Nanotechnology and the IRB: A New Paradigm for Analysis and Dialogue

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Nanotechnology ("NT") appears to represent the next technological revolution. Much has been written about the need for scientists, technologists, and the public to work collaboratively to balance the promise and peril of this emerging science. A National Science Foundation (NSF) sponsored report (Roco & Bainbridge, 2001) states

> [N]anotechnology will fundamentally transform science, technology, and society. However, to take full advantage of opportunities, the entire scientific and technology community must set broad goals; creatively envision the possibilities for meeting societal needs; and involve all participants, including the general public, in exploiting them.

Meanwhile, critics point to a "paucity of serious, published research into the ethical, legal, and social implications of NT" (Mnyusiwalla, Daar, & Singer, 2003). While a more advanced understanding of the various implications of NT is needed, relatively little has been proposed regarding practical steps to systematically minimize or control potential negative impacts. The Center for Responsible Nanotechnology, the Foresight Institute, and Nanotechnology Now have proposed principles, guidelines and policy goals, respectively. Yet, without formal mechanisms for assessment and approval that can address unanticipated technological developments and their unique contexts, such generalized, conceptual and research efforts may fail to effectively guide the advancing science

This paper stems from an unpublished white paper prepared by the Task Force on Nano-ethics and Societal Impacts of the Colorado Nanotechnology Initiative (CNTI, 2003). The task force recommended a common framework, method and forum to facilitate dialogue to inform technological and policy decision-making. Such dialogue should take into account both the context and process of NT development through regular assessment integrated into the fabric of basic and applied research, design and development, commercialization, and public policy formulation.

In keeping with this broad recommendation, we suggest ethical reasoning can identify issues and help guide decision-making regarding research for the benefit of society. Following the precedent set by current practices in human subjects research, we propose the development of an ethical framework, using carefully crafted ethical principles and assumptions, that can be integrated into key decision points throughout the evolutionary processes of science, engineering, and technology ("techno-science"). This paper describes the foundations and general direction such a framework might take, followed by the challenging context of dialogue within technology development. We conclude with a practical method for engagement and action. Interdisciplinary dialogue, rooted in ethical principles, can heighten awareness and foster ethically informed decision-making and accountability at key technical-ethical intersections.

The Belmont Report and Human Subjects Research

If we are on the brink of a rapidly approaching revolution in human industry, perhaps it is time to consider all research contributing to technological development as human subjects research. Sarewitz and Woodhouse (2003) reach a similar conclusion in describing the "unfolding revolution as a grand experiment – a clinical trial – that technologists are conducting on society" (p. 80). They cite a societal consensus, codified by the Helsinki Declaration of the World Medical Association, requiring fully informed consent prior to the participation of human subjects in any scientific research. This poses the question of what form informed consent on a broad societal level might take. In the United States, the consent process itself is carefully evaluated in relation to the goals and risks of the particular research study by an institutional review board (IRB), at the proposal stage for approval and funding of qualified research. Both the CNTI (2003) and Sarewitz and Woodhouse (2003) propose using the IRB process broadly as a model for NT assessment, approval and oversight. The advantages of employing an existing, functional, and highly standardized process are numerous; however, the adoption of an IRB model for NT requires a far more broadly situated paradigm for both conceptual analysis and practical application.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979) established the common conceptual basis grounding all IRBs in the United States with the publication of the Belmont Report. Three basic ethical principles are articulated. Briefly, the first is respect for persons, establishing the dual assumptions that individuals should be treated as autonomous agents and those persons with diminished autonomy are entitled to protection. The combined assumptions charge IRBs to ensure that voluntary and informed consent is routinely sought with clear protections for subjects whose voluntary and informed participation is questionable at any point prior to or during the research. Beneficence, the second principle, obligates researchers and IRBs to refrain from harm and to maximize potential benefits while minimizing the potential risks inherent in any research involving human subjects. The third principle, justice, requires consideration of whether or not the benefits and burdens of the research are likely to be fairly distributed and a justification for the basis of such distribution.

As applied, these principles are narrowly suited to the individual interests of human subjects involved directly in a specific, pre-commercial, research study. Likewise, in the research context, assessment of these principles is reasonably straightforward given the individualized and highly standardized approach to informed consent and the detailed nature of the proposal process for authorization and funding. Well-established guidelines address the standards for informed consent, assessment of risks and benefits, and selection of subjects. In contrast, a more broadly situated paradigm for IRB review of NT would need to occur at multiple points, while addressing the process and outcomes of NT research and development (R&D) on large populations, with respect to both individual and communal interests, and without benefit of the elements of individually focused informed consent or voluntary participation. Despite the obvious complexity of the task, the need for some foundation within which common concerns and interests can be explored is a prerequisite for collaborative participation and is worth pursing in light of the current scarcity of alternative approaches. Before proposing new principles that expand on the assumptions in the Belmont Report, we recognize the valid critique certain to be raised in response to a "principlist" approach.

Evans (2003) traces the growth of principlism in bioethics from a sociological viewpoint, finding it deeply rooted in Western views of public deliberation. He notes common criticisms, including principlism as overly rationalistic, reductionistic, simplistic and rigid in application. Likewise, Callahan (2003) finds principlism in bioethics to be overly focused on the individual and charges it with too often blocking more substantive ethical inquiry.

While issues in bioethics have become highly polarized despite widespread acceptance and use of principles, this is not necessarily because the principles are simplistic or reductionist in themselves. Rather, the failure to discern common definitions for other foundational concepts, such as quality of life or the nature of personhood, have rendered interpretation of the principles difficult with respect to given issues. Nonetheless, the principles often provide a common ground from which even the most polarized dialogue can proceed. Few people will argue against the need to protect basic human dignity or to distribute scarce resources justly, and this modicum of agreement enables dialogue and reasoned debate.

An approach based on commonly defined principles offers three significant advantages. First, well-articulated principles provide a starting point and common language for dialogue. Second, NT review boards are likely to be populated with scientists, administrators, regulators and citizens not readily conversant in the disciplines of philosophy and ethics. A limited range of principles, carefully crafted into guiding questions, can enhance the depth of dialogue. Finally, using principles to craft questions that reflect a variety of ethical concerns can moderate overt conflict through the implicit recognition of various anticipated views.

The risks of being overly simplistic, reductionist and rigid are inherent in any effort to analyze issues as complex as those posed by NT. The ethical concepts offered here are best viewed as a starting point with the expectation that the combination of dialogue and experience can, over time, effectively narrow, expand and refine as needed.

Ethical Framework Foundations

The three principles of the Belmont Report are narrowly aimed at protecting individual research subjects within the clear boundaries of a designated research study. The goals are to ensure fully informed consent or, in the absence of informed consent, reasonable protections from any narrow, self-serving intentions and goals of the researchers at the expense of individual research participants. The ethical analysis of NT we propose includes assessing the broader societal outcomes of products after market introduction. A new ethical framework must redefine the general principles with respect to the larger society without diminishing the original concern for the dignity and well being of individuals as summarized in Table 1.

Ethical Principles
Principle of Respect for Communities Act in ways that respect the ability of communities to act as autonomous, self-governing agents.
Principle of the Common Good Act in ways that respect shared values and promote the common good of communities.
Principle of Social Justice Act in ways that maximize the just distribution of benefits and burdens within and among communities.

Table 1: Ethical Principles

Respect for Persons and Respect for Communities

The principle of respect for persons assumes the primary worth of each human being and requires treating such beings with the dignity owed autonomous agents capable of deliberating about personal goals and acting in the interests of those goals. Absent compelling reasons to do otherwise, researchers must always respect the considered judgments and choices of autonomous beings and refrain from denying them freedom to act on those judgments and choices in the context of their own self-determined interest.

A critical component of this process ensures that persons have the information needed to conduct reasoned deliberation. Informed consent thus embodies two additional ethical principles. Veracity involves the obligation to speak the truth about all pertinent information, including what is not known regarding potential harms from participation. Fidelity requires keeping promises and openly balancing conflicting loyalties to competing interests such as the well being of research subjects, the intent to advance science, the requirement to demonstrate progress to ensure continued funding, and the profit margins of sponsoring institutions.

At the same time, the principle of respect for persons acknowledges that the ability to function in a fully autonomous fashion can be compromised by incapacitating physical or mental conditions and various social circumstances that render the person vulnerable. Persons institutionalized or marginalized by virtue of poverty or illiteracy fall into this latter category. Under these circumstances we have a duty to protect persons until such time as they are able to make and act on their own informed decisions.

At first glance, this principle does not seem to play out equally well in the larger scheme of the societal outcomes of R&D. In fact, much of the outcome of techno-science imposes the involvement of society without benefit of the informed choices of its members. Sarewitz (2003) characterizes this effect as the "compulsory nature of technological assimilation" (p. 194), labeling it a central cause of social change.

Calls for enhanced public dialogue in techno-science including NT are, however, essentially calls for informed consent on a societal level. Just as we acknowledge certain individuals to be compromised in their ability to be fully self-determining, it is not realistic to expect every individual within a society to be fully informed and in agreement at every step of the techno-scientific enterprise. Nonetheless, more general mechanisms of societal consent are possible.

This line of thought suggests an expansion of the principle of respect for persons to a ***principle of respect for communities***. Stated as ***researchers must act in ways that respect the ability of communities to act as autonomous, self –governing agents***, this principle rests on two assumptions. First, communities are capable of considered, autonomous self-governance. Such societal autonomy assumes a foundation of communal values and goals, that themselves require ongoing dialogue and negotiation, applied to a process of societal informed consent requiring the same basic range of truthful information provided in human subjects consent. The second assumption is accountability within the techno-scientific enterprise, based upon similar duties of veracity and fidelity in decisions made about technology development and dissemination. Many writers have addressed the absence or inadequacy of this type of moral foundation in the sciences, most recently Sarewitz (2003) and Visvanathan (2003). Furthermore, we see a clear analogy with corporate responsibility once technologies are ready for transfer to the marketplace. Both science and business occupy privileged positions insofar as they may influence social change in ways that are becoming increasingly rapid, complex and potentially irreversible.

The mutual recognition of the need for communities to ascertain common values and goals, and for the agents of science and the marketplace to acknowledge their own embedded position as members of the larger community, with multiple loyalties and obligations can, if formalized, facilitate a meaningful process of informed consent to moderate techno-scientific advance in ways that preserve the dignity and self determined interests of the larger community, while allowing for beneficial progress in so far as it can be predicted and assessed. A precise definition of community is beyond the scope of this paper. Nonetheless, communal interests can be readily discerned at many levels and an evolving dialogue is likely to identify more than one appropriate definition, allowing for broad representation of both majority and minority stakeholders. .

Beneficence and the Common Good

In the context of human subjects research, the principle of beneficence directs researchers to act in ways that promote the well being of subjects. The Belmont Report's obligatory interpretation of beneficence translates it into two general rules. The first is to avoid harm by identifying known harms and likely risks, making provisions to avoid or minimize them. The second requires maximizing possible benefits.

Once again, a relatively straightforward principle in the context of medical research on human subjects becomes far more ambiguous in the larger scope of societal impact. Ideally, avoiding harm requires knowing what those harms might be and, likewise, promoting the well being of society requires knowing what actually benefits society as a whole in both short and long term contexts.

The question of harm is marginally clearer. Technologies that result in widespread environmental degradation, rapid economic, political or cultural destabilization, or exposure of segments of the population to high levels of risk all would seem to violate the principle of beneficence. However, there is disagreement on what constitutes harm respecting more subtle technological impacts. At what point is environmental degradation acceptable in light of enhanced food production or innovations in transportation and human comfort? As noted by Lightman (2003), technology has routinely operated as a two edged sword. It has solved many problems and enhanced living conditions for much of the human population, while creating problems along the way. When considerations of harm and benefit are applied in simplistic utilitarian terms, focusing on short term happiness of either the greatest number or the few who stand to gain economically, there is potential to overlook the happiness of those who either dissent, are unable to benefit, or are actively harmed by a particular innovation.

The question of what constitutes well being in relation to the larger society is perhaps more challenging. For example, when defining well being in terms of happiness, Sarewitz (2003) questions the basic assumption that technological progress has on balance increased human well being by citing the "robust conclusion that over the past several decades of historically unprecedented scientific, technological and economic advance, people's happiness and satisfaction with their own lives has not increased" (p. 190). To the contrary, he sees evidence of an overall decrease in life satisfaction.

Our approach to assessment of innovation places a balance of individual and communal interests at the center of a definition of beneficence. We employ the ethical perspective of communitarianism and the concept of a common good, differentiated from the utilitarian concept of the greater good by focusing on shared human values and a mutual balance of communal and individual responsibilities. Tam (1998) defines the common good as those conditions under which common values can best be realized. For Etzioni (1995), the paramount assumption is that both individual human dignity and the social, or communal, dimension of human existence be recognized and embodied through values of mutual respect, individual liberty, and civic responsibility. Etzioni contends that individual liberty can only be preserved when self interest is moderated by communal obligations. Reeve (2002), in discussing the social implications of technological development, seems to echo this assumption in asserting "scientists owe a public justification of their activity transcending immediate self interest, both within their own community and to the wider society" (p. 121).

While the ability to articulate one common set of human values or ideals is reasonably open to debate, common sense dictates that candidates can be proposed with particular respect to our ability to live effectively in community. Such a list might include cooperation, caring, reciprocity, truth, fairness, justice, protection from unnecessary harm, access to basic human needs including shelter and sustenance, and personal fulfillment. Etzioni (1995) identifies a core ideal of democratic decision-making by an informed and responsive community concerned with serving the shared human needs of all members.

Focusing on a general conception of shared values, a ***principle of the common good*** requires that ***researchers must act in ways that respect shared values and promote the common good of communities***. As suggested by this brief list of potential values, the assessment of benefits, harms and overall risk transcends simplistic, all-or-nothing questions of whether or not to proceed with particular techno-scientific objectives, and must include more contextual questions of how best to accomplish specific ends. Rather than being a static barrier to techno-scientific goals, the common good can be viewed as a cooperative, interdependent, and highly discerning partner capable of defining and redefining its own interests and priorities in relation to innovation.

Individual Justice and Social Justice

The principle of justice in the Belmont Report questions the fairness of how specific benefits and burdens of research are distributed. This principle effectively becomes an extension of both respect for persons and beneficence by prohibiting scientific practices that target individuals in vulnerable populations for research, especially considering that such populations often have limited access to the devices and procedures developed following the research due to limited economic resources and political power.

Accordingly, we redefine the principle of justice more globally as a ***principle of social justice*** that requires researchers to ***act in ways that maximize the just distribution of benefits and burdens within and among communities.*** The power of NT as an economic force has been credited with the potential to redistribute political and economic power across the globe (Smith, 2001). The pursuit of NT has already resulted in large allocations of scarce governmental funds to R&D efforts. Envisioned military applications have the potential to remake traditional warfare and ultimately redraw geopolitical boundaries. Traditional industries face potentially massive investments in retooling manufacturing processes and large scale disruption of the workforce. Inherent in each of these scenarios is the potential for community segments or entire communities to experience a much higher level of burden or risk, while receiving little or no benefit. A principle of social justice calls upon decision makers to look within and beyond their own community borders and consider their short and long term interests in light of those of all other communities.

As with beneficence, this approach to justice might best be grounded in a communitarian ethos. Etizioni (1995) contends that the preservation of rights is highly dependent on the acceptance of communitarian assumptions such as the preservation of individual liberty through creation and maintenance of active civil institutions that promote service to self and others, and the mutual obligations of communities to their members and vice versa.

A particularly distinguishing feature of communitarian thinking is a focus on sustainability in both the short and long terms. Whether considering issues of environmental, social, economic or political sustainability, this conception of a common good based on mutual responsibility forces the close examination of current market practices that accelerate technology assimilation for purposes of short term profits without consideration or accountability for longer term outcomes. The modern social enterprise viewed as a myriad of nested communities presents the opportunity for dialogue about short and long term accountability between the communities of science, private enterprise, government, and representative citizenship. Meeting the common needs and aspirations of all current members while also preFiguing resources, avoiding environmental degradation and ensuring intergenerational justice extends communal boundaries to a global scale.

Opportunities for Dialogue within Science and Technology

NT design and development guidelines have begun to proliferate and the principles proposed here add to this list. Developing guidelines and principles is necessary for ethical assessment, but effectively applying them to specific situations involves additional considerations. Any effort to guide responsible NT development must be contextually geared if to have any bearing on subsequent socio-technological outcomes.

The problem of effectively addressing social and ethical dimensions of NT development is compounded by the tendency to regulate technologies either at the beginning or ending stages of their development cycles, while largely ignoring the development process itself. Early regulation often takes the form of "yes or no" funding decisions and priorities, and "end of the pipe" regulation is often too late to be fully effective. Similarly, Idhe (1993) states that much applied ethics comes "*too late*….after all the technologies are in place." Accordingly, even NT promoters are calling for moving ethical analysis "upstream" and much earlier in the techno-scientific development process (e.g., Roco & Bainbridge, 2001; Royal Society, 2004). Efforts to assess emerging technology during R&D make sense in terms of cost and effectiveness. As Tepper (1996) observes, "technology assessment is most effective when applied in the early stages of R&D, when changes are easier."

Successful "upstream" analysis, assessment, and regulation must naturally take into account existing processes of scientific and engineering R&D activities. Hence, upstream ethical assessment should be integrated rather than externally imposed. Integrated assessment would ideally follow a given technology through its development cycle, beginning with funding and culminating in a publicly embedded product.

A straightforward "technology development continuum," however, is not always very realistic. An appropriate and accurate model of technology development is currently lacking (Pielke & Byerly, 1998) and the challenges of monitoring its crucial stages are plentiful. An additional challenge to integrating ethical analysis involves enlisting the support and participation of technical experts.

The classic model of techno-science development is articulated in Vannevar Bush's "Science, the Endless Frontier" (1948). Bush outlines a linear progression in which knowledge generated in basic research is then used in applied research, enabling technology development, and culminating in societal benefits. According to the linear model, illustrated in Figure 1, knowledge and its products generally "flow" from each stage to the next more or less automatically. A separation of basic research from applied research, the autonomy of scientists in determining research agenda, and the inevitable and unidirectional stream of knowledge characterize the model. Accordingly, basic research is unconstrained by any practical or external considerations, whereas applied research is "mission-oriented" insofar as it is directed at practical objectives (Branscomb & Florida, 1998).

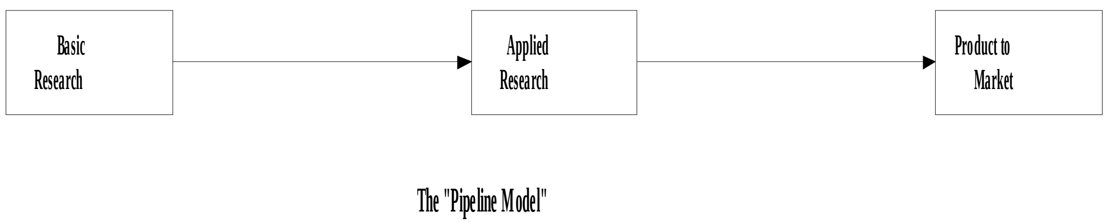


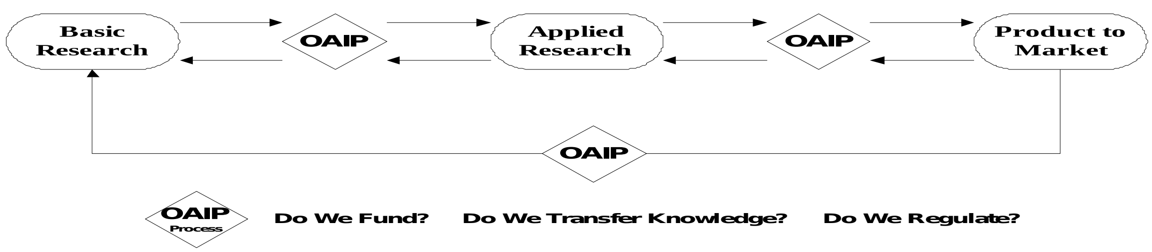
Figure 1. The Pipeline Model

The idealized account of the linear model has been subject to a number of criticism and objections. For instance, knowledge often does not "flow" in the direction dictated by the model. It is often chaotic and recursive and can even move backwards, as when technology expands scientific frontiers (Pielke & Byerly, 1998). Moreover, the model is founded on a "myth of purity" which seeks to remove any consideration of external contexts from the R&D process (Kitcher, 2001). Nevertheless, the linear model is often accurate and provides insight into vital aspects of the process, in some cases precisely because it glosses over them.

The linear model only implicitly acknowledges what can be termed "transfer points." While the Bush report emphasizes the independent stages of research, it puts subtle emphasis on the links between basic and applied, using terms such as "coordination" and "liaison." These links or transfer points are largely unpredictable and anomalous. It is therefore more accurate and useful to employ a process model that is *consistent with, but not fixated upon* a set of discrete phases. To effectively introduce ethical analysis into the course of technology development, a sound policy must identify potential points and junctures within the phases of the development process that allow for productive intervention.

Identifying transfer points requires a technology development process model less concerned with the chronology of macro stages and more sensitive to the potential of research to lead to outcomes. It is much easier to envision societal outcomes with respect to potential applications than with respect to the epistemic considerations of "pure science." Transfer points would accordingly involve any conditions in research that could influence technical decision making with regard to potential "downstream" ethical and societal outcomes. Assumptions, values, and social exchanges, as well as discoveries and enhanced capabilities, could all be considered "conditions" insofar as they influence or occasion a decision.

Often, the transfer between and among processes is seamless or fluid, occurring in the same lab or under the same general project. However, it can also be discontinuous, such as when results are applied or modified or adopted by different researchers at different times, in different projects or institutions, and sometimes without the knowledge of those initially responsible for an earlier phase or process point. Likewise, the phases of the linear model themselves can relate in ways that resist linear characterization: they may overlap, occur simultaneously, flow backwards, and take place after considerable delays. To attempt to identify possible conditions and intervention points, we suggest a grid-like scheme (See Figure 2) to identify "hot spots" based on pragmatic process considerations and outcomes significance. This scheme would seek to allow flexible invocation of analysis and dialogue at crucial intervention points.



The "Process Model" with Outcomes Assessment Intervention Points

Figure 2. The OAIP Model

Although easier to make changes in early research, it is harder to identify what changes need to be made at these stages than during applied stages. Hence, there is much talk of early intervention, but little in the way of a systematic intervention approach to existing R&D practices. We posit a two-dimensional model, incorporating general phases, similar to those in the linear model, yet with specific transfer points designated as "outcomes assessment and intervention points" (OAIPs).

With potential OAIPs identified, dialogue regarding ethical considerations can be seamlessly introduced into the practical decision-making regarding funding, regulatory implications and potential limitations on further development or transfer that routinely (though often implicitly) occurs during phase and transfer processes. Here we return to that the suggestion of creating a formal review process modeled upon the IRB model of human subjects research, but expanded to integrate ethical analysis more closely with technical processes and focused on broader post-market release outcomes.

Existing IRBs tend to be populated by scientists and administrators internal to the organizational sponsor. Since the progression of techno-scientific R&D is complex, spanning multiple unique contexts and a variety of stakeholders, NT-focused IRBs are likely to require differing structures and compositions depending on what level of the process they are addressing. For example, while "NT-IRBs" concerned with approving specific research proposals and small scale funding at the level of basic science might operate very much like current IRBs, review boards dealing with the policy level are likely to require broader representation and more flexible processes for fact finding, analysis, and reporting of conclusions. Such externally driven and broadly populated review boards might be labeled as external review boards (ERBs), and established with an operating structure and processes that reflect the larger scope of review.

Application of the Framework

We offer the ethical framework proposed above as a rough template for conducting dialogue within the system of NT development. Practical application of the framework would take the form of review boards variously designed to operate primarily internal to the institution (IRB) or externally (ERB), depending on what format is appropriate at that particular decision point. For example, initial funding of basic science in the private sector is generally an internal decision while the transfer of publicly funded and classified military technologies to the open market may involve extensive external review and policy considerations. Similarly, decisions to limit funding or regulate the development of highly controversial technological applications may occur at both the internal and external levels of review. Membership of the boards may also vary in emphasis but would always include some level of representation external to the institution, balancing scientific, engineering and business expertise with public scrutiny. The review process itself could be referred between internal and external boards as needed to mediate competing interests. We now propose formulating the ethical principles outlined above in the form of standardized questions, as illustrated in Table 2, that can be modified to inform the dialogue at any contextually appropriate OAIP. For conceptual simplicity, we envision OAIPs as being characterized by the need to answer one or more of the following pragmatic questions.

Should we provide initial or continued funding?

All techno-science development and dissemination requires the sustained investment of public and/or private funding. Initial and continued funding is routinely assessed, at multiple points, in light of technical, economic and other practical considerations. Activities that raise ethical issues could also evaluate funding at each decision point on purely ethical grounds.

Should we allow transfer of knowledge?

Techno-scientific knowledge evolves within a complex and largely unpredictable system of relationships. Every transfer of knowledge has the potential to spin off in unanticipated directions. This particular question challenges the notions that such knowledge is value neutral and that its originators are not morally responsible in facilitating its subsequent application. A decision to transfer knowledge should be made with acceptance of a willingness to remain morally committed at some reasonable level for potential applications.

Should we regulate?

This question primarily addresses potential or known outcomes that are harmful or otherwise undesirable. In this context, regulation should be defined broadly as any limitation imposed on the process, either self-imposed by individual researchers and corporate entities, or externally imposed by agents of governmental oversight. Furthermore, regulation might refer to any number of specific limitations: exploration of alternatives, requirements for strict quality control, extended testing, or even outright relinquishment of further research, development or market release.   Alternatively, the regulatory process may also be used to encourage or even reward a particularly promising line of R&D by providing incentives or lifting existing regulatory obstacles. To satisfactorily address these questions, whether in the form of a funding proposal, market release assessment or similar decision point, decision makers should have an ethically grounded rationale to complement other pragmatic considerations prior to action.

Conclusion

The proposed process, which will require testing and refinement, embodies several desirable features. It moves ethical analysis “upstream” within the techno-scientific enterprise, with an emphasis on influencing outcomes up front rather than addressing primarily negative outcomes after R&D. It also provides a starting point for common dialogue, involving a range of stakeholders, and occurring at multiple, clearly identified decision points within the system. Finally, it is based on an established model that has successfully minimized unethical practices in human subjects research.

Clearly, no amount of analysis will generate simple, straightforward answers to these questions in most circumstances; however, basic ethical analysis, using a few well crafted principles, can acknowledge the utilitarian value of technological progress and the marketplace, while also balancing the inherent self interest of those entities with the ethical obligations owed individuals and communities within the larger society. The evaluative framework we propose can take into account a broad range of activities and operations comprising technology development and dissemination. To accomplish this end requires an evolutionary process, in which a meaningful dialogue can be carried out with the disciplined and informed participation of scientists, engineers, business leaders, policy makers, societal and ethical experts, and ordinary community members, with an overriding goal of encouraging a socially responsible global perspective on NT innovation.

Given the enormous potential of NT for both good and bad outcomes, its pursuit obligates us to anticipate scenarios and mitigate potential harms by engendering creative approaches to integrating ethical analysis with technology development for the sake of the public interest. Despite the myriad challenges, critical and reflective methods applied in genuinely collaborative forums can make clear the obvious issues, tease out the more subtle ones, and identify less certain but important potentials, along with guiding action as we move into new and complex territory.

Outcomes Assessment and Intervention Guiding Questions
Principle of Respect for Communities How is human dignity served? Is there potential to violate fundamental human rights including privacy, freedom of conscience, or other basic liberties? Is there sufficient information available regarding potential outcomes for communal informed consent? Have we employed due diligence in securing a representative level of communal informed consent? Does the consent meet at least minimal standards of competence and voluntariness? Have vulnerable populations been identified and are there sufficient protections to ensure that vulnerable populations within larger communities have a meaningful voice?

Principle of The Common Good
How are the values and priorities of communities represented and served? How might the values and priorities of communities be violated or undermined? What are the potential short-, medium- and long-term benefits and burdens for individuals and communities? What are the most likely outcomes – positive, negative or neutral? What unintended outcomes can be anticipated? What is the level of risk? What limitations or safeguards are prudent to prevent negative outcomes including misuse?
Principle of Social Justice
What communities are likely to benefit? What communities are not likely to benefit? What communities are likely to experience burdens? Are one or more vulnerable populations at higher risk than the community at large? How are benefits and burdens balanced across communities and between communities? How might current social, economic and political boundaries be enhanced or disrupted? How will the balance of benefits and burdens be measured? How will those communities that are harmed be compensated? How will social and economic accountabilities be assessed and established in the event of negative outcomes?

Table 2: OAIP Guiding Questions

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