



Published in final edited form as:

Am J Bioeth. 2008 March ; 8(3): 4–13. doi:10.1080/15265160802109322.

Strangers at the Benchside: Research Ethics Consultation

Mildred K. Cho, Sara L. Tobin, Henry T. Greely, Jennifer McCormick, Angie Boyce, and David Magnus

Stanford Center for Biomedical Ethics

Abstract

Institutional ethics consultation services for biomedical scientists have begun to proliferate, especially for clinical researchers. We discuss several models of ethics consultation and describe a team-based approach used at Stanford University in the context of these models. As research ethics consultation services expand, there are many unresolved questions that need to be addressed, including what the scope, composition, and purpose of such services should be, whether core competencies for consultants can and should be defined, and how conflicts of interest should be mitigated. We make preliminary recommendations for the structure and process of research ethics consultation, based on our initial experiences in a pilot program.

Keywords

Research ethics; ethics consultation; institutional review boards; core competencies

In *Strangers at the Bedside*, David Rothman describes the social and technological changes in the practice of medicine in the United States (US) that have led to the involvement of bioethicists, lawyers, judges, and others into the medical decision-making process that was once solely the domain of the physician (Rothman 1991). For instance, the introduction of innovative procedures such as organ transplantation raised societal and ethical issues that seemed too large for physicians to address on their own as isolated individuals—who gets a kidney, who can give one, and who pays for it? We are witnessing a similar phenomenon in biomedical research. New technologies, including cloning, stem cell research, and genetic engineering raise new issues and new anxieties in the public that are best addressed by the inclusion of a wide range of voices.

The interactions between science and society have long been a source of tension. Potential conflicts have arisen over genetically modified organisms and whether they should be evaluated strictly on the basis of a science-based risk assessment or whether other values should be taken into consideration. Political debates over such research reveal a wide range of attitudes from proponents of research to those favoring bans. Even the recommended guidelines for human embryonic stem cell research issued by the National Academies (Washington, DC) explicitly consider broad ethical and social concerns. The public reaction

Address correspondence to Mildred K. Cho, PhD, Stanford Center for Biomedical Ethics, Center for Integration of Research on Genetics and Ethics, 701A Welch Road, Suite 1105, Palo Alto, CA 94304. E-mail: micho@stanford.edu.

Publisher's Disclaimer: Full terms and conditions of use: <http://www.informaworld.com/terms-and-conditions-of-access.pdf>

This article may be used for research, teaching and private study purposes. Any substantial or systematic reproduction, re-distribution, re-selling, loan or sub-licensing, systematic supply or distribution in any form to anyone is expressly forbidden.

The publisher does not give any warranty express or implied or make any representation that the contents will be complete or accurate or up to date. The accuracy of any instructions, formulae and drug doses should be independently verified with primary sources. The publisher shall not be liable for any loss, actions, claims, proceedings, demand or costs or damages whatsoever or howsoever caused arising directly or indirectly in connection with or arising out of the use of this material.

to the announcement of the cloning of Dolly the sheep created a new era in the relationship between science and the public, one in which the bioethicist often provides commentary and mediation.

It is increasingly clear that a reactive bioethics that responds to scientific developments after they have taken place is not optimal to meet the needs of either the public or the scientific community (Cho et al. 1999). This article proposes a collaborative, team-based model, which we have implemented at Stanford University (Palo Alto, CA), to make ethics advice available to biomedical researchers as the science unfolds. Because this approach solicits ethics input into emerging scientific approaches, it has the potential to influence the way that research is designed and conducted.

BACKGROUND: ETHICS IN RESEARCH

In the US, several methods have been tried to incorporate ethical concerns in research. In the 1970s, institutional review boards (IRBs) became the first major insertion of formal ethics review into research. Other mechanisms have since been instituted that have brought other “strangers” to the benchside, such as the National Institutes of Health (NIH, Bethesda, MD) committees: Recombinant DNA Advisory Committee, Institutional Animal Care and Use Committees, Institutional Biosafety Committees, and most recently, Embryonic Stem Cell Research Oversight committees. To the extent that ethical issues in research have been handled primarily through oversight bodies, this might have inadvertently fostered an adversarial relationship between researchers and ethicists (de Melo-Martin et al. 2007). Furthermore, while these oversight committees have certainly brought non-scientific considerations to the design and conduct of biomedical research, they are each constrained to examine research in specific areas (such as research involving human subjects, or embryonic stem cells), generally at a project level. IRBs are also specifically prohibited from addressing possible societal harms (Department of Health and Human Services 2005), and thus focus on the potential harms to individual research subjects.

To address broader societal and ethical issues that have ramifications for many researchers, for several decades, the federal government has assembled expert groups with broad mandates, from the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the President’s Commission, the National Bioethics Advisory Committee, and the President’s Commission on Bioethics, as well as other groups with narrower jurisdictions, such as the Human Embryo Research Panel of the National Institutes of Health or the Secretary’s Advisory Committee on Genetics, Health, and Society (all Washington, DC). Other groups have been constituted primarily by and of academics to address relatively broad research policy issues such as managing financial conflicts of interest in biomedical research (Association of American Medical College [AAMC] Task Force on Financial Conflicts of Interest in Clinical Research 2001) or more specific issues such as informed consent for genetic research (Beskow et al. 2001). The National Academy of Sciences and the Institute of Medicine (both Washington, DC) often incorporate ethical and legal views in the production of their recommendations and reports.

The congressionally-mandated Ethical, Legal and Social Implications (ELSI) program within the Human Genome Project, funded both by the National Human Genome Research Institute (NHGRI, Bethesda, MD) and by the US Department of Energy (US DOE, Washington, DC), represented an effort to foster examination of ethical issues raised by genetic research (National Institutes of Health Revitalization Act of 1993). The ELSI program has relied largely on grant mechanisms to provide support for research, training, educational programs, and conferences to achieve its goals, and this support has largely gone to social scientists, philosophers, law professors, and ethicists. The ELSI program has had

some tangible successes in shaping policy for the appropriate uses of genetic technologies (Rothenberg 1995; Rothenberg et al. 1997) and has also been credited with “cultivating a community of committed and expert genomics-watchers that has the capacity to influence policy.” (Juengst 1996) However, the program has also been criticized for lack of effectiveness in meeting its goals (McCain 2002; Turner 2003).

More recently, institutions such as the NHGRI have moved toward a variant of the expert group model to address issues raised by specific, large-scale, government-funded projects such as the haplotype mapping (HapMap) project. For this, NHGRI established both a scientific working group and an ELSI working group to identify and resolve the ethical, legal and social issues raised by the project. NHGRI and other institutes in the NIH have promoted the use of community consultation and community engagement for scientists to elicit advice from laypeople about ways to minimize harm and maximize benefits of the research involving communities. In contrast to much of the research funded under the ELSI program, which tended to address broad issues such as genetic discrimination or identity in the context of social science or philosophical research, the working group and community engagement models are more limited in scope, in that they are project specific and tend to address a narrow range of issues specifically facing researchers such as how to conduct informed consent. However, they have the benefit of being more likely to involve the scientists who are actually conducting the projects, rather than an unconnected group of experts, while bringing other perspectives to the table. Can elements of these models be extended to make relevant expertise available to a broader spectrum of biomedical researchers?

THE CONCEPT OF RESEARCH ETHICS CONSULTATION

Our model of research ethics consultation has the overall goal of maximizing the benefits and minimizing potential harms of research to society. This goal is analogous to that of clinical ethics consultation articulated by Fletcher & Siegler, “To maximize benefit and minimize harm to patients, families, healthcare professionals, and institutions...” (1996, 122) Research ethics consultation aims to achieve this by considering the risks and benefits of research to researchers, research subjects, institutions and the general public. Consultation provides a forum in which scientists can engage with experts from other disciplines who can bring a broader set of perspectives for consideration. The consultation has a short-term goal of providing real-time advice to scientists on the conduct and dissemination of research to help identify and incorporate ethical and societal considerations into their research (Cho et al. 2003). The context of consultation can be a specific research project, and the advice can be focused, but the consultation can also lead to a discussion of broader, related ethical, societal, legal, regulatory or policy issues.

Recognition of the importance of ethics consultation services for clinical researchers is growing. Several research ethics consultation services have been established recently for clinical research, such as those at the Weill Medical College of Cornell University (New York, NY) (de Melo-Martin et al. 2007), the University of Texas Medical Branch (Galveston, TX) (available at: <http://www.utmb.edu/imh/ethics/research.asp>), the NIH (available at: <http://www.bioethics.nih.gov/clinical/whatisconsult.html>), and at the Johns Hopkins School of Public Health (Baltimore, MD) (<http://phirst.jhsph.edu/sph/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5B0ID%5B11FC8A0AC761A043898C85539B681288%5D%5D>), as well at Stanford University. Importantly, the NIH’s Clinical and Translational Science Awards (CTSA) require a research ethics component. The CTSA program is a major initiative that will replace the ubiquitous General Clinical Research Centers in the US with the aim of transforming

clinical science. An early indication of the key role of ethics consultation is that an ethics consultation service, mostly focused on clinical research, is to be included in most CTSA programs at academic medical center that has or will receive a CTSA. Given the important implications of basic research and the special nature of the issues it raises, however, there is a need to make consultation services available for non-clinical researchers as well.

Of course, with the growth of bioethics centers and bioethics as a profession, individuals have long been providing advice to both basic and clinical researchers on an ad hoc basis, as well as others such as IRB members. These ad hoc consultations have their own limitations — individual consultants might not have the breadth of expertise of a larger group — and, importantly, do not provide the kind of evaluation data needed to track and resolve issues that may arise.

The history of “bedside” ethics or clinical ethics consultation shows some of the benefits as well as the pitfalls of such services. There have been several attempts to show the positive value of clinical ethics consultation (DuVal et al. 2004; La Puma et al. 1988; Schneiderman 2006; Yen and Schneiderman 1999) such as reduced intensive care unit times (Schneiderman et al. 2003), and patient and surrogate satisfaction (Orr et al. 1996). Multiple professional organizations have supported the importance of clinical ethics consultation, including the American Hospital Association (1986), and the American Medical Association (1985). However, several studies reveal problems with the implementation of consultation services (Fox et al. 2007; McGee et al. 2001), even through a period of growth. There is a great deal of heterogeneity in how such services are run; who performs the consults; whether consults are carried out by small teams, large inclusive groups, or by single individuals; and how many consults a service carries out. Most clinical ethics consultation services make concrete recommendations, but some services do not. Different programs use different theoretical frameworks. Most challenging is the variation in the training of who conducts consultation. In a recent study, only 41% of consultants were found to have formal supervised training (Fox et al. 2007). A significant step forward in addressing this variation was the creation of a set of standards for knowledge and skills by the American Society for Bioethics and Humanities in 2000 (Aulisio et al. 2000).

It is too early to know whether there will be formal approaches to research ethics consultation analogous to the various methods used by clinical ethics consultation services (e.g., the four-box method (Jonsen et al. 1992), or clinical pragmatism (Fins et al. 1997; Fletcher et al. 1997) but it is possible that the core competencies for a bedside ethics program can be identified much more quickly in the development of these services compared with standards for clinical consultation, which only became codified in 2000. We make some initial recommendations about areas for core competencies below. The accumulated practice wisdom for clinical ethics consultations holds several lessons for a bedside ethics consultation service. One is to expect disagreement among clinicians, hospital staff, family members, and members of the ethics committee. Though the team approach brings out diverse perspectives, critics have charged that ethics committees have become a way for clinicians to avoid their obligations to their patients (Siegler and Singer 1988). Several commentators (Braddock and Tonelli 2001) have objected to the role of the stranger at the bedside as an unwanted, unnecessary, and undesirable intrusion into the domain of the physician. It is not difficult to imagine similar concerns over bedside ethics consultation. Indeed, when Beecher (1966) produced his influential article on informed consent in research his goal was not to create independent oversight (or a system of advising) but to exhort clinical researchers to recognize the importance of the inculcation of virtue as an essential part of the practice of good science. For bedside ethics consultation to work, it will need to establish its role in the same way that other forms of consultation have been incorporated within the biomedical research community.

Other critics have questioned the independence of most institutionally based ethics consultation and have raised the worry that a built-in conflict of interest could undermine the value of such a service. This criticism has also been raised with respect to many of the oversight mechanisms for research such as Institutional Review Boards (IRBs) (Cho and Billings 1997) and Embryonic Stem Cell Research Oversight Committees (ESCRO) (Baylis and Robert 2006) and will almost certainly be an issue for research ethics consultation. The extent to which this will be a problem depends upon how the consultation is conceptualized, and how the activity is structured.

GENERAL MODELS FOR ETHICS CONSULTATION

There are several existing models for consultation, some of which involve group process. At one extreme of the group process model, use of a “moral community” paradigm (Rubin and Zoloth-Dorfman 1994) would require a fairly large group be involved in every consult. This model would entail bringing together all of the scientists involved in the research project, perhaps colleagues doing similar research, and for clinical research, a mechanism for bringing in the voices of research subjects. All of the participants in research, from the various scientific collaborators to the subjects of the research would be a part of the process.

Given the difficulties of working out the logistics of such a group process as well as the challenges of identifying appropriate representatives of the subject population (which is not usually an issue in clinical ethics consultations), the moral community model of consultation would take time if applied to the research consultation process. It is not designed for relatively rapid response to questions. It is also much more time consuming for the researchers as well as more daunting. The result would be a relatively small number of consults, each of which potentially could have a broad educational function. The goal of such a consultation service would not be simply to resolve a particular ethical dilemma, but to educate the research community and to create institutional consensus about practices.

At the other end of the spectrum, an alternative model would offer a single expert consultant with the expertise necessary to address any ethical issues that arise in a particular case. This has been a dominant model in clinical ethics, though it has come under considerable attack (Golenski 1992). Many critics worry that a generalist from the outside will lack the detailed knowledge of the relationships and the nature of a particular specialty to provide adequate advice to all of the different kinds of units that might call a consult. In addition, having a single individual with the necessary knowledge and skill set to carry out consultations is a significant challenge that is more easily met by a group process.

It is worth noting that there is a precedent for something like the “single expert” model of research consultation. Biostatistics and design consultants offer a possible model of consultation that may be informative for the individual clinical consultant model. In the statistical consult model, the goal of consultation is to offer very specific skills and knowledge to help the researchers “ensure adequately designed studies and scientifically sound findings” (Deutsch et al. 2007, 710). Consultation is typically performed initially by a single individual (or a pair of individuals) and is usually best done early in the research process (though consults are often sought later in the process (Altman et al. 2002). Consultants can provide advice about research design, including the framing of the hypothesis under investigation, how data are to be collected and interpreted, power and sample size of the trial, interpretation of results, and other aspects of research. In biostatistics, it is common to distinguish between serving as a consultant (which usually entails having time paid at an hourly rate) and serving as a collaborator. In the collaborative role, the expertise of the advisor is captured by service as a co-investigator on the research and a percentage of their time is paid for by the grant that they are assisting in putting

together. Such a collaborator is likely to be a co-author of resulting publications rather than receiving acknowledgement.

Additional debates have arisen in clinical ethics consultation over the kinds of roles that should be played by individuals who serve as consultants. One model would have the consultant be a generalist with sufficient knowledge of research ethics to be able to help any group. An alternative would be to have unit-based consultation (Agich 1990; Fox et al. 1998). In clinical ethics, certain units have tended to be the primary locus of ethical concern, and in many institutions, ethicists spend considerable time in those units, often attending rounds on a weekly or even daily basis. The unit-based approach has the advantage that consultants will know the individuals and their relationships as well as the nature of the field, particularly the specific norms of the field. Being “embedded” in these units also offers the potential for both learning (through observation over time) about the field while also offering advice on a regular basis without the need for the occurrence of the “crisis” that typically gives rise to clinical ethics consults.

THE STANFORD MODEL

The model that we have employed at Stanford grew out of an experimental pilot program initiated by Cho and colleagues, and funded by the NIH and US DOE as part of a Center for Excellence in Ethical, Legal and Social Implications Research (CEER). This is a hybrid approach, combining elements of individual and group consultation, and something in between a unit-based and institutional model, which most closely resembles biostatistics consultation. We initially focused on genetic research, thus resembling a unit-based approach, but quickly received requests from a broad spectrum of biomedical and clinical researchers.

In this model, a protocol for consultation is activated by a request for consultation to either the team or a team member. In the future, such a request could be made through a central research portal for researchers that integrates biostatistics, biodesign, bioinformatics and bioethics (NIH 2005), a process which was initiated at Stanford as part of its planning grant for the CTSA, or through referral from one of the other consulting services (particularly biostatistics). Integration among the different services for referral purposes (e.g., so that biostatisticians recognize when a protocol will benefit from ethics input and vice versa) was envisioned as part of the “one-stop shopping” model for clinical researchers that took advantage of a research portal already implemented at Stanford and that was expanded as part of planning for the CTSA. The idea is to make such consults more convenient and attractive to researchers and to facilitate discussion of the links between study design and ethics, of which both statisticians and bioethicists are aware (Finney 1991). Currently, we have prepared brochures (based partly on data collected from a needs assessment among researchers) that allow researchers to access the consult team directly. Other options have been utilized at the Johns Hopkins School of Public Health, where researchers can request help on-line in a system similar to the way they request help with their computers.

Our approach grew out of some informal consultations in the early 2000s and became formalized in 2005. Since that time, we have done 20 of these “benchside” consults.

The core team of our consult service consists of three academics with training in philosophy, law, and biology, all of whom have knowledge of research ethics, as well as administrative staff. The core team was responsible for the initial response to consultation requests. Others in the broader team, who could be recruited if additional expertise were needed, include those with expertise in neuroscience, genetics, epidemiology and clinical research, as well as research ethics. None of the team members are members of the institutional review board. An individual consultant (either designated or the person contacted) triages the case,

deciding whether the request could be answered or resolved simply and on the spot by a single individual (“curbside consults”), or whether it requires either a meeting of the core team or the core team plus others (based on a judgment about the expertise needed). In the pilot phase of the program, about half of the contacts required a full team consult and about half were handled by an individual consultant on a curbside basis.

The use of a team, rather than an individual, allows for an assessment and recruitment of the expertise that will be required to conduct the consult, including scientific expertise. Our pilot survey indicated that a major concern of researchers is that ethics consultants will lack the necessary scientific expertise to provide adequate understanding of their research (McCormick et al. 2006). For many of the consults it has been important to have expertise that is relevant, either in genetics, neuroscience, or research design, as part of the process. The likely increase in research ethics consultation as a result of the CTSA program highlights the importance of bringing scientists into the field of bioethics, so that they can obtain the interdisciplinary training necessary to facilitate consultations. The ELSI program at NHGRI and US DOE has helped foster a group of sophisticated geneticists, but it will be necessary for scientists from other fields and disciplines to develop a similar range of expertise.

Overall, this approach incorporates many of the advantages of unit- or team-based consultation, and group consultation, while avoiding the disadvantages of the moral community, group-based consultation model. It focuses on providing a service (just as biostatistics does) that can be assessed and adjusted to best meet the needs of those who request the service. And the more the service is seen as analogous to biostatistics and bio-design, and hence a routine and integral part of the research process, the more the consultation service will move away from “crisis” management.

It is possible that ethics consultation will follow the biostatistics model and result in the development of collaborative relationships for some research projects. However, for a variety of reasons, it may prove difficult for ethicists to be incorporated into research protocols as co-investigators. In one of our consults, a funding agency at NIH requested ethics input and that researchers demonstrate that ethicists will be involved in providing input in an ongoing basis for the research, but balked at including an ethicist on the grant at 5% on the grounds that the ethicist would be conflicted by reporting to the principal investigator. This suggests that it may be necessary to find alternative ways to fund consult services in such a way that investigators do not directly pay for their consults. This could be done by commitment of funds from the institution, or by grants such as the CTSA and the Center for Excellence in ELSI Research (CEER) program at NHGRI and US DOE that has funded several pilot consultation programs.

While some issues that arise will be relatively straightforward for a skilled and experienced ethics service to manage, there may be other issues and topics that will be much more difficult to assess. This is especially likely to happen in cutting-edge science. Our service was inspired by our activities working on benchside consults that were requested by researchers, first a project on the ethics of synthesizing genomes (Cho et al. 1999) that was requested by the Institute for Genomic Research (TIGR) and then a project on replacing a mouse neurostem cells with human stem cells (Greely et al. 2007) requested by researchers at Stanford. In both of these cases, there was substantial time for a very thorough analysis that led to publication of the results of the group deliberation on the process. These consults are likely to be rare, but can also be a significant outgrowth of the consultation process.

Initial Experiences

Our initial experience with the consultation program has demonstrated that consults will come from a variety of sources and at different parts of the research process. A number of consults in our program have come from researchers prior to the initiation of a research project, suggesting that the researchers requesting consultations were thinking about ethical issues in advance of conducting the research. Some of the consults came during the conduct of research and one case occurred post-publication. The consults have ranged from requests for help in responding to concerns raised by a granting agency, to helping to shape the design of a research project. This experience is also similar to the biostatistics model in that consultations may be called at many stages of the research process but are usually more effective if a consult is initiated as early as possible. However, it is always possible that unanticipated issues will arise that may usefully require ethics consultation later in the research process.

When team meetings are deemed necessary, we try to hold the meetings with the researcher present as soon as possible and aim to provide a written report within 48 hours of the meeting. We also ask researchers whether their request has a specific time frame for resolution, such as a grant deadline. Most of our cases thus far have not required immediate attention, but one requested a report in 2 weeks, another within 6 weeks, and one had to be addressed quickly because of possible clinical significance of a research result. At the beginning of the meetings, we collect information about and negotiate the terms of the consultation, defining it as advisory and collaborative rather than having decision-making authority. We offer confidentiality at a range of levels, from agreeing not to talk about or identify the individual case to being able to discuss any element of the case openly. In a pilot survey of Stanford researchers (including graduate students, post-doctoral fellows, faculty and research staff), confidentiality was a concern and potential barrier to use of our consultation service, so the option of confidentiality is important to offer (McCormick et al. 2006). Researchers are also informed that there are limits to the confidentiality if, for instance, illegal or clearly unethical behavior by researchers were observed by consultants. In these cases, we would point out the behavior and also would be obligated to report it to the appropriate authorities. None of our cases has yet required such reporting. In one case of a consultation with a company, consultants were asked to sign non-disclosure agreements, which raised questions about the limits of confidentiality that we will discuss in following text.

We do not use specific algorithms or emphasize reaching a conclusion because the nature of the team's activities do not necessarily require a discrete decision. However, in our experience, researchers have appreciated receiving specific recommendations, and we have been able to reach consensus among the consultants about the ethical and social issues identified in the case and about how to respond to the researchers. Our written reports are structured to cover background information, followed by a description of the request, the ethical, social and other issues identified, and, if appropriate, specific recommendations to the researcher. The lead consultant has taken responsibility for gathering the key information about the case and reference material during and immediately after the meeting in order to draft the report. During the course of consultation, we also collect data for the purposes of tracking and evaluation, such as the institutional affiliation of the researcher(s), whether the request for consultation has a specific time frame, whether the research involves human subjects, what type of research is involved, and the stage of research (e.g., planning, grant-writing, during the project, publication or dissemination, or later).

At Stanford, consultations have been requested by Stanford investigators, and by the IRB. Outside of Stanford, consults have been requested by researchers at other universities, by granting agencies within NIH, and by companies conducting research. The potential for

conflicts of interest is a significant issue in general, but the prospect of consulting for industry raises an additional set of concerns. To date, the program at Stanford has engaged in conversations with companies who are interested in our consultation program, but we have declined to accept any funding or to sign non-disclosure agreements. Instead, we have been somewhat successful in including industry consultation within our (federal) grant proposals. However, in the face of declining federal support, this solution may be only temporary.

It is important to delineate the boundaries of a consult service. It functions in an advisory capacity, and does not seek to carry out mediation, nor does it serve as a decision-maker because such a service has no authority. Also outside the scope of such a service are areas that are already in the jurisdiction of other governmental bodies such as the US Food and Drug Administration (Washington, DC), the Recombinant DNA Advisory Committee, and the National Science Advisory Board for Biosecurity (Bethesda, MD), as well as institutional bodies including IRBs, Institutional Animal Care and Use Committees (IACUC), ESCRO, and conflict of interest committees. Our recommendations may, however, affect how the researcher deals with those bodies and, in at least one case, an IRB has requested a consult from us. Because our consultations to date have not overlapped with the function of the IRB, we have been able to serve a complementary role, providing education in the planning stages of research as well as during and post-publication phases.

Our service also does not address misconduct or resolution of conflicts in the scientific process, such as disputes over authorship or intellectual property. These cases are more appropriately handled by an institutional ombudsperson or legal counsel, and research institutions already have procedures specifically mandated for alleging, investigating and resolving alleged cases of misconduct. Some of our experience suggests that researchers may not be aware of or may not find these procedures to be adequate. Given that we call ourselves research ethics consultants, and that our data suggest that researchers associate the very term “research ethics” with misconduct, as the service grows we may encounter cases in which researchers bring misconduct issues to the table. If the subject of any of our consults fall squarely within the jurisdiction of these other bodies, we refer the issues to them. However, as described by Martinson et al. (2005), most concerns about scientific behavior fall far short of true misconduct. (Scientific misbehavior is far more common and often involves a lack of discernment of difficult distinctions, such as when data cleaning crosses a line. Our initial survey indicated that these issues matter a great deal to investigators (McCormick et al. 2006) and may be a future source of significant activity for consultation services, particularly for behaviors that are problematic, but fall outside the scope of current regulations and rules (and hence may be outside the scope of institutional committees).

Unresolved Questions

Scope—The range of issues that researchers might bring to a research ethics consultation service is enormous. For practical purposes, the scope of such a service could be limited (e.g., to clinical research, or stem cell research). But the question still exists as to whether and how the consultants can address very broad issues, such as the societal implications of bio-weapons research. Although our consultations have addressed very specific questions (e.g., how should a specific genetic finding of clinical significance to a known research subject be handled), as well as broader ones (e.g., should research that would replace neurons in mouse brains with human neurons go forward?), there may be a point at which the consultation should be referred to a more expert group.

Composition—This brings us to the question of the composition of the consultation team, which has also been raised in the context of clinical ethics consultation (Aulisio et al. 2000; Fletcher and Siegler 1996). The relative paucity of individuals with expertise in both biomedical research and ELSI issues suggests that committees with a range of backgrounds will be needed. The sheer breadth and number of topic areas potentially within the scope of a consultation service also means that rarely will any single individual on a committee be expert in all areas needed to identify, analyze, and resolve issues. However, the overall composition of the committee should be designed to include individuals with recent or current experience in the conduct of biomedical research, as well as expertise in research ethics, research regulation, law and policies, and social science. It is also important that most if not all of the ethics consultants have a decent understanding of bioscience, not so that they will understand the intricacies of the science immediately, but so they can learn enough to grasp whatever special issues arise from this particular scientific activity. Because a more detailed understanding of specific biological, social science or legal issues might be needed, the consultation service should have the resources to bring in external consultants (either from within or outside the institution) for specific cases. Being aware of the limits of expertise of the consultants and recognizing when outside advice is necessary is perhaps more important than having expertise directly on the panel.

Core Competencies—Just as for clinical ethics consultation, the question of whether there is a set of core competencies that each consultant should possess needs to be answered. As a research ethics consultation service evolves, this is a question that should be incorporated into the evaluation plan. On the face of it, it seems that, compared to core competencies articulated for clinical ethics consultation (Aulisio et al. 2000), interpersonal and conflict resolution skills may be less important, but ethical assessment skills are critical. It also seems that six of the nine knowledge areas identified for clinical consultation would also be necessary for, and have analogs in research ethics consultation: moral reasoning and ethical theory, bioethical issues and concepts, local institutional structure relevant to the conduct of research, local institutional policies, relevant codes of ethics and policies, and law. Other knowledge areas that may be necessary for research ethics consultants but much harder to delineate include basic knowledge of commonly used biomedical research methods and terminology, basic knowledge of the social and historical context of biomedical research in the US, and familiarity with the scientific process and norms of research culture.

Some background knowledge about biological systems, methods and terminology is extremely useful for each consultant. Because research ethics consultation ideally will elicit some cases arising from frontier research, it will be necessary for consultants to learn about new techniques and concepts. Thus, an ability to obtain and incorporate new scientific knowledge into an existing framework of understanding is likely to be more important than possessing direct knowledge of or experience in research. However, in order to promote successful interactions with researchers, having a basic understanding of the research will be crucial to earning credibility with scientists.

Some understanding of how science is conducted on a day-to-day basis, including how researchers collaborate and share ideas and materials and how research is published and funded, would be useful for consultants to know in order to make realistic recommendations that are feasible within the structure of research culture and norms. Making unrealistic recommendations on a regular basis would undermine the credibility of the consultation service.

Consultants will need to be familiar with at least some major areas of interaction among science, technology and society, such as incidents that have led to the development of research regulation or otherwise had major effects on the conduct of research. Awareness of

areas of public concern about biomedical science and its application, including research events that have had major influence on public perception of science, will also be important for consultants. In addition, knowledge of cultural and other factors (such as concepts about health versus disease, or normal versus abnormal, or conflicts of interest) can influence research design and outcome and will be key concepts for consultants. Whether consultants should be familiar with specific cases or literature as part of a core competency is unclear.

Because research ethics consultation is conceived as an ongoing service, in contrast to an ad hoc group that meets for a limited number of times and is dissolved, it could be more practical for all the committee members to be at the same institution as the researchers, or at least near each other. However, with improving communications technology, it could be feasible to include physically distant members as active consultants.

Conflicts of Interest—The location of a research ethics consultation service within a research institution, and funding of the service with intramural or extramural support raise issues of both financial and non-financial conflict of interest. As members of the institution, consultants are (such as IRB members) in a conflicted position that could interfere with providing unbiased advice, especially if the consultants suggest that certain research should not be performed. In order to provide a safe and accessible environment for researchers to discuss the ethical implications of their work, and to foster trust between scientists and those from other disciplines, we argue that consultation groups are best situated locally (Arndt and Woolson 1991). However, we acknowledge the conflicted position of the consultant.

Financial support of consults from funders who also support research that is the topic of consultation raises similar conflicts. Thus, funding would ideally come from outside the institution but from sources that do not support the research that is discussed in consultations. This also holds for consultations for for-profit companies, who may be willing and able to pay for ethics consultation. While consultation services require resources, providing consultation on a fee-for-service basis may exacerbate the conflict of interest.

Clarification of the nature of the role of the consultants may be critical to success. As Sontag recently pointed out (Sontag 2007), there are often different expectations in terms of public interest depending on the role one plays. Public accountants have a duty to the public that creates a conflict of interest when the same individual has a financial stake in a company. In contrast, accountants who have no auditing function are free to provide advice to clients with far less of a conflict of interest because they lack the conflicting duty that comes with auditing responsibilities. Whatever view one takes of corporate consulting by individual bioethicists, it is far more difficult for an institution based at an academic medical center to undertake consults with industry, but the closer that the role corresponds to the role of the biostatistician, the clearer the guidance for how to engage in relations with industry.

Perhaps the most serious challenge for consultants is the possibility that researchers, either from universities or the private sector, seek ethics consultation to gain an imprimatur of morality, especially for research that is socially controversial or does not meet ethical norms (Brody 2002; Donaldson 2001; Schadick 2005; Sharpe 2002). Consultants should decline to take these cases, but identifying such cases may be challenging. While consultants cannot be expected to read the motivations of the researchers accurately, they can take their cues from evaluation of the client and the terms of the consultation. For example, has the client's past behavior been ethical? Is the individual requesting the consultation a researcher or a representative from a public relations department? What is the regulatory and legal context of the consultation? Is the client attempting to misrepresent the role of the consultants, the consultants' advice or the client's actions in response to the advice?

Purpose—Scholarly Research or Service?—In addition to raising questions of conflict of interest, our consultations with for-profit companies caused us to interrogate the boundaries of the consultation service in several ways. Perhaps the most fundamental question raised was the extent to which the service should also be a scholarly activity to advance ethics or social science. Our experience to date is that in the course of providing a service, the consultation provided rich material that easily became a source for productive ethics scholarship (as well as educational material for biomedical researchers). However, if contribution to scholarship is seen as a desirable element or even a requirement of a consultation service, the structure of the service would be affected. For example, such a requirement would suggest which cases to take, and perhaps influence or be influenced by the expertise of the chosen consultants. Putting weight on scholarly contributions would potentially use consultants' and researchers' time more profitably toward advancing issues pertinent to research policy, but if consultants must turn down some cases in order to address the more unusual or substantial, the service risks alienating researchers. On the other hand, "bread and butter" requests that recur frequently can point consultants to a need to develop directed educational materials for researchers.

Interestingly, the juxtaposition of "internal" consultations with Stanford researchers and "external" consultations with companies or other entities raised questions about academic freedom and confidentiality. When we conducted consultations with Stanford researchers, we provided them in service mode, and did not hesitate to offer broad confidentiality, which would preclude a scholarly discussion of the case without the permission of the researchers. However, when we were asked by companies to sign non-disclosure agreements, we resisted, using academic freedom as the defense. We justified this by making a distinction between providing a service to our institution (as a clinical ethics committee would do) and scholarly activities. While institutional service is part of an academic's portfolio, and offering confidentiality to users of a consultation service would likely encourage the use of the service for some, if the results of deliberations cannot be disseminated at least in summarized or aggregate form, the usefulness of the service to the wider research community is diminished. In addition, the opportunity for researchers to demonstrate how ethical issues are considered to trainees and to the public would be lost. Finally, the institution has concerns about liability of providing consultation to external groups.

At this early stage of our consultation service, the topics of most of the consultations have been fairly circumscribed, raising questions relevant to specific research projects rather than raising broad societal issues. However, we believe that the process of deliberations between biomedical researchers and those from other disciplines is valuable in itself and will lead to broader awareness and more frequent discussion of the wider implications of research. This may in turn lead to conversations that go beyond solving problems for individual researchers about specific projects, and turn to larger questions about the societal impact of research. It is likely that other mechanisms that do not rely on scientists to initiate discussions or that are composed only of "experts" will always be useful to address some of these issues. However, we hope that the consultation mechanism will bring these discussions to one of the most important venues—at the benchtops of biomedical scientists. Only by involving the scientists themselves will the full implications of scientific technologies be explored.

CONCLUSION

The hybrid ethics consultation model proposed here includes integration, but encompasses a broad mandate for addressing the ethical issues inherent in benchside research, not just clinical research. Our approach attempts to make such consultation a routine and integral part of the research process by advocating anticipation and involvement early in the research process, just as biostatistics and bio-design do. But we diverge slightly in our approach

through creating a hybrid model that permits a flexible process to meet the needs of researchers in specific cases. It will be far more common and necessary for a group process for bioethics research consultation than with biostatistics, bioinformatics, or bio-design consultation. At the same time, that will not always be the case, and initial triage may make it possible to select an appropriate mode of consultation for a broad spectrum of potential consults. The flexibility of a hybrid model will permit resources to be used efficiently, and thus to address a significant number of consults.

The CEER program has helped to initiate and formalize this hybrid model of research ethics consultation. The CTSA program has seeded a new crop of consultation services, including programs at Duke University (Durham, NC), Columbia (New York, NY), and most other institutions with CTSAAs, some explicitly based on this model. Collaboration among consultation groups to evaluate these programs in a coordinated fashion will be critical to the assessment and success of this type of ethics consultation. Measuring the value of such services should include not only the impact on scientists and their research, and the value to the consultants, but also whether there is value to the public and any impact on public trust in science.

References

- Agich GJ. Clinical ethics: A role theoretic look. *Social Science & Medicine* 1990;30:389–399. [PubMed: 2315723]
- Altman DG, Goodman SN, Schroter S. How statistical expertise is used in medical research. *JAMA* 2002;287:2817–2820. [PubMed: 12038922]
- American Hospital Association. Guidelines: Hospital Committees on Biomedical Ethics. In: Ross, JW., editor. *Handbook for Hospital Ethics Committees*. Vol. 57. Chicago, IL: American Hospital Publishing; 1986. p. 110-111.
- American Medical Association. Judicial Council. Guidelines for ethics committees in health care institutions. *JAMA* 1985;253:2698–2699. [PubMed: 3989946]
- Arndt S, Woolson RF. Establishing a biostatistical core unit in a clinical research center. *The American Statistician* 1991;45:22–27.
- Association of American Medical College (AAMC) Task Force on Financial Conflicts of Interest in Clinical Research. Protecting subjects, preserving trust, promoting progress: Policy and guidelines for the oversight of individual financial interests in human subjects research. Washington, DC: AAMC; 2001.
- Aulisio MP, Arnold RM, Youngner SJ. the Society for Health and Human Values — Society for Bioethics Consultation Task Force on Standards for Bioethics Consultation. *Health Care Ethics Consultation: Nature, Goals and Competencies*. *Ann Intern Med* 2000;133:59–69. [PubMed: 10877742]
- Baylis F, Robert JS. Human embryonic stem cell research: An argument for national research review. *Accountability in Research* 2006;13:207–224. [PubMed: 17124758]
- Beecher HK. Ethics and Clinical Research. *New Engl J Med* 1966;74:1354–1360. [PubMed: 5327352]
- Beskow L, Burke W, Merz JF, et al. Informed consent for population-based research involving genetics. *JAMA* 2001;286:2315–2321. [PubMed: 11710898]
- Braddock CH, Tonelli MR. Too much ethics, not enough medicine: Clarifying the role of clinical expertise for the clinical ethics consultant. *Journal of Clinical Ethics* 2001;12:24–30. [PubMed: 11428152]
- Brody B. Bioethics consultation in the private sector. *Hastings Center Report* 2002;32:14–20. [PubMed: 12085509]
- Cho, M.; Greely, HT.; Magnus, D.; Maienschein, J. Developing a new paradigm for integrating ethics and biomedical research: proposal for a benchside consultation program. Presented at the American Society for Bioethics and Humanities/Canadian Bioethics Society Joint Meeting; October 26, 2003; Montreal, Canada. 2003.

- Cho MK, Billing P. Conflict of interest and institutional review boards. *Journal of Investigative Medicine* 1997;45:154–159. [PubMed: 9154295]
- Cho MK, Magnus D, Caplan AL, McGee D. Ethics of Genomics Group. Ethical considerations in synthesizing a minimal genome. *Science* 1999;286:2087–2090. [PubMed: 10617419]
- de Melo-Martin I, Palmer LI, Fins JJ. Developing a research ethics consultation service to foster responsive and responsible clinical research. *Academic Medicine* 2007;82:900–904. [PubMed: 17726404]
- Department of Health and Human Services. 2005. Title 45 Public Welfare Part 46 Protection of Human Subjects.
- Deutsch R, Hurwitz S, Janosky J, Oster R. The role of education in biostatistical consulting. *Statistics in Medicine* 2007;26:709–720. [PubMed: 16625526]
- Donaldson T. The business ethics of bioethics consulting. *Hastings Center Report* 2001;31:12–14. [PubMed: 11478101]
- DuVal G, Clarridge B, Gensler G, Danis M. A national survey of U.S. internists' experiences with ethical dilemmas and ethics consultation. *Journal of General Internal Medicine* 2004;19:251–258. [PubMed: 15009780]
- Finney DJ. Ethical aspects of statistical practice. *Biometrics* 1991;47:331–339. [PubMed: 2049508]
- Fins JJ, Bacchetta MD, Miller FG. Clinical pragmatism: A method of moral problem solving. *Kennedy Institute of Ethics Journal* 1997;7:129–143. [PubMed: 11654986]
- Fletcher, JC.; Lombardo, PA.; Marshall, MF.; Miller, FG. *Introduction to clinical ethics*. Hagerstown, MD: University Publishing Group, Inc; 1997.
- Fletcher JC, Siegler M. What are the goals of ethics consultation? A consensus statement. *J Clinical Ethics* 1996;7:122–126. [PubMed: 8889887]
- Fox E, Myers S, Pearlman RA. Ethics consultation in United States hospitals: A national survey. *American Journal of Bioethics* 2007;7:13–25. [PubMed: 17366184]
- Fox M, McGee G, Caplan AL. *Paradigms for clinical ethics consultation practice*. Cambridge Quarterly of Healthcare Ethics 1998;7:308–314. [PubMed: 9663351]
- Golenski, JD. *Forming a moral community: A methodology for case review*. Berkeley, CA: Bioethics Consultation Group, Inc; 1992.
- Greely HT, Cho MK, Hogle LF, Satz DM. Thinking about the human neuron mouse. *American Journal of Bioethics* 2007;7(5):27–40. [PubMed: 17497502]
- Jonsen, AR.; Siegler, M.; Winslade, WJ. *Clinical Ethics: A practical approach to ethical decisions in clinical medicine*. New York, NY: McGraw-Hill; 1992.
- Juengst ET. Self-critical federal science? The ethics experiment within the US Human Genome Project. *Social Philosophy and Policy* 1996 Summer;:63–95. [PubMed: 11653300]
- La Puma J, Stocking CB, Silverstein MD, DiMartini A, Siegler M. An ethics consultation service in a teaching hospital. Utilization and evaluation. *JAMA* 1988;260:808–811. [PubMed: 3392812]
- Martinson BC, Anderson MS, de Vries R. Scientists behaving badly. *Nature* 2005;435:737–738. [PubMed: 15944677]
- McCain L. Informing technology policy decision: The US Human Genome Project's ethical, legal and social implications programs as a critical case. *Technology in Society* 2002;24:111–132.
- McCormick, J.; Boyce, A.; Garg, R.; Cho, M. Societal and ethical considerations in life science research: In the eyes of scientists. Presented at the American Society of Human Genetics; October 11, 2006; New Orleans, LA. 2006.
- McGee G, Caplan AL, Spanogle JP, Asch DA. A national study of ethics committees. *American Journal of Bioethics* 2001;1(4):60–64. [PubMed: 11954647]
- National Institutes of Health. Request For Applications (RFA) Number: RFA-RM-06-002. US Department of Health and Human Services; 2005. Institutional Clinical and Translational Science Award.
- National Institutes of Health Revitalization Act of 1993 September 14, 1993
- Orr RD, Morton KR, deLeon DM, Fals JC. Evaluation of an ethics consultation service: Patient and family perspective. *American Journal of Medicine* 1996;101:135–141. [PubMed: 8757352]

- Rothenberg KH. Genetic information and health insurance: State legislative approaches. *J Law Medicine Ethics* 1995;23:312–319.
- Rothenberg KH, Fuller B, Rothstein M, et al. Genetic information and the workplace: Legislative approaches and policy challenges. *Science* 1997;275:1755–1757. [PubMed: 9122681]
- Rothman, DJ. *Strangers at the bedside: A history of how law and bioethics transformed medical decision making*. New York, NY: Basic Books; 1991.
- Rubin S, Zoloth-Dorfman L. First-person plural: community and method in ethics consultation. *Journal of Clinical Ethics* 1994;5:49–54. [PubMed: 8003726]
- Schadick K. Bioethics consultants: Corporate reliance on a new field of consultation. *Case Western Reserve University health matrix. Journal of Law and Medicine*. 2005 Summer;
- Schneiderman LJ. Effect of ethics consultations in the intensive care unit. *Critical Care Medicine* 2006;34(11 Suppl):S359–S363. [PubMed: 17057599]
- Schneiderman LJ, Gilmer T, Teetzel HD, et al. Effect of ethics consultations on nonbeneficial life-sustaining treatments in the intensive care setting: A randomized controlled trial. *JAMA* 2003;290:1166–1172. [PubMed: 12952998]
- Sharpe VA. Science, bioethics and the public interest: On the need for transparency. *Hastings Center Report* 2002;32:23–26. [PubMed: 12085511]
- Siegler M, Singer PA. Clinical ethics consultation: Godsend or “God squad”? *American Journal of Medicine* 1988;85:759–760. [PubMed: 3195599]
- Sontag DN. What is wrong with “ethics for sale”? An analysis of the many issues that complicate the debate about conflicts of interest in bioethics. *Journal of Law, Medicine and Ethics* 2007;35:175–186.
- Turner L. The Tyranny of “Genethics”. *Nature Biotechnology* 2003;21:1282.
- Yen BM, Schneiderman LJ. Impact of pediatric ethics consultations on patients, families, social workers, and physicians. *Journal of Perinatology* 1999;19:373–378. [PubMed: 10685260]