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RESEARCH ARTICLE

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A conjunctural analysis of the origins of ‘embedded ELSI’ in U.S. genomic medicine

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ABSTRACT
Calls to identify, explore, and address ethical and social issues as part of the design and implementation of scientific research are now widespread. One way of doing so is through an embedded approach, where ethical, legal, and social implications (ELSI) researchers are situated within larger scientific research studies. We trace the emergence of the ‘embedded ELSI’ approach to integration alongside the development of genomic medicine. In particular, we conduct a conjunctural analysis that draws attention to contests and struggles over the forms and meanings of good science – in this case, genomics – and the role(s) of ELSI scholars and researchers in producing good science. We demonstrate that the embedded ELSI approach emerged from these contests, which left ELSI research and interventions constrained – institutionally, topically, and methodologically. We end by calling for an opening up of embedded approaches to integration so that they might better meet calls for justice and equity in the present conjuncture.

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Introduction

Thirty-five years after the creation of the National Center for Human Genome Research (NCHGR) and the Human Genome Project’s (HGP) Ethical, Legal, and Social Implications (ELSI) program, calls to identify, explore, and address ethical and social issues as part of the design and implementation of scientific research are now widespread. Indeed, today there is nothing remarkable about a call to fund ethical and social analysis as part of the creation of new and emerging forms of technoscience. It has become a model of what it means to do ‘good science’ (Thompson 2013), adopted and adapted globally through programs such as the Responsible Research and Innovation (RRI) program in the European Union and the Genomics, Economic, Ethical, Environmental,

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Legal and Social aspects (GE^{3}LS) program in Canada (see Dolan, Lee, and Cho 2022 for a longer list of initiatives).

The 'ELSI model' – initially conceived of as a particular institutional 'set-aside' funding mechanism to integrate concerns for ethical, legal, and social implications into the HGP – has now come to signify a broader field of research where ethical and societal analysis is conducted as part of larger scientific research projects (Gannett 2023; Klein 2010; Pullman and Etchegary 2021). The funding and integration of ethical and social analysis has come to take many different forms – usually either investigator-initiated ELSI research taking place alongside the science (Boyer et al. 2017), the consultant model where scientists engage experts in other disciplines for ethics advice (Cho et al. 2008), or the 'embedded' model where ethicists and/or social scientists are embedded within larger scientific research teams (Outram et al. 2022). Of these, integration through the direct embedding of ethicists and social scientists in large scientific research consortia has increased in prevalence over the last two decades due to shifts in research and funding structures (Fisher et al. 2015).[1]

Additionally, policy makers and research funders have increasingly called for integrating ethics into STEM research (Hilgartner, Prainsack, and Benjamin Hurlbut 2016). In 2003, for example, the U.S. National Nanotechnology Initiative mandated 'integrating research on societal, ethical, and environmental concerns with nanotechnology research and development' (U.S. Congress 2003, 117). More recently, in 2022, the authorizing legislation for the newly established Directorate for Technology, Innovation and Partnerships (TIP) at the National Science Foundation (NSF) similarly required the Directorate to include ethical and social considerations in funding proposals. Viseu (2015, 642) characterizes this trend in legislation as 'one of the most significant shifts in science policy.' The integration of social and ethical issues into science and technology research and development is increasingly expected as a standard practice.

Given the increasing prevalence of integration, there is a need to review, evaluate, and revitalize approaches to integration to elucidate best practices.[2] Indeed, we are part of a research initiative – the Leadership in the Equitable and Ethical Design of Science Technology Engineering Mathematics and Medicine (LEED of STEMM) – that is engaged in one such evaluation (see Reardon et al. 2023). The first phase of the research project includes a case study analysis of ELSI integration in three domains: genomics, neuroscience and AI.[3] However, before we can effectively evaluate and revitalize best practices, we must first understand how we arrived at this moment where integration is valued. Where did the idea of 'integrating' ELSI research and expertise come from, and what are the different forms it has taken? How, in particular, did the 'embedded ELSI' model become a preferred form of integration at the National Institutes of Health (NIH)?

To answer these questions about the origins and orientations of integration, we analyze the complex histories – or what cultural studies theorist Stuart Hall (1996) calls *conjunctures* – in which calls for the integration of bioethicists, social scientists, and scholars in the humanities into large scientific consortia became the preferred formation. We begin by describing the historical conjuncture in the U.S. in which ELSI emerged – one marked by the waning of post-WWII scientific boosterism, the rise of social movements critical of genomic research, and the emergence of neoliberalism and its effect on the governance of science (Lave, Mirowski, and Randalls 2010). We then trace how the effort to integrate ELSI expertise within scientific consortia emerged from efforts to contain the ELSI program to one of anticipating and addressing social concerns about genomics, resulting in what we have called – building on the work of the interdisciplinary medical anthropologist Melissa Creary (2021) conception of 'bounded justice' – the bounded formation of ELSI (Adsit-Morris et al. 2023).

We conclude by considering the analytic insights of our conjunctural analysis, and its import in the current conjuncture, one that finds integrated ethics increasingly invoked as needed in response to growing ethical and political import of science. We highlight the power of a conjunctural analysis to eschew any easy embrace of integrated ethics as central to good science and to instead hone in on the different sociotechnical forms that integration takes, and the specific epistemic and political affordances of these forms. In particular, we call for attention to be paid to the ways in which the current conjuncture enables and constrains the possibility for integrated ethics to meet growing demands for justice and equity in the sciences.

A conjunctural analysis of integration

From the latin *conjectūra*-meaning a throwing or casting together-a conjunctural analysis seeks to lay out and analyze the historical and social forces, political considerations, and scientific and ethical aspirations that produced widespread support for the integration (i.e. the joining together) of ethics expertise and scientific initiatives (OED 2024). We draw upon the notion of *conjuncture* as it has been articulated by Hall to understand both the possibilities and constraints of this turn towards integration and the emergence of the 'embedded ELSI' model. Drawing on the work of the Italian Marxist Antonio Gramsci, Hall uses conjuncture to describe the ways that contradictory cultural forces come together at a particular historical moment to give a society a specific and distinct shape (Hall 1996). For Hall, history moves from one conjuncture to the next, usually through moments of crisis, as contradictions condense and social relations partially shift. These moments of crisis create opportunities for intervention and negotiation of the hegemonic order. A conjunctural analysis of a specific phenomenon or formation (in our case 'embedded ELSI') requires attending to the 'different social, cultural, political, economic and ideological contradictions' and forces at work within a specific conjuncture (Hall and Massey 2010, 57).

Within the U.S. contemporary context, a conjunctural analysis helps to bring into focus how in recent years new demands for ethical integration have emerged alongside, and in response to, the conjuncture of two crises: (1) the COVID-19 pandemic, which carried with it concerns about disproportionate impacts along lines of race, vaccine hesitancy, and trust in science (Kazemian, Fuller, and Algara 2021; Nanaw et al. 2024); and (2) the reinvigoration of the Black Lives Matter (BLM) movement and mobilizations against structural racism (including in the sciences) that was ignited by the murders of Breonna Taylor and George Floyd (Hammonds 2021; Thorp 2021). Both crises focused attention on the ongoing deadly effects of systemic racism 'at the highest levels of the US government' (Krieger 2020, 1620) and within scientific institutions, and led many to argue that what was needed was not more data, but rather systemic institutional change and accountability.[4] This included shifting the focus from 'race to racism' (Hammonds 2024; Milner and Jumbe 2020; Yudell et al. 2020) by addressing disparities in funding, representation, and retention (Barber et al. 2020; Pilkington 2020; Stevens et al. 2021). In response, many institutions including *Nature*, *Cell*, NIH, and the American Association for the Advancement of Science (AAAS) published statements in support of measures to address long standing issues of systemic racism (Cell Editorial Team 2020; Collins 2021; Nature 2020; Thorp 2021). These moments brought forth an increase in calls to center equity and justice in scientific policy and research.[5]

Yet, as Hall might suggest, although each conjunctural moment provides an opportunity for transformative change, this change (or lack thereof) is not determined in advance and results from contestations born out of underlying tensions and contradictions (Bennett 2016). Drawing on Hall, we delve into an analysis that brings to the surface the tensions in calls for ethical and social analysis as part of scientific practice. We focus in particular on contests over the degree to which ethical and social analysis could (or should) question the governance of genomics, and over their ability to take up concerns for social and racial justice. More specifically, we describe how the idea of integration grew out of a struggle to define and contain the first major national initiative to integrate ethical and social science expertise in scientific research: the ELSI program of the HGP. To do so, we draw on an analysis of gray literature from the HGP and its supporting institutions – the NCHGR (now the NHGRI) of the NIH and the U.S. Department of Energy (DOE) – news coverage, secondary literature, and our own research interviews with those involved in the effort to make ethical and social analysis integral to the HGP.[6,7] We show how the integrated model was shaped by political and cultural struggles prompted by concerns that human genomics would reignite scientific racism.

ELSI's emergence

In a press conference held at NIH in September of 1988 to announce his appointment as the director of the HGP, James Watson announced that under his leadership 'considerable emphasis' would be placed on 'ethical considerations' (Watson quoted in Stern 1988). He evoked the terrible legacy of what 'happened in Germany before the war' in which genetics was 'misused' in a 'totally irresponsible' manner, promising that the NIH's genomics program would ensure that 'the public is protected against misuse' (*ibid*, 15). Days later in another press conference, Watson told a reporter that the NIH would devote up to 3% of the HGP funds to ethics, leading to the creation of the ELSI program (Schmeck 1988).[8] Studies, reviews, and commentaries on the ELSI program often cite Watson's announcement as the originating moment of the ELSI program (see for example, Fortun 2005; Juengst 2021). They describe it as 'spur of the moment' and 'off the cuff' (Hanna 1995; Marshall 1996; Yesley 2008), characterizing it as an unplanned, unscripted, and unexpected declaration, particularly to the NIH, who had not previously discussed or agreed to this reallocation of funding.

Yet this reductive account of ELSI's origin misses the larger socio-political and cultural forces at play that gave rise to the possibility of, and motivations for, Watson's so-called surprise announcement. ELSI arose in the midst of the rise of a new politics of science that began during the turbulent decades of the 1970s and 1980s, in which social critiques of science acquired greater public prominence. This period saw the rise of various social movements that critiqued illiberal, unjust concentrations of power and what Eisenhower dubbed the 'military-industrial complex' (Agar 2008). Organizations and groups such as the Women's Health Movement (WHP) and Science for the

People (SfP) – and then later the AIDS Coalition to Unleash Power (ACT UP) – argued that science was not immune from social critique and needed to be transformed to be in the interests of the people, and not the powerful. By the late 1980s and early 90s, these groups had made substantial headway through activism aimed at spurring public debate, advocating for public oversight of science, and changes to legislation and public policy (Nichols 2000; Schmalzer, Chard, and Botelho 2018). Despite the post-WWII institutionalization of the notion of 'pure science' (Hollinger 1990), scientists and the institutions that supported them did not remain immune from criticism that science was not sufficiently serving public interests.

One particular and highly relevant focal point of increasingly intense public debate about the constitution and governance of science was recombinant DNA (rDNA) technology. rDNA technology involves the manipulation and isolation of DNA segments that then get combined (or spliced) into different species to create genes with new functions. Members of the SfP, including prominent scientists, argued that there should be public oversight and regulation of rDNA research given the risks, which included concerns over the release of dangerous organisms and, for some, the potential for the technology to advance human genetic engineering capabilities creating new eugenic practices (Shapiro, Eron, and Beckwith 1969). In response, some geneticists and molecular biologists suggested that these groups' fears were based in ignorance, not science, and that the governance of science should be left to scientists (see Fredrickson 1991). To realize the goal of self-governance, in February 1975, biologists involved in rDNA research – what some described as 'molecular biology's elite' – gathered at the Asilomar Conference Center in Monterey, California (U.S.A.) to set forth principles to guide rDNA research, principles that included banning rDNA research with highly pathogenic organisms (*ibid*, 274).

While many of the molecular biologists who participated held up Asilomar as a successful example of effective self-governance (see, for example, Berg 2001; Falkow 2012), others have interpreted the Asilomar conference as an instance wherein risks and accompanying solutions were defined and addressed in technical terms at the expense of addressing the broader social, ethical, and political challenges (Schäfer and Low 2014). SfP, for example, argued in an open letter to the Asilomar Conference (Ausubel et al. 1975, 2–3):

> Decisions at this crossroad of biological research must not be made without public participation. … We do not believe that the molecular biology community, which is actively engaged in the development of these techniques, is capable of wisely regulating this development alone. This is like asking the tobacco industry to limit the manufacture of cigarettes.

The rDNA debates, which included many of the subsequent proponents of the HGP, left a lasting mark. Notably, Watson – who served as a member of the 1974 National Academy of Sciences Committee on rDNA and participated in the Asilomar conference – emerged from the debates worried that 'irrational' public concerns would spur regulations that unjustly interfered with scientific freedom (Watson 1979). Reflecting back in a 1979 article in the *New Republic*, he argued that fears of the harms of rDNA had been overblown. The whole episode, he concluded, was the result of 'misguided egalitarianism' (*ibid*, 15).

A decade later, the HGP ignited similar debates, as policy reports, scientific meetings, and media coverage weighed in on the feasibility and desirability of the proposed project.

In addition to the technical considerations, considerable attention was given to social and ethical questions, including concerns over access and ownership of genomic data, commercialization, and eugenics (e.g. OTA 1988). The debate over the scientific feasibility and desirability of the project could not be disentangled from debates about its social and ethical concerns. In the midst of these discussions, during a 1988 Congressional hearing on the project – at which Watson was present – bioethicist Tom Murray (OTA 1988, 54) called for funding to address these concerns:

> The [human genome] initiative will accelerate the practical applications and, therefore, the ethical, legal, and social problems brought by that knowledge. We must confront these issues with the same tenacity and energy and ingenuity that we've brought to the scientific problems. And I hope that Congress, Federal agencies and private foundations will encourage scholarly research and public debate on these questions.

Placed within a political context in which the value of the HGP was being questioned, Watson's announcement of HGP funding for ethics appears less like it arose from thin air. Indeed, any effective leader of a scientific initiative that sought to command the level of resources committed to the HGP ($27.9 million in the first year) could not avoid navigating these mounting pressures to bring science out of the cloistered spaces of the lab and into the public light of ethical and political oversight (Juengst 1994). In the context of this conjuncture – a moment in which science and technology had become major sites of contestation and struggle – Watson's commitment to fund the consideration of ethical and social issues seems less surprising and more of a *fait accompli*.

The proposal that the HGP should itself fund a program to address ethical and social issues did not go unchallenged. Not only did Watson have to defend his decision to NIH officials, but concerns and speculations about Watson's motivations also circulated in the biomedical field (Hanna 1995; Juengst 1996). Genome scientists, for example, expressed concern that the ELSI program was aimed at policing them, fearing Watson gave the social scientists too large of a platform (Andrews 1999). At the same time, bioethicists were worried that the primary function of such a program would be to act as a 'shield' to protect both Watson and the HGP from wider criticism from the public, rather than functioning as a legitimate effort to integrate social and ethical considerations (Hanna 1995; Marshall 1996). Still others believed Watson genuinely cared about ethical and social issues, and truly believed that 'the science was too important to leave to the scientists' (Goggin 1984; Wright 1990).[9] Yet how exactly this funding would be used and for what purposes – whether it would be a shield, a way to produce good science, or something else entirely – remained an open question.

ELSI's early experiments

Upon its inception, the ELSI program had little more to its name than four letters. Or perhaps only two, as one of our interviewees explained: 'In the beginning, people interpreted [ELSI] as the letters L and C and asked me, what in the world that might stand for, learning curve or lost cause?' Given that the HGP's allocation of funds to the ELSI program was the largest national investment in bioethics ever made, it was very unlikely to immediately become a lost cause (Marshall 1996). However, the unprecedented nature of the endeavor did necessitate a learning curve. The program quickly became framed as 'an unprecedented experiment' – the first time a national science initiative had directly funded a component dedicated to taking up social and ethical considerations (Hanna 1995; Juengst 1996). As Watson and the ELSI program's first director, Eric Juengst, wrote, the experiment carried with it an 'ELSI hypothesis,' namely that scientific funding should include complimentary funding for social science and ethics research in order to support policy development and socially informed genomic research (Watson and Juengst 1992).

Yet here is where the clarity ended. There was a hypothesis, but what methods should be used to test it? Who should set the ELSI agenda? What goals should focus its activities? How should outcomes be measured? The lack of definitive answers to these questions, and the build-as-we-go quality of the ELSI program (Rapp and Outram 2022), allowed it to quickly become a site for experimenting with existing (and often contradictory) notions of 'good science'. To oversee this experiment and the budget allocated to it, the NIH and DOE advisory bodies of the HGP formed the ELSI Working Group (ELSI WG) in early 1989. The NIH appointed Nancy Wexler, who studied the genetics of Huntington's disease, as the chair. The hope was that Wexler could ground discussions of ethics and society in an understanding of the science (Cook-Deegan 1994). The other members of the initial ELSI WG included those with genetic, clinical, ethics, and policy expertise. Their first task was to develop a plan for the first 5 years of the program, including identifying specific goals and objectives for the extramural research component. The NIH and DOE HGP planning report (NIH-DOE 1990, 21) identified a number of responsibilities for the ELSI WG including to:

> [A]ddress and anticipate the implications of mapping and sequencing the human genome; examine the ethical, legal and social sequelae of mapping and sequencing the human genome; stimulate public discussion of the issue; and develop policy options to assure that the information is used for the benefit of the individual and society.

The ELSI WG also identified a number of priority focus areas: confidentiality, genetic counseling, reproductive decisions, integration of genetics into mainstream medical practices, misuses of genetics, and the commercialization of HGP products (NIH-DOE 1990). In addition to funding research, explicitly naming a policy responsibility was one way the ELSI WG aimed to be responsive to external political pressures on the HGP, and was a way of signaling the intention for ELSI research to produce more than just knowledge. The policy aspirations for the ELSI program also later became a point of frequent criticism of the ELSI program and a site of contention within the NIH (Roberts 1993b).

Cystic fibrosis (CF) screening became an early testing ground for the ELSI program to demonstrate its value, and a site in which it attempted to create research that could inform policy. The ELSI program identified CF screening in its first five year plan as an area of interest because screening-related ELSI concerns were anticipated to proliferate following the completion of the HGP (NIH-DOE 1990). The 1989 discovery of a gene linked to CF ignited discussions over whether to develop policy to support population-level screening for the gene (Cook-Deegan 1994). Additionally, at the time, CF screening was a politically contentious topic. Given that a genetic determination of CF carrier status was primarily used for the purposes of informing reproductive choices, CF screening animated political concerns about abortion and some scientists thought research facilitating its advancement should not continue (Cook-Deegan 1994; Hanna 1995). In 1991, after other NIH institutes failed to fund CF screening studies, the ELSI program cofunded a series of focused investigator-initiated (R01) extramural grants to study the ELSI concerns associated with CF screening. It was an early demonstration that the ELSI program could address politically contentious topics, engage geneticists and clinicians, and facilitate novel research with a policy focus (Cook-Deegan 1994).

While some viewed the work on CF as a success, the question of what should be in the purview of the ELSI program and how much autonomy the program should have, continued to be debated. Specifically, whether and how it should directly engage or influence policymaking continued to be an open question. Tensions between those who thought scientists could self-govern and those who felt they should not proceed without external oversight – the very tensions essential to the rDNA debates – remained unresolved. This would become clear as Watson resigned from his position at the NIH amid a dispute over the NIH's patenting of genes, and the physician-scientist Francis Collins took over NIH's direction of the HGP (Anderson 1992).

Efforts to bound ELSI to clinical translation

Collins became Director of the HGP in 1993 in the midst of a set of growing concerns about a wide range of ethical and social issues surrounding genomics, including genetic privacy, intellectual property, and scientific racism. These growing concerns extended to the ELSI program itself, which was facing growing criticism from within and outside of the NIH. As *Science* reporter Leslie Roberts (1993a, 21–22) summarized: '[N]ow, having spent 4 years and $20 million, the ELSI program is at a critical juncture, with numerous critics wondering what it has produced.' Congressional funders, genome scientists, and public interest groups critiqued the ELSI program as insufficiently structured to significantly impact policy, given the program's low position in government bureaucracy, and ill-suited to act as a 'watchdog' due to its lack of independence (Roberts 1993b; U.S. Congress 1992). NIH and DOE scientific advisors to the HGP expressed concern that the ELSI program was too disconnected from the science, spending much of its time defining and discussing high-priority issues at meetings and conferences with little to show in the way of direct policy impacts (*ibid*).[10] Collins agreed to some extent, saying: 'It's time to move on [from identifying the issues] and produce some general policy recommendations' (Collins, quoted in Roberts 1993a, 22).

Collins aimed to diffuse these concerns by drawing attention to the medical benefits of genomics, using the CF screening study as one example of the way the ELSI program could demonstrate its value (Roberts 1993b). He and his staff became more directly involved in the ELSI program than his predecessor Watson, and sought to refine and refocus its research agenda on the ELSI concerns surrounding the clinical use of genomics. Lori Andrews, a legal expert on genetics who would replace Wexler as chair of the ELSI WG, recounted that in one funding cycle all but one project supported by the ELSI program's research funding went to studies on the two genes Collins' research group was studying (Andrews 1999). At the same time, Collins and his staff moved to slowly limit the policy agenda and capabilities of the ELSI WG by adding a genome scientist to the WG without nomination or voting, and limited the working group's budget and number of meetings (Dolan, Lee, and Cho 2022; Beckwith 2002; Marshall 1996; Andrews 1999).

In the midst of the growing tensions with the NCHGR leadership, the ELSI WG attempted to hold onto a broader understanding of the 'social' in 'social implications' by identifying and addressing issues extending beyond clinical applications of genomic research. Specifically, it sought to address concerns over the role of genomics in reigniting scientific racism sparked by the 1994 publication of *The Bell Curve* – which claimed there were racial differences in IQ test scores – and the sensationalized media coverage of behavioral genomics studies that followed (Andrews 1999; Beckwith 2002). In response, the ELSI WG moved to allocate funds to study the social implications of behavioral genetics and to quickly publish a statement on the inaccuracies of *The Bell Curve* (*ibid*). Arguing that the HGP had nothing to do with 'race' and behavioral genetics, Collins and his staff vetoed a plan for an anthology on the ELSI of behavioral genomics and delayed the publication of the ELSI WG's statement on *The Bell Curve* (Hilgartner, Prainsack, and Benjamin Hurlbut 2016; Andrews 1999; Beckwith 2002; Reardon 2017).

In response, Andrews resigned from the ELSI WG in February 1996 and expressed deep concern about the autonomy of the ELSI WG. An evaluation of the ELSI program, initiated by Collins and released in December 1996, corroborated Andrews' concern about the program's autonomy and called for a complete restructuring of the program. The restructuring placed greater emphasis on the extramural research aspects of the ELSI program and drastically limited its ability to make policy recommendations (Thomson, Boyer, and Meslin 1997). In its place there would now be the ELSI Research Planning and Evaluation Group (ERPEG) and an Advisory Committee on Genetics and Public Policy housed within the Department of Health and Human Services (DHHS) Office (Dolan, Lee, and Cho 2022). As one interviewee recounted it:

> They [NCHGR leadership], I think, wanted to have complete control of the legislative agenda. And so … they basically managed to kill the working group. And that … left a pretty big vacuum because … they had this extramural grant giving mechanism but they didn't have anything that was at the interface between the research and policy change.

For some, like this interviewee, this change impeded the ELSI program's effectiveness for addressing broader social concerns. The restructure marked the end of ELSI's early experiments, a result of which was the narrowing of opportunities available to the ELSI program and ELSI researchers to directly translate research insights into ethically and socially informed policy recommendations.

Charting the course to genomic medicine

Despite removing policy from the ELSI programs' purview, the restructure arguably gave the ELSI program more epistemic power by granting it the ability to direct its own research agenda. The ELSI program would no longer be subject to the research interests of any one genomics leader, though it would still have to function within the frame set by the newly formed NHGRI (Dolan, Lee, and Cho 2022).[11] These changes can clearly be seen in the ELSI research agenda put forth in the 2003 strategic plan, which was the first plan put forth following the completion of the HGP. In this plan, entitled 'A Vision for the Future of Genomics Research,' Collins and NHGRI leadership laid out an ambitious vision focused heavily on the 'therapeutic promise of genomics' and the 'flowering of translational ELSI research' (Collins et al. 2003, 840). Rather than positioning policy as the idealized means for change and oversight of science, the report framed closer integration of ELSI researchers with genomics researchers as the main mechanism for anticipating and addressing ELSI concerns associated with the translation of genomics research into the clinic.

According to some of our interviewees, the closer integration of ELSI researchers with genomics researchers happened, in part, as a result of the push to move genomics into the clinic – a move that arose partially from the mounting pressures the NIH felt to demonstrate the ability of genomics to have positive health impacts, and provide a return on the hefty investment of the HGP (NHGRI 2006). Additionally at this time, the lack of racial diversity in clinical and genomics studies became increasingly recognized in policy and research spheres as a problem threatening the ability of genomics to realize its promise of having widespread health benefits (Epstein 2007). ELSI researchers were thus positioned to engage more directly with researchers and clinicians to facilitate the translation of genomics, help increase the recruitment of racially diverse patients, and address ethical concerns that might arise from these efforts. Rather than exploring the more philosophical questions in anticipation of the completion of the HGP, these researchers would address specific empirical questions at the site of the clinical encounter.[12] While still contributing to the production of ELSI knowledge, their actions and the knowledge produced would be oriented toward and in service of translating genomics into clinical applications.

According to our interviewees, the 'embedded model' of ELSI research began with the funding of a large, multi-sited consortium study of hereditary hemochromatosis (HH), the Hemochromatosis and Iron Overload Screening (HEIRS) Study.[13] The $30 million study ran from 2000-2006, with preparations beginning by 1997. The 1996 discovery of a candidate gene (HFE) for HH led to discussions on whether to implement population-level genetic screening, similar to the discussion of CF screening years prior. However, unlike in the case of CF screening, HFE screening was less politically controversial (though similar concerns over abortion did surround HH screening; see Allen and Williamson 1999). This was likely because HH was, at the time, one of the few genetic conditions with a relatively simple and effective therapy (Burke et al. 1998). For proponents of genetic screening, HH screening served as an ethically uncomplicated opportunity to demonstrate the value of genomics in medicine and public health. As one of our interviewees described it:

> [Hereditary] Hemochromatosis was interesting because when … they first identified … the genetic profile, it was held up as this is a perfect example of something where we have an intervention. It's an easy intervention … and so they [genome scientists] were holding it up as … this is kind of the poster child of how genomics can be integrated into medicine and … have a huge impact and not be complicated and there aren't a lot of ethical issues here. But what they found as they … did the research was it wasn't that simple.

NIH involved the ELSI program and ELSI researchers early in the design of the HEIRS Study. In 1997, the ELSI program cosponsored an expert workshop with the U.S. Centers for Disease Control and Prevention (CDC) to develop a consensus statement on the ELSI and clinical implications of the HFE discovery, including the possibility of implementing population-wide genetic screening (ERPEG 2000). The workshop panel unanimously decided that it would be premature to recommend implementing population-wide screening given uncertainties around its prevalence, genotype-phenotype correlations, psychosocial impacts, and the potential for screening to facilitate employment and insurance discrimination (Burke et al. 1998). The authors emphasized the necessity of addressing social concerns, even if evidence appeared to support implementation, writing in conclusion (*ibid*, 177):

> As research goes forward, it will be important to ensure that advances in genetic knowledge are linked to an understanding of their social consequences. If future studies strengthen the case for DNA-based testing in hemochromatosis, strategies will be needed to prevent social harm resulting from such testing.

In addition to developing this consensus statement, the research recommendations from the workshop helped shape a 1998 NIH request for proposals (RFP) for the creation of the research consortium for the HEIRS Study (ERPEG 2000). The emphasis placed on generating evidence to support HH screening, combined with the identification of ELSI concerns as a barrier to implementation, set up the structure of the study in a way that bounded the ELSI research component through its embeddedness within the larger study.

The 1998 RFP tasked applicants with determining the feasibility, benefits, and risks of genetic screening for HH in primary care. Unique for the time, the RFP explicitly outlined and detailed how and when the ELSI research components would be structured and implemented within the larger research consortium.[14] The RFP also specified the questions and methodology of the ELSI component, a quantitative study in the form of 'ELSI assessments.'[15] The ELSI research questions for these assessments were narrowly scoped to focus on the acceptability of genetic screening and testing, experiences of genetic discrimination and stigmatization, and the personal and familial impacts of screening information. The questions and topical focus limited the range of ELSI concerns to those raised by the direct experience of screening, leaving unexamined the perspectives of those who might have chosen to decline to participate in screening. Methodologically, the RFP also dictated that ELSI research would only take place during specific periods of the clinical study, effectively bounding the research and researchers temporally. It also placed ELSI researchers in the role of generating empirical evidence to help guide decisions on implementing HH screening.

As our interviewee alluded to, the findings from the HEIRS Study led to recommendations to not implement HH screening in the general population given inconclusive evidence on the potential health benefits and risks, and the persistence of ELSI concerns related to costliness, insurability, genetic association with race and ethnicity, and psychosocial impacts of return of results (Qaseem et al. 2005; U.S. Preventive Services Task Force 2006). The embedded ELSI research had an impact, in this case informing the development of clinical and public health guidelines. The embedded configuration also meant that ELSI researchers were able to directly engage with scientists, creating the possibility of (in theory) directly shaping scientific research in real time (Conley et al. 2020).

Yet the questions and ELSI research produced had become narrowed to focus on the clinic and clinical experience. Rather than serving as an opportunity for the ELSI program to demonstrate its ability to engage politically contentious topics, as it did in the case of CF, the HEIRS Study demonstrated the ability for ELSI research to advance genomics on its scientific terms (i.e. its ability to facilitate the science). The ELSI research could not effectively question or challenge whether genetic screening in general, or the HH screening study in particular, should proceed and on what terms. Indeed, the empirical survey-based ELSI research findings – which included widespread acceptability of genetic screening and no evidence of self-reported experiences of genetic discrimination among those surveyed – justified support, in the view of the scientific researchers, for furthering the clinical implementation of genomics (Adams et al. 2009).

The HEIRS Study marked the arrival of the 'embedded ELSI' model of integrated research. As the NHGRI reported, it would 'serve as a model for future large scale studies of genetic screening in diverse communities' (NHGRI 2000, Goal 1, Initiative 2). Embedded ELSI research would soon become more widespread at NHGRI, becoming a model for integrating a concern for ethics into other large scientific research consortia in genomics, particularly those focused on the participation of 'diverse communities' and the translation of genomic research into clinical application. This includes the Electronic Medical Records and Genomics (eMERGE) Network which ran from 2007–2023 (Clayton et al. 2010), and the Clinical Sequencing Evidence-Generating Research (CSER) consortium which ran from 2011–2023 (Green et al. 2016).

As we suggest through our analysis, the embedded ELSI model emerged out of contests over the role of the ELSI program and its researchers, and experiments with forms of ethics integration. Tensions accumulated and accelerated as the NHGRI began charting a course for genomic research to move from 'base pairs to bedside' (Green and Guyer 2011), constraining what ELSI research and interventions could be institutionally, topically, and methodologically. As exemplified by the HEIRS Study, within the embedded ELSI model, ELSI research was topically narrowed to focus on facilitating genetic screening, and methodologically limited to empirical research. It bounded ELSI researchers to forms of work that could advance the goal of using genomics to create a new form of scientific medicine grounded in biological knowledge, what NHGRI at the time newly described as 'genomic medicine' (Green and Guyer 2011). Contests over the roles of and spaces for ELSI researchers reformed and constrained the autonomy of ELSI researchers and their ability to govern scientific research, yet produced a new terrain on which to continue contesting the meanings and forms of good science.

Embedded ELSI at crossroads

In early 2019, the NHGRI began meeting to discuss its new strategic plan in the midst of the emergence of a new conjuncture, one we argue has been shaped by cultural shifts produced by responses to the COVID-19 pandemic and mobilizations against structural racism. In this conjuncture, scientists continue to face pressures to demonstrate their societal value and respond to the social issues produced by their science. This is particularly true for genome scientists, who in recent years have witnessed their studies invoked by white supremacists to justify racial violence (Panofsky, Dasgupta, and Iturriaga 2021), and faced criticism for lack of diversity and representation in genomic studies (Popejoy and Fullerton 2016). In this current conjuncture – one that is distinct from and yet still an echo of the earlier – scientific funding agencies have doubled down on their support for integrating social and ethical considerations as they attempt to respond to calls for equity and justice in science (OSTP 2022; Nelson 2021). Many social scientists and bioethicists hoped this particular conjuncture would provide an opportunity to respond and speak more directly to the intersecting crises of racism, structural violence, and health inequities in science and biomedicine (Ray et al. 2023; Reardon et al. 2023).

The 2020 NHGRI updated strategy – the 'Strategic vision for improving human health at The Forefront of Genomics' – took responsibility for addressing societal injustices, urging scientists to 'seek to ensure that the benefits of genomics are available to all members of society' and 'reckon with systematic injustices and biases, fully mindful of their importance for health equity' (Green et al. 2020). The NHGRI offered ten aspirational 'bold predictions', one of which was that 'individuals from ancestrally diverse backgrounds will benefit equitably from advances in human genomics' (*ibid*, 690). This has positioned ELSI researchers, particularly those embedded within larger genomics projects, in what Simon Outram et al. (2022, 225) describe as a 'peculiar and uncomfortable position' wherein they are asked to focus on facilitating the implementation of genomic medicine while also tasked with anticipating and addressing broader ethical and societal issues – a contradictory position with aims that may be directly at odds with each other.

Within this conjuncture, social science and bioethics scholars are placed in dual roles and conflictory spaces by being asked to perform governance functions with little infrastructure and power to do so. It is an 'inherently contradictory and troubling space' that is both bounded and filled with opportunities (Outram et al. 2022, 225). Our conjunctural analysis calls us to recognize moments of opening and foreclosure, and to turn toward these spaces of friction and contestation. If the last conjuncture produced the ability to work in – and to potentially influence – the sites where genomics research is taking place, what can be gained from experimenting with integration in the current conjuncture? This remains an open question, both in NIH-funded embedded ELSI research in the U.S., and in the growing number of sites and forms of integrated ethics around the globe.

As we attempt to make sense of the continued rise of integrating societal and ethical concerns into genomic research – and STEMM research more broadly – we caution against the uncritical embrace of integrated ethics as necessarily (or inherently) producing more just and equitable forms of science. Rather, more clear-eyed assessments will arise by analyzing the specific forces that shape the sociotechnical forms that integrated ethics takes, and the affordances and constraints of each of these forms. This will require definition and measurement of the salient outcomes of integrated ethics and normative assessment that includes diverse perspectives and analysts. These analyses can help us understand how practitioners of integrated ethics leverage the epistemic and institutional apparatus of integration to contest the very scope and terms of ethical, legal and social analyses. Our attention should focus on these contests and struggles, especially if integration in the current conjuncture is to meet calls to center equity and justice. Who decides what equity and justice means in the context of genomics, and how they are operationalized? It is in these sites of struggle – as well as at others where a broad range of scholars, policymakers, artists, publics, scientists, and other actors today engage in creating the terms and practices of integration – that the possibilities for good science and more just worlds can be created.

Notes

1. The terms 'integrated' and 'embedded' are used interchangeably and inconsistently throughout the literature. Pullman and Etchegary (2021, 68) describe 'integrated' ethics projects as 'not separate from [the] science project but is part and parcel of the project from its inception' whereas in 'embedded' projects 'there is no necessary connection between the science and the [ethics] research being conducted.' Fisher et al. (2015, 40) define 'socio-technical integrations' as a distinct type of participatory research that 'involves close, transformational interaction with scientific and technical experts.' In their mapping, integration may not necessarily involve embedding social scientists or ethicists into larger scientific projects, it may occur separately, counter to the distinction offered by Pullman and Etchegary (2021). The 'embedded ELSI' model discussed in this paper is generally described as the embedding of ELSI researchers, usually through the presence of an ELSI component, into the 'protocols' of larger scientific consortium projects. This embedded ELSI model is argued to promote greater collaboration and respect between ELSI scholars and scientific investigators, and enables ELSI researchers to directly engage with scientists, creating the possibility to directly shape scientific research in real-time (Boyer et al. 2017; Conley et al. 2020). For the purposes of this study, we are only focusing on the embedded ELSI model that has increasingly become a preferred model at the NHGRI which now often requires an 'embedded ELSI team' as a component of the funding on large collaborative research initiatives (see for example the Human Pangenome Request For Applications).
2. In 2015, Fisher and colleagues offered a map of the by-then growing field of ethics integration, and called for the development of theoretical accounts that could both explain and critically inform practices of integration. Almost a decade after this call, still little systematic work exists that critically assesses the emergence of ELSI as a way to integrate ethics. Nor has there been a systematic analysis of the historical evolution of an increasingly preferred model of integration in the U.S., described by some as the 'embedded ELSI' model (Outram et al. 2022).
3. For more information, see https://leed.ucsc.edu/.
4. Scientists also acknowledged the relevance of these events to public health and science, as they exposed racial disparities in terms of data gaps and classification bias (e.g., police categorizing Floyd's murder as a 'medical incident' due to 'excited delirium syndrome' [Beliso-De Jesus 2024]).
5. See, for example, the 2022 White House Office of Science and Technology Policy (OSTP) Equity Action Plan, which calls for advancing *equity in* science and technology, and science and technology *for equity* (emphasis original in OSTP 2022).
6. The NIH is made up of 27 different Institutes and Centers, each with their own research agenda and budget from the federal government. The NCHGR was established in 1989 as a Center and later transformed into an institute (the NHGRI) in 1996.
7. The research in this study is IRB exempt at all participating institutions. The interviews informing this paper were conducted by researchers at the University of California, Santa Cruz, (UCSC) which was reviewed by the UCSC IRB housed within the Office of Research. The IRB reviewed the research protocol and determined it was exempt under Category 2 (IRB Project Number HS-FY2023-48). However, the interviews followed an informed consent protocol and we received informed consent prior to each interview. Interviewees were made aware of the study goals, the efforts being taken to maintain confidentiality, given the chance to ask questions, withdraw consent at any point, and that they would be described without affiliation and with generalized descriptions or pseudonyms.
8. The story of Watson's comment gets told with varying percentages, usually 3-5%, but NYT coverage suggests 'as much as 3%' was said during the originating October 1, 1988 press conference (see Schmeck 1988). Later, in a 1991 House subcommittee hearing, Watson suggested the portion of funding could increase to as much as 10% by 1996 (Hanna

1995). The percentage was relatively arbitrary, as Watson (2001, 202) later wrote, saying: 'A lower percentage might be seen as tokenism, while I then could not see wise use of a larger sum.' The percent set aside for ELSI would later be written into the National Institutes of Health Revitalization Act of 1993 at 5%.

9. Passing mentions of comments from Watson on the ELSI program help to disambiguate this event and challenge the standard interpretation of Watson's ELSI announcement. Weiner (2000) quotes Watson describing, with a smile, his decision to set aside funding for ethics research as a way to 'preempt the critics,' given the difficulty ethicists were causing the HGP to get started. And, as Watson (2001) himself writes, well aware of how he might be perceived: 'My not forming a genome ethics program quickly might be falsely used as evidence that I was a closet eugenicist, having as my real long-term purpose the unambiguous identification of genes that lead to social and occupational stratification as well as to genes justifying racial discrimination.'
10. The lack of policy impact through the ELSI program may have been intended from the start as Andrews (1999, 206) quotes Watson at a genetics policy meeting saying 'I wanted a group [the ELSI WG] that would talk and talk and never get anything done, and if they did do something, I wanted them to get it wrong.'
11. See footnote 6.
12. Though beyond the scope of this piece, the move away from speculation and philosophical questioning to empirical questioning at the site of the clinical encounter might also represent a shift in what forms of ELSI knowledge and methods are valued. The turn to empiricism may arguably emphasize a role for social scientists at the expense of more interpretive, qualitative, and humanistic forms of ELSI research.
13. Whether this is the first embedded ELSI project depends on how 'embedded ELSI' is understood. In our interpretation, we agree that it is, given that the ELSI component of the HEIRS Study is positioned as part of, rather than in parallel to or the primary motivation for, the entirety of the HEIRS Study. The 1992 CF screening study is similarly structured (i.e., a multi-sited study linking ELSI research questions and concerns to a clinical study) and may be understood as an earlier embedded ELSI project. However, the CF screening project had the primary aim of identifying and addressing ELSI concerns, rather than situating a narrower set of ELSI questions and concerns to be investigated through research, and as only one of many aims.
14. See RFP No. NIH-NHLBI-HC-99-04, available at https://webharvest.gov/peth04/20041020115310/http://www.nhlbi.nih.gov/funding/inits/archive/rfp9904.htm
15. What an ELSI assessment includes methodologically is not defined in depth in the RFP. Per the study design, the ELSI assessments primarily consisted of self-administered surveys and questionnaires (see McLaren et al. 2003).

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