Paved With Good Intentions: Rethinking the Ethics of ELSI Research

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Abstract

Ethical, Legal and Social Implications ("ELSI") research has played an increasingly important role in scientific research. Tens of millions of dollars, many of which are public, are spent funding scientific research projects. Taxpayers are demanding that scientific advancement move forward, hand-in-hand with careful examination of the many ethical and social issues that are raised by the emerging sciences. It is not uncommon to find grants that include ELSI components. This raises a potential problem relating to the ability of ethicists to undertake serious, objective reflection and make independent, normative suggestions. If the Principal Investigator (PI) of the grant controls the funding of the ethics component and ELSI reflection suggests acts or omissions that would negatively affect the PI's scientific project, especially given the current economic climate in which reductions in ethics and humanities funding jeopardize other employment, ethicists may be placed in a position of having to decide between seriously jeopardizing their career, or ignoring the moral problem and compromising their professional integrity. One suggestion to avoid this conflict is to separate the funding of ELSI components from the scientific portion of the grant and to erect a secure firewall between the two. Other solutions certainly exist, and the purpose of this paper is to raise the issue to stimulate debate.

Keywords: conflict of interest, ELSI, ethics, funding

Introduction

Ethical, Legal and Social Implications ("ELSI") research has been a new constant in basic genomic projects for two decades. In the last 10 years, the inclusion of ELSI research as a required component in a wide range of sponsored basic and translational research projects – from medicine to chemistry – has reassured the public that scientists who receive public funding work closely with academic bioethicists, legal scholars and social theorists to carefully explore the implications of new science. These grants have also inspired a generation of bioethics research on genetics, genomics, stem cells, climate change, synthetic biology and nanotechnology. This article, while celebrating this attention to ethics, raises the issue of whether the structure of funding such work creates inadvertent conflicts of interest and commitment. This paper asks: if the Principal Investigator (PI) of the grant controls the

funding of the ethics projects, can ethicists undertake serious, objective reflection and make normative suggestions independently and fearlessly, especially in an economic climate in which reductions in ethics and humanities funding jeopardize other employment?

Ethical issues in science research have concerned both scientists and the public for decades. The first formal designation of funding for study of basic research by federal agencies is most clearly linked to biological advances in the 1950s and 1960s that eventually led to the development of recombinant DNA (rDNA) technology in the early 1970s. Paul Berg of Stanford developed a method of joining fragments of monkey virus SV-40 (a tumor gene) and bacteriophage lambda. Further work, however, was halted due to concerns that this rDNA could find its way into E. coli, the most widely used bacterial species in laboratories, also commonly found in human intestine, and risk infection of lab workers. This concern was deepened by the fact that, at that time, researchers working with rDNA increasingly were biochemists not practiced in the standard safety measures used by microbiologists. Due to concern within the field itself, in 1975 a conference was organized at the Asilomar Conference Center in Pacific Grove, California to discuss the potential biohazards and regulation of rDNA. Known as the Asilomar Conference, this meeting of scientists drafted voluntary guidelines to address the concerns of rDNA technology and research (Profiles in Science).

History of ELSI

The history of the specific funding called "ELSI" began in the mid-1980s as the NIH and Department of Energy undertook the task of mapping out the human genome, under what was to become the Human Genome Project (HGP). Harking back to the Asilomar Conference, those in charge of the HGP, as well as researchers, social scientists and lawmakers, understood that exploring uncharted areas of science was likely to raise a number of complex moral issues for individuals and society (Human Genome Project). James Watson was appointed the Director of the HGP in 1988 and determined that the project would set aside funds specifically to study the ELSI issues arising under the HGP, openly explaining that the intent was to reassure a public concerned with the increasing reach and power of science. Each year, between three and five percent of the funds earmarked for HGP was dedicated to ELSI. From the beginning, the HGP's ELSI program has examined a variety of issues, ranging from privacy, to commercialization, to the use of Genetically Modified Organisms (GMOs) as food. While it was initially contemplated to address the potentially harmful consequences of the project, the HGP and ELSI programs shared the common goal of addressing larger moral issues from the outset; thus ELSI, rather than impeding HGP progress, was "viewed as an important adjunct that would facilitate its success" (Everson 2007, p. 124). The expansion of the ELSI program to a variety of emerging technologies provides evidence of its success. Such expansion includes the National Nanotechnology Initiative, which dedicates approximately five percent of its budget to ELSI issues. The emergence and increasing understanding of the importance of, and funding for, ELSI allowed rigorous consideration of essential ethical questions within emerging science projects.

Issues with ELSI Funding

As with many scientific methods, however, continued practice reveals weaknesses embedded in the ELSI programs' strengths. While the intentions of government support of ELSI are to be lauded, unintended consequences have emerged that must be addressed for serious research in ethics to have power and credibility. While a few centers are funded directly and dedicated entirely to ELSI research (Centers of Excellence in Ethics Research, or "CEER" grants), most of the current funding schemes for ELSI projects result in serious structural conflicts of interest. Specifically, when the PI of the larger grant also controls the finances of its ELSI component, the ELSI faculty and staff are placed in the untenable position of evaluating critically the project that pays their salary.

The problem of ethics centers being funded by the labs they "oversee" was most clearly revealed in the case of human genetic intervention trials. In 1999, while participating in a Phase I clinical trial at the University of Pennsylvania, 18 year old Jesse Gelsinger died from an immune reaction to the viral vector containing a potential future gene therapy to correct X-Linked SCIDS, a defect that was, in his case, fully treatable by diet and medication. It was later revealed that the physician leading the research, Dr. James Wilson, was president and a major shareholder of Genovo, Inc., the company that not only supplied the funding for the research, but also held the patents on the gene therapy procedure being used (Hoey, 2003). Additionally, Genovo provided limited funding for Pennsylvania's Center for Bioethics. The Center's director, Arthur Caplan, Ph.D, held a tenured appointment in a department headed by Dr. Wilson. While not speaking to the issue of wrong-doing by Caplan, the Danforth Committee – an independent panel of experts gathered by the University of Pennsylvania to evaluate their gene therapy group after the Gelsinger incident – recognized the potential for compromise of the bioethicist's work and identified "the need for independence between bioethicists and the researchers" (Wilson 2009, p. 236).

A similar situation occurs when the ethicist is working as part of a larger project in which funding for the ELSI researcher's position comes from, and is administered by, the project's PI. This hierarchical relationship between PI and ethicist is common to many NIH- and NSF-funded projects. Should a dispute arise over the subject matter of the ethical research itself (e.g., ethical concerns about a potentially commercially lucrative product; questions about publication protocol; conflicts of interest; questions about relative safety; or issues that emerge from concerns of students in the lab), this leads inexorably to a potential conflict of interest. The scarcity of research tax dollars and, at least in emerging technologies, comparatively strong governmental support of commercialization of federally funded research mean that scientists and universities increasingly find themselves in situations in which research offers an opportunity for substantial and desperately needed monetary rewards. What would occur if the ethicist recognized ethical, legal or social issues, which, when further researched and published, could interfere with the progression, commercialization or direction of the scientific research? While one would hope that the ethicist's research and recommendations would be granted due deference, it is quite possible that the PI and/or university, calculating the potential loss of income dollars from patents or commercialization

of the research, would choose not only to disregard the ELSI issues, but also to take action to dissuade that particular line of inquiry. The issue of conflicts is just as problematic in the reciprocal situation in which the ELSI researchers do not object to the nature, goal, or interpretation of the emerging science, but rather come to respect deeply and, in this sense, advocate for the work. This advocacy can be a form of "regulatory capture," made worse if the continued funding for ethics is linked to the successful extension of the grants.

Undue influence to get the "right answer" about the implications of research can be exerted in a variety of ways when the research funds for ELSI issues are controlled by the PI on the larger grant. Pressure can be applied on the ethicist by reducing funding, or threatening to terminate it entirely, under the argument that, with limited overall funds, the PI can only allocate funding to successful lines of research (subjectively determining that the ethical line of research is "going nowhere"). It is not clear that a PI could actually de-fund a mandated set-aside; however, the PI can dismiss the particular ethicist and replace him or her with one who is more cooperative. This position of economic superiority can create a hostile workplace, in addition to an implicit understanding that the particular ethicist (or entire ethics group) will not be included on future grant proposals. Likewise, the PI may make vague claims that the particular ethicist's research, because it is not as easily quantifiable as science research because it raises moral issues considered outside of the narrow science goal, is inapplicable and therefore is no longer eligible for funding, thus providing a basis to dismiss the ethicist in favor of one who will be more cooperative. Pressure can be subtle, because the culture of science creates specific norms that often operate within hierarchical systems, and it also creates a fiercely competitive atmosphere where criticism is perceived as interference with a goal all agree is noble in intent. Attention to data that are troubling, or attention to quiet voices of dissent within labs, can raise issues of "loyalty" and "teamwork," fatal nomenclatures for graduate students who are dependent on recommendations from the very PI whose work might be worrisome. ELSI research is intended to be the voice of the "stranger" in the lab, but if the stranger is dependent on the host for his or her support, the situation can become more vexed. The dependence for funding places ethicists in the untenable position of deciding between pursuing the ethical inquiry and risking their career, or ignoring the moral problem and compromising their professional integrity.

The situation is compounded when the ethicist is in a position of power inferior to the science PI. For example, the ethicist may be a post-doctoral researcher or a non-tenured professor, or simply a faculty member from a humanities department, while the PI on a large government grant is likely not only to be tenured, but also to have some notoriety in the field and a capacity to wield a certain amount of professional respect. This disparity of power may cause the ethicist to back down from pursuing a line of research that could be confrontational, a public conflict that would pit the unknown ethicist against the well-respected scientist. Finally, the university, having its own conflicts of interest, may weigh the potential research dollars the PI has already brought in and the potential future dollars through future grants and patents, and be biased in favor of the PI in internal disputes that could arise between the PI and the ethicist.

As the Danforth Committee has previously argued, "the need for independence between bioethicists and the researchers [is] advised." In the above scenarios, the lack of independence is a direct result of the funding structure: the party who is subject to ethical review funds the ethicist, in whole or in part, and has the power, if not to withdraw that funding at will as relates to the particular ethicist and seek a more agreeable ethicist, at least to exclude the ethicist from any future funding opportunities lead by the PI. If the PI is well-renowned and has significant influence at the institution, such exclusion may, if not overtly, at least covertly, influence the decision of other PIs in determining whether to include a "troublesome" ethicist in their future grant proposals, or to seek an ethicist who will be more cooperative. As research funding becomes more difficult to obtain and as the rewards for success in science become more lucrative, the potential for conflict intensifies. The authors would argue that the entire premise of academic freedom depends on the ability to speak truth to power, to publish critiques freely, and to be able to explore the implication of powerful research by powerful researchers transparently and rigorously. To do so, ELSI research needs a firm financial and intellectual foundation, entirely separate from the control of the investigators who undertake the scientific research. One solution is for granting agencies who call for ELSI research — as they should on all emerging science research — to bifurcate the ethics administration and budget of the ELSI research from the research administration and budget of the science itself, by requiring each proposal to include separate ELSI PIs who are awarded and administer their own funds and whose success or failure is judged by their peers in the field via publication and paper acceptance, not by the science PIs whose work is at stake. Critical to this strategy would be the review of grants by committees that include ELSI trained scholars. However, such an approach encounters the inherent problem of ethics-as-critique. If funding is dependent on research understood as "problematic" in some way, then the ethicist is oddly incentivized to see problems everywhere. Ideally, universities should fund ELSI centers directly and independently of the research undertaken.

Possible Solutions

While one may properly laud the efforts and intentions of the many who have recognized the need to fund ELSI projects, in particular funding for difficult ethical conundrums, one must recognize that putting ideas into practice can take time, effort and, most importantly, the ability to adapt. Like any good project that is devoted both to descriptive and normative goals, ELSI projects must be funded and administered separately from the research groups with which they partner. Experience has led the authors to understand the deep value of collaborative research projects that include what has been termed the "embedded ethicist" (Zoloth, 2009) who is serious about listening to and learning the science content and method in the lab. It is to a research group's long-term advantage to cultivate a productive, candid working relationship with ELSI projects so that the scholars truly can understand the research and help researchers think about the moral pitfalls (and potentials!) of their projects along the way. By this integrative, but separately funded and administered method, a research group and the ELSI group can hope to develop and "encourage a broader societal capacity to manage [the research] for the public interest while

such management is still possible" (Guston 2010, p. 1). The failure to give ELSI groups sufficient independence in publicly funded research undermines the purpose of investing in ELSI – to identify early the ethical, legal and social issues inherent in basic research that may become problematic. ELSI scholarship is intended to point to critical issues of public concern about science research that are outside the scientist's area of expertise, but which are critical to the process of discovery in a democratic society.

Public funding of science depends on public support and trust: trust that scholars of ethics, social theory and law keep a steady, independent, and informed academic gaze on the research in the lab and clinics. What this paper suggests as a way forward – the separation of funding and the erection of a secure firewall between funding of ethics and science within grants – is only a beginning. For truly collaborative interdisciplinary work to proceed, full recognition and authority for each discipline in the collaboration will be critical. This paper raises this issue directly to the funding agencies for their consideration and calls for a new national standard for ELSI research.

The Research Administrator's Role

The Research Administrator can play an important role in advancing this new national standard, from the top on down. One recommendation is that it begins with the Office of Research Integrity (or similar department responsible for ensuring ethical compliance with grant requirements) developing recommendations encouraging the inclusion of ethical elements in all major grant proposals of the institution. While an ELSI component may already be required in some grant proposals, many RFPs do not currently require an ELSI element. The inclusion of an ELSI component can strengthen any proposal and provide additional incentive for a grant to be awarded. By implementing an institution-wide policy recommending that ELSI issues be, at the very least, openly discussed in all proposed research, research administrators can work to advance research at their institution that not only is ethically conscientious but also promotes the goal of developing ethically aware scientists.

Institutions may be hesitant to promulgate even "recommended" policies on the basis that such action encroaches upon the academic freedom of faculty. Academic freedom has been considered a First Amendment right by some courts, including the Supreme Court (Sweezy v. New Hampshire, 1957). The imposition of recommended policies affecting research plans may be seen in a negative light by faculty. Much as faculty generally object to the use of student evaluation forms, which are seen as prima facie evidence of administrative intrusion into the laboratory promulgated by administrations to impose politically correct standards on faculty members (Haskell, 1997), faculty may argue that recommending ESLI components to grant proposals places administrative interests in laboratory research plans and attempts to coerce faculty researchers to conform to politically correct standards. However, while much credence is given to the notion of academic freedom, the Commission on Academic Tenure in Higher Education believes adequate cause for dismissal of tenured faculty exists where there is "demonstrated incompetence and dishonesty in teaching and

research" or the researcher engages in "conduct which substantially impairs the individual's fulfillment of institutional responsibilities" (Haskell, 1997). Thus, any complaint that ELSI consideration in grant proposals infringes upon academic freedom is specious given the obligation for researchers to perform competent and honest research and to fulfill institutional responsibilities to honor funding institutions' guidelines. This is especially true for NSF and NIH grants, which have responsible and ethical conduct of research ("RCR") requirements that obligate grant recipients to develop a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduates, graduate students, and postdoctoral researchers who will be supported by NSF to conduct research.

Department and individual research administrators, therefore, may use the ethical discussions as primary or secondary investigator education opportunities. By following an institution-wide recommendation of discussing ELSI in grant proposal planning and drafting meetings, and coordinating the inclusion of the university's ethics staff, the research administrator can assist the PI in developing a plan to comply with RCR requirements and promote the transformation of institution culture, by advancing ethical consideration in research. While RCR requirements are a strong step in the right direction, any plan that provides for training and oversight from a captive ethical resource is subject to the same conflict issues described above.

By these methods, research administrators can advance their roles and responsibilities in ensuring that faculties are aware of regulations, policies or procedures which may affect the conduct of their research; ensure that they and their institutions are keeping abreast of evolving standards, thereby promoting appropriate stewardship of external funds supporting research; and recognize and fulfill responsibilities to the local communities as relates to health and safety issues of research.

Perhaps most importantly, the promotion and adoption of separate ELSI funding, and research administrator involvement, will help ensure that the potential for, or appearance of, conflicts of interest which could have serious ethical and monetary consequences to the university are addressed in an appropriate and timely manner.

Conclusion

There is a strong need for continued ELSI funding. As scientists continue research in areas of science that raise potentially troubling outcomes, the public needs to be assured that science advances in a safe, legal and ethical manner. While there is not a problem, per se, in the funding of ELSI research, it has become clear that the current funding scheme raises the potential for serious conflicts of interest. When scientists control the administration of ELSI funding, overt and covert pressures may be placed upon ethicists to make conclusions conducive to the progression and advancement of the overall science of a project. This raises serious questions of independence that undermine the ability of the ethicist to speak truthfully, critique freely, and research rigorously the ethical, legal and social aspects of scientific research. This not only violates the academic freedom of the ethicist, but also places the research institution in danger of violating its duty of responsible research to the public. Such acts may conclude with the disintegration of public trust and public backlash against important scientific research. By separating the ELSI funding from the science funding – separating the observer from the observed, from a monetary standpoint – institutions can better ensure that ELSI research dollars advance ELSI goals. Research administrators can take a lead role in advancing ELSI roles in a number of important ways. First, research administrators can help adopt and advance rules or recommendations relating to the inclusion of ELSI components in research. By promoting dialogue early in the research planning process, research administrators can advance ethical awareness among scientists. This can help develop a culture of interdisciplinary cooperation and ensure that research administrators are advancing their obligations to the institution and the community at large.

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