001 European trip.

Those who are insistent on applying the standards of their day to the human subjects research of others in the 1920s and 1930s might at least want to consider the consequences of doing so. To apply early twenty-first century standards to early twentieth century research will mean that, for the next few years, professional societies, research universities, and other institutions will be issuing apologies to the thousands of experimental subjects of that time, if not writing checks for billions of dollars as well. Indeed, one journalist has already seriously suggested they should be doing just that. John Carlson, "U of I, State Owe Yesteryear's Orphans the Whole Truth," *Des Moines Register*, June 17, 2001, p. 1B.

26. Although best known as a speech pathologist, Dr. Wendell Johnson was also one of the founders of the International Society for General Semantics. His book, *People in Quandaries*, first published in 1946, was still available in 2001.

27. It was December 2002 before the State of Oregon first acknowledged that its program of forced sterilization was no longer acceptable. From 1917 through 1983 over 2500 Oregonians, "girls in reform school, people in mental institutions and poor women selected by welfare workers," were sterilized. AP, "Ore. Gov. Apologizes for Sterilization," December 2, 2002.

28. Gina Kolata, "U.S. Suspends Human Research at Johns Hopkins After a Death," *The New York Times*, July 20, 2001.

The most detailed reporting regarding the Johns Hopkins controversy was, not surprisingly, in *The Baltimore Sun*.

Jonathan Bor and Tom Pelton, "Hopkins Study Was Exempt from FDA; Asthma Project Tested Function of Lungs, Wasn't a Drug Trial," *The Baltimore Sun*, June 22, 2001.

Jonathan Bor, "Hopkins Panel to Study Death of Volunteer," *The Baltimore Sun*, June 23, 2001.

Eric Siegel and Diana K. Sugg, "Management of Crisis Key to Public Trust," *The Baltimore Sun*, June 24, 2001.

Douglas M. Birch and Gary Cohn, "The Changing Creed of Hopkins Science; What Once Was Heresy Is Now the Mission: A Partnership with Business to Advance Research," *The Baltimore Sun*, June 25, 2001.

Editorial, "Death at Research Center; Hopkins Study: Volunteer's Death Raises Questions About Protection, Role of Human Research Subjects," *The Baltimore Sun*, July 1, 2001.

Editorial, "Of Profits and Patients; Medical Research: Academic Institutions Face Huge Conflicts of Interest as They Pursue Business Ties," *The Baltimore Sun*, July 2, 2001.

Tom Pelton, "Asthma Study Violated Safety Rules, FDA Says; Hopkins Experiment Ended with Death of Volunteer, 24," *The Baltimore Sun*, July 3, 2001.

Tom Pelton, "Respected Doctors Confront a Tragedy; Experiment: With a Research Subject's Death, Two Distinguished Scientists Confront What Colleagues Say Is the Worst Imaginable Outcome," *The Baltimore Sun*, July 8, 2001.

Editorial, "An Unnecessary Death; Hopkins Study: Tighter Controls on Human Research Projects Needed; Institution's Inquiry Finds Faults," *The Baltimore Sun*, July 18, 2001.

Jonathan Bor and Tom Pelton, "U.S. Halts Hopkins Research; Most Experiments on Human Subjects Ordered Suspended; Federal Funding Withheld; Oversight Agency Decries Safety Lapses in Volunteer's Death," *The Baltimore Sun*, July 20, 2001.

Michael Stroh, "Shutdowns Have Wide Effect on Programs; Cutting-edge Treatments Become Unavailable; Funding, Name Damaged," *The Baltimore Sun*, July 20, 2001.

"Hopkins Calls Federal Agency's Action 'Precipitous,'" *The Baltimore Sun*, July 20, 2001.

Editorial, "Protecting Humans in Research; Hopkins Shutdown: Government Is Right to Be Concerned, but Wrong to Punish Researchers so Harshly," *The Baltimore Sun*, July 21, 2001.

Diana K. Sugg, "Despite Suspension, Hopkins Researchers Continue Vital Tests; Doctors, Nurses Rush to Reassure Patients, Appeal Research Bans," *The Baltimore Sun*, July 21, 2001.

Tom Pelton and Jonathan Bor, "Hopkins Vows to Improve Research Safety; Changes Outlined in Letter School Sent to Federal Agency; 'It's Been Utter Confusion;' Lifting of Suspension Sought by Next Week," *The Baltimore Sun*, July 21, 2001.

29. See also, "UI Apologizes for Stuttering Study," *San Jose Mercury News*, June 14, 2001; "University Apologizes for '39 Experiment," *Chicago Tribune*, June 14, 2001, p. 19. University of Iowa President Mary

Sue Coleman was quoted as saying, "There's no way I can condone that kind of research." Jim Jacobson, "UI Denounces Experiment," *Iowa City Gazette*, June 13, 2001, p. 1A. Richard Hurtig, Chair of the UI Department of Speech Pathology and Audiology was quoted as saying that "this is not the kind of study anyone today would even think of proposing or would an institutional review board authorize." Kathryn A. Ratliff, "UI Stuttering Study Doubted," *Iowa City Press-Citizen*, June 12, 2001, pp. 1, 7.

30. James Dyer, "The Twisted Experiment of Dr. Wendell Johnson," *The Iowa City Mercury*, April 1992, p. 1. Franklin Silverman reported on the Tudor study as early as 1988 in the *Journal of Fluency Disorders*. It was also the subject of a novel by Jerry Halvorson in 1999.

31. The suggestion that today's research institutions and individuals possess a moral superiority to their predecessors, that there are standards in place today to prevent any possibility of the problems of earlier times, is a triumph of arrogance over experience. The abuses detailed in the DHHS Office of Inspector General's report, "Protecting Human Research Subjects," were published as recently as April 2000. It is available online in pdf format, http://www.oig.hhs.gov/oei/reports/oei-01-97-00197.pdf

The NIH requirement of "education on the protection of human research participants for all investigations" was established even later, in October 2000. One institutional response has been a simple online summary presentation of some highlights that researchers are required to scan. An example is the University of Michigan's "Protection of Human Research Subjects Computer-Based Training for Researchers." A comparable online training program is The National Cancer Institute, "Human Participant Protections Education for Research Teams," http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp (requires free online registration). Stanford University offers a similar "Use of Human Subjects in Research: History" tutorial module, http://www.stanford.edu/department/DoR/hs/History/his01.html

32. Less than one week after the Johns Hopkins revelations the *Des Moines* [Iowa] *Register* headlined on page one: "U of I Faces Probe Over Research." The story noted that, among other things, "the issues raised . . . focus on internal review boards that sometimes rushed approval of changes in experiment guidelines and did not document

procedures in enough detail." Colleen Krantz, "U of I Faces Probe Over Research," *Des Moines Sunday Register*, July 22, 2001, p. 1.

A letter to the university in 1999 from the Food and Drug Administration referred to its reviews at the university in 1992, 1995, and 1998. Each of those reviews involved violations that "are of particular importance because many of them have been observed during past inspections where corrections were promised by your institution but not implemented." According to the news story, an FDA spokesperson said it is "fairly rare to see issues remain unresolved after several visits, as inspectors suggested was the case at the University of Iowa."

A spokesperson for the university tried to minimize, even trivialize, the violations as "minor administrative details." Said another, "the more complex the research the greater the likelihood there are some failures because we are, after all, all human." Thus was it revealed that the standard of at least some educational administrators is to be forgiving of their own ethical and legal errors, but morally outraged by those of their predecessors.

The same University spokesperson who joined in the chorus of moral outrage, saying that the Tudor study was "unfortunate and indefensible," was later quoted in a local paper's follow-up on the *Register* exposé of the University's own failings. The *Register* reported that, "The university calls into question both the headline and its [the story's] placement as Sunday's leading story," while acknowledging that the story itself was "mostly accurate if read in its entirety."

The University of Iowa's continuing tenacious campaign against the *Des Moines Register's* headline and placement was represented in a letter to the editor with a headline presumably finally thought acceptable, David Skorton, "No Action Pending Regarding U of I Research," Opinion, *Des Moines Register*, August 5, 2001, p. 9A.

The contrast between this protest by the University over the headline and placement of a story it concedes was "balanced and mostly accurate," and its response to the media's unethical and broadside attacks on the 1939 Tudor study are striking. In the latter case it not only failed to protest *anything* about the stories, whether content, headlines, or placement, it actually joined in the moral castigation of its own former faculty member.

There was, of course, no reference to how "unfortunate and indefensible" it is that clear governmental standards have not been complied with in spite of repeated government investigations and university

assurances of correction. See generally, George Pappas, "Gov't Probe of UI Research 'Minor,'" *The Daily Iowan*, July 23, 2001, p. 1; George Pappas, "UI Fires Back at Register's Headline," *The Daily Iowan*, July 24, 2001, p. 1; Ryan Foley, "'Monster Study' Reporter Under Fire," *The Daily Iowan*, July 26, 2001, p. 1.

33. One of many possible consequences of such a hurried rush to public relations offensive is its impact on litigation. With potential plaintiffs waiting in the wings, to launch a gratuitous assault on a former faculty member as someone who supervised "a study that should [n]ever be considered defensible in any era," however much thought to be potentially useful in the public relations short run, is a somewhat reckless gamble with a state university's resources.

34. As one speech pathologist has noted, "Even more startling than the [Dyer] article itself was its front-page placement and space allotment, this for an article appearing to provide no useful information whatsoever to the public. . . . How much more useful would an article about stuttering problems have been if readers had instead been informed of resources. . . . As a speech pathologist, I am particularly disheartened that the opportunity to help people prevent and treat stuttering problems was squandered in what seems to be efforts to engage in sensationalism, for what purpose or purposes one can only speculate." Ellen-Marie Silverman, "Paper Missed Chance to Better Inform Readers," *Milwaukee Journal Sentinel*, June 18, 2001, p. 10A.

35. See, for example, Dorothy Moeller, *Speech Pathology and Audiology: Iowa Origins of a Discipline* (Iowa City: University of Iowa, 1975); Wendell Johnson, *Because I Stutter* (New York: Appleton, 1930); Wendell Johnson, *People in Quandaries* (New York: Harper & Brothers, 1946); Wendell Johnson (Ed.), *Stuttering in Children and Adults* (Minneapolis: University of Minnesota Press, 1955); Wendell Johnson (Ed.), *The Onset of Stuttering: Research Findings and Implications* (Minneapolis: University of Minnesota Press, 1959).

36. There are numerous ethical issues in human subjects research truly deserving of academic reflection and public education by journalists. Here is but one example.

An April 2000 report of the DHHS Office of Inspector General, "Protecting Human Research Subjects," notes a great many "disturbing inadequacies." One, it says, is that "The increased commercialization of

research and the growing importance of research revenues for institutions heightens the potential for conflicts of interest in clinical research."

On August 5, 2001, the *Washington Post* reported that overreaching by pharmaceutical companies was so bad that "editors at the world's most prominent medical journals, alarmed that drug companies are exercising too much control over research results, have agreed to adopt a uniform policy that reserves the right to refuse to publish drug company-sponsored studies. . . . " Susan Okie, "A Stand for Scientific Independence: Medical Journals Aim to Curtail Drug Companies' Influence," *Washington Post*, August 5, 2001, p. A1. (The story was reported in Iowa City as, "Journals Adopt New Policy: Editors Aim to Clip Drug Companies' Influence," *Iowa City Press-Citizen*, August 5, 2001, p. 1A, and "Medical Journals Battle Drug Firms' Grip on Research," *Iowa City Gazette*, August 5, 2001, p. 3A.)

The author quotes "several observers of biomedical studies who have become alarmed about the influence of the drug industry on the integrity of medical research." A University of California professor of clinical pharmacy is quoted as saying that if negative results are published "you can still get pressure put on you for fear that you won't get any future funding." Companies not only control access to data, but may even control who writes the papers, or ghost writes them for the academics who "are too busy to take all the time needed to create the publication." She cites examples in which reports of side effects, no benefits, or cheaper alternatives have led to blocked publication or even lawsuits.

One would think the significance of an ethical issue of this magnitude would be worth at least as much media attention as a masters thesis from 1939.

37. Compare Greg Mitchell, "Reporters Trail Badly (Again) in Annual Poll on Honesty and Ethics," Editor and Publisher, December 7, 2004 ("Once again, newspaper reporters score poorly in the annual Gallup Poll . . . on 'honesty and ethical standards' in various professions . . . lower than bankers, auto mechanics, elected officials, and nursing-home operators"), http://www.editorandpublisher.com/eandp/news/article_display.jsp?vnu_content_id=1000732750 with Michelle Z. Spielman, "U.S. Journalists Get High Marks on Ethics, Study Finds; LSU and University of Missouri professors analyze the 'moral minds' of journalists and advertisers," *LSU's Biweekly Newsletter for Faculty & Staff, 21*(12), February 25, 2005, http://www.lsu.edu/lsu-today/050225/pageone.html , and Kelly McBride, "Journalists: More

Ethical than People Realize?," Poynteronline, December 17, 2004, http://www.poynter.org/content/content_print.asp?id=75962&custom=

38. "As you can see, the woman 'featured' in Dyer's articles actually got more fluent over the four months." Dr. Robert W. Quesal, E-mail to author, June 21, 2001, with accompanying analysis of the Tudor study data.

39. The *Mercury News* ethics policy, violated by the journalist, provides:

> Under ordinary circumstances, reporters or photographers ought to identify themselves to news sources. There might be times, however, when circumstances will dictate not identifying ourselves. Only the Executive Editor or Editor may approve such exceptions. (*Mercury News* Ethics Policy, September 21, 2004, http://www.grandforks.com/mld/mercurynews/contact_us/about/9723906.htm)

To which the Executive Editor added in his editorial, "I didn't." David Yarnold, "Setting the Record Straight," *The San Jose Mercury News*, July 25, 2001.

40. The quote is from a promotional, public relations release from Patty Wise, the *Mercury News'* Public Relations Manager, distributed nationally by the PR Newswire Association, "to medical, family and features editors," June 8, 2001. It made both stories available to other papers prior to their publication in the *Mercury News*, thus ensuring the re-enforcing impact of the national media blitz.

41. The false claim that the study was "revealed for the first time" in the *Mercury News'* stories of 2001 is particularly ironic and unethical given that the stories' author, Jim Dyer, was *himself* one of those who wrote about it earlier in the *Iowa City Mercury*. James Dyer, "The Twisted Experiment of Dr. Wendell Johnson," *The Iowa City Mercury*, April 1992, p. 1. Franklin Silverman reported on the Tudor study as early as 1988 in the *Journal of Fluency Disorders*. Franklin Silverman, "The monster study," *Journal of Fluency Disorders*, *13*, 225–231 (1988). (For a different view of the Tudor study and its media coverage from the Silverman family see the quote from Ellen-Marie Silverman, "Paper Missed Chance to Better Inform Readers," *Milwaukee Journal Sentinel*, June 18, 2001, p. 10A, note 34, above.) The study was also the subject of a novel by Jerry Halvorson in 1999, Jerry Halvorson, *Abandoned: Now Stutter My Orphan* (1999) (with foreword by Franklin Silverman).