Restoring and Preserving Trust in Biomedical Research

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Abstract

Recent media depictions of the dangers of biomedical research have fueled public and regulatory scrutiny of academic research institutions. The authors argue that if these institutions are to preserve the trust that the public has historically bestowed upon them, they must go beyond mere compliance with regulatory mandates. Several steps are suggested that institutions can take to strengthen and supplement ongoing compliance efforts, steps the authors believe will bolster the public’s confidence in the integrity of academic research institutions. These steps grow out of the authors’ analysis of three key components of institutional trustworthiness: (1) shared goals between research institutions and the communities they serve, (2) robust institutional oversight of research activities, and (3) training programs that build professional character. The authors’ recommendations include the use of research advisory councils to assure the public that research goals reflect community interests, more collaborative relationships between institutional review boards and members of investigative teams, and educational programs that emphasize the importance of professional integrity in biomedical research. These efforts will help preserve public confidence that an institution’s research priorities are appropriate and that the research it conducts is ethical. Preserving this public trust is central to the long-term success of biomedical research and the institutions in which such research takes place.

These are important times for institutions involved in biomedical research. Compelling financial and professional incentives to conduct research with human subjects have increased public scrutiny of academic institutions and placed tremendous strain on the ever-fragile consensus regarding the ethics of research.1,2 Recently, these concerns have been fueled by media coverage of the tragic deaths of two participants in research, a young man participating in a gene-modification study at the University of Pennsylvania and a young woman involved in an asthma study at Johns Hopkins University. These two incidents have drawn attention to a number of systemic problems reported in recent government reviews of the regulatory system for research involving human subjects.3,4 In light of these developments, it is not surprising that federal regulatory agencies have toughened their stance with research institutions regarding compliance with existing regulations governing human-subjects research.4,5 Gone is the time when government and the public unhesitatingly trusted research institutions to serve as responsible advocates of the public welfare. Research institutions are now searching for ways to restore and preserve public confidence in biomedical research.

Given the reality of increased government oversight and greater scrutiny by the public, it behooves research institutions to search for ways to preserve and build public trust that biomedical research is conducted responsibly and that the academic institutions wherein much of this research is conducted are responsible advocates of the public welfare. Despite the recent developments leading to greater regulation and scrutiny of research, the scientific community continues to occupy a position of tremendous influence and authority. The perspectives of this community, its ways of knowing, its goals and values, all predominate in medicine and biomedical research. This extraordinary influence is emblematic of the trust that historically has been bestowed by the public on the research community and the institutions where its members work. But do investigators and the institutions where they work deserve this trust? What are research institutions doing to promote and reinforce that trust?

Many institutions’ answers to these questions consist of little more than references to compliance with federal regulations. In this article, we explain why mere compliance with federal regulations reflects a minimal concern on the part of an institution with matters of ethical research. We argue that if institutions hope to inspire public trust and confidence, additional actions are required. If such efforts are not made by institutions to preserve and foster the public’s trust and confidence, investigators may find it more difficult to recruit participants for their studies, and federal oversight of research may become more burdensome. Such developments would result in the delay or loss of the benefits of research. Consequently, how research institutions respond to public and government concerns about the conduct of research is critical. As stated above, we believe that the common institutional response to this decline of public confidence, namely, greater compliance with federal regulations pertaining to the conduct of research, while important, is of limited value in preserving and building public trust. With their heavy focus on informed consent and risk minimization, these federal regulations are limited in scope and thus do too little to inspire the public’s trust. The degree of public support for and confidence in the research enterprise is a direct reflection of other considerations, high among them being the degree of trust the public has that research priorities are correct and that research practices are ethical. Thus, it behooves research institutions to search for additional ways to bolster the public’s trust in their research mission and activities.

We illustrate how this can be accomplished by discussing three distinct
but complementary components of institutional trustworthiness: (1) how research institutions and their investigators determine what should be studied, (2) how oversight mechanisms ensure that research is conducted in a morally appropriate manner, and (3) how investigators are trained to conduct responsible research. These three components of trustworthiness merit attention from research institutions because whether people trust physician investigators and the institutions where they work largely determines whether they will volunteer to participate in research. We argue that a broad institutional focus on the three elements of institutional trustworthiness described above more fully reflects the moral landscape of contemporary biomedical research than do institutional efforts that are limited to compliance with federal regulations. If we are correct, then institutions need to begin to view the restoration and preservation of trust as comparable in importance to regulatory compliance.

The Components of Institutional Trustworthiness

As we discuss each of the three components of institutional trustworthiness, we avoid review of specific institutional policies, such as those designed to identify and address conflicts of interest or obligation. We focus instead on delineating several broader institutional reforms that promote trustworthiness by creating mutually respectful relationships between research institutions and their constituents, relationships based upon shared goals and ongoing collaboration. Institutions may implement a variety of activities at the local level to establish these institution–constituent relationships that inspire trust. Since our suggested reforms involve institutional efforts, they differ from other proposals, which rely primarily on individual actions, external accrediting organizations, or professional societies.

Shared research goals: setting research priorities

The goals of biomedical research—the relief of suffering, the advancement of knowledge, the preservation of life, and the promotion of human well-being—are goals that research institutions share with the supporting community. Since these shared goals justify the social resources dedicated to research, it is important to include community perspectives in deliberations about research priorities. This is especially so since a basic tenet of medical professionalism is that health care professionals “engage with the public in negotiating social priorities that balance medical values with other societal values.” According to this tenet, responsible research advocacy implies that the prioritization of research areas within an institution should not be chosen at the sole discretion of the institution or its individual investigators. Rather, in working to serve the public welfare, institutions should regularly consult members of the broader community regarding their research.

One way for institutions to assure regular community consultation is to establish a research advisory council whose members are drawn from both inside and outside the institution. Key leaders in the institution who are responsible for and knowledgeable about the organization’s research should be among those who represent the institution on such an advisory council. Community council members should be selected from among the institution’s various constituencies. Research sponsors, both public and private, should also be represented on such councils. Members of an advisory council can be selected according to a variety of criteria, but minimally these criteria should include the following. All members should care about the public welfare and the role of biomedical research in promoting that end. No member should be so closely wedded to any one particular research need or problem that he or she would be unwilling to negotiate the values that frame research priorities or the numerous potential research initiatives competing for resources. Finally, all members should be deeply committed to the notion that research ought to be conducted in a responsible manner.

If community advisory councils are to be effective, institutional administrators and institutional council members should not view community members as cheerleaders or uncritical champions of the institution and the research conducted there. Rather, because of their shared vision regarding the value and conduct of research, institutions must encourage and permit the active participation of community council members in discussing and shaping research goals and activities. This will require the institution to adopt a degree of humility and to believe there is something useful to be learned about the research enterprise by soliciting input from its constituents. If council members do not find within the institution a spirit of openness and a commitment to be held accountable for institutional research activities, convening an advisory council or some similar collaborative process will prove to be little more than window dressing gained at the expense of the participants’ time, efforts, and commitment to serve the public welfare.

We recognize that institutions face difficulties implementing a meaningful collaborative process and making the transition from institutional insularity to active community collaboration. There are many powerful forces at work that influence what specific research gets done at an institution. Research advisory councils will have limited capabilities to counteract these influences. The most powerful of these, of course, is funding. Industry, private foundations, and government sponsors fund most biomedical research done today, and they typically work directly with individual investigators rather than institutions to conduct their research. Nevertheless, sponsors and investigators still require compliant institutions as well as a compliant public in order to conduct their research. So, institutions and the communities they serve are not powerless to shape research practices unless they choose to be so.

We further recognize that if an institution is to fully embrace a research advisory council or some similar collaborative process, risks are involved. Where industry-sponsored human-subjects research establishes financially lucrative ties between an institution and a corporate sponsor, but does little to serve the public welfare, community advisory councils will likely wrestle with the appropriateness of using human and institutional capital to serve corporate goals. While not all industry-sponsored research is of this sort, the investigative community ought not underestimate the threat that industry-sponsored research can pose to its integrity.
advisory councils will likely be very sensitive to this threat, especially since all research expends the good will, trust, and resources of the supporting community. In its worst form, using public trust and resources to advance private interests borders on exploitation and erodes rather than builds trust. Consequently, councils may determine that some industry-sponsored research exacts a high cost to the institution that exceeds the revenue that the research generates.

The presence of an active research advisory council will invite rather than deflect greater scrutiny of industry ties, and institutions must be willing to permit such scrutiny and heed the advice that results from it if a collaborative process between the institution and its community is to thrive. Such a process can serve as a counter, even if it might be a modest one, to the financial clout of research sponsors. That is why we believe it is worth it in the long run for institutions to accept these challenges and fully embrace research advisory councils or some similar collaborative process. The partnership that will result will ensure that no one loses sight of the fundamental fact that all biomedical research uses other people’s time, money, and bodies. Those who offer their bodies as clinical laboratories for research do so because they believe that the sacrifices they make on behalf of the common good will in fact serve the common good. A successful partnership will promote public confidence in the research enterprise by reassuring laypersons that the public welfare, not institutional prestige or financial gain, is the principal beneficiary of the institution’s research efforts. This assurance is essential to building trust between the institution and its constituents.

**Robust research oversight**

It is also essential that the public trust that they will not be treated like guinea pigs in clinical investigations; this reminds us that in every aspect of biomedical research there is a fundamental duty to treat research subjects with dignity and respect. Informed consent has emerged as the accepted sign of respectful treatment of research subjects, with investigators and institutional review boards (IRBs) having acquired the primary institutional responsibility to ensure that informed consent to research occurs. Institutional consent practices have their limits, however. Numerous studies question whether the obtaining of permission to conduct research by having subjects or their surrogates read and sign informed consent forms truly signifies that individuals have volunteered, based upon the information with which they have been presented, to be research subjects in investigational studies. These findings suggest that while current informed consent practices may be useful in gathering information relevant to informed decision making, they frequently are ineffective at conveying that information to prospective research participants and thus assuring voluntary consent. Hence, neither IRBs nor research institutions should presume that signed consent forms guarantee that research subjects are true volunteers. Instead, IRBs need to pay more attention to the capacity of members of investigative teams to inform research subjects about the nature of their research and alternatives to participating in it as well as their capacity to assess subjects’ understanding and consent. IRBs might routinely require study recruiters to assess subjects’ understanding by having those who want to enroll in a study verbally explain the purpose, risks, and benefits of the study as well as their options besides that of enrolling in the study. They might also encourage the use of educational strategies that have proved effective at conveying information to patients and research subjects, such as the use of video recordings and computer programs.

Despite the limitations of informed consent documents, scrutiny of such forms, along with consideration of risk minimization and risk-benefit assessment, occupies the bulk of IRB deliberations. Yet there are other equally important requirements for the ethical conduct of research. Seven essential ethical requirements, adapted from major codes and declarations relevant to medical research, recently have been set forth in a framework for evaluating the ethics of clinical research. In addition to matters related to risks and informed consent, these requirements address social value, scientific validity, subject selection, independent review, and respect for subjects of research trials. Some of these, such as the scientific validity of proposed studies, fall beyond the scope of most IRBs’ deliberations. For others, such as subject selection and respectful treatment of participants, IRBs are often poorly positioned to oversee their practical application and implementation. Consequently, if each of these requirements of ethical research is to be met, IRB members and others within the institution must put forth additional efforts to assure the public that research subjects are treated with the full measure of respect they are due.

With the increasing number of government mandates being placed on investigators and IRBs, this change will be difficult to achieve, but the mandates themselves accentuate the need for the change. Anyone familiar with the transformation of IRBs over the last several months as well as with much of the literature about IRBs is aware of the primary emphasis on protecting research subjects from risks. This emphasis on protectionist concerns obscures other salient ethical dimensions of research and in the process creates an inappropriately narrow focus of IRBs, a focus at odds with a more robust understanding of the fundamental ethical dimensions of research: respect for persons, beneficence, and justice. A primary concern for protection from risks creates a tendency to reduce the demands of respect for persons to an obligation to disclose risks, to reduce the demands of beneficence to an obligation to minimize risks, and to reduce the demands of justice to an obligation to fairly distribute research risks.

While IRBs are institutionally positioned to prompt a broader emphasis on the ethics of research if they are provided with adequate financing and expertise, they cannot do it in isolation from those who conduct the research. This is especially true when one considers that IRB members, compared with members of investigative teams, may have limited understanding of the most ethically salient aspects of many clinical investigations if they lack adequate familiarity with unique clinical and other characteristics of a given research project. Although IRB members by and large are very familiar with the general ethical framework for the responsible conduct of research, ethical deliberation and decision making requires bringing these general considerations to bear on specific questions that arise in specific settings. No IRB has comprehensive scientific and clinical representation. Astute
investigators, on the other hand, can be very knowledgeable about the ethical challenges embedded in a particular study. Hence the need for strong collaboration between investigative teams and their IRBs.

Such collaboration can be difficult to achieve, since the IRB is viewed by many investigators as an entity whose approval is an obstacle to be overcome rather than a group of research colleagues whose counsel is valuable. Consequently, until there is a climate of regular communication and collaboration about specific investigations among members of the investigative team and the IRB, neither the IRB nor the investigators can fully discharge their obligations to complete a thorough ethical review of research activities. This is true even when institutional educational programs about the ethics and regulation of research with human subjects are in place and comply with existing federal mandates. In order to foster this collaboration, IRBs need to have members with research ethics expertise that goes beyond an understanding of research regulation, and they need to make these members available for consultation with investigative teams. In this way, IRBs can play an institutional role similar to that currently played by clinical ethics committees when they conduct ethics consultations.

When ethically challenging research issues arise, expert IRB members can foster moral deliberation and provide “hands on” ethical counsel. This consulting role is critical because when IRBs work closely with individual investigative teams, they promote the public’s trust by establishing a climate of moral deliberation within the institution regarding its research enterprise. Joining moral circumspection with the intellectual curiosity of research scientists assures the public that the institution is interested not just in doing good things, but in doing them in the right way. Thus, these activities promote public confidence in research in a much stronger way than is possible when institutional efforts are limited to mere compliance with federal mandates.

**Training responsible investigators**

Most institutions that conduct biomedical research simultaneously train the next generation of investigators. To continue to warrant the public’s trust, new researchers must be trained as responsible investigators, i.e., researchers who conduct investigations with both scientific and ethical rigor. Recognizing this, the NIH has recently augmented its longstanding requirement that its trainees have access to education in research ethics. While we are in agreement with this development, we believe that compliance with this new mandate is insufficient to ensure that the next generation of researchers will be adequately trained in the ethics of research. If research ethics education is to be effective, it is important that this educational focus be experienced by students as an integral part of their professional training. Standalone courses or lectures, while they may satisfy sponsor-mandated training requirements, are insufficient for building and maintaining professional commitments to the integrity of research. To assure the public’s trust, it is essential that junior investigators learn why research with human subjects must be conducted ethically and how this is done. This requires training programs to mentor students to acquire the virtues of self-effacement and self-sacrifice so that they will learn to habitually set aside personal interests in professional advancement for the sake of their research subjects. Such training will not stifle development of the predominant professional characteristic of wanting to investigate hypotheses so as to generate new knowledge. Instead, it will join with this characteristic a willingness to discontinue research investigations when their continuation would require compromising the ethical tenets that assure trustworthy science. Such willingness reflects the acquisition of the requisite virtues and characteristics. These are acquired over time through education, through careful mentoring, and with experience; hence the need for a longitudinal, multifaceted emphasis on professionalism and ethics throughout biomedical training programs.

Changes that have occurred over the last few decades in the way science is conducted also support the need for this emphasis. Biomedical research today is highly sophisticated, requiring a variety of discipline-specific skills and creating a division of labor for the successful completion of research. The consequence of this division of labor is that most research is conducted by teams of researchers, frequently at different geographic locations. As a result, no single team member is intimately familiar with all the evidence in support of the findings of the team. Rather, team members believe what is reported to them from colleagues, illustrating how important trust is in gathering, reporting, and interpreting data. In the absence of such trust, it is impossible to derive any conclusions. Thus, trustworthiness is not only an ethical requirement of research; it is an epistemologic requirement of modern science.

**From Institutional Compliance to Informed Trust**

Responsible research is best described as a joint partnership that seeks to improve the public welfare through a better understanding of human health and disease and that treats those who participate in the enterprise with the full measure of respect and dignity they are due. This partnership is characterized by notable asymmetries of knowledge and power as well as of privilege and vulnerability. Often joined with these asymmetries are tempting and pervasive conflicts of interest, all existing in institutional settings frequently characterized by the decentralization of institutional power and oversight. The many disparate elements of this partnership are held together by trust. Hence our contention that the creation of institutional processes that promote and preserve trust ought to be a central focus of research institutions.

Investigators and others who work for biomedical research institutions can take pride in being part of an enormously valuable effort that has enhanced human well-being by mitigating the effects of human disease. It is the public that is the beneficiary of the ever-growing capacity of medicine to extend the duration and quality of human life. It is important to remember, however, that the public has also been an essential contributor to this success. Without volunteers, this research would never have occurred. And the funds for much research are public ones. We believe the public should and will continue its support of research, provided institutions create opportunities to promote the public’s informed trust.

We are not the only commentators to recognize the importance of trust for the
future of biomedical research. Many organizations have recently signed a “reaffirmation of trust between medical science and the public.” We think researchers and institutional officials should take care in signing such declarations until they have established institutional processes along the lines of those we have described. Although these kinds of statements are intended as a signal to the community that biomedical institutions consider themselves trustworthy, such declarations may prove counterproductive. More than anything else, they may null institutional leadership into believing a declaration alone signifies that they are already deserving of the very trust they need to actively seek.

Affirmations and declarations mean nothing if they are not backed up by a meaningful institutional commitment to promoting public confidence in research. Trustworthiness is an accomplishment, not a pronouncement. If it exists, it is embodied in the daily actions of the institution and its members. This in turn requires that an organization take time to deliberate about whether it is in fact trustworthy and whether it is doing what it ought to promote and preserve that trustworthiness.

**Conclusion**

The public must trust that research priorities sufficiently reflect social priorities if they are to be expected to support research. Research participation is based on the assumption that the goals of the investigator (and supporting research institutions) coincide with those of the subject and the public at large. This trust is also based in part upon public confidence that appropriate oversight of research occurs, that researchers are accountable to their colleagues and their research subjects, that safeguards are in place to prevent unnecessary harm from befalling research participants, and that there are oversight mechanisms in place to reduce and address mistakes of judgment if they should occur. Additionaly, trust is founded upon assurance that investigators are persons of exemplary professional character who inspire confidence and respect. Since the findings of research are only as reliable as the trustworthiness of scientific investigators, the development of virtuous researchers is a critical part of an institution’s commitment to bolstering public trust in biomedical research.

The adoption of institutional processes such as those we have described will reflect a broad and deep interest in promoting the informed trust of the public in research. Strong and consistent advocacy for research that promotes the public welfare, the use of oversight mechanisms to create a culture of moral deliberation regarding biomedical research, and the training of new investigators with a keen sense of professionalism all demonstrate to the institution’s partners in research that the institution has an abiding commitment to advance the public good in an ethically responsible fashion. These activities serve not only to secure but also to promote the trust essential to the research enterprise. Conversely, institutions that limit their efforts to mere regulatory compliance, with a narrow focus on protecting the public from harm rather than a broader focus on promoting public welfare, place the future of the research enterprise at risk.

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