

## ETHICS

# Six Questions About Translational Due Diligence

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**To maintain stable respect and support, translational research must be guided by appropriate ethical, social, legal, and political concerns and carry out culturally competent practices. Considering six key questions concerning due diligence will enable the translational research community to examine critically how it approaches these endeavors.**

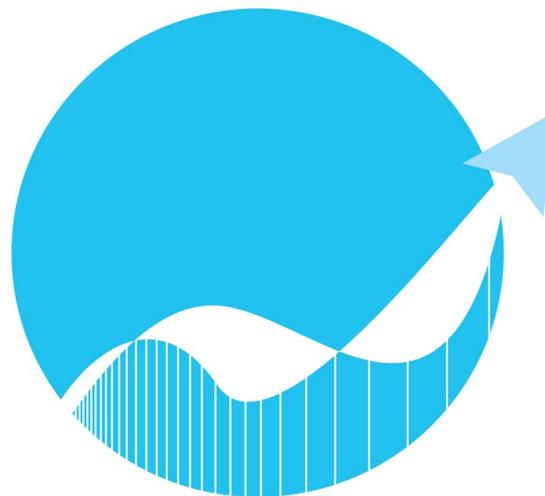
## SECURING SUSTAINABLE RESPECT AND SUPPORT

Ensuring that translational research is respected and supported over the long run requires more than the conversion of basic research into technologies that professionals can use to improve medical outcomes and the reverse translation of findings from clinic to bench. To be sustainable, translational research must be guided by appropriate ethical, social, legal, and political concerns and exhibit culturally competent behavior. Presently, educational initiatives guided by bioethics, as well as a myriad of regulatory controls and agencies, aim to ensure that the field behaves responsibly. Additionally, class-action lawyers, investigative journalists, and screenwriters shape public perception and institutional norms. Even with this potent mix of internal and external checks, it seems premature to believe that a robust conception of translational due diligence exists (1, 2). To a large extent, these responsibility-instilling efforts focus on important but well-understood territory, such as protecting informed consent, ensuring honest data reporting, and setting minimal standards for regulating professional activities and conflicts.

Are existing approaches adequate, or is a more collaborative undertaking warranted? In response to this query, I offer six questions that are based on the premise that enhanced partnerships with philosophers of technology, science and technology studies (STS) scholars (from disciplines such as history, sociology, and anthropology), and legal scholars will

prove useful to the translational research community. This utility can manifest in improved curricula, fruitful coauthored research and joint research conferences, and enhanced public outreach. My goal, therefore, is to improve translational research's capacity for a long-term and fruitful social contract.

I alone bear full responsibility for the recommendations offered in this Commentary, noting that my perspective is informed by dialogue with the participants



**Fig. 1. From research to optimism.** This logo, designed for a 2009 interdisciplinary workshop on translational research, symbolizes how research, once converted to technology, can lead to hope.

at a 2009 interdisciplinary workshop on translational research, sponsored by the Central New York Humanities Corridor Project of the Andrew W. Mellon Foundation: Daniel Kevles, Arthur Caplan, Robert Martensen, Susan Lindee, Thomas Pearson, Samuel Gorovitz, Cathryn Newton, Richard

Dees, Mark Noble, Barbara Alving, Chin-to Fong, Kelly LaMarco, and Theodore Brown (3) (Fig. 1). It also reflects my professional identity as a philosopher of technology who regularly collaborates with STS researchers.

## SIX QUESTIONS ABOUT TRANSLATIONAL DUE DILIGENCE

**First, is the translational research community making effective use of history?**

Because it is imperative to grasp the institutional, social, and cultural drivers that have facilitated suboptimal outcomes from translational research, some case studies are more valuable than others. Case studies of translational projects in which hype has not yielded promise, especially those that identify deleterious institutional patterns, thus are important to consider. Instances of tacit and explicit encouragement of researchers to engage in questionable conduct to secure research funds, research participants, and favorable research publicity also are especially salient. Such studies can illuminate a range of issues related to uses and abuses of power, including the strategies used to secure maximum compliance from different racial, social, and gendered groups. Of equal importance are case studies that give voice to individuals and communities whose hopes have been dashed by unfulfilled promises from translational research. Susan Lindee's workshop paper on the rise and fall of gene therapy for treating cystic fibrosis even suggests that it may be possible to enhance programs of planning for translational research by expanding evaluation standards to include empirically based and potentially quantifiable assessments of hope.

These case studies of mistakes, failures, unfulfilled aspirations, and tradeoff-rich outcomes will prove of little value if the translational research community interprets them merely as documentary evidence that "bad apples" and bad practices have existed. If readers of these testimonials presume that the present is substantially more enlightened, just, and less error-prone than the past, these studies will prove ineffective. For the case studies to have value, they must be tools that bridge past and present by refocusing interpretations of current activity away from overblown optimism. By drawing attention to insufficiently acknowledged persistent behaviors or threats to research integrity,

broadly conceived, such refocusing can engender a profound shift in a researcher's or administrator's imagination.

The case studies also can sharpen judgment if used as tools for translational researchers to brainstorm about alternative courses that history could have taken, paths that might have led to less suffering and greater acknowledgment of risk. I am not suggesting that exercises in counterfactual historicizing be used to allow participants to feel superior to their predecessors. Nor am I suggesting that the participants treat minimally constrained exercises in imagining alternative histories as robust models that can be appealed to to talk confidently about how things could have been. I do suggest that case studies can resonate powerfully when used to illuminate the present via the past, instilling an appreciation of analytical frameworks on which present conduct can be improved.

**Second, can mechanisms be created for nonacademic stakeholders, such as patients, to convey, in institutionally meaningful ways, their understanding of the drivers that facilitate both optimal and suboptimal translational outcomes?** I make this recommendation because there are limits that bound the expertise and experience of the professionals who bring patient concerns into the research loop. For example, no matter how capable case study authors may be, their interpretations of historical episodes typically revolve around analyses of other people's experience. As a result, case studies do not always account for crucial dimensions of personal and collective experience. Sometimes they minimize important detail, misrepresent important information, and cast other people's experience in a language that the represented parties would contest. Similarly, professionals who design patient feedback surveys and arrange group meetings do not always detect how their methods for obtaining feedback influence the type of feedback that is offered. To their credit, philosophical and STS researchers are schooled in problems of reflexivity and the patterned ways in which form structures content.

**Third, can the translational research community develop greater insight into how its standards for conducting studies, communicating with professionals and the public, securing funds, and assessing results can influence how problems and solutions are framed?** Once research communities establish standards, a

temptation often takes hold—a temptation to see rational planning as maintaining and reproducing established standards. If the translational research community adopts this perspective, it will perceive the status quo as a necessary constraint and resource and be disinclined to rethink or abandon its operational patterns. Enhanced collaboration with outsiders such as STS scholars and philosophers of technology may help the field avoid the pitfalls of insularity.

**Fourth, are translational researchers adequately identifying and addressing new problems?** Whereas the case studies that I have emphasized will help illuminate the present by calling attention to persistent problems, this recommendation emphasizes novelty and the importance of grasping unprecedented issues. The following illustrative examples all concern translations issues that STS researchers and philosophers of technology are skilled at studying.

It is important to know whether the new entrepreneurial university structure that values public/private partnerships and creating capital through intellectual property actually offers administrative conditions that permit, much less encourage, translational researchers to engage in the due diligence required to minimize harm and acknowledge risk. Additionally, it is crucial to determine whether the terms of risk conveyed through the new direct-to-consumer paradigm of pharmaceutical marketing exploit patients by treating them as experts who should be leading conversations with their physicians and requesting brand-name drugs (4). Also, it is pressing to critically review the practices that deal with the indeterminate ethical and legal status and unclear policy implications of new biological objects, such as those created with transgenic animal technology (that is, asking what new biological objects should be created, what purpose they should be put to, and how to confront the challenges they pose to conceptions of property), and the large-scale processes of manufacturing doubt against scientifically credible evidence, especially in cases in which public health is compromised by industry executives who prioritize profit over public safety and collaborate with unscrupulous scientists and lobbyists to achieve their goals (5, 6). And it is imperative to determine whether translational operations pose a risk to ethical deliberation by producing a technological end-run around normative discussions, as has been alleged, for example,

by critics who view enthusiasm for altered nuclear transfer (a means of producing human pluripotent stem cells—the functional equivalent of embryonic stem cells—without generating or destroying human embryos) as enthusiasm for using technology to reframe and potentially bypass the complex ethical issues raised in the embryonic stem cell debates (7).

**Fifth, are members of the translational research community engaged sufficiently with humanities and social science scholars who study knowledge and technology transfer in nonmedical contexts?** Such cross talk with other fields can be a valuable tool for confronting problems that are central to translational research. For example, philosophical discussions of technology transfer have shown how difficult it can be to anticipate the cultural barriers that may prevent one group of people (such as people in developing countries) from adopting or optimally using technologies that other groups of people (such as people in developed nations) have put to seemingly good use (8). Likewise, philosophical discussions of the reasons why African countries reject genetically modified foods, despite leaders of these nations receiving assurances from Western scientific experts that the food is safe, illuminate why different perceptions of risk exist and why technical risk assessment can play only a minor role in personal and policy decisions related to health (9).

**Finally, is the translational research community making a sufficient effort to imagine new conceptions of translational research that are not bound to bench-to-bedside images?** Although judiciously chosen images and metaphors can help to motivate innovative and effective practices, poor ones can create unintended and undetected meanings. They can constrain perceptions exhibited by leaders and ordinary practitioners alike, inclining both to lose sight of important problems and misjudge progress toward identified goals. Crucially, determining how visions should be expressed falls outside the scope of any single field. STS and philosophical input can be especially helpful in this context, especially for determining whether the concept of “translation” evokes detrimental associations. Although some communities may find it apt, others might be dismayed by Euclidean connotations. They might associate translation with rigid motion and a specified direction. From this perspective,

it may appear that insufficient opportunity exists for canceled or thoroughly revised research projects to count as good translations, even when valid ethical and political reasons underlie such outcomes. Such perception could exist because the Euclidean connotations may be interpreted as suggesting that only one outcome can count as a good translation: rigid motion over all opposition that leads to the development of technologies that are specified early in the research process.

For translational research to fulfill its promise, critical responses to the questions I am raising need to exert substantial influence on institutional cultures. For example, if curricular change ensues and the “halo effect” of good press about an institutional

embrace of “ethics education” is the only result, acceptance of my recommendations will probably prove worthless. Without connecting robust reflection to structured organizational change, the translational process risks substantial damage to its social contract.

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