Considering the Social Implications of Science with the Scientific Research in the U.S. and Canada: What role should integration play?

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Frazier Benya

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Introduction

While the social implications of research are not discussed regularly in scientific or medical research projects, this is beginning to change. This thesis details where considerations of the social implications are occurring, how scientists are encouraged to participate in these discussions, and how different programs are integrating science and social implications research. Social implications research encompasses a wide range of considerations such as long-term social implications, public health concerns, benefits and risks to society rather than the individual, the responsibilities of researchers to society, and the relevance to public policy and the law. Ethical, Legal, and Social Implications (ELSI) programs, such as at the National Institutes of Health, and Ethical, Legal and Social Aspects (ELSA) programs are where considerations of social implications often occur, but it is important to note that considerations of social implications is only a subset of what these programs do. These ELSI programs also focus on other issues that are more immediate such as issues of informed consent and other topics in human subjects research ethics and clinical ethics. The term ELSI originates from the National Institutes of Health (NIH) Human Genome Project in the U.S., which set aside some of the scientific research funding to examine the implications of genetics research in humans. In this thesis, ELSI will be used to describe the type of research being done, not specifically the NIH ELSI program, and it will also be used to describe the scholars that work on those topics when used as “ELSI scholars” or “ELSI researchers,” rather than to refer specific to the scholars and researchers that receive funding through the NIH ELSI program. “ELSI scholars” in this thesis includes scholars in bioethics, but also encompasses a broader group of scholars who maybe do not identify as bioethicists.

To begin this thesis will examine the argument that scientists should be involved in, and have a responsibility to consider, the social implications of their work. The first section will begin with the historical origins of scientific social responsibility during the 20th century in the U.S. and make the argument that this is a professional ethic that scientists established over a period from the 1940s through the 1970s. The next section of the thesis will place this scientific social responsibility into the context of current literature in research ethics, demonstrating that scientific involvement in discussions of the social implications of science are an important part of the professional ethic. It will argue that a lack of institutional supports is discouraging many scientists from considering the social implications of their work and from being involved in work to address the social implications. The thesis will then review the current cases in the U.S. and Canada, as well as one international non-government organization where scientific research is being integrated with research on the social implications and ethics of science. In describing the U.S. cases I will focus on the ELSI program in the NIH's Human Genome Project, but will also present an overview of other places where some integration is occurring, including the National Academy of Sciences (NAS), and research ethics consultation services. In Canada, I will analyze Genome Canada's GE^3LS component of their scientific research funded projects. The international NGO case is the Ethical, Social, and Cultural (ESC) program started by the Bill and Melinda Gates Foundation's Grand Challenges in Global Health initiative. These cases will reveal that there are multiple ways to integrate science into discussions of the social implications and that the various different ways serve different purposes. There are also various ways to study social implications, which serve different purposes, and not all of them need to be integrated. This thesis will conclude that complete mandatory integration should not be the ideal, as scientists should be encouraged to be and supported in being involved rather than forced to do so.

Understanding how certain systems of funding and institutional support can encourage or discourage integrated discussions of social implications, can allow for more productive and frequent discussions within the scientific community and for collaboration with ELSI scholars. To analyze these integrated systems, I will use the four "key features" of an integrated system as identified by Hub Zwart and Annemiek Nelis.[1] The four features are proximity, anticipation, interactivity, and interdisciplinarity. Using these features I will map how different types of integrated systems and social implications work meet those criteria and finally place the current social implications research systems on a continuum from most to least integrated.

This analysis will reveal which methods for encouraging integration are successful at involving scientists in discussions of social implications and suggest ways to support integration at the institutional level. In addition, by identifying historical and current examples of scientists fulfilling their social responsibility, we will discover concrete examples of what social responsibility means in practice, which can then be taught in research ethics training classes. The historical examples of researchers fulfilling their social responsibility are valuable for teaching research ethics and understanding the context in which this responsibility arose. These historical examples also establish the professional ethic for scientists considering the social implications of their research. Current examples of how individual researchers are putting their social responsibility into

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[1] Hub Zwart and Annemiek Nelis, "What is ELSA Genomics?" *European Molecular Biology Organization (EMBO) Reports* 10, no. 6 (2009): 540-544.

practice can be even more influential in setting a good example of researchers working in collaboration on the social consequences of their work and in providing concrete and relevant guidelines for other scientists to do so.

History of Scientists Considering the Social Implications

This overview of the origins of scientific social responsibility during the 20th century in the U.S. focuses on discussions of controversial science between 1945 and 1975. It reveals where the expectations of researchers' social responsibility grew from and demonstrates that the social responsibility to consider and warn about the social implications of their work is part of a professional ethic that developed among scientists between the 1940s and 1960s. In addition, it describes how researchers have fulfilled this responsibility in the past and how their considerations resulted in changes in oversight and regulation. This historical overview gives important context to the role researchers play in considering the social implications of their work, to why society expects scientists' involvement, and to the importance of integrating the work of scientists with ELSI scholars.

During and after World War II, the United States federal government began to invest heavily in scientific research. This growth in funding spurred rapid advancements in atomic weapons, nuclear power, medicine, pharmaceuticals, and genetics. With these rapid advancements grew an increasing concern about the consequences of these discoveries and about the new control that humans had over life. During this period of rapid advancement and growing public concern, a discussion about the social implications of federally funded research developed and included discussions about research ethics and researchers' social responsibility. These historical discussions defined and created an expectation for scientific social responsibility, and in the process they established precedents for how U.S. society discussed the broader social implications of research and who should be involved.

Nuclear Science in the late 1940s

Toward the end of World War II and in the decade following the war, physicists became concerned over the technology and knowledge they had produced during the Manhattan Project and over the government's use of this technology. The product of the Manhattan Project, the atomic bomb, and its use on Japan led many physicists to discuss and reconsider their responsibility to society. Two atomic bombs were dropped on the Japanese cities of Hiroshima and Nagasaki, killing roughly 150,000 to 200,000 people. What was significant about the new weapon was that it took one bomb per city to kill all those people and that the destruction of life was not just from the immediate impact of the bomb but continued for weeks and even years through the destructive power of atomic radiation poisoning. The dangers of radiation poisoning and the destructive power of atomic bombs meant that a future war with atomic bombs threatened not just the countries involved in a war but also countries throughout the world. The atomic scientists actions following the end of WWII to warn of these dangers and prevent nuclear war, defined scientific social responsibility for future scientists.

Physicists' initial concerns about their research began before the plutonium bomb was tested on July 16, 1945 and as a result all discussion were classified and kept secret by the military.[2] On at least two occasions at Los Alamos, in March 1943 and late 1944,

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[2] Daniel J. Kevles, *The Physicists: The History of a Scientific Community in Modern America* (Cambridge: Harvard University Press, 1995); Barton J. Bernstein, "Four Physicists and the Bomb: the Early Years, 1945-1950," *Historical Studies in the Physical and Biological Sciences* 18, no. 2 (1988): 231-263.

scientists organized meetings where the idea of demonstrating the bomb over an unpopulated area before using it in the war was proposed.[3] In the spring of 1945, I.I. Rabi, a physicist who officially did not work on the Manhattan Projects but served as a senior consultant to J. Robert Oppenheimer, the director of the project, warned that after the completion of the atomic bomb physicists would become servants of the "munitions makers" and lose the respect of the public.[4] Rabi was concerned with physicists being co-opted by the military and losing their independence and intellectual freedom. Meanwhile Leo Szilard along with a group led by James Frank at the University of Chicago were concerned with the product of the research: the bomb. Szilard, who was instrumental in getting the atomic bomb project started in the U.S., also became a leader in speaking up against the use of the bomb on Japan.[5] Those scientists, known as the Frank group, were mostly concerned with how the product they had created was to be used and they feared the unwarned use of the bomb on a populated area.

Four leading physicists serving on the Scientific Advisory Panel created by the military, Arthur H. Compton, Ernest O. Lawrence, Enrico Fermi and J. Robert Oppenheimer, raised the option of a demonstration in a May 31, 1945 meeting with military and government leaders. Ultimately, the conclusion of these discussions was to move forward with the bomb. This was not well received by other physicists working on the Manhattan Project, including Leo Szilard and James Frank. Both men, along with five

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[3] Barton J. Bernstein, "Four Physicists and the Bomb: the Early Years, 1945-1950," Historical Studies in the Physical and Biological Sciences 18, no. 2 (1988): 231-263.

[4] Daniel J. Kevles, *The Physicists: The History of a Scientific Community in Modern America* (Cambridge: Harvard University Press, 1995): 334-335.

[5] Gregg Herken, *Cardinal Choices: Presidential Science Advising from the Atomic Bomb to SDI* (Stanford: Stanford University Press, 2000), 25; see also Gregg Herken, *Brotherhood of the Bomb: The Tangled Lives and Loyalties of Robert Oppenheimer, Ernest Lawrence, and Edward Teller* (New York: Henry Holt and Co., 2002).

other researchers, sent a report to the Secretary of War in which they "pleaded that the A-bomb not be used on Japan, suggested a non-combat demonstration and warned of a postwar race if the weapon was used."[6] Historian, Daniel Kevles, argues that the Los Alamos generation, the generation of atomic scientists who worked at Los Alamos on the atomic bomb, as a whole agreed with the declaration by the Frank group and believed that scientists could no longer deny responsibility for the technologies and knowledge they produced.[7] However, the Frank report and the support among atomic scientists did not persuade the military or the four members of the Scientific Advisory Panel to change the plan to drop the bomb on a Japanese city, and neither did the very dramatic first testing of the atomic bomb in Alamogordo, New Mexico on July 16, 1945. During this time discussions of the atomic bomb were still classified and thus were kept from the general public. The physicists letters and requests to military and government leaders were the furthest the scientists could take their concerns at the time; they could not go public by writing an editorial to the New York Times or expressing their concerns to Congress.

When the atomic bomb was dropped on Japan in August 1945, the public and military saw it's use as a successful end to the war, however many of the scientists immediately saw the implications of the use of the bomb for international and national affairs. The atomic scientists raised concerns about the prospect of other countries developing an atomic bomb and the resulting dangers of an arms race and possible nuclear war. These concerns led some scientists and the military to look toward keeping

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[6] Barton J. Bernstein, "Four Physicists and the Bomb: the Early Years, 1945-1950," *Historical Studies in the Physical and Biological Sciences* 18, no. 2 (1988): 236.

[7] Daniel J. Kevles, *The Physicists: The History of a Scientific Community in Modern America* (Cambridge: Harvard University Press, 1995): 335.

the research secret and toward creating the next bigger bomb, the Hydrogen bomb, as a means of preventing a nuclear war or arms race. However, other scientists warned that the knowledge could not be kept secret and they held views that creating a new bigger bomb or keeping the knowledge of how to create an atomic bomb secret would not prevent the dangers of nuclear war. Instead these scientists, such as those among the Frank group, argued for civilian and international control of atomic science research and atomic weapons as opposed to American military control.[8]

The prospect of funding research on the H-bomb provided atomic scientists with a second opportunity to express their opinions and influence policy about the use of nuclear science. Historian Gregg Herken describes how scientists after the war believed that their opinion on how the results of their work were used now mattered. Yet there remained disagreement among scientist about if they were qualified and obligated to advise on issues outside of science and technology.[9] Despite this disagreement, many atomic scientists and physical scientists worked to influence policy and public opinion because they felt it was their responsibility. Herken describes that the initial reluctance by atomic physicists to speak publicly about the societal consequences of their work gave way as discussions of the next generation of nuclear bomb, the Hydrogen bomb, began.[10]

For part of the atomic scientists' community, creating an H-bomb was an area of science that was too dangerous to pursue. The prospect of an even more destructive

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[8] Gregg Herken, *Brotherhood of the Bomb: The Tangled Lives and Loyalties of Robert Oppenheimer, Ernest Lawrence, and Edward Teller* (New York: Henry Holt and Co., 2002).

[9] Gregg Herken, Cardinal Choices: Presidential Science Advising from the Atomic Bomb to SDI (Stanford: Stanford University Press, 2000): 34.

[10] Gregg Herken, Cardinal Choices: Presidential Science Advising from the Atomic Bomb to SDI (Stanford: Stanford University Press, 2000): 34.

nuclear weapon raised concerns among these physicists. Combining with these concerns, the Cold War fears surrounding the Soviet Union's development of an atomic bomb only furthered the fears of an arms race and nuclear war. U.S. atomic scientists sharing these fears and believing that the public needed to be informed about nuclear science's social implications formed a number of groups in late 1945, including the Atomic Scientists of Chicago, the Association of Oak Ridge Scientists, and the Association of Los Alamos Scientists. These local groups eventually combined into the Federation of Atomic Scientists and shortly thereafter, in January 1946, broadened yet again and became the Federation of American Scientists (FAS) to reflect its expanding membership. These atomic scientists believed that the research on atomic science should be separated from the military and put under civilian control. They also encouraged an open exchange of knowledge regarding the science of nuclear weapons and peaceful uses of atomic science. The Chicago scientists from the FAS started a journal called the Bulletin of Atomic Scientists to discuss issues involving atomic science and its implications. While the journal was never officially the journal of the FAS, it served as the voice of the FAS movement.[11] Later in the 1960s, this same journal would broaden to include discussions of the implications of biological weapons and basic biology research, demonstrating how the concerns of atomic weapons research expanded to considering the implications of biomedical research as well.

While the FAS scientists were against further bomb development, other atomic scientists saw the H-bomb as necessary to reestablish American dominance

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[11] Jessica Wang, *American Science in an Age of Anxiety: Scientists, Anticommunism, and the Cold War* (Chapel Hill: University of North Carolina Press, 1999): 18-19; see also Spencer R. Weart, *Nuclear Fear: A History of Images* (Cambridge, Mass: Harvard University Press, 1988).

internationally and to counter the growing fears over communism. The debate over pursuing research on the H-bomb would continue back and forth within the scientific community, and among those scientists advising the government, for the next five years until January 31, 1950, when President Truman declared that the U.S. would aim to develop the bomb. These differing opinions and on-going discussions are evidence of these scientists engaging in considerations of the social implications of their work and also examining what a social responsibility meant in practice. While they had different opinions on what was best for society they were actively engaged in considering the implications of their work. They were not just voicing their opinions, but were also trying to influence policy.

As historian Barton J. Bernstein writes, "most A-bomb physicists… agreed that they had a special responsibility, and burden, because they had helped build the bomb."[12] Prior to and during the 1950s, many physicists and scientists defined and fulfilled this responsibility by speaking openly about the dangers and risks of the knowledge that they had created, specifically citing the risks of a nuclear holocaust. A letter by Leo Szilard and three other atomic scientists, described the responsibility they believed all scientists had:

> Scientists do not aspire to political leadership but, having helped man to make this first step into this new world, they have the responsibility of warning and advising him until he has become aware of its perils as well as its wonders.[13]

These discussions surrounding the moral and social implications of atomic energy research and the social responsibilities of scientists established an expectation within the

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[12] Barton J. Bernstein, "Four Physicists and the Bomb: the Early Years, 1945-1950," *Historical Studies in the Physical and Biological Sciences* 18, no. 2 (1988): 250.

[13] Barton J. Bernstein, "Four Physicists and the Bomb: the Early Years, 1945-1950," *Historical Studies in the Physical and Biological Sciences* 18, no. 2 (1988): 250.

U.S., and increasingly among the scientific professions, that researchers had a responsibility to warn of the consequences of their work and that they were at least partially responsible for what their research produced. The majority of the atomic scientists saw warning and educating the public to be a primary responsibility for them, and of those that took up this responsibility, following the war and after much of the secrecy surrounding the research had been lifted, many of them did so by speaking publicly in the form of public letters and through the media.[14]

Atomic scientist also defined scientific social responsibility in two other ways: by influencing legislation and by pursuing peaceful uses of atomic energy. Some atomic scientists become very involved in the post-war policies for arms control and nuclear research, either by advising the government individually, as Oppenheimer did, or by influencing the legislation through professional groups, like the Federation of American Scientists (FAS), which issued public statements on atomic weapons legislation.[15]

One of the examples of this organizing to influence policy is the Pugwash Conference series. Pugwash was an international organization created by physicist Joseph Rotblat in 1957 that held private conference focused on addressing the problems with nuclear weapons and later biological and chemical weapons. The people attending the

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[14] Jessica Wang, *American Science in an Age of Anxiety: Scientists, Anticommunism, and the Cold War* (Chapel Hill: University of North Carolina Press, 1999).

[15] For further information on atomic scientists as advisors see Gregg Herken, *Cardinal Choices: Presidential Science Advising from the Atomic Bomb to SDI* (Stanford: Stanford University Press, 2000). For more on the political actions and influence of atomic scientists see: Jessica Wang, *American Science in an Age of Anxiety: Scientists, Anticommunism, and the Cold War* (Chapel Hill: University of North Carolina Press, 1999). She states: “By September 1945, scientists who had worked on the bomb began to organize what later became known as the atomic scientists’ movement. They worked to influence the nuclear policies of the United States and, by extension, the shape of postwar international relations.” p. 11.

conferences were mostly atomic scientists but it also included the philosopher Bertrand Russell. The conferences considered the weaponized uses of science and how to control the dangers of them internationally. The early conferences on atomic weapons produced statements that were signed by the attending scientists and scholars and were adopted by a few scientific organizations internationally. Initially Pugwash conference statements were not in incorporated into policy on atomic weapons, but by the 1960s Pugwash was having an impact on policy by helping to establishing the 1963 Partial Test Ban Treaty, the 1972 Biological Weapons Convention, and the 1972 Anti-Ballistic Missile Treaty.[16] Pugwash did not just focus on atomic weapons, rather it also expanded its initial concerns about atomic weapons to research in biology. Biological weapons were first considered at the 1959 VIIIth Pugwash meeting but it was concluded that nuclear weapons were a higher priority for the attention of the Pugwash members. In 1964, at the XIIIth Pugwash Conference, a working group on biological weapons was included and these discussions were continued in the subsequent year by the Study Group on Biological Warfare.[17] Just as the scientists involved with the journal, the Bulletin of Atomic Scientists, had expanded to consider the implications of biomedical research, so too did Pugwash expand, in parallel, to consider the dangers of biological weapons.

The other method for atomic scientists to fulfill their responsibility was to focus on peaceful and medical uses of atomic energy. Some scientists directed their research toward more peaceful goals, which according to historian Angela Creager, "seemed to

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[16] Martin Underwood, *Joseph Rotblat: A Man of Conscience in the Nuclear Age* (Brighton: Sussex Academic Press, 2009); J. Rotblat, *Scientists in the Quest for Peace: A History of the Pugwash Conferences* (London: Heinemann, 1972).

[17] Martin Underwood, Joseph Rotblat: A Man of Conscience in the Nuclear Age (Brighton: Sussex Academic Press, 2009).

carry the burden of redemption."[18] One scientist who took the peaceful and medical goals very seriously was physicist Joseph Rotblat. Rotblat was the organizer of the Pugwash conferences, but prior to that he had shifted from doing basic physics research, even doing some work for the Manhattan Project, to research applying physics to medicine. Eventually Rotblat would take a position in 1949 at St. Bartholomew's Hospital Medical College in England and become a well-known medical physicist working on radio-therapy.[19] In addition to the handful of physicists who began to focus on medical applications, many physicists fought for a civilian controlled U.S. Atomic Energy Commission (AEC) so that atomic science would be kept public, so the peaceful uses of atomic science would be encouraged, and so that a system of international control could be encouraged for atomic weapons.[20] The creation and subsequent work of the AEC would carry out some of these goals during the 1950s, especially through the work of the Atoms for Peace program.[21]

The atomic scientists set an example for all scientists, not just atomic scientists, to fulfill a social responsibility that they defined as expressing opinions, warning the public and government officials, and generally having a say about what happens to the knowledge they produce. The atomic scientists fulfilled their social responsibility by

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[18] Angela N. Creager, "Nuclear Energy in the Service of Biomedicine: The U.S. Atomic Energy Commission's Radioisotope Program, 1946-1950," *Journal of the History of Biology* 39 (2006):665.

[19] Martin Underwood, *Joseph Rotblat: A Man of Conscience in the Nuclear Age* (Brighton: Sussex Academic Press, 2009).

[20] Jessica Wang, *American Science in an Age of Anxiety: Scientists, Anticommunism, and the Cold War* (Chapel Hill: University of North Carolina Press, 1999): 11.

[21] This program did encourage the peaceful uses of atomic science, such as atomic energy, but it also served to draw attention away from the United States' continued military work on atomic weapons and to encourage other countries to devote resources to peaceful purposes. See: John Krige, "Atoms for Peace, Scientific Internationalism, and Scientific Intelligence," *Osiris* 21, no. 1 (2006): 161-181.

speaking publicly, influencing policy through government advising and through international organizations, and by pursuing more peaceful research. This argument for and demonstration of scientists fulfilling a social responsibility would be picked up by researchers in biomedicine in the 1960s. While the biomedical researchers would not go about fulfilling their social responsibility in exactly the same way, they were clear about where their right to speak up about the implications of their work came from, the atomic scientists, and why it was important to consider the implications of research, to prevent a repeat of atomic science research. Throughout the 1960s in many of the professional conferences, in the growing public discussions in newspapers, and later in congressional hearings, the atomic scientists were cited to explain the concern among biomedical scientists about their own work, and among politicians who were justifying congressional examination of biomedicine. In addition, the journal the Bulletin of Atomic Scientists connected concerns about atomic science with concerns about biology as it broadened its topical coverage to include issues with biology in the middle of the 1960s.[22]

Biomedical Research in the 1960s

The 1960s saw a number of advancements, scandals, and public policy changes in biomedical research, all of which raised increasing questions about the ethics of biomedical research. The advancements, such as human organ transplantations, oral contraceptives, and pharmaceutical therapies seemed promising, but they also raised concerns among the public and researchers. During this time numerous practices in biomedicine began to raise concerns among the medical profession, politicians, and the

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[22] One example is an article by Joshua Lederberg in 1966: Joshua Lederberg, "Experimental Genetics and Human Evolution," *Bulletin of the Atomic Scientists* 22, no. 8 (October 1966): 4-11.

public. The definition of death was being questioned and reexamined in light of heart transplantation, the thalidomide disaster was casting doubt on physician responsibility and drug safety oversight, and the exposed cases of abuses in human experimentation were tarnishing the reputation of physicians and raising the perception of a need for physician oversight. In addition to these events, those in public policy were becoming concerned with the rising costs of health care after the passage of Medicare in 1965, and with the problem of population growth. These and other events would provide justification for the field of bioethics to institutionalize in the early 1970s, but in the 1960s these events led many researchers to consider their social responsibility, as well as the role they, other scholars, and the public should play in considering the implications of biomedicine.

One of the first discussions of the social implications of biological research was the September 1960 Dartmouth Convocation, which marked the "refounding" of the medical school campus.[23] The topics at the symposium ranged beyond the traditional areas of medicine, covering concerns from environmental pollution to end of life care, and from man-made radiation exposure to population growth. This symposium was distinct from other conferences and discussions on medical ethics at the time because it did not focus on issues of informed consent and human experimentation, but instead focused on the potential uses of medical and scientific research to human society and the impact of those uses, or the social implications. The speakers at the symposium were primarily physicians and biological scientists who were leaders in their fields, but they

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[23] The "refounding" marked the dedication of a number of new buildings that had been build on the original medical school campus. Much of the medical school was rebuild around this time and thus it was not the founding but the "refounding" as they called it, of the medical school.

had also been active outside of the lab and clinics by working administratively, advising in the government, and publishing outside the profession.[24] This outside experience meant they were predisposed to be alert to the concerns of society.

Participants of the 1960 Dartmouth Convocation identified issues in need of ethical and social consideration, such as man-made pollution, human genetics, and research on controlling the brain, but most significantly it included an active discussion on what responsibility the scientific profession had to society. A recurring opinion expressed during the symposium is here stated by René Dubos[25]:

> "Medical science only tells us *how* to do things, not *what* we should do among all the things we can now do and the many more we will be able to do in the near future – and the choice as to *what* we do will have to be the responsibility not of the doctors and scientists but of all society, because

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[24] The speakers included Rene Jules Dubos, microbiologist and author of the books titled *Man and Society* and *The Mirage of Health*; Brock Chisholm, physician and Director-General of the World Health Organization from 1948-1953; Ward Darley, physician and Executive Director of the Association of American Medical Colleges; Ralph Gerard, psychiatrist and director of Laboratories at the Mental Health Research Institute at the University of Michigan; George B. Kistiakowsky, chemist and President Eisenhower's Special Assistant for Science and Technology; Walsh McDermott, physician in public health and consultant to the U.S. Public Health Service and Veterans Administration, he would go on to help organize and serve as chairman for the Board of Medicine at the National Academies, which became the Institute of Medicine; H.J. Muller, geneticist and Nobel Prize winner in physiology and medicine in 1946, also served on the Atomic Energy Commission's team to study the effects of the atomic bomb on Japanese survivors; Wilder G. Penfield, neurosurgeon from McGill University; Sir George Pickering, physician and authority on cardiovascular disease from London; Sandor Rado, Dean and Professor of Psychiatry for the New York School of Psychiatry; Sir Charles Snow, physicist by training turned novelist and starting in 1945 the Civil Service Commissioner in charge of scientific appointments; Warren Weaver, trained mathematician and Vice President of the Alfred P. Sloan Foundation and former Rockefeller Foundation Vice President for the National and Medical Sciences.

[25] Dubos was a microbiologist and ecologist who had written many books about the ecology of medicine and health. He would become, in 1969, a member of the advisory council of the newly founded Institute of Society, Ethics, and the Life Sciences, which we now know as the Hastings Center. This organization was the first organized center for the study of bioethics when it was formed in 1969.

> the questions to be answered are moral questions."[26]

While Dubos believed that society should make the decisions, physicist and novelist C.P. Snow argued that science was inherently ethical and thus scientists should take on more responsibility in these discussions.[27] Saying:

> Therefore, it seems to me that the first thing is to tell the truth. I believe that is the first duty of all scientists – I believe it's a built-in feature of science itself, and one which makes me feel that it's wrong for us to say that 'science is ethically neutral.' I never have believed that – and I don't now! I believe that the very fact that truth is part of the very grain of science means that we have an ethical component right in us.
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> The first thing, then, is to tell the truth. The second thing is not to leave it to society in quite as easy a fashion as some of my wiser friends… would suggest.[28]

Meanwhile, geneticist, H. J. Muller took a middle ground and encouraged interdisciplinary discussions. Saying:

> I think it is up to everyone in fields they're conversant with to speak up and try to work out the truths together with others whose fields overlap, and even with complete outsiders, because *only* with such free discussion, and not with dictatorship, can we arrive at the decisions that will benefit mankind.[29]

In the decade that followed this conference, some physicians and scientists began to adopt the role of leaders of these discussions on the implications of their research by holding more conferences and by inviting outside scholars in fields such as philosophy, theology, and law to help with the discussions.

In addition to conferences, scientists and physicians discussed the social

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[26] Dartmouth Convocation on Great Issues of Conscience in Modern Medicine, *The Great Issues of Conscience in Modern Medicine: Selections from the addresses and panel discussions* (Hanover: Dartmouth Medical School, 1961): 1.
[27] Dartmouth Convocation, 10.
[28] Dartmouth Convocation, 14.
[29] Dartmouth Convocation, 14.

implications of science in professional journals such as *Science* and *The Bulletin of the Atomic Scientists*. While the articles in these journals discussed the potential or foreseen implications, the articles, like the discussions in the conferences, also made the argument that the profession had a social responsibility to predict and warn the public about the implications of research and to inform the public.

Beginning in 1966, Joshua Lederberg, chairman of Stanford University's Department of Genetics, took on a leading role in discussing the social implications of science and engaging the public in the discussions. Beginning in his childhood, Lederberg desired to pursue science research for the purpose of solving medical problems and society's ills. Lederberg earned a Ph.D. for his research on genetic recombination in bacteria by 1947 at the young age of 22 and would go on to share the 1958 Nobel Prize in Physiology or Medicine for this work. He helped start two medical genetics departments in the U.S. and following his international success, Lederberg began to consider the implications of scientific research and technology.[30]

Lederberg was an active participant in many of the conferences and professional discussion during the 1960s. He attended a Ciba Foundation conference on "The Future of Man" in 1962, served on a National Academy of Sciences committee from 1966 to 1970 that created a report on the life sciences and its application to human affairs, and was a member of the National Academy of Sciences' Committee on Life Sciences and

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[30] National Library of Medicine, "The Joshua Lederberg Papers: Biographical Information," http://oculus.nlm.nih.gov/cgi/f/findaid/findaid-idx?c=nlmfindaid;cc=nlmfindaid;view=reslist;subview=standard;didno=lederberg552;focusrgn=bioghist;byte=15948706 (accessed on June 28, 2011).

Social Policy starting in 1968.[31]

In an article by Lederberg published in the October 1966 issue of the *Bulletin of the Atomic Scientists*, he considered the application of genetic research to medical care and eugenic practices. He placed the research into its possible medical and social applications by describing the implications and connections to society and the general population. He described the realities and difficulties of identifying an ideal genotype in our changing society. He examined the prospect of genetically modifying human germ cells so treatments would be applied to future generations. And he considered the possibility of cloning humans. Lederberg argued that crafting social policy was best achieved by both scientists and society because scientists were not experts on social matters any more than members of society were experts on these social issues. However, he believed that scientists were specifically skilled at providing the understanding and interpretation of the science for taking political action and for developing scientific solutions in response to technological challenges because of their expertise in scientific and technical matters.[32]

In 1967, an article by Robert Sinsheimer, also in the *Bulletin of the Atomic Scientists*, continued Lederberg's consideration of the responsibility of scientists, and argued that scientists must do more than produce research results. Sinsheimer was a

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[31] F. Peter Woodford, *The Ciba Foundation: An Analytic History 1949-1974* (New York: Associated Scientific Publishers: 1974); Committee on Research in the Life Sciences of the Committee on Science and Public Policy, *The Life Sciences: Recent Progress and Application to Human Affairs, the World of Biological Research, and Requirements for the Future* (Washington, D.C.: National Academy of Sciences, 1970); From Henry David to Dr. Frederick Seitz Memorandum on Membership - Committee on the Life Sciences and Social Policy, August 9, 1968, Committee on the Life Sciences and Social Policy Collection, National Academies Archive.

[32] Joshua Lederberg, "Experimental Genetics and Human Evolution," *Bulletin of the Atomic Scientists* 22, no. 8 (October 1966): 4-11.

professor of biophysics at the California Institute of Technology when he published his article titled "The End of the Beginning." It was based on a lecture Sinsheimer had presented earlier at a Conference on Scientific Progress and Human Values in October 1966. In the article he considers the future implications from research in molecular biology, but he begins by asking scientists "to emerge from their laboratories to exercise their prophetic vision" and to foretell and forewarn about the implications of their research. He believed this was scientists' responsibility because they were the ones making sweeping changes to society. He uses the article to make the case that scientists should study this matter further by demonstrating that there are issues with how the biomedical research will be implemented in the future into society. For Sinsheimer the advances and resulting level of control foreseen in the biological revolution require those pushing and creating this new knowledge to consider, foretell, and warn about what the implications may be.[33]

While Lederberg and Sinsheimer were active within the profession, Lederberg also believed that he and other scientists had a responsibility to communicate beyond the profession and with the public about science. Lederberg took this responsibility so seriously that in 1966 he began a weekly column in the *Washington Post* to discuss topics related to medical science, biological science, and physical science and explain how these sciences could be or were being applied to humans and society. Lederberg continued the column through 1972.

During the 1960s, when the social implications of biomedical research were discussed by scientists and by politicians, the example of atomic energy research was

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[33] Robert Sinsheimer, "The End of the Beginning," *Bulletin of the Atomic Scientists* 16, no. 2 (February 1967): 9-12.

often used to suggest that scientists were responsible for the consequences of their work and that earlier consideration of the consequences needed to occur to prevent another case like research on atomic energy. While the physicists had set the standard for considering and advising within the government on the implications of their work, biomedical researchers were taking it one step further and encouraging interdisciplinary and pubic discussions of the social implications of their research. In addition to the discussions of the social consequences of research occurring in professional conferences on genetics and biomedicine, they were also occurring in Congressional hearings on drug regulation, and most significantly in the Senate hearings on Senator Walter F. Mondale's proposal to create an advisory commission on Health Science and Society. The hearings on Mondale's proposal asserted that legislators had the right to participate in the discussions of the social consequences and that these discussions should occur in public, not hidden behind the doors of the medical and scientific professions or government military security. Thus a group of biomedical researchers and politicians believed that these discussions required input from multiple fields and from the general public.

While not all scientists, and especially not the physicians, were as eager as Lederberg to open up the discussions of the social implications of their work to the public, they did open up by 1973. In 1973, the discussions were urged forward by a continuing series of Senate hearings on a national commission, the leadership of key scientists such as Lederberg, and the exposés of human subject abuses such as the Tuskegee syphilis study. This resulted in the creation of the first federal bioethics commission, composed of scholars from various disciplines and not just from the sciences and medicine. Biomedical researchers during the 1960s believed in their social responsibility and fulfilled it by identifying issues, informing the public, and inviting scholars from the social sciences and humanities, along with the public, in to the discussions to help examine the social implications of biomedicine.[34]

Recombinant DNA in the 1970s

In 1973, geneticists at a Gordon Research Conference on Nucleic Acids wrote a letter to the NAS asking the Academy to examine the developing techniques in recombinant DNA (rDNA) for potential hazards. The geneticists also published this letter in the journal of the American Association for the Advancement of Sciences (AAAS), called *Science*. In response, the NAS assigned chemist Paul Berg to examine the issue. Berg held a meeting with other geneticists at MIT on April 17, 1974, at which the scientists concluded surprisingly that they should request the international genetics community to uphold a moratorium on certain kinds of experiments involving rDNA. The "Berg Letter," as this request would later be called, was published in *Science* and additionally in the journal *Nature.*[35] The response from scientists was supportive, with one biologist, Michael Stoker, writing: "it is encouraging that the very leaders in the field have taken the initiative… For many it will be a test of self denial and social responsibility in the face of strong intellectual temptation."[36] The moratorium was upheld

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[34] The scholars from the social sciences and humanities provided perspectives on sociology, philosophy, ethics, and history. These scholars provided perspectives other than those from the scientists and helped to inform the debates about the social implications of science.

[35] Charles Weiner, "Drawing the Line in Genetic Engineering: Self-Regulation and Public Participation," *Perspectives in Biology and Medicine* 44, no. 2 (Spring 2001):208-220.

[36] Charles Weiner, "Drawing the Line in Genetic Engineering: Self-Regulation and Public Participation," *Perspectives in Biology and Medicine* 44, no. 2 (Spring 2001):210.

until a February 1975 conference in Asilomar, California could be held to discuss restrictions and safety policies.

When the Asilomar Conference was held, the focus of the discussions was strictly technical. The scientists had interpreted the dangers with rDNA as technical safety problems of immediate concern to those in the labs, rather than as broader long-term concerns about the social implications of rDNA research. As historian Charles Weiner writes, “The motive from the start was to reduce potential hazards and to proceed with the research, avoiding public interference by demonstrating that scientists on their own could protect laboratory workers, the public, and the environment.”[37] After the meeting, the researchers worked with the National Institutes of Health to establish guidelines for conducting research on rDNA through the newly created NIH Recombinant DNA Advisory Committee (RAC).

The Asilomar rDNA case is an example of researchers being proactive about the safety of their research and it has served as a prime example of researchers taking responsibility to consider and warn about the consequences of their work. However, in this case the scientists focused on immediate dangers, not on broader social implications. In addition, while the Asilomar conference did include some lawyers, in comparison to the 1960s biomedical conferences it was not interdisciplinary. The geneticists feared the public and the government taking control of the regulation of their research, so they went beyond discussing and advising and created their own policies to restrict how their research was done. While the Asilomar case is often cited as scientists behaving ethically

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[37] Charles Weiner, "Drawing the Line in Genetic Engineering: Self-Regulation and Public Participation," *Perspectives in Biology and Medicine* 44, no. 2 (Spring 2001):211.

and responsibly, when put into perspective of the 1940s and 1960s scientists, it appears less like scientists considering social implications and more like scientists taking control of the considerations, focusing them on safe research practices, and distancing themselves from outside scholars. The actions of the Asilomar group started a trend to take control of regulatory issues but also to distance the science and scientists from the considerations of social implications. The continuation of this trend can be seen in the creation of the NIH ELSI program, which is described later in the thesis, in which scientists had funding control of the ethical considerations and then insulated themselves from the actual ethical considerations by separating ELSI from the science research. This history of scientific social responsibility establishes the professional ethic but also demonstrates that this responsibility is not something that was imposed on the profession by outsiders, rather it was something that the profession claimed for themselves in the 1960s. In addition, the history also reveals that it was scientists themselves that sought the involvement and inclusion of both outside scholars and the public in the discussions of social implications.

Social Implications and Research Ethics

Consideration of the Broader Social Implications as Part of Research Ethics

In the U.S., the responsibility for considering the social implications of scientific research is generally not held by any one specific group. Many experts from a variety of fields, including bioethics, public policy, public health, philosophy, science, medicine, engineering, sociology, and history, have considered the implications of scientific research in the past and still do today. Of all these groups, the researchers from science, medicine, and engineering have a unique social responsibility because they actually produce the knowledge or technology. Beyond the historical rationale for scientists having this professional social responsibility, there are a few common arguments for why scientists should be involved in bioethics discussions, especially considerations of social implications. The first is that the traditions of openness and critical thinking present in science can be a useful approach for ethical discussions. This is a practice that can encourage and spur considerations of the implications of advancing areas of science and technology as they are being developed rather than after they are created. The second is that scientists and physicians have special insights into ethical issues arising from their work because they are so close to the work. Scientists are on the "front lines" of research and thus may be the first to recognize and identify potential social implications, however their proximity also makes it harder to recognize the broader issues of the impact on society. The third and final reason is that scientists can provide the "facts" that keep an ethics debate informed. In areas of new and developing science, the researchers are the experts on the science and thus their expertise is necessary to have well informed and productive discussions of the social implications.[38]

While bioethics scholars today generally accept the case for researcher's involvement in discussions of social implications, there is no written code of research ethics or set of regulations in the U.S. that explains how they should successfully fulfill this social responsibility, nor is it discussed in research ethics education. This is a reflection of the narrowed focus of the research ethics field. Research ethics is a large area of bioethics which focuses on the ethical actions of researchers and encompasses scientific integrity, collegiality, the protection of human subjects, animal welfare, institutional integrity, and social responsibility.[39] The focus of research ethics has been primarily on the protection of human subjects and on scientific integrity because of abuses in these areas. As a result there are detailed federal guidelines for human subjects research, definitions of research misconduct and scientific integrity, and requirements for the training of researchers who receive federal funding in both areas.[40] However, the emphasis on protecting human subjects and preventing research misconduct has resulted in other areas of research ethics, such as social responsibility, being ignored.[41]

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[38] Ruth Ellen Bulger, Elizabeth Meyer Bobby, and Harvey V. Fineberg, eds., *Society's Choices: Social and Ethical Decision Making in Biomedicine* (Washington, D.C.: National Academy Press, 1995): 5.

[39] Kenneth D. Pimple, "Six Domains of Research Ethics. A Heuristic Framework for the Responsible Conduct of Research," *Science and Engineering Ethics* 8, no. 2 (2002):191-205.

[40] Kenneth D. Pimple, "Six Domains of Research Ethics. A Heuristic Framework for the Responsible Conduct of Research," *Science and Engineering Ethics* 8, no. 2 (2002):195.

[41] Kenneth D. Pimple, "Six Domains of Research Ethics. A Heuristic Framework for the Responsible Conduct of Research," *Science and Engineering Ethics* 8, no. 2 (2002):198.

Recent discussions in research ethics are beginning to formalize what social responsibility means for scientists and are trying to determine how scientists can fulfill this responsibility in practice. Kenneth D. Pimple and Michael Kalichman, in their articles examining research ethics, have made the argument that social responsibility is a key component of the research ethics framework. Pimple argues that while it is not clear precisely what is required of an individual scientist in fulfilling the professions' social responsibility, each individual should be made "cognizant" of the professional responsibility and trained about it in research ethics education because each scientist has "an obligation to carry some part of the burden."[42] Kalichman argues that research ethics education should be based on the specific responsibilities that define responsible conduct. He states that due to there being numerous cases of concern among the public about areas of sciences, such as atomic weapons, intelligence research, and genetically modified food crops, scientists have a responsibility to consider the impact of their work on society.[43]

In addition to Pimple and Kalichman, there is also a literature examining the meanings of scientific social responsibility, how it should be taught, and how it is understood by researchers. Vivian Weil's article on the meanings of scientific social responsibility summarizes the work done by philosophers of science, a scientist, and a sociologist of science on the meaning of scientific social responsibility. One meaning of scientific social responsibility by Kristen Shrader-Frechette, a philosopher, describes it as "the duty to abstain from certain research, to engage in research, to disseminate research

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[42] Kenneth D. Pimple, "Six Domains of Research Ethics. A Heuristic Framework for the Responsible Conduct of Research," *Science and Engineering Ethics* 8, no. 2 (2002):191-205

[43] Michael Kalichman, "Ethical Decision-Making in Research: Identifying All Competing Interests," *Science and Engineering Ethics* 8, no. 2 (2002):215-218.

(to lay people, as well as scientists) so as to avoid misuse and misapplication by others and to 'engage in whistle blowing whenever the situation warrants it.'"[44] Weil argues that Shrader-Frechette based her philosophical argument on the understanding that science is a profession with an "implicit contract" with society. The "implicit contract" associated with a profession is based on the idea that "professions" are committed to serving society in exchange for the benefits, such as education, that they receive from society. Another scholar's argument described by Weil is Melanie Leitner's argument that the increasing powers of science to affect society and the increasingly closer relationships between societal decision-making and scientific evidence and rationales means that scientists have a greater responsibility to society. Weil argues that this view is shared by sociologist of science Ullica Segerstrâle, who examines scientists' involvement as expert witnesses in legal matters. According to Weil, Leitner, a scientist herself, defines what it means to fulfill this responsibility as scientists communicating to society and as professional societies and other institutions examining the implications of science. Weil concludes that the literature on the meaning of scientific social responsibility is a good beginning and that the analysis that has been done so far can move the discussion further along toward eventually defining core areas of scientific social responsibility.[45]

Other literature on social responsibility by Penny J. Gilmer and Michael DuBois has focused on how to teach social responsibility and they argue that scientific social responsibility should be taught through the use of historical case studies, such as the case

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[44] Vivian Weil, "Making Sense of Scientists' Responsibilities at the Interface of Science and Society," *Science and Engineering Ethics* 8, no. 2 (2002):224.

[45] Vivian Weil, "Making Sense of Scientists' Responsibilities at the Interface of Science and Society," *Science and Engineering Ethics* 8, no. 2 (2002):223-227.

of the Manhattan Project.[46] Meanwhile, a research group led by J. M. Ladd at Stanford University examined researchers' views on research ethics through focus groups and one-on-one interviews. Their research revealed that scientists believed that part of why they do research is to positively impact their external community or society and that scientists believed they fulfilled the responsibility to consider the implications of their work through their writing in publications and grant proposals.[47] The literature focused on determining the meaning of scientific social responsibility and how to fulfill it is only at the beginning and many questions still remain unanswered, such as what scientific social responsibility means in practice and what the responsibility means to researchers today. The result of this lack of clarity and standards on scientific social responsibility is a lack of institutional support for researchers to take time and money to consider the broader social implications of their work. While the bioethics community more often considers these broader social implications, there is limited institutional support for researchers to collaborate with bioethics scholars, though this is beginning to change.[48]

Scientists Considering the Social Implications

Research on the scientists' work practices reveal that the high level of competition in science, to advance scientific knowledge and ones career, is a large motivating factor in researchers' regular work experiences. Melissa S. Anderson, et. al. have argued that

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[46] Penny J. Gilmer and Michael DuBois, "Teaching Social Responsibility: the Manhattan Project," *Science and Engineering Ethics* 8, no. 2 (2002):206-210.

[47] J. M. Ladd, M. D. Lappé, J. B. McCormick, A. M. Boyce, and M. K. Cho, "The 'How' and 'Whys' of Research: Life Scientists' Views of Accountability," *Journal of Medical Ethics* 35, no. 12 (2009): 762-767.

[48] Most recently this is changing with a program initiated by the NIH to fund bioethics research as a supplement to specific scientific research projects. This program was announced this year, and there is not much information on how it is working, but it is certainly a program to pay attention to.

this competition leads to many effects on researchers' behavior, including strategic game-playing, decline of free and open sharing of information and methods, sabotage of others' ability to use one's work, interference with the peer-review process, deformation of relationships, and careless or questionable research conduct.[49] What is significant is that this same competition can also dissuade researchers from considering the social implications of their research, as these considerations do not directly further the advancement of scientific knowledge or their career. It is understandable that researchers' main priority is advancing their career and the knowledge within their field, as this is the case for most professionals. Yet the problem arises when the competition leads to a conflict of interest for the researcher, between upholding the ethical standards of the profession and advancing one's career and research. The institutional structure and funding systems result in salaries being dependent on grant funding, and tenure appointment standards becoming increasingly high and focused on the number of publications. As a consequence of this, non-scientific activities, such as public engagement and ethical considerations, are not being supported because there is no career or professional benefit to doing them.

Outside of the limited ethics education that scientists receive in the United States, most scientists will only consider the ethics of their research at animal safety committees, material safety committees, and at Institutional Review Boards (IRBs), which review research on human subjects to uphold ethics regulations. Most scientists do not learn about research ethics or the profession's social responsibility unless or until it is required of them by funding agencies or institutions. The reason animal and human

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[49] Melissa S. Anderson, et. al., "The Perverse Effects of Competition on Scientists' Work and Relationships," *Science and Engineering Ethics* 13 no. 4 (2007):437-461.

experimentation ethics, material safety and responsible conduct education occurs is because it is required by funding regulations and institutional rules, thus the infrastructure supports it. While committees, such as IRBs and material and animal safety committees, do serve a valuable purpose and uphold a certain standard for a specific area of research ethics, they often ignore considerations of the broader social implications of research.

In the case of IRBs, considerations of the social implications are specifically restricted. IRBs are instructed to focus on the immediate risks and benefits primarily to the individual research subject and to ignore the long-term or broader risks to society. In describing the criteria for IRB approval of research the federal regulations state when clarifying considerations of risks from the research that “the IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.”[50] As Alan Fleischman, et. al. argue in their recent article, there are good reasons for the IRB not to consider these social implications when approving or rejecting research proposals, specifically because it insulates IRBs from politics, and prevents IRBs from basing their decisions on the very speculative nature of predicting possible social implications.[51] However, because IRBs are one of the few places a researcher would consider the ethics of their research and unfortunately because IRBs are supposed to drop the consideration of social implications, the result is that these considerations may never occur with scientists. In many ways IRBs discourage

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[50] U.S. Department of Health and Human Services, *Code of Federal Regulations Part 46 Protection of Human Subjects* 45CFR46.111 a.2.

[51] Alan Fleischman, et. al., "Dealing with the Long-Term Social Implications of Research," *American Journal of Bioethics* 11, no. 5 (2011):5-9.

researchers from considering these questions because IRBs set the example that these considerations are not necessary to conduct research.

There is one other situation where researchers can consider the social implications of their research: when writing grant proposals and publications. This situation is actually what scientists identified on their own when they were surveyed, through focus groups and one-on-one interviews, as a way that they fulfill their social responsibility.[52] The problem with fulfilling their social responsibility by discussing the social implications of their work in this manner is that there is a conflict of interest that emerges. Funding proposals and publications are intended to promote the research done and the researchers themselves. Thus there is a conflict when some of the social implications of the research are negative. In this situation, and in the case of IRBs, the institutional structure and funding system do not encourage or even support researchers considering the broader, potentially negative, social implications of their research. In order for researchers to consider both the negative and positive social implications of their work, the places and people that do examine the social implications need to encourage researchers' participation, and in addition the institutional structures and funding systems need to support researchers' involvement. However, it is important to note that this is not an argument for all scientists to be involved in social implications for all of their research, rather that scientists should be encouraged to become involved and to think of these issues regularly even if they don't take the step to pursue integrated research on social implications.

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[52] J. M. Ladd, M. D. Lappé, J. B. McCormick, A. M. Boyce, and M. K. Cho, "The 'How' and 'Whys' of Research: Life Scientists' Views of Accountability," *Journal of Medical Ethics* 35, no. 12 (2009): 762-767.

Systems for Considering the Social Implications

Overview of U.S. Systems

Currently, the considerations of the social implications of research are conducted in the U.S. in multiple ways. The most well-known place for these discussions to occur are the federal bioethics commissions which began in 1974 and have continued off and on up to today. In addition to the federal or Presidential bioethics commissions, the states of New York and New Jersey have also created state bioethics commissions, and the NIH and Department of Health and Human Services (DHHS) have also created commissions. Many of these commissions include members from a wide array of specialists, including scientists and physicians as well as the humanities and social sciences. These commissions are often used to explore the ethics and make recommendations on specific and sometimes new areas of research, such as when the current bioethics commission under President Obama examined the area of synthetic biology in 2010. As a result, the social implications - such as the risks and benefits to society - are often addressed in these commissions, as was done with the discussions and report on synthetic biology. However there are only a small handful of commissions and thus only a few leading scientists actually engaged in these discussions. Often the scientists chosen to serve on these commissions are older scholars at the height of their career; meanwhile younger scholars are not encouraged to consider these types of issues.[53]

Outside of bioethics commissions, consideration of the social implications of science occurs most frequently by bioethicists and by professional organizations.

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[53] Ruth Ellen Bulger, Elizabeth Meyer Bobby, and Harvey V. Fineberg, eds., *Society's Choices: Social and Ethical Decision Making in Biomedicine* (Washington, D.C.: National Academy Press, 1995): 5-9.

Academic work in bioethics, by philosophers, theologians, lawyers, sociologists, and public health workers, just to name a few, examines the social implications but often does not include collaboration with the scientists doing the scientific research. Professional organizations, such as the Hastings Center and the Kennedy Institute for Ethics more often include scientists and physicians in the considerations of the social implications of science through conferences, workshops, and grant projects. However, these organizations are similar to bioethics commissions in that they examine and discuss new and controversial topics but are not regularly integrated with many scientific researchers.

IRBs, which review all research funded by the federal government involving humans, seem like the place where social implications would be considered. However, as described earlier, IRBs are specifically restricted from discussing the long-term social implications of research and must instead focus on the immediate risks and benefits primarily to the individual research subject.

As described above, the consideration of the social implications of science occurs in a variety of ways in the U.S. These next few sections of the thesis will describe where scientific research and ethical research are being integrated together in the U.S. and internationally, such that scientific researchers are included in the ethical discussions held by Ethical, Legal, and Social Implications (ELSI) scholars. The involvement of scientists in the ethical consideration of science is an important part of the professional ethic of science and is an area of growing significance in research ethics education. Thus it is important to understand how scientists' involvement in the considerations of the social implications of science is occurring thus far. This section will examine the different types of integration and explore what purposes they serve.

National Academies

One professional organization that has integrated the science with the social implications is the National Academies. It is a prestigious body set up by the government but not within the government, which regularly advises the government on science, technology, engineering and medicine. It produces reports and recommendations on science, engineering, and medicine, but has focused some attention on ethical and social implications of these areas. The committees that create these reports have been composed of research scientists, physicians, as well as social scientists, philosophers, theologians, lawyers and bioethicists. The National Academies is a membership body that contains the leaders in science, engineering, and medicine, many of whom serve on some of these report committees. Its focus on studying ethical and social implications of science sets an example for scientists to consider these implications and further reinforces the argument that scientists and scientific organizations have a role to play in bioethics. In 2005, the National Academies produced guidelines for research with human embryonic stem cells (hESC). This report examined not just issues of informed consent for donation but also issues with encouraging the benefits of the research for society while discouraging abuse of embryos, which some consider human life. Tackling the topic of ethical and socially responsible hESC research demonstrates just how seriously the National Academies takes scientists' social responsibility. These guidelines have been influential and are used by scientists across the U.S. to guide research on hESC, specifically to fill the guideline gaps left by the NIH guidelines and restrictions on hESC research in the last decade.

Research Ethics Consultation Services

Another place where social implications work is integrated with the science is in research ethics consultations. Research ethics consultation arose out of the success of clinical ethics consultation and is still in its infancy. Clinical ethics consultation services are set up by hospitals to provide advice on ethical issues that arise in medical care. The members of the consultation team are often members of the hospital or university where the service is located. The aim of the consultation services is to listen and talk with those they are consulting with about the issue and then to provide advice and help in considering the risks, benefits and implications of research to researchers, research subjects, institutions, communities and the general public. These services are intended to provide quick advice beyond that of the IRBs and to give practical advice for how to move forward with research.[54] However, these consultation service meetings are also a place that can host and lead discussions of broader, less immediate implications of research. These research consultation services usually consist of a team of research ethicists trained in social science, humanities, philosophy, and/or law who consult independently when requested or through meetings of the whole consultation team. The main critique of ethics consultation services is the conflict of interest and questionable independence that results when the consultation services are in-house. Yet this is a critique that is also true of the widely accepted method for human subjects ethics examination, the IRB.

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[54] Mildred K. Cho, et. al. “Strangers at the Benchside: Research Ethics Consultation,” *American Journal of Bioethics* 8, no. 3 (2008): 5.

Despite the concerns over independence, the development of research ethics consultation services have been growing recently because of the requirement to have these services by NIH's Clinical and Translational Science Awards. Only a few universities have set up research ethics consultation services so far, but Stanford University was one of the first and its development was funded by the NIH's ELSI program. The Stanford model was designed to respond to requests from individual researchers or research teams. The consultation team consisted of academics from Stanford with training in philosophy, law, and biology who all had knowledge of research ethics. Individual consultants would "triage" the cases to determine if an individual consultant could address the issue or if a team meeting was required. The team meetings allowed for a broader range of expertise, especially when a specific area of scientific knowledge was required. The Stanford team believed that the consultation services should not have a goal of advancing bioethics literature for fear that it would alter the consultation services provided. However they do acknowledge that the consultations do result in information that would advance bioethics literature. The results from the early implementation of the Stanford consultation services showed that both researchers and IRBs requested the services, and that the issues discussed focused on the development of research projects and on issues that developed during or after the research project was conducted.[55] The research ethics consultation services are still developing, but have the potential to be an ideal forum for integrating science and social implications work because the venue supplied by consultation services provides the opportunity for scientists to discuss the social implications of their work.

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[55] Mildred K. Cho, et. al. "Strangers at the Benchside: Research Ethics Consultation," *American Journal of Bioethics* 8, no. 3 (2008): 4-13.

Ethical, Legal, and Social Implications (ELSI) Program within the Human Genome Project at the National Institutes of Health

The most obvious place where science and social implications are integrated is where the idea was first implemented, the ELSI program within the Human Genome Project (HGP) at the National Institutes of Health (NIH). In 1988, James Watson announced that along with the National Institutes of Health's funding of the Human Genome Project there would also be funding for the Ethical, Legal, and Social Implications of genetics. As the Associate Director of the Human Genome Project at the time, Watson made the decision to fund these ethical studies with a portion of the money from the scientific research funds for the Human Genome Project. The amount of money was originally set at 3% of the Human Genome Project funding by Watson, but he soon increased it to 5%. Anecdotal reports describe the idea for the funding of the NIH ELSI program as one that Watson came up with and announced "off the cuff," without discussing it with anyone.[56] As the earlier described history in scientific social responsibility has shown, there was an understanding among scientists that they take responsibility for considering the implications of their research. However, the idea of devoting a portion of scientific research funding to the study of ethical, legal, and social issues was novel. In 1988, the memories of the Asilomar Conference and the issues with rDNA were still in many researchers' minds, in some cases with bad connotations because it had resulted in the regulation of their research. As a result, the announcement

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[56] Eliot Marshall, "The Genome Program's Conscience," *Science* 274 (1996): 488-489; Nancy S. Wexler, "Climbing the Ladder of Life: James D. Watson and the ELSI Years," in *Inspiring Science: Jim Watson and the Age of DNA*, ed. John Inglis, Joseph Sambrook, and Jan Witkowski (Cold Spring Harbor: Cold Spring Harbor Laboratory: 2003), 403-412.

of the NIH ELSI program was not received warmly by some of those in genetics research. Some researchers saw the NIH ELSI program as something that would only slow the scientific research down through regulation and they did not see what help the ethical and legal scholars could provide through their scholarly writing. However, as Wexler describes, it was because of Watson's stature within the genetics field and within the science policy world that the NIH ELSI program was created despite objections from the scientific community.[57]

The NIH ELSI Research Program, which is now located within the NIH's National Human Genome Research Institute (NHGRI), began with two main goals: to (1) anticipate the pertinent ethical, legal, and social implications of new genetic information; and (2) to develop policy options to address them, through the support of research projects, conferences, workshops, and education projects.[58] During the first five years, the NIH ELSI program aimed to fulfill those goals by funding research in three main areas.[59] The first research focus was on the integration of new genetic tests into medical practice. This focus had a significant policy emphasis, with aims of establishing professional standards for accuracy and quality in genetics tests, professional responsibility, confidentiality, standards for allowing access to test results, and policies for the reimbursement of costs. The second research focus was on educating and counseling

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[57] Nancy S. Wexler, "Climbing the Ladder of Life: James D. Watson and the ELSI Years," in *Inspiring Science: Jim Watson and the Age of DNA*, ed. John Inglis, Joseph Sambrook, and Jan Witkowski (Cold Spring Harbor: Cold Spring Harbor Laboratory: 2003), 403-412.

[58] Elinor J. Langfelder and Eric T. Juengst, "Ethical, Legal, and Social Implications (ELSI) Program, National Center for Human Genome Research, National Institutes of Health," *Politics and the Life Sciences* 12, no. 2 (1993): 273-275.

[59] Eric T. Juengst, "The Human Genome Project and Bioethics," *Kennedy Institute of Ethics Journal* 1, no. 1(1991):71-74.

individuals about genetic test results. This focus was much more oriented toward medical care and the informing of patients, rather than policy issues and social implications. The third focus had a more legal leaning by emphasizing the legal privacy issues with third-party access to the results of genetic tests. None of the initial goals looked at the aims of the scientific research, or concerns with the practice of genetics research, which include concerns with researchers patenting genes, the selection of research populations, the selection of genetics characteristics to study, or the informed consent issues with non-therapeutic genetics research.

Despite the NIH ELSI program successfully "identifying and defining major issues and areas of concern with genetics research," it began to draw criticism.[60] Some scientists and policy makers questioned the effectiveness of the NIH ELSI program because it had not made any progress in crafting public policy to protect genetic privacy. Other scientists and policy makers thought that the NIH ELSI program was not taking enough action and translating the knowledge from scholarly literature. Some of these critics believe that this problem was a result of the NIH ELSI program being too far removed from the actual science being done to make any real difference. Yet some bioethics scholars questioned the NIH ELSI program's independence from the control of the Human Genome Project. They saw the NIH ELSI program as an oversight body that could criticize and check the research being done. To function as an oversight body the NIH ELSI program needed financial and administrative independence from the scientists performing the research, which it did not have.

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[60] Eric M. Meslin, Elizabeth J. Thomson, and Joy T. Boyer, "The Ethical, Legal, and Social Implications Research Program at the National Human Genome Research Institute," *Kennedy Institute of Ethics Journal* 7, no. 3 (1997): 291-298.

Some of these concerns led the new director of the Human Genome Project, Francis Collins, to push the NIH ELSI program to emphasize results in public policy and public education in 1993. However, even this did not satisfy some critics, who believed that a change in focus would not be enough to address the lack of influence on public policy. Kati E. Hanna, et. al. argued that because the research agenda was determined by NIH ELSI researchers rather than by Congress or the Department of Health and Human Services, and because there was no direct and influential link back to the policy process, the NIH ELSI program would not be effective at influencing policy.[61]

In 1995, in response to the criticism, the NHGRI made changes to focus on translating the NIH ELSI program's extramural research to policy and to focus on ethical research practices. Two offices were created within NHGRI: the Office of Policy Coordination and the Office of Genome Ethics. The Office of Policy Coordination was set up to do what its name implies: to develop policy and legislation on ELSI-related topics and work with Congress, government agencies, and non-government organizations on policy issues. However, questions still remain about whether the NIH ELSI program's research is making its way into public policy. Michael S. Yesley argues that it is not. He says this can be shown by looking at the genetic discrimination laws that were passed around the country: "The proponents of this legislation can cite virtually no ELSI research to support their position."[62] However, not everyone is in agreement that policymaking should be a goal of the NIH ELSI program, because it risks politicizing the

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[61] Kathi E. Hanna, Robert M. Cook-Deegan, Robyn Y. Nishimi, "Finding a Forum for Bioethics in U.S. Public Policy," *Politics and the Life Sciences* (August 1993): 205-219.

[62] Michael S. Yesley, "What's ELSI got to do with it? Bioethics and the Human Geneome Project," *New Genetics and Society* 27, no. 1 (2008): 1-6.

issues and the program.[63] The focus on the NIH ELSI program's effect on policy has largely been on federal policy. Yet there is a great need for ELSI type research and social implications research to have an effect on professional standards and administrative policy in research institutions and at universities. Focusing policy changes at the local level could have a quicker effect on professional research practices and allow for more community involvement both from the research community and the general public. What is increasingly clear from the criticisms of the NIH ELSI program is that multiple groups have different purposes in mind for it, and one NIH ELSI program or office may not be able to address them all.

The Office of Genome Ethics was set up to provide in-house ethics services to the many researchers within the NHGRI on the NIH campus (intramural research only). It has provided a consultation service, conducted workshops and discussion groups, held public seminars, and offered courses on research ethics for NHGRI personnel. According to Ronald M. Green, who served as its first director, the office was so successful that in its first eighteen months it "helped to 'open the doors and windows' of the Genome Institute, facilitating two-way communication between NHGRI researchers and others interested in genetic ethics."[64] In his article, Green lists examples of the usefulness of the consultation services and the workshops that were conducted to encourage scientists and ethicists to discuss these issues together.

In one case study from the consultation service in the Office of Genome Ethics, the staff was asked to assist an IRB in the review of a research protocol involving a

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[63] Eliot Marshall, "The Genome Program's Conscience," *Science* 274 (1996): 488-489.

[64] Ronald M. Green, "NHGRI's Intramural Ethics Experiment," *Kennedy Institute of Ethics* Journal 7, no. 2 (1997): 181-189.

minority community. The staff from the Office of Genome Ethics was able to inform and persuade the researchers that their research posed additional risks to the community involved, and thus that the researchers should involve the community more in the design of the research protocol. What was significant about this case is that this discussion, regarding the social implications of the research, focused on what would be best ethically for the community, not just those scientists directly involved in the research, and it went beyond what the federal regulations required for protecting human subjects. Without the involvement of the Office of Genome Ethics, this discussion and change in research protocol might not have occurred if left up to the IRB's application of the federal human subjects research regulations. The Office of Genome Ethics has succeeded in connecting the scientists with the ethicists and in getting the ethical discussions to deal with the realities of the actual science being done. However, this has only been achieved for the intramural research being done at the NHGRI. The extramural science research on genetics and the research in other areas of ethically complicated science, do not have this sort of collaboration because it is not being encouraged or supported institutionally. In addition, the social implications research being done extramurally, by the NIH ELSI program, does not encourage the face-to-face interaction with scientists and genetic research the way the Office of Genome Ethics has done through the consultation service.

It is unclear from the NHGRI website if the Office of Genome Ethics continues today. It appears that it might have became the Social and Behavioral Research Branch, however this new branch does not do the consulting work or hold the workshops or educational courses that the Office of Genome Ethics did. Rather this Branch seems to be an intramural funding area for ethical, legal and policy related questions about genetics.[65]

The NIH ELSI program's ability to serve as a watchdog, while it is funded and overseen by the people it is supposed to be watching over, has been questioned many times during the '90s and in the past decade.[66] No actions have been taken to change or improve the NIH ELSI program's independence either. This is likely due to the idea that most people do not accept the notion of the NIH ELSI program serving as a watchdog. According to Elliot Marshall, Watson has admitted that he saw the NIH ELSI program, when he set it up, as a "shield and a sounding board" that would protect the scientists from "being attacked."[67] This lends support to the idea that the NIH ELSI program is simply the handmaiden for genetic research, rather than a watchdog, and explains its administrative structure and location within the NHGRI. Michael S. Yesley, in his article, describes the situation and results from the NIH ELSI program's organization and structure in this way:

> ELSI is limited to funding extramural research projects in areas that are specified by the HGP's scientist-administrators. The results of the ELSI research are generally published without regard or, indeed, relevance to any policymaking body or procedure. As a result of this restricted focus and methodology, ELSI has produced a large portfolio of academic and professional literature, but little impact on public policymaking.[68]

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[65] NHGRI, "Social and Behavioral Research Branch," http://www.genome.gov/11508935, accessed on August 9, 2011.

[66] Leslie Roberts, "Taking Stock of the Genome Project," *Science* 262 (1993):20-22; Leslie Roberts, "Capital Report: Whither the ELSI Program?" *Hastings Center Report* 23, no. 6 (1993): 5.

[67] Eliot Marshall, "The Genome Program's Conscience," *Science* 274 (1996): 488-489.

[68] Michael S. Yesley, "What's ELSI got to do with it? Bioethics and the Human Geneome Project," *New Genetics and Society* 27, no. 1 (2008): 1-6.

Yesley goes on to argue that the NIH ELSI program has been administratively controlled to examine only issues in genetics that facilitate and support further genetics research and technology. He cites the lack of any funding on stem cells and genetic ethics, the absence of any examination of the financial priority given to genetics research in perspective of the total federal health budget, and the ignoring of issues with genetics and biological weapons.[69] Ultimately, Yesley argues for an independent ethics advisory commission to address the issues with genetics. Janice Jin also supports the idea that the NIH ELSI program be more independent, suggesting as Yesley does that it would be better off if it was not funded by the HGP. Jin however thinks that having the NIH, rather than the HGP, directing the funding would be sufficient, while Yesley believes that the funding should come directly from a congressional allocation and to an independent advisory commission.

Yesley's criticism and suggested changes do not encourage integration, rather separation. He views the NIH ELSI program as a success if it challenges and limits the advance of genetic biotechnology, much in the way a bioethics commission might do. In addition, Yesley's view is pessimistic, as it implies that genetics produces negative social effects, the technologies are dangerous to use, and that the research does not have any positive effects for health. If we look at genetics from the perspective of dual use technologies then we realize that limiting the research is not always the right answer. Dual use technologies are areas where the knowledge can be used to create dangerous and helpful technologies, such as in the case of virus research where the knowledge can be used to create a biological weapon or to create a vaccine. Heavily regulating dual use

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[69] Michael S. Yesley, "What's ELSI got to do with it? Bioethics and the Human Geneome Project," *New Genetics and Society* 27, no. 1 (2008): 4.

technologies can result in not just the negative impacts being prevented but also the positive impacts being prevented. Yesley's approach, while good in meeting one need, that of a watchdog and preventing negative results, does not encourage positive impacts.

In 2004 the NIH ELSI program instituted a new funding program called Centers for Excellence in ELSI Research (CEER). These centers are multi-year funded centers set up at various universities to integrate ELSI-type research. They pull together faculty from bioethics, law, behavioral and social sciences, clinical research, theology, public policy, and genetic and genomic research. The purpose of these centers is to allow an "even more dynamic and broad-based approach to identifying and addressing" the issues facing society from genetic research. A secondary purpose of funding the centers is to have them foster environments that support the next generation of researchers in ELSI issues, or the next generation of ELSI scholars. The NHGRI states that a successful CEER will "promote intensive and sustainable interactions among basic genomic and genetic scientists, clinical and social scientists, and researchers from law, bioethics and the humanities." However there is no requirement to provide a plan for how these interactions will be supported when the grant is over. Unfortunately, while the CEER program does improve the interaction between ethicists and geneticists during the grant through a requirement, it does not provide institutional support for long-term integration across the country in all universities when there is no requirement.

On the scientific side of the NHGRI, outside of the NIH ELSI program, the interaction with those who work on social implications research is encouraged in only a few situations. NHGRI also has a center-funding program like the NIH ELSI program, which is called the Centers for Excellence in Genomic Science (CEGS) program. In the description of CEGS on the NHGRI's website, the inclusion of an ELSI component in a center is listed as an additional characteristic, which "may" be included "if it is integrated with and closely related to the main focus or theme of the project."[70] This language does suggest that collaboration between scientists and ELSI scholars is an option but it does not encourage or promote the collaboration. Without the institutional support for encouraging collaborative centers, there is little motivation for CEGS to do so.

In addition to the CEGS program there is a current request for applications for a U01 Research Project Cooperative Agreement, which aims to connect science and ethics research in one grant. The request outlines three projects, the first being a clinical genomic study, the second research focused on sequencing, analyzing and interpreting sequencing data, and the third on the ethical and psychosocial implications of returning genetic testing results.[71] While this U01 request is an interesting step toward continued interaction, it is a unique case currently. The NIH ELSI program and NHGRI have yet to make the funding and institutional structure for genetics research support long-term interactions between scientists and ELSI scholars. In many ways the separation of the NIH ELSI program from the scientific research grants has promoted the idea that scientist should not be involved in discussions of social implications, and this is a bad precedent to set, both for those in bioethics and for those in the sciences. This is not to say that scientists should always be involved but their involvement should be encouraged and supported rather than discouraged.

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[70] National Human Genome Research Institute, "Centers of Excellence in Genomic Science," http://www.genome.gov/10001771 (accessed on July 29, 2011).

[71] National Human Genome Research Institute, "Clinical Sequencing Exploratory Research (U01)," http://grants.nih.gov/grants/guide/rfa-files/RFA-HG-10-017.html (accessed on July 29, 2011).

What is encouraging about the NIH ELSI program is that the NHGRI is aware of these failings and in its most recent Role Report, from 2002, they identify these weakness and make their correction a priority. This report describes five areas for the NIH ELSI program to focus on: (1) broadening the scope of the research and policy activities to cover the interactions between genetics and biology, genetics and health, and genetics and society, (2) encouraging basic or 'tool building' research activities in philosophy and theology, (3) promoting dialogue and collaboration between scientific researchers and ELSI researchers, (4) enhancing integration between research and policy activities, and (5) evaluating and reformulating NHGRI role in education and outreach activities. The report goes on to suggest specific practical changes that can be made, such as holding workshops and fellowships to provide cross-disciplinary education for both ELSI scholars and scientific researchers, and grants that reward multidisciplinary research efforts.[72] It has been nine years since this report was produced and another report might help to reveal if progress has been made and what else needs to be done.

Genome Canada's GE3LS Component

Compared to the more separated NIH ELSI program in the U.S., the system at Genome Canada requires the integration of ethical considerations and ELSI scholars into the science grant. The GE^{3}LS (Genomic and its Ethical, Environmental, Economic, Legal and Social aspects) component of the Genome Canada funded project was included in

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[72] National Human Genome Research Institute, "The Role of ELSI Research & Policy Activities in the NHGRI Plan," http://www.genome.gov/10005516 (accessed July 29, 2011).

Genome Canada's founding agreement with the federal government in 2000.[73] In it the agreement sets out the objective to assume the "leadership in the area of ethical, environmental, economic, legal, social and other issues related to genomics research" and to communicate "the relative risks, rewards, and successes of genomics to the Canadian public."[74] The GE^{3}LS program describes its self as unique from the NIH ELSI program in two main aspects: the explicit inclusion of environmental and economic aspects, and the requirement of a GE^{3}LS component in every genomics research grant awarded by Genome Canada.[75] While GE^{3}LS is unique, it also shares similarities with the NIH ELSI program. GE^{3}LS funds large scale projects only on ELSI research just as the NIH ELSI program does, and has focused on translating the social implications work in to public policy, such as with the event series called "GPS Series: Where Genomics, Public Policy and Society Meet."[76]

The part of GE^{3}LS that makes it important to this thesis is its required integration of genomic science with considerations of social implications. The specific requirement for a GE^{3}LS component in the genomic research grants is included in the grant guidelines and is stated as follows:

> All applicants must consider the GE^{3}LS aspects of their proposed research

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[73] Patricia Kosseim and Sheila Chapman, "Science and Society: Some 'Made-in-Canada' Options for Integration," *Accountability in Research* 18, no. 3 (2011): 194-216.

[74] Genome Canada, "GE^{3}LS at Genome Canada: Objective," http://www.genomecanada.ca/en/ge3ls/about/ (accessed on August 4, 2011).

[75] This requirement did not start until July 2004 with Competition III and was made explicit across all funding in 2005. Genome Canada, "GE^{3}LS at Genome Canada: Strategy," http://www.genomecanada.ca/en/ge3ls/about/ (accessed on August 4, 2011).

[76] Genome Canada, "GE^{3}LS Research Projects Funded by Genome Canada," http://www.genomecanada.ca/en/ge3ls/research/ (accessed on August 4, 2011); Patricia Kosseim, "Message from the Chief GE^{3}LS Officer," http://www.genomecanada.ca/en/ge3ls/message.aspx (accessed on August 4, 2011).

> and, where appropriate, seek advice from one or more GE^{3}LS experts (as a co-applicant, collaborator, or through membership on an advisory committee) to develop a plan to address those GE^{3}LS issues directly raised by the proposed research.

This requirement implies that all research projects within Genome Canada have GE^{3}LS issues and makes the consideration of these issues occur in the project development stage, the project execution stage and/or the post project completion stage. The requirement does not require the collaboration or integration with scholars from GE^{3}LS, but states that the issues must be considered, and “where appropriate” a scholar from GE^{3}LS should be included.

Patricia Kosseim and Sheila Chapman, in an article reviewing the success of the GE^{3}LS program, described the response from both GE^{3}LS scholars and genomic scientists to the program.[77] GE^{3}LS scholars expressed that the projects were not as integrated as they could have been, that occasionally the GE^{3}LS component was “thrown together” at the last minute, and that collaboration with the scientists were “often accidental and usually regional, not national.” In addition, GE^{3}LS scholars felt isolated as a group and wished for more nation-wide collaboration among the GE^{3}LS scholars. Meanwhile the genomic scientists expressed that they were “not very convinced of the usefulness of GE^{3}LS,” that the GE^{3}LS component seemed “tacked on” or like a “tax” on the science, and that GE^{3}LS scholars did not sufficiently understand the genomic science. However it was noted by some genomic scientists that when the GE^{3}LS component was “well integrated with the science,” it did work well and was useful. Kosseim and Chapman concluded that some of the problems would be resolved with time, as

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[77] Patricia Kosseim and Sheila Chapman, "Science and Society: Some 'Made-in-Canada' Options for Integration," *Accountability in Research* 18, no. 3 (2011): 194-216.

guidelines and processes become clearer, review criteria are refined, collaborative relationships are strengthened, and the research community grows more accustomed to the integrated model.

As Kosseim and Chapman point out, the benefits of the GE^{3}LS system is that it ensures the consideration of social implications through “built-in incentives and mandatory funding requirements.”[78] By Genome Canada requiring ELSI considerations and planning, they have leveled the playing field for all researchers to consider social implications of their work, thereby providing institutional and funding support for doing so. However, there are downsides to the system as well. Because it is a requirement for all research projects, there are likely situations where there is not a unique ELSI issue to be considered and thus one must be “tacked on” or repeated to meet the funding requirement. In addition, because the funding of the GE^{3}LS component is funded by the same research grant that the GE^{3}LS component should be critiquing, there is a conflict of interest for GE^{3}LS scholars who disagree with the genome researchers. However, in projects where the scientists and GE^{3}LS scholars are truly collaborative, and where the GE^{3}LS component is not supposed to fill an advising or oversight role, the two fields can work together on a project and the conflict of interest is not as prevalent because they are sharing the same objective.

Gates Foundation Funded Ethical, Social, and Cultural Program

One additional case of the integration of science and social implication work is the Ethical, Social, and Cultural (ESC) program within the Grand Challenges in Global

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[78] Patricia Kosseim and Sheila Chapman, "Science and Society: Some 'Made-in-Canada' Options for Integration," *Accountability in Research* 18, no. 3 (2011): 206.

Health (GCGH) initiative. The GCGH initiative was created in 2003 by the Bill and Melinda Gates Foundation to get science and technology translated into solutions to address some of the most critical health problems in the developing world. The ESC program was started in 2005 to address the issues associated with the research being done by the GCGH initiative. The ESC program consists of a couple different methods for integrating science and social implications research. There is an advisory service that is similar but different than the research ethics consultation services described earlier. There are four working groups, each focused on a specific technology: vaccines, genetic control of vectors, nutritionally enhanced foods, and diagnostics. These working groups are composed of not only ESC staff but also researchers from the GCGH projects. In addition to these two integrated methods, the ESC program is also publishing papers based on the knowledge gained by working through problems, conducting cases studies on ESC issues, and developing internet-based public engagement methods.[79]

The ESC advisory groups, while initially appearing like research ethics consultations, are more like research projects performed at the request of GCGH researchers. When requested, the ESC staff consult to frame the problem or project, then they identify resources to research the issue, research the issue and report the results to the GCGH team, at which point the GCGH team reviews and discusses the report, and finally the report is revised and submitted to the principal investigator.[80] The final product is advice on how to move forward, however the process of coming to the advice

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[79] McLaughlin-Rotman Centre for Global Health, “ESC Program: Ethical, Social and Cultural (ESC) Program for the Grand Challenges in Global Health Initiative,” http://www.mrcglobal.org/esc (accessed on August 5, 2011).

[80] Peter A. Singer, et. al., "Grand Challenges in Global Health: The Ethical, Social and Cultural Program," *PloS Medicine* 4, no. 9 (September 2007): 1440-1444.

involves independent research and collaboration with the GCGH researchers, which differs from research ethics consultation (REC) services. REC services usually consists of consultants being on-call for consolations and providing answers on short notice, where as the GCGH team is requested for research services which they collaborate on and report back at a later time.

The ESC advisory groups are distinct from the GE^{3}LS program because the integration is voluntary rather than required. In the first year of ESC the requests came from the GCGH researchers just as they do in REC services. In the second year an adjustment was made to make the connections between GCGH researchers and ESC staff stronger; each GCGH project was assigned a lead bioethicist and advisory service co-leader from the ESC staff. The integration was still not required but a connection was made at the beginning to ensure easy access for the research and to connect the expertise of the ESC staff to the GCGH research topic or area. These simple changes provide institutional and funding support for scientists to consider the social implications and even encourage them to make use of the ESC services. The ESC program also holds bi-weekly ESC team meetings at which program officers from the GCGH projects often participate.[81]

Kosseim and Chapman describe the ESC program as “centralized” because it is composed of one group of ESC staff that serve all the GCGH projects, rather than the “distributed” model of the GE^{3}LS program where connections are made at local

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[81] Peter A. Singer, et. al., "Grand Challenges in Global Health: The Ethical, Social and Cultural Program," *PloS Medicine* 4, no. 9 (September 2007): 1440-1444.

universities with GE^{3}LS scholars.[82] One of the main concerns with the ESC program that Kosseim and Chapman see is that only after a GCGH project is approved does the collaboration between the ESC staff occur. Therefore, the ESC program is unable to assist in project design. This gap could be addressed by allowing consultation with ESC staff during the proposal writing and application process.

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[82] Patricia Kosseim and Sheila Chapman, "Science and Society: Some 'Made-in-Canada' Options for Integration," *Accountability in Research* 18, no. 3 (2011): 194-216.

Comparison and Analysis

Types of Social Implications Work

The various systems of integrating science and social implications research include a few different aims. These different aims include: oversight, advice, perspective/analysis, knowledge translation, embedded research, and integrated research. These different types of work on the social implications of science come from the case studies described previously and from the work of Kosseim and Chapman.[83] It is important to distinguish between the different types of work on the social implications of science because the different aims can make issues, such as conflict of interest, independence, collaboration, and public engagement, more or less important. For instance, if the aim is to oversee or advise, then having the ethics staff paid directly by the group being overseen or advised would prove a large conflict of interest and might tie the hands of the person providing the ethics services. However, if the aim is to collaborate on a problem, both the scientists and ELSI scholars want to solve it and then the conflict of interest is not as great a concern because the researchers and ELSI scholars are colleagues or co-investigators and their relationship is equivalent to that of other researchers on the project.

The different types of work on the social implications of science can be seen in the cases described in the previous section. "Oversight" is when scholars are on committees to provide "external, independent, and critical perspective," on the science.[84]

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[83] Patricia Kosseim and Sheila Chapman, "Science and Society: Some 'Made-in-Canada' Options for Integration," *Accountability in Research* 18, no. 3 (2011): 194-216.

[84] Patricia Kosseim and Sheila Chapman, "Science and Society: Some 'Made-in-Canada' Options for Integration," *Accountability in Research* 18, no. 3 (2011): 201.

This can be seen in the GE^{3}LS program where the option is to include GE^{3}LS scholars on an advisory board. Most commonly this "oversight" role would be associated with the work performed by the Recombinant DNA Advisory Committee (RAC), which oversees research on rDNA at the NIH or is associated with IRBs. "Advice" is the role most commonly fulfilled by consultation services, such as Research Ethics Consultation programs. The ESC advisory program in many ways also fulfills the "advice" aim. "Knowledge Translation" is the aim of encouraging and advancing the interaction between the science and outside public groups such as the general public, politicians, patient rights groups, non-governmental organizations, industry, and media. The purpose is to translate the scientific information, into more accessible forms such as for outside groups to engage with or to turn into public policy. This has been one of the goals or aims of the NIH ELSI program, the GE^{3}LS program, the ESC program, the National Academies, bioethics commissions, and academic bioethics, though some have placed more emphasis on this than others. "Embedded Research" is social implications research where the subject of the research is a scientific project, and where the ESLI researchers are "embedded" within the scientific research project they are studying. In the case of the GE^{3}LS program, this has occurred when ELSI scholars are included on the research grant but are using the genomic research project as a case study to advance the scholarship in bioethics or other related ELSI fields. "Integrated Research" is, as the name implies, the most integrated form of social implication work. This type of research is the interdisciplinary interaction that occurs when both the ELSI scholars and the science researchers are both collaborating on an issue from the beginning of conceiving the project proposal, to designing the project, to performing the research, and finally to publishing the results.

Kosseim and Chapman identify “oversight,” “advice,” “knowledge translation,” “embedded research,” and “integrated research.” I propose that “perspective/analysis” also be added to define the academic work and scholarship that is produced to inform fields like philosophy, ethics, law, or sociology, and can also include the work by bioethics commissions examining and producing reports on ethical topics. This is an area with little to no integration between the science and social implications research. The NIH ELSI program and the ESC program both have this as an aim, though the NIH ELSI program focuses more on this.

Key Features of Integrated Science and Social Implications Systems

Hub Zwart and Annemiek Nelis identify four key characteristics of integrated systems: proximity, early anticipation, interactivity, and interdisciplinarity. Proximity, the most obvious characteristic, is the closeness between the social implications research and the scientific research. Early anticipation, argue Zwart and Nelis, comes from integrated research’s connection to the field of technology assessment. A successfully integrated system would be able to anticipate, rather than react to, the results of research. Interactivity is the engagement that occurs with outside groups to determine goals, aims, and the agendas for the science. This involves interaction between citizens, physicians, policy makers, patient advocacy groups, ethnic communities, non-government organizations, media, and scientists. The final characteristic, interdisciplinarity, is defined by Zwart and Nelis as the bringing together of different non-scientific academic research fields such as philosophy of science, science and technology studies, sociology, bioethics, and technology assessment.[85] I suggest that this should also include the interdisciplinary interactions of these non-scientific fields with the sciences and medical fields, because "integrated research," as identified by Kosseim and Chapman, includes the collaboration between the scientists and the ELSI scholars.[86]

These four key characteristics are really ideals or goals of integrated systems, although as the cases reveal, not all them meet these characteristics. It is most useful to understand each of these characteristics as each existing on a spectrum with the ideal characteristic identified by Zwart and Nelis representing just one end of the spectrum. Beginning with proximity, the spectrum ranges from close proximity to complete separation of the work. In the case of proximity, the goal of proximity has been questioned specifically in regard to the NIH ELSI program. When the aim of the integrated research is "oversight," the proximity of the ELSI research to the science is problematic because of issues of independence and conflict of interest. The proximity of the NIH ELSI program has led many to call it the handmaiden of genomic research.

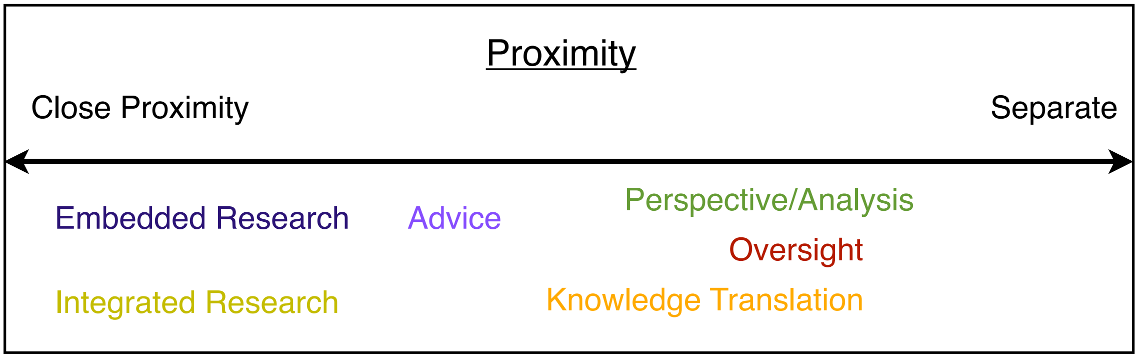

Figure 1: Proximity Spectrum

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[85] Hub Zwart and Annemiek Nelis, "What is ELSA Genomics?" *European Molecular Biology Organization (EMBO) Reports* 10, no. 6 (2009): 540-544.

[86] Patricia Kosseim and Sheila Chapman, "Science and Society: Some 'Made-in-Canada' Options for Integration," *Accountability in Research* 18, no. 3 (2011): 194-216.

However on the other end of the proximity spectrum, a close proximity allows the aims of "integrated research" and "embedded research" to occur and, some argue, leads to more relevant research and more timely predictions of the impacts. On the proximity spectrum, starting with close proximity and moving towards separation, the types of social implications work would go from "integrated research" and "embedded research" to "advice," then to "knowledge translation," and finally to "perspective/analysis" and "oversight" (see Figure 1).

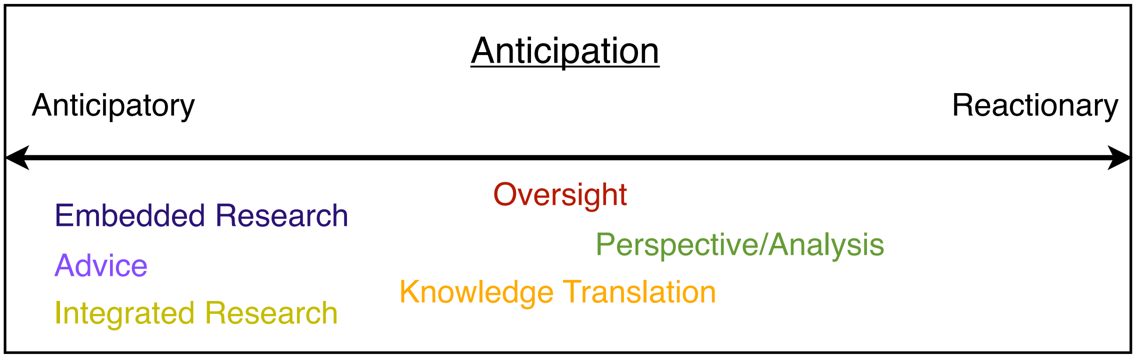

Figure 2: Anticipation Spectrum

Early anticipation exists on a spectrum as well, with the other end being reactionary. Just as with proximity, there are positives and negatives to both ends of the range. While early anticipation does allow for preparation and planning, it relies on prediction and on the ELSI research being very informed of the basic science being done. This anticipatory goal is less important for "perspective/analysis" and "knowledge translation" and partially for "oversight" work. "Oversight" work in the U.S. has in the history often not focused on anticipating so much as reacting to problems and abuses, which can be seen with the history of abuses in human subjects research during the 1960s and 1970s, which led to the IRB oversight system developed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. A reactionary system is more independent, relies on data showing impacts, and allows the basic research stage to advance without restrictions. However, a reactionary system allows the impacts of science to take effect before examining the impacts. Then it reacts to the impacts that are appearing. Somewhere in the middle lies "knowledge translation," which occurs in politics and media and is where the impacts of science are promoted (and too often hyped) and assessed through anticipation and reactions. On the Anticipatory to Reactionary spectrum, the types of research go from "embedded research," "integrated research," and "advice" to "perspective/analysis" on the opposite end, with "oversight" and "knowledge translation" in the middle but closer to the reactionary side of the spectrum (see Figure 2).

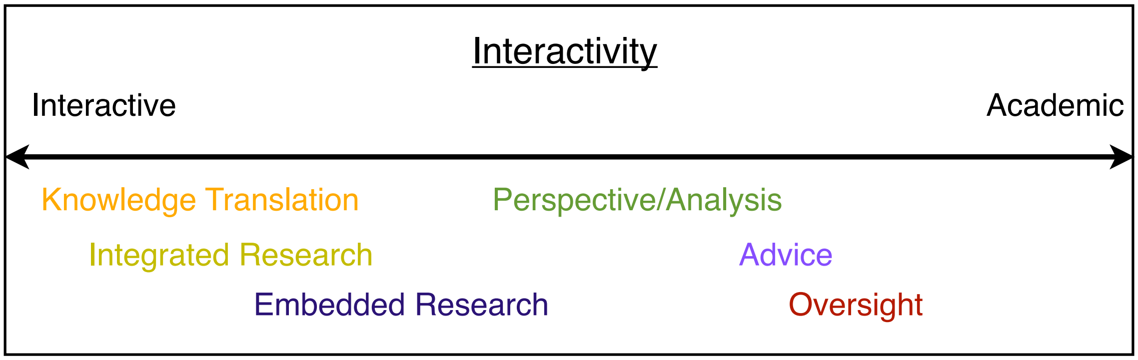

Figure 3: Interactivity Spectrum

The interactivity spectrum ranges from a high level of interaction with outside groups to isolated, private or internal academic work. This other end of the spectrum includes basic research that informs mainly the field in which it occurs, or can also include work that is not meant to be public, such as "oversight" work. In some cases "perspective/analysis" work and "advice" services are also included as being less interactive, because they either serve just to inform their own field or are meant to provide advice on individual cases. The NIH ELSI program has often been criticized for producing research that only adds to the bioethics literature, which is really a critique of the purpose of the ELSI program not the work being done. Work that is interactive occurs more with work that aims to engage the public and policy makers, and this is the type of work that more recently the NIH ELSI program has been taking steps to encourage more of. The most interactive part of social implication work is "knowledge translation," followed by "integrated research," "embedded research," "perspective/analysis," "advice," and then "oversight" (see Figure 3). A good example of research that is not interactive is basic science research. It does not have much in the way of applicable impacts at this stage and thus has little need of integration with social implications research.

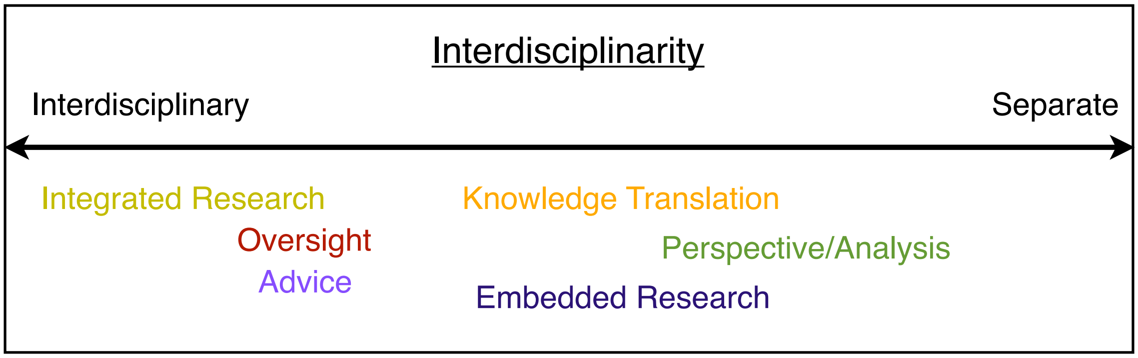

Figure 4: Interdisciplinarity Spectrum

The interdisciplinarity spectrum ranges from very interdisciplinary to work that only occurs separately and primarily within its academic research field. The interdisciplinarity characteristic is one of the main features of integrated research. Many of the reasons to encourage interdisciplinarity are the same reasons to have integrated science and social implications work: it gives context and perspective to an issue, it can advance the application of science to society's needs, and it can produce more relevant work on both the science and ELSI side. However, interdisciplinarity is not easy.

Interdisciplinarity often suffers from language translation difficulties, where scholars from different fields talk over each other, not with each other. “Integrated research” is the most interdisciplinary because it requires different disciplines to communicate with each other. It is followed by “oversight” and “advice,” which needs communication and understanding between them but not to the extent needed when conducting combined research projects. Then “knowledge translation” and “embedded research,” are placed on the scale because they require one-way communication rather than two-way communication with the science; ethics scholars just need to understand the science, but scientists do not need to understand the ethics for the research to occur. Lastly, “perspective/analysis” research is the furthest away from interdisciplinarity because of the “academic” nature and language barriers associated with work that is meant to advance one’s own academic field rather than be applied to areas of policy, law and public education. (see Figure 4).

Implementation: Voluntary or Required?

An important factor in whether a system is fully integrated is how it is implemented: voluntarily or through requirements. This distinction can be seen most clearly between the GE^{3}LS program and the ESC program. In GE^{3}LS the integration is required, and as was described in the case description, some of the GE^{3}LS integration felt “tacked on” or was not given a great amount of consideration. In addition, the required GE^{3}LS system can also result in the duplication of social implications work, where research projects have the same issues but because the GE^{3}LS component is required they must include something. However, the positive of the required GE^{3}LS system is that all of the science research is integrated with the social implications research. In the ESC program the integration is optional but encouraged. The researchers request integration when they feel it is relevant and this allows for a more natural and honest development for the integration. This is compared to the optional system described in the NIH CEGS program, which does not provide any encouragement to pursue integration, but rather just describes it as an option.

A system that requires integration may result in more integration but it is questionable if the integration is of a good quality. With required systems there is the concern that it would led to frustration among scientists, who feel it is just one more requirement that does not help them advance their research, or will take them away from what they love to do, bench science. The NIH ELSI and the ESC programs are both voluntary, but the NIH ELSI program does not encourage the integration in the same manner the ESC program does. There is significantly less widespread structural, institutional, or funding support for science researchers to integrate their work with those studying the social implications in the NIH ELSI program. The ESC program is a good balance between ignoring integration and requiring it. The risks with not integrating science with social implications work are not as great as the risks with conducting human experimentation without standards in the 1970s because the social implications of science can still be studied and considered without them being integrated. Thus integrating science and social implications work should not be mandated by regulations as the standards for human experimentation were, rather it is just another method for studying social implications that should be encouraged.

Integrated Science and Social Implications Spectrum

By combining the evaluations of the different cases along the spectrums of the four key characteristics, a combined spectrum for the integration of science and social implication can be created. The spectrum shown in Figure 5 below, has the fully integrated GE^{3}LS program on one end, with the least integrated system of academic bioethics on the other end. While full integration may be a goal, I argue that quality integration that is initiated and desired by both science researchers and ELSI researchers is the ideal for integrated research. The spectrum also displays the level of integration for the various types of social implications work. What this reveals is that certain types of social implications work do not need to be fully integrated and even more so that some, like "oversight," should not be integrated because of the risks of being unable to carry out the duties of that aim. Programs that intend to integrate science and social implications

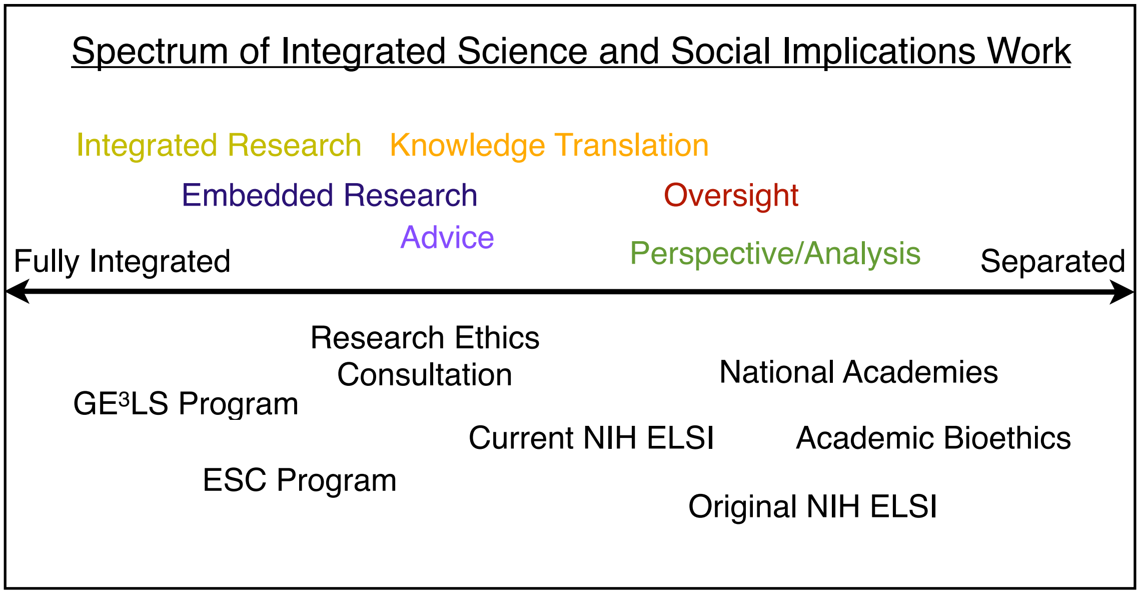

Figure 5: Integrated Science and Social Implications Work Spectrum

should focus on performing the types of work that are strengthened by integration rather than the types that are weakened by integration.

Conclusion

Consideration of the social implications of science is an area that benefits from the integration of both science and ELSI scholarship and should be encouraged. The historical descriptions of the origins of scientists acting on this social responsibility to consider implications, to interact with outside scholars, and to communicate with the public, sets the precedent for the integrated programs being developed today. The history also demonstrates that the origins of scientists' involvement in considering the social implications of scientific research began with the scientists themselves. It was scientists who raised questions about their own work and who invited the public and outside scholars into the discussion during the post war period and during the 1960s. This history sets an important precedent for students of science today to be informed of because it establishes a professional ethic that is important to their professional training. The historical cases, along with contemporary case studies, are important tools in teaching scientists research ethics and should be used more.[87]

The growing scholarship in research ethics, which is emphasizing and exploring scientific social responsibility, is providing increasing support for integrated systems and the involvement of scientists in ethical discussions. The research into scientists' understanding of ethics and social responsibility is also revealing that average scientists do not participate in considerations of the social implications.[88] In addition, ethics

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[87] Penny J. Gilmer and Michael DuBois, "Teaching Social Responsibility: the Manhattan Project," *Science and Engineering Ethics* 8, no. 2 (2002):206-210; Jacques Dubochet, "Teaching Scientists to be Citizens," *EMBO Reports* 4, no. 4 (2003): 330-333.

[88] J. M. Ladd, M. D. Lappé, J. B. McCormick, A. M. Boyce, and M. K. Cho, "The 'How' and 'Whys' of Research: Life Scientists' Views of Accountability," *Journal of Medical Ethics* 35, no. 12 (2009): 762-767.

research on scientists' competitive environment is reinforcing how institutional structures and pressures can influence the actions of scientists.[89]

The multiple cases, both historical and contemporary, of considering social implications of science in the U.S., Canada, and within NGOs have provided numerous examples of different aims and ways to achieve these considerations, including using an integrated method. The ideal integrated system does not aim to oversee, but rather attempts to collaborate between fields, to advise, and to translate the science to the public. It also does not force integration, but rather encourages the integration of science scholars with ELSI scholars through institutional partnerships, grant funding, and workshops. The ESC program within the Grand Challenges in Global Health (GCGH) initiative is the most successful at meeting these ideals for integrating science and considerations of social implications. While there is a large emphasis on considering the social implications of genetics, the ESC program has also demonstrated that this integration model can be translated to other areas of research that are ethically controversial. One place that is ideally situated to institute a system like the ESC program would be the California Institute of Regenerative Medicine (CIRM). Stem cell research is an obvious area of controversial science and CIRM is an organization that has the capacity, organization, and even the responsibility, because of its creation by the voters of California, to consider the social implications of the research they are conducting. While CIRM has yet to institute any form of integration so far, they have the opportunity to do so now and to learn from the systems that have been created thus far.

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[89] Melissa S. Anderson, et. al., "The Perverse Effects of Competition on Scientists' Work and Relationships," *Science and Engineering Ethics* 13 no. 4 (2007):437-461.

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