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BIOETHICS METHODS IN THE ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS OF THE HUMAN GENOME PROJECT LITERATURE

Rebecca Walker and **Clair Morrissey**

Abstract

While bioethics as a field has concerned itself with methodological issues since the early years, there has been no systematic examination of how ethics is incorporated into research on the Ethical, Legal and Social Implications (ELSI) of the Human Genome Project. Yet ELSI research may bear a particular burden of investigating and substantiating its methods given public funding, an explicitly cross-disciplinary approach, and the perceived significance of adequate responsiveness to advances in genomics. We undertook a qualitative content analysis of a sample of ELSI publications appearing between 2003-2008 with the aim of better understanding the methods, aims, and approaches to ethics that ELSI researchers employ. We found that the aims of ethics within ELSI are largely prescriptive and address multiple groups. We also found that the bioethics methods used in the ELSI literature are both diverse between publications and multiple within publications, but are usually not themselves discussed or employed as suggested by bioethics method proponents. Ethics in ELSI is also sometimes undistinguished from related inquiries (such as social, legal, or political investigations).

Keywords

Bioethics methods; ELSI; Human Genome; Ethics

INTRODUCTION

Bioethics as a field or area of inquiry has concerned itself with methodological issues since the early years.[1] This has led to the development of a rich literature on bioethics methods as diverse as feminist,[2] narrative,[3] principles based[4] and casuistry.[5] Enrichment added through historical, legal, sociological, and many other disciplinary perspectives has created a multi-disciplinary arena of bioethics methods scholarship.[6] Consideration of ethics methods has a long history within philosophical ethics. For example, Henry Sidgwick introduces his Methods of Ethics by writing, 'a 'Method of Ethics' is explained to mean any rational procedure by which we determine what individual human beings 'ought'—or what is 'right' for them—to do, or to seek to realize by voluntary action.'[7] While Sidgwick limits his consideration of ethics methods to rational procedures for determining what individuals should do, the bioethics literature on methods includes consideration of methods of so-called

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Contact: Dr. Rebecca Walker University of North Carolina - Social Medicine CB# 7240 348 MacNider Hall , Chapel Hill North Carolina 27599-7240 United States T: 919 843-6896 F: 919 966-7499 rlwalker@med.unc.edu.

‘descriptive ethics’ and does not limit prescriptions to those oriented to individuals, but includes recommendations to professional organizations, regulatory bodies, and the like.

In one sense, ethics research within the Ethical, Legal and Social Implications (ELSI) of the Human Genome Project is a subset of bioethics, since ELSI questions are directly concerned with advances in technology, science, and medicine relating to human genomics. At the same time, ELSI research is distinctive within bioethics both in terms of its history and focus. It is the only area of bioethical inquiry with a dedicated National Institutes of Health research program and currently six publicly funded Centers of Excellence in ELSI Research (CEERs) along with four exploratory centers. Further, the moral questions in this area of research may appear to be driven by scientific and technological advances in ways that may seem less pronounced or self-conscious in some other areas of bioethical inquiry.

In the United States, ELSI research has been supported under the auspices of the ELSI Research Program within the National Human Genome Research Institute (NHGRI) since the first grants were issued in 1990.[8] Early goals of the program were to stimulate public discussion by generating deeper understanding of these implications and to spur policy developments that would be responsive to the relevant scientific advances.[9] Over the years, criticisms of the ELSI Program have remained remarkably stable and include concern over a lack of independence from the NHGRI (i.e. the very scientists whose work is the subject of critical inquiry), ineffectiveness in generating policy in the area of human genomics, and a dearth of actual public engagement.[10] Despite these critiques, the ELSI Program has been seen as a potential model for focusing research on the social implications of other areas of bioethical interest including neuroscience[11] and biodefense.[12]

The cross-disciplinary approach to the ‘implications’ of human genomics is written into the name of the ELSI Program (the acronym ‘ELSI’ is also sometimes further expanded in the literature, e.g. to ‘ELSIP’ for policy inclusion, ‘ELSIP+’, or, in the Canadian context, ‘GE^{3}LS’ to include the environment and economy). In addition, encouragement from the ELSI Program to involve genome scientists in ELSI research and to expand dialogues to include affected communities brings even greater diversity of perspective. The cross-disciplinary and multiple ‘stakeholder’ aspects of the field of ELSI research results in a literature in which discussions of ethics often take place alongside consideration of other social issues such as legal, policy, or cultural questions. It is not unusual for the broader conversation to be dubbed ‘ethical’ nor is it unusual (as we discovered) for the ethical issues to remain either undistinguished from these other socially salient issues, questions, and investigations, or to be rolled into a broader type of investigation: ‘ELSI analysis’ as such.

The nature and context of ELSI research underscores prominent questions within the bioethics methods literature regarding the appropriate relationships between empirical research and moral or policy prescriptions[13] as well as regarding the contributions of various specific disciples such as history or law to ethical claims.[14] Yet, despite the close but complex relationship of ELSI research to bioethical research more generally, there is little self-conscious reflection on ELSI ethics methods within the ELSI literature, as we discuss below.[15] Further, while some critics have addressed the impact of the ELSI Program on bioethics as a field[16] little attention in the literature has been paid to substantive questions about the quality and scope of the ELSI literature itself. [17]

Elsewhere, we offer an analysis of the scope of the field by defining and describing various types of ELSI research and scholarship.[18] Here, we report on a qualitative content analysis of a random sample of ELSI articles and book chapters published between 2003-2008 with the aim of better understanding the methods, aims, and approaches to ethics that ELSI researchers employ. While public funding of ELSI research in some ways raises the stakes regarding careful employment of ethical analysis, we aimed to encompass the diversity and depth of the field of ELSI ethics research regardless of funding source. We included all relevant publications from ELSI Centers of Excellence along with publications from a wide variety of other sources (see Study Methods below). While our descriptive analysis cannot directly assess the quality of ethics research within ELSI, it can provide a starting point for critical self-reflection within the field of ELSI as well as offer those interested in bioethics methods an illustration of the actual uses and understandings of ethics within one area of bioethics.

We found that the aims of ethics research and scholarship within ELSI are largely prescriptive and oriented to multiple groups including the science research community, the health care community, bioethics and ELSI research community, government, and society as a whole. We also found that the ethics methods used in the ELSI literature are both diverse between publications and multiple within publications. These included discipline specific methods, empirical methods, broader bioethics methods, and general methods of moral reasoning. Methods are rarely employed in the manner suggested by their promotion within the bioethics methods literature, but are instead used more in a ‘toolbox’ mode – employed as useful for addressing a particular issue or problem. In addition, ethics in ELSI is sometimes undistinguished from related inquiries (such as social, legal, or political concerns) and the methods employed are rarely themselves commented on or indicated as methods, approaches or frameworks to ethics, ELSI or bioethics. This state of affairs represents a disconnection between the bioethics methods literature and the field of ELSI as a body of practical bioethics literature. It is unclear, however, whether this means that the ELSI literature should ‘shape up’ or whether the bioethics methods literature is ‘out of touch’.

STUDY METHODS

To reflect the variety and complexity of the ELSI literature, we drew our publications from six different sources, targeting a five-year period from 2003-2008. The six sources were chosen to provide a comprehensive data set, capturing: (A) work of people more directly identified as ELSI researchers, through ELSI Archives (Case Western University's Center for Genetic Research Ethics and Law), the Bio-Medical Ethics Reference Server (BMERS, hosted by Stanford University's Center for Integration of Research on Genetics and Ethics), and CEER webpages; (B) research from more broadly medical, social and other science researchers, through Pubmed and Web of Science; and (C) work of humanities researchers, through the GenETHX database (Bioethics Research Library at Georgetown University). The multiplicity of sources dictated some variation in the search strategies utilized. A narrowly tailored Boolean search was used for Pubmed, Web of Science and GenETHX; a keyword search was used for BMERS; all of the references from the CEER webpages were collected; and the ELSI Archives were searched by hand for relevant publications. Search terms included variants and combinations of the terms ‘ethics’, ‘morality’, ‘ELSI’, ‘genomics’, and ‘genetics’. Specific search strategies were developed with the help of health science research librarians at one author's (RLW) home institution as well as from the Georgetown Bioethics Research Library.

This process generated 1,010 unique references. Based on citation and abstract review, we excluded all publications that were not research or review journal articles, book chapters, or commentaries (where this was the only forum for ethics content within a journal). We further refined the group of publications by excluding articles that did not address both human genomics or genetics and relevant ethics content. A final group of 642 unique references is reported on elsewhere for topics, types of publication, and first author field of expertise[19] and for funding and forums for dissemination.[20]

Here we review a random sample of 61 publications from the refined group to more closely assess the ethics aims, methods, and the extent to which ethical inquiry is distinguished from other socially salient investigations.[21] This analysis of ethics content was based on the relevant text within the article or chapter, but categories of analysis were applied to publications as a whole. For example, while a publication could aim to prescribe a particular approach to a scientific question within genetics/genomics, the same article could also aim mainly to describe the ethical issues that arise with respect to that same scientific question. Hence, in our analysis, this publication would have a descriptive aim with respect to ethics. Similarly, for a publication that was a report of a social science study, empirical methods would be noted as methods of ethics only if the publication appeared to draw its ethical (or other ELSI if undistinguished) conclusions from the data discussed. This same publication could additionally, or alternatively, use other methods of analysis to support the ethical claims made. Each method was noted through indication of relevant textual support.

Our categories for analysis and definitions for each category were initially developed on the basis of review of the bioethics methods literature and discussions with ELSI experts with differing disciplinary backgrounds. These initial categories were then refined and modified on the basis of an iterative review of randomly selected non-study samples of publications from our refined population. A total of 34 non-study publications were reviewed in creating our final analytic template. Each of the 61 study publications were analyzed independently by two of a group of four readers (two of whom were the investigators and two of whom were readers only). Where there was initial divergence in analysis, agreement was reached through a consensus process. The proportion of initial agreement across all categories of analysis reported here was 89%.

RESULTS

Demographics

To give a sense of the diversity within our study sample, there was a significant range in the first listed author's advanced degrees and country of institutional affiliation, publication funding sources, and publication placement. First listed author advanced degree disciplines included: humanities (18), law (16), medicine (11), social science (5), other science fields (8), public health (3), and business (2).[22] First listed author's affiliated institutions were located in: North America (38), Europe (15), Asia (3), Australia/New Zealand (2), and other (3). The majority of publications did not list any funding sources (43), while the others listed either one source (16) or two sources (2). Among funding sources, most were National Institutes of Health sources including NHGRI (9), other US Government sources (2), Non-US Government (4) and non-profit organizations (3). Most publications appeared in bioethics (19) or medical (14) journals or as book chapters (11).

Ethics and ELSI

While addressing ethical, legal, policy, and other socially salient issues within a single publication is the norm for the ELSI field, we found that 18% of the publications in our study also did not clearly distinguish between analysis of ethical and other socially salient issues. These publications sometimes addressed ‘ELSI’ analysis as an endeavor itself (usually in contradistinction to some aspect of genomic science). This approach to the field is heralded by statements such as: ‘The HapMap has been an exemplar of *integrated and proactive ELSI analysis* in genetic variation research [emphasis added].’[23]

In other instances, ethical considerations were identified along with other socially salient issues, but not significantly distinguished in terms of their later analysis or discussion. For example:

> These benefits [of pre-natal genetic testing] are, however, tempered by a series of complex ethical, legal and social risks, which must be identified and managed if the benefits are to be maximized... *These include*: the risk of state intervention into private lives and the consequent loss in reproductive freedom; the risk of coercive testing emerging from medical paternalism; the risk of ambivalence in knowing whether prenatal testing should be offered for all conditions, or only for severe medical conditions; the risk prenatal testing will amplify existing racial, sexual and disability discrimination... [emphasis added].[24]

In this passage, we learn that the risks of pre-natal genetic testing include ethical, legal, and social factors, however, the author does not identify the specified risks as falling under any particular factor(s).

We may contrast this approach to ethics with that of another publication on pre-natal genetic screening, in which ethical issues are addressed alongside other socially salient factors, yet are nevertheless distinguished from these other factors. For example:

> When genetic screening results are positive, an otherwise low-risk pregnancy is changed. What was once viewed as an enjoyable pregnancy experience is quickly transformed into a tentative or high-risk pregnancy experience filled with anxiety, fear, isolation, *and complex ethical issues, including* concerns about freedom of choice in reproductive decisions, discrimination, and stigmatization [emphasis added].[25]

In this quote we learn of psychological (anxiety, fear), social (isolation) and ethical factors involved in positive pre-natal screening results, but the ethical issues are specifically delineated as those involving freedom of reproductive choice, discrimination and stigmatization.

Ethics Aims

The vast majority of publications in our study aimed, to at least a substantial degree, to recommend, direct, or otherwise suggest some action, policy, practice, or view (89%). For some publications, the directive or prescription regarded some policy, legislation, or other social action. For example:

> ...this paper concludes that while Federal legislation is needed to prevent genetic discrimination, such legislation must take into account the interests of both employees and employers. Further, it concludes that *the need for such legislation is immediate* [emphasis added].[26]

For other publications, the directive regarded how to conceptualize, theorize about or categorize certain activities or perspectives. For example:

> This paper defends a pragmatic approach to the question of the appropriateness of the OMB group categories in pharmacogenetics research, *an approach that is local and context-specific* rather than global, incorporates practical and ethical as well as theoretical dimensions, and recognizes intersections of the social and the biological in the constitution of group categories [emphasis added].[27]

The remaining publications aimed, on the whole, to descriptively characterize, explain, or relate ethical concepts, issues, problems or contexts. For example:

> ‘We *identify the new trends in ethics* as reciprocity, mutuality, solidarity, citizenry and universality... wider contextual factors help to explain the shifts that we identify here. We aim to show how these shifts are framing the current discussion of issues without totally replacing the ethical norms of the 1990s [emphasis added].[28]

The different communities or groups toward whom the publications prescribed an action, practice, policy, or ethics consideration or view were diverse and included: the science research community (genetic/genomic scientific researchers and bodies, such as Institutional Review Boards, that guide and regulate these practices), the health care community (those involved in medical practice and the bodies, such as Hospital Ethics Committees or the American Medical Association that help guide these practices), the bioethics research community (both ELSI researchers in particular and bioethics researchers more generally), government (including political bodies like the Food and Drug Administration and legal bodies like state legislatures), and society as a whole. Other miscellaneous specific groups not fitting within these more general categories were also prescribed to (for example, people ascribing to egalitarian theories or future possible parents of designer babies). Publications in our sample prescribed to, on average, 2.1 groups, with the most frequently addressed specific groups being the science research community (24 publications), and government (23 publications). The bioethics community was addressed in 18 publications, the health care community in 15, society in general in 10 and other miscellaneous specific groups in 21 publications.

Ethics Methods

Our analysis of ethics method captures a publication's means, tools, or frameworks used to establish or further the ethics related aims. As with the other categories of investigation, bioethics methods were analyzed at the publication level based on relevant text. Each publication could be categorized as employing multiple (or no) methods of bioethics. An average of 2.2 methods were ascribed to each publication. The ethics methods, definitions, examples, and the proportion of publications in which each occurred, are listed in the Table. The 10 methods listed represent those found in the study sample. In addition to those listed, we also looked for, but did not find in the study sample, employment of narrative ethics or the common morality approach supported by Gert, Culver and Clouser.[29]

In the Table, the methods are listed in order of frequency of employment. However, other organizations and delineations of the methods are possible. Legal, Philosophical, Historical and Theological methods might be grouped together as ‘discipline specific’ while Principles and Case-Based analyses might be grouped as traditional methods of broader bioethics. Empirical methods might be set off from ‘normative’ methods and expanded to cover multiple specific approaches. It is important to note that our approach to delineating the methods is slightly unconventional within the literature both as a result of our own theoretical leanings and as a reflection of the actual methods that authors in our study used. For example, as we discuss below, argument is rarely listed as a specific method of ethics, whereas we think this is a critical oversight in the methods literature. Additionally, some have seen principlism and casuistry as specifically philosophical methods of bioethics, while we understand the philosophical methods more narrowly. Finally, while attention to professional oaths and codes is common in the methods literature[30] the broader heading of ethics as based on practice standards is closely related to the question in medicine specifically of whether an ‘internal’ moral standard is possible or desirable.[31]

We employed a minimal threshold for evidence of use of an ethics method. For example, appeal to ‘the principle of autonomy’ to further an ethics aim of the piece would be sufficient for attributing the ‘principles’ method to the publication.[32] However, a more robust employment of the principles based method involves specification of the principle in context[33] and potentially balancing relevant principles against one another in cases of conflict.[34] In the example cited in the Table, we see a claim regarding the ‘weight’ of the principle of beneficence against respect for autonomy, but no specification of the principle of beneficence in this context. Similarly, the use of an illustrative case was sufficient for attributing a casuistry or case-based method. However, the more robust employment of casuistry as a method of ethics involves the use of analogical reasoning in moving between identified paradigm cases and novel or problematic cases.[35] In the example cited in the Table of case-based method we see the use of cases to illustrate some ethical ‘dilemmas’ but the author does not engage in analogical reasoning in order to answer a moral question regarding the appropriate approach to a specific case.

It is important to note that, had we required a more robust use of any particular ethics method in our analysis, we would have found very few uses of each method. We did not attempt to track publications according to the depth of method use as: 1. We found on the basis of our non-study sample (see ‘Study Methods’ above) that a low threshold for method attribution was necessary given our aim of tracking the diversity and extent of actual approaches used, and 2. It proved both conceptually and practically too difficult to develop a reliable inter-rater template for such descriptive depth-of-use measurement for each method. Thus our reflections on the depth of method use in the publications is based on qualitative analysis and discussion within our group of readers but is not captured quantitatively.

We were able to analyze whether ethics methods in general, or a particular ethics method, was discussed by the author(s) or was simply used in some manner within the publication. Leaving aside the publications using empirical methods, which standardly include a methods discussion section, less than a quarter of the publications (23%) discussed any of the methods appealed to in that publication. Of those discussed, the principles-based and applied normative theory approaches received the most attention. Some publications discussing a principles-based method also offered a general critique of bioethics *as* principles-based. For example, Kuszler (2006) writes:

> Bioethics has, to date, been largely a creation of Western research and medical norms...this is wholly inadequate to respond to the cascade of ethical issues that flow from a vibrant biotechnology industry.[36]

After careful elaboration on what a principles-based approach to bioethics requires in the way of analysis she writes:

> Some of the difficulty with the principles-based approach to biomedical ethics is that it focuses on the individual subject or patient – this of course is problematic in cultures where the relevant unit is not the individual, but the family or the community.[37]

She concludes that:

> The future will demand an ethical construct that is focused [less] on the individual and more on populations.[38]

DISCUSSION

The task of characterizing different approaches to ethical issues and questions as ‘ethics methods’ is fraught with both complexity and controversy. Two related, but importantly distinct, questions contribute to this situation: 1. What is properly *ethics* (as opposed to descriptions of morally salient practices, beliefs, or contexts, regulatory guidance, or other normative disciplinary approaches)? 2. What is an ethics *method* (as opposed to a framework, approach, or discipline)?

With respect to the first question, while the appropriate relationship between empirical social science methods and prescriptive ethics is particularly controversial,[39] we did find empirical methods employed in support of normative ethical claims in the ELSI literature. In the example in the Table, Suthers et al. aim to respect ‘at risk’ relatives’ autonomy and privacy and, to measure whether they succeed in this endeavor, look for complaints registered from those receiving letters describing their potential genetic risk.[40] While the authors' aim may be to test a practice to see whether it meets ethical standards, the specific use of number of complaints received (or not) to test whether at risk relatives' autonomy and privacy are respected directly implies that a lack of registered complaints supports a normative claim – specifically that at risk relatives autonomy and privacy are *not disrespected* by the practice. In another example, Tano explicitly claims that appreciating 'the perspectives of native peoples' will be 'effective to answer questions concerning ethical uses of genetic information' and appeals to qualitative measurement tools, specifically a 'discursive dialogue' process, as a manner of gathering these perspectives.[41] Other empirical papers engaged in what some would characterize as purely 'descriptive ethics'[42] by aiming to describe the moral views of particular groups or populations without prescribing a specific ethical approach based on these views. For example Pentz et al. (2005) aim to ascertain hereditary nonpolyposis colorectal cancer families', 'views on the duty to inform with particular focus on the role of health professionals [...]'.[43]

The large percentage of publications appealing to practice standards or professional norms is also important to note with regard to the question of what counts as ethics, as the reliance on these established norms for purposes of moral prescription is also controversial.[44] On the one hand, following established professional norms is crucial for practicing professionals who may even see the established norm – for example the Institutional Review Board standards in research ethics – simply *as* the ethical standard. On the other hand, at a theoretical level, practice standards and professional norms are themselves appropriate targets of normative moral consideration and critique. Similarly, whether and how law and history can best contribute to the support of ethical claims is a matter of debate (Childress 2007, p. 16; Hodge and Gostin 2001; Capron 1999; Amundsen 2001; Pernick 2009; Rosenberg 1999),[45] yet more than a third of the publications in our study appealed to the law (38%) and a not insignificant number to history (13%) in support of ethics or broader ELSI claims.

While the question 'what is *ethics*?' is interesting from a comparative disciplinary stand point, it may misdirect evaluation of an already multi-disciplinary endeavor such as ELSI. In this largely practical field of inquiry, broader questions of whether descriptive ethics is actually a type of ethics or of the relationship between ethics and institutional norms such as practice standards, may be better substituted for critical reflection on the specific ways that moral conclusions are in fact supported. In this regard, the question of 'what counts as an ethics *method*?' is particularly salient.

With respect to that second question, despite substantial discussion of method in the bioethics literature, it is unclear which of the bioethics methods listed in the Table are methods of ethics in Sidgwick's sense of a rational procedure for determining appropriate action. We are inclined to think that simple moral argumentation, which requires sound logical structure in moving from premise(s) to conclusion, fits this particular understanding of method most closely, though such methods as casuistry, a principles-based approach, or some types of applied moral theory may also fit Sidgwick's understanding (he was, of course, a utilitarian) as long as the procedure for using these methods is carefully specified and followed. Other methods, such as feminist or narrative, are probably better understood as approaches or frameworks for understanding and appreciating moral contexts and appropriate responses. Still others (legal, historical and theological) are not methods, but disciplinary headings that cover a variety of different methods and approaches to moral problems and issues.

While we think that moral argumentation is clearly a method of ethics, we have noted that this designation is not consistent with other taxonomies of bioethics methods. This may be because argument, as a general method of reasoning, also does (or should) play a crucial role in other approaches or methods. However, we found it important to analyze appeal to argument independently. First, this level of specification draws attention to the existence of general and foundational methods for furthering ethics aims that may be used either from within any of the other methods or independently. Second, while some of the other methods listed in the Table are really umbrella terms for broader approaches to ethics, giving an argument indicates a particular means of achieving an ethics aim that is particularly well suited to prescriptive claims.

The point here is not that methods of ethics in Sidgwick's sense are better for solving moral problems or are more appropriate to the ELSI context. For one thing, using a method is not the same as using it well, and claiming to make an argument is not the same thing as doing so. But at a broader theoretical level, such a conclusion would overlook important questions regarding the moral significance of particular contexts as opposed to general moral principles and the importance of practical wisdom in contrast with specific rational procedures for determining right action. Rather, this complexity suggests a need to disentangle and examine notions of ethics method, approach, discipline, framework and the like in order to appreciate what each can best contribute to bioethics work in general and to the ELSI field in particular.

CONCLUSION

Public funding of the ELSI Research Program, the perceived significance of adequate ethical and policy responses to advances in genomics, and the cross-disciplinary and multiple-stakeholder contributions to the field of ELSI all seem to point to a need to reflect on ELSI ethics methods. Surely, we need to be able to reassure the public that ELSI researchers are not simply ‘shooting from the hip’ or taking the advice of the genome scientists themselves when they recommend particular policies, laws, or changes to institutional ethics frameworks in response to advances in genetics/genomics research or technologies.[46] Yet, the ELSI literature to date has been remarkably void of self-conscious reflection on the nature or adequacy of its methods of ethics. Furthermore, despite a vibrant methods literature within bioethics, there has been no empiric inquiry into the use of the various methods within any specific domain of bioethics research.[47]

In this contribution to the critical assessment of ELSI within the context of the bioethics methods discussion, we capture the extent and manner in which bioethics methods are actually taken up within the ELSI literature including methods and approaches that are widely used despite playing a somewhat lesser role in the methods discussions (such as a reliance on practice standards, the law, and argument). Interestingly, we found both a wide variety of methods used in the literature, but also very little discussion of the methods as such as well as very little depth of use. Publications often employed multiple methods and did not engage in the more rigorous forms of analysis promoted by supporters of the different bioethics methods. Thus, there appears to be a gap between the theory level discussion of methods of bioethics and actual application, at least within the ELSI literature.

As bioethics researchers look to export the ELSI model to areas of developing science beyond genomics, they would do well to consider substantive questions regarding ELSI research and scholarship alongside the already well-established institutional concerns about the ELSI Program. While our study does not directly answer the question of whether ELSI ethics methods are adequate to their tasks, our analysis provides a starting place for furthering such critical reflection and discussion. Crucially, the ELSI literature's tendency to conflate ethical and other socially salient issues, adopt multiple and varying ethics methods depending on the context, and largely neglect discussion of ethics methods may be cast as either vices or virtues of the field, depending on one's perspective.

Some will claim that a narrow fixation on sound methodology is limited from the start since our conclusions (as well as the questions we ask) are justified both by their content as well their execution (in science as in ethics). A largely practical field like ELSI may produce the best results by using bioethics methods in the ‘tool-box’ mode- employing whatever method is ready to hand and serves the author's constructive (or destructive) purpose. Furthermore, it may be pointed out that, in reality, policy, law, morality, economics and culture interplay and intertwine to such a degree that providing distinct analyses of each factor in a question over the desirability of expanding pre-natal genetic screening, for example, would place artificial boundaries around naturally intertwined questions. Perhaps, then, rather than ignoring disciplinary boundaries or constraints of ethics methods, ELSI has ‘gone beyond’ them.

For those for whom a closely followed method of ethics holds out hope for justificatory grounding of moral claims, on the other hand, a relatively shallow use of multiple methods depending on context surely will appear to be a vice of the field. Furthermore, such a critic might argue, when ethical issues are not adequately disentangled from other socially salient concerns such as policy or cultural implications, they risk receiving inadequate attention or, worse, generating inappropriate recommendations. Unwarranted policy solutions to a moral or social problem can be inept at best and harmful at worst.

We have offered a descriptive analysis of the methods, aims and approaches to ethics within the ELSI literature with the hope of focusing discussion on these crucial areas of potential disagreement within both bioethics and ELSI. Yet, without begging the larger-scale questions regarding the role of methodology in the grounding of ethical claims and the appropriate scope of ethical deliberation, we propose that clarity in the approach to ethical questions as such and attention to the modes and means of answering those questions, are both important virtues to strive for in the developing field of ELSI.

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Biography

Rebecca Walker is Associate Professor in the Department of Social Medicine and Core Faculty in the Center for Bioethics at the University of North Carolina at Chapel Hill. She also holds an Adjunct Appointment in the Department of Philosophy. Her work in bioethics focuses on practical ethics methods, non-human animal research, and issues in distributive justice.

Clair Morrissey is Assistant Professor of Philosophy at Occidental College. Her work in philosophy focuses on practical ethics methods, and foundational issues in global justice.

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17. Importantly, ELSI research as a field or area of inquiry neither originated with the ELSI Program (though the particular nomenclature does) nor is the fate of that research entirely dependent on the ELSI Program (though surely such research will diminish if the Program does). One reason for this is that a number of international programs have been developed to address similar sets of social concerns. Examples of these programs include: Genome Canada—Genomics and Its Ethical, Economic, Environmental, Legal and Social Aspects, Instituto Nacional de Medicina Gen'omica—Department of Legal Studies, Ethical and Social Research Directorate, and the Wellcome Trust—Ethics and Society Programme, among others. Perhaps more importantly, however, our research has shown that only about one third of research in the field of ELSI has claimed *any* source of funding. Morrissey C, Walker RL. Funding and Forums for ELSI Research: Who (or What) is Setting the Agenda? AJOB Primary Research. 2012; 3(3):51–60. [PubMed: 22888470] Hence, just as we would associate, but not conflate, human genomics research with the NHGRI, we should associate, but not conflate, ELSI research with the ELSI Program.

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Table

Bioethics Methods

Method	Definition	Example	N=61	%[*]
Legal	Uses legal analysis, case law, legal decisions, or specific law/regulations in examining or establishing ethical claims.	‘While American *federal and state laws exist to prohibit discrimination within these laws, significant gaps exist that may allow for discrimination against people based on their genetic characteristics. Consider,* for example... *two pieces of federal legislation,* the Americans with Disabilities Act... and the Health Insurance Portability and Accountability Act of 1996... [emphasis added]’[48]	23	38%
Philosophical	Traditionally philosophical tools, such as applied moral theory or conceptual analysis, are used to examine or establish the ethics aims of the article.	‘a variety of reasons could be given for according different moral standing to humans and non-human primates... For *Kantians, human capacities for rationality and autonomy demand that persons be treated as ends in themselves. Mill,* on the other hand, *found an* especially fecund *source of utility in the richness of human mental life. Singer,* although strongly defending equal consideration of non-human interests *allows that self awareness affects the ethically allowable treatment of a creature...* [emphasis added].’[49]	20	33%
Argument	Appeal to construction of a set or series of propositions which, taken together, are meant to logically support a conclusion relevant to the ethics aims of the article.	‘This paper *argues, firstly,* that individuals may have a legitimate interest in not knowing their genetic make up to avoid serious psychological consequences; *secondly,* that this interest, far from being contrary to autonomy, may constitute an enhancement of autonomy; *thirdly,* that the right not to know cannot be presumed, but must be “activated” by the individual's explicit choice, and *fourthly,* that this is not an absolute right... [emphasis added].’[50]	20	33%
Practice Standards	Appeal to professional norm(s) or practice standard(s) such as codes of ethics, IRB ‘ethics’ regulatory mechanisms, or to research or clinical ‘best practices’.	‘If we *extrapolate from the AMA's position,* one could conclude that it would be acceptable for a physician to patent a DNA invention, such as diagnostic test, provided that patenting does not limit the availability of the invention to practitioners and patients [emphasis added].’[51]	18	30%
Casuistry or Case-based	Appeal to relevant paradigm cases to illuminate a moral problem or appropriate response to a case in question.	‘I examine public concerns about genetic information and discuss *a few recent cases in some depth to highlight a few of the dilemmas* presented by genomics and emerging solutions... [emphasis added].’[52]	14	23%
Principles	Appeal to one or several ‘prima facie’ normative principles of biomedical ethics (respect for autonomy/persons, nonmaleficence, beneficence and/or justice).	‘This approach is supported by the *ethical principle of beneficence,* whereby a public health agency has the right to determine that *the benefit of a new test for newborns would outweigh the potential disrespect of the autonomy* of a minority of parents [emphasis added].’[53]	13	21%
Historical	A specific account of some past social or cultural event(s) or period(s) of time is presented or appealed to in examining or establishing ethical claims.	‘Although advisory committees always face the danger of being abused for political purposes, perhaps a worse fate is being irrelevant... *A look back at these deliberative bodies shows us that they can and have played an important role in enhancing the legitimacy and power of the lay public... difficult moral decisions* made in a modern pluralistic society *require that all those with a vested interest in the outcome be brought into the discussion* at some point... *A central lesson from this chronology* of national efforts is that *there will always be tensions between various factions on issues that we all care about* such as those raised by reproductive technologies [emphasis added].’[54]	8	13%
Feminist	Sex, gender, and/or other socially salient categories are considered in conjunction with power relations in establishing ethical claims or examining ethical concerns.	‘While the research population defined by the investigative team may be local, its membership may not be representative of the broader local community because... *age, gender, or socioeconomic status may affect participant recruitment...* the *voices of those persons in positions of authority and power* in the local community may come through more clearly than *the perspectives of those lacking such positions* [emphasis added].’[55]	7	11%

Method	Definition	Example	N=61	%[*]
Empirical	Either quantitative, qualitative or mixed measurement tools (including: survey, observation, in depth interview, focus group, document studies, and case studies) are used to further the ethics aims of the article.	‘Objective: To increase the awareness among at risk relatives of the availability of genetic testing for a familial disorder *while respecting their autonomy and privacy*. Methods: ...The main *outcome measures were*: (A) proportion of unaffected first and second degree relatives of the proband ... whose genetic status was clarified within 2 years of the mutation being identified... and (b) *concerns regarding privacy and autonomy voiced [measured by number of complaints] by relatives receiving these letters* [emphasis added].’[56]	6	10%
Theological	Specific religious doctrine(s), point(s) of view, community perspective(s), or text(s) is/are presented, appealed to, or interpreted in examining or establishing ethical claims.	‘Some HPG research and the technologies resulting from it may make it possible to extend human life well beyond the average life span... *According to Catholic teaching, human life is not an absolute good*. Charity, or *friendship with God, is the only absolute good*... People committed to the *stewardship of scarce resources* must be concerned about the products and programs emerging from HGP research. *Attempts to extend life may well deplete* the *resources* needed for basic health care.’[57] (O'Rourke 2007, p. 219)	5	8%

[*] The average number of methods used per publication was 2.2, thus the total for this column is more than 100%.