

RESEARCH MISCONDUCT AND THE SCIENTIFIC PROCESS: CONTINUING QUALITY IMPROVEMENT

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The response to research misconduct involves the attempt to regulate behavior through (a) creating and enforcing a rule and (b) ethics education. The roles of each must be shaped by considerations of the nature of scientific practice. Given the nature of science, the role of (a) must be limited in scope: both in the types of behavior it covers and in the level of intent that must be present for an allegation of misconduct to be proven. Since one important role of ethics education is to fill the gaps that regulatory rules leave open, it is this limitation in scope and its source in theoretical concerns that better reveals the type and kind of education needed. It is argued that much of the current ethics education falls short. Since the gaps left by the rule are largely due to theoretical concerns about the very nature of the scientific process and the nature of that process is constantly evolving, ethics education must focus more heavily on theory and must reach a wider audience. It is argued that ethics education can be more effective if it aims, in part, in creating a discipline-specific, constantly evolving scientific standard of care.

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Throughout the 20th century, the theoretical and experimental success of science made notable contributions that had a profound technological influence ranging from health care services to the commercial value of new products. This success, along with the perceived objectivity of science (its aiming at objective truth), gave the scientific community newfound authority. Impressed by this authority, the public demanded solutions to new, even more complex problems and was willing to pay for them. The scientific community responded; the research enterprise, its funding, and the complexity and scope of its product (scientific knowledge)

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grew at incredible pace (NAS, 1992). The implications for society grew as well. The growth and direction of science now has greater economic implications; effecting the distribution of goods and services, job growth, and wealth. It has implications for academia; for the staffing of labs, training opportunities, and funding for various scientific disciplines. It has implications for those who use and consume the products of research as well as those who participate in or pay for the research. It has increasing global implications. Thus, concerns of government, funding agencies, universities, businesses, interest groups, and the general public (stakeholders in science) lead each to have their own ideas about what research to fund, how to fund it, and the extent of restrictions placed upon it, and this has implications of vital importance for the direction of science and for those who practice it. For example, the very direction of scientific research, influenced by the “ear-marking” of funds and the push for more interdisciplinary research, has led to the creation of new scientific disciplines and has profoundly affected those who practice in others (NSF, 2003). Thus, there is a growing circular relationship between the scientific community and other stakeholders in scientific research; scientists (what they do and how they do it) greatly affect stakeholders, but increasingly and in response to these effects, stakeholders are greatly affecting the scientific enterprise. Recently, the National Science Foundation (NSF, 2003) sponsored a workshop called “Research Policy as an Agent of Change.” While the idea that research policy has implications for the way science is practiced may seem platitudinous, when one thinks deeply about how complex this is — its implications for society and the moral, political, and practical concerns this raises for the scientific community — one can get overwhelmed.

This article addresses one such aspect of this complex circular relationship; research misconduct and its goal of assuring scientific integrity. In recent years, there has been much discussion about this topic. It has become clear that scientists have fraudulently collected or reported data, exaggerated results, or otherwise practiced “unscientific” procedure. Such behavior, in addition to compromising the research enterprise, has had harmful effects on the stakeholders in scientific research and thus demands to regulate the behavior of scientists grew. One response to these demands has been to demarcate and define

unethical research behavior and on the basis of those definitions, regulate and assess scientific practice and the behavior of scientists. Another response is to require education in various aspects of ethical behavior, including that connected directly to the integrity of science. Both responses have a role to play in the shaping of misconduct policy and questions of just what the roles are (where the first response ends and the second begins), are part of this significant discussion.

Clearly, whatever policies are created to address scientific integrity will greatly affect the way science is practiced and given the circular relationship, this will have effects on the concerns of stakeholders. This makes discussions of appropriate research policies unquestionably political. Indeed, the ability of scientists to insulate their discipline from politics is becoming increasingly difficult. Yet, the concerns are not only political. Some questions of research policy also have a theoretical and practical component, which actually makes the political component even more significant. There is a clear connection between some unethical behavior that threatens the integrity of science and scientific methodology or standard scientific practice. Thus questions about how to regulate science in response to questions of scientific integrity have profound moral, political, practical, and theoretical implications for the scientific community.

I will argue, as many have, that the definition of research misconduct in the federal guidelines must be limited in its scope: covering only fabrication, falsification, plagiarism (FFP) despite numerous other unethical behavior that might threaten the integrity of science and covering only cases where the intentions of scientists can be proven (that they engaged in FF or P knowingly, intentionally, or recklessly) rendering some negative behavior, perhaps done negligently, unregulated. I will show that this limitation of scope is necessary because a definition of misconduct cannot properly include any statement of the details of scientific method. Given the necessary limitation in scope, though, the federal guidelines governing research misconduct still leaves oversight and regulation of the integrity of research open to considerable controversy. There is much behavior that affects the integrity of science not regulated by the definition. Surely this is problematic.

It has long been suggested that the shortcomings of a regulatory definition of research misconduct be dealt with by ethics education. But given the important connection I will show between integrity and the scientific method, I would suggest that the scope and kind of such current education in science is lacking. I suggest that ethics education and its subsequent effect on behavior can be more effective if one of its central aims is to create an ever-evolving standard of care to evaluate and better understand the procedures followed by scientists. Such a standard of care, which bears some analogy to Tort Law, will fill the gaps of the current definition of research misconduct. Indeed, I will argue that the definition itself calls for such a standard of care; it has aspects that are open for interpretation and without some consensus the chances for applying the definition and upholding integrity successfully are diminished.

Integrity, Community Standards and Torts

Behavior that might undermine the integrity of scientists, the scientific community, and indeed the process of science has commonly been separated into two main categories. Some unethical conduct (which is not the subject of this article) is not unique to the conduct of science or not tied to the scientific process. Such behavior, referred to in the literature as “other misconduct” includes inappropriate relations with research subjects or clients, inappropriate or unauthorized authorship, and publishing data or results in two or more publications. For good reason, these kinds of misbehavior were separated from those that fall into the other main category; those directly related or unique to the scientific process. It is with this second kind of conduct that this article is concerned.

Clearly, many questions about ethics or integrity in science are related to questions about scientific methodology (appropriate/sound scientific procedure). Science has the overall goal of advancing human knowledge by obtaining and discovering objective truths; facts about the world independent of human interests, values, ideologies, and biases (Resnik, 1998). Scientists aim to reach this goal through a particular community accepted, discipline specific process called the *scientific method*. Each of the

steps of this method, if done correctly and honestly, help reach the aim of justification and hence, the epistemic goal of discovering objective truth, which increasingly has implications for the well-being of society. Yet, if these same steps are done incorrectly or dishonestly, the goal is undermined and harm to others and to the integrity of the research record may occur as a result. Of course, speaking of a scientific method implies some rigid set of rules clearly articulated and understood by those who engage in it. This, I discuss below, is not the case. Nonetheless, there are principles and rules that should govern the conduct of scientists because they make scientists more successful in pursuing their cognitive aims (Resnik, 1996) which, in turn, helps protect many stakeholders from harm. Many of the ethical standards in science then are directly related to the process of science; to whether the concepts and principles most successful in pursuing cognitive aims were followed correctly and honestly or, as I will describe it, whether community standards of behavior were met. The scientific method, it seems, represents a standard of behavior gross violation of which can lead to sustainable loss or harm to others.¹

Given the increasingly stronger relationship between scientists and its stakeholders, this type of behavior (behavior that falls below community standards of scientific methodology) has potential and real negative effects; many stakeholders sustain a loss or harm as a result of such behavior (Kionka, 2005) including economic loss and, sometimes, physical harm, in addition to stifling the growth of science and effects on the reputation of the scientific community, funding agencies, and the institutions at which scientists who engage in such behavior work. Following appropriate scientific method (community standards) then can be seen as both a professional and moral duty for all researchers to uphold.

¹Of course, there are questions as to how specifiable and stringent such methodology really is; and this is precisely what this article addresses. There is some behavior that clearly and uncontroversially violates standard methodology. Yet there are others that are questionable. This is because scientific methodology is not a step-by-step affair; and science needs creativity to thrive. Thus we will argue that any regulatory definition of research misconduct must be limited to behaviors that clearly and uncontroversially violate standard protocol and other more controversial, potentially problematic behaviors must be dealt with by ethics education.

Indeed, in some cases, “good science” means both ethical/moral science *and* rational, epistemically justified, or competent science.

Moreover, the main characteristics of gross breaches of behavior related to scientific conduct bear much resemblance to the main characteristics that must be present for a breach of Tort Law; namely, that there is a breach of a duty on the part of a person to engage in behavior according to a community recognized standard and such a breach has a harmful effect on some person(s). There are some characteristics here that would make research misconduct different from torts, namely that damages/harms are more speculative than tangible (e.g., misconduct harms more directly the “scientific record,” as opposed to necessarily or directly damaging government property or causing physical harm) and the individual victims of a deceptive or “fraudulent” scientific practice may be difficult to identify (Kulynich, 1998). This is one reason why rules governing misconduct in research should not and cannot be handled directly by the legal system, although particular acts may be prosecuted under some other more general criminal statute. But the similarities between some misconduct in science and Tort Law surely point both to the need for some way of regulating and controlling such behavior (some way of assuring the integrity of the scientific process thereby also protecting stakeholders from some potential harm) and to the fact that a proper response to such a need might be to create a rule that, similar to Tort Law, speaks to community standards of behavior. This represents in part the current approach, I will argue. However, not everyone believed this response was necessary.

Prior to the 1980s, the integrity of the scientific process was left primarily up to scientists. The scientific process, it is argued, has a built-in three-pronged mechanism (replication, refereeing, and peer review by the larger scientific community) that effectively weeds out faulty or fraudulent science without the need for explicit standards that Congress wanted to articulate. Many scientists argued that these internal mechanisms (the three Rs) were largely effective. Most scientists understand and respect standard methodology and any breaches of such standards of behavior are rare (the result of a few crazy, ill-minded, or reckless scientists) and easily detectable by the three Rs. Some people, it was argued, are bad seeds and deliberately or recklessly deviate from acceptable and knowable scientific method.

Yet in the early 1980s, publicized cases of egregious violations of scientific methodology and other standards of behavior played a significant role in challenging the authority of science in this regard. Stakeholders, now more affected than ever by science, demanded to know why the government, which spends billions of taxpayer dollars funding research, had yet to formally demand accountability from the scientists it funds. Many argued that the internal mechanisms were no longer effective in the face of major changes the scientific community has seen, ironically due in some measure to pressures generated by the stakeholders of science. The incredible growth of science and the pressure of competition rendered keeping up with the field (peer review) difficult and time for adequate refereeing inadequate. The push for new material by journals and the competition for funds took away incentive for replication. Moreover, even if instances of misconduct are rare, given the increasingly significant relationship between science and society, such instances have the potential to do more significant damage. Thus, many argued, the significance of misconduct lies not in its prevalence, but in its effects on public health, public policy, and the scientific enterprise. Clearly, gross violations of scientific standards have the potential to cause harm to society and thus must be dealt with effectively. Something was needed to replace the waning of the three Rs. And without an attempt by scientists to find a suitable replacement, the government (likely pressured by other stakeholders) reasoned that it would have to define standards that govern professional conduct in science and on the basis of those norms develop regulations to help assure public safety and the appropriate use of tax dollars.

The approach, then, was to create a rule to be followed by scientists and enforced by some regulative body (NAS, 1992). But this approach was not without controversy. This is because there are generally three important considerations or goals when creating any rule aimed at defining and regulating standards of behavior and disagreements often occur as to whether a particular rule successfully reaches those goals. One goal is that the law or rule created is compatible with community standards of fairness. Another is that the rule acts as a deterrent which serves to make society safer. A third goal is to create a rule that can be fairly and effectively administered; a rule too cumbersome or difficult to understand/apply fairly cannot be effective in regulating behavior (Kionka, 2005). In the next section, I will explain the political,

practical, and theoretical concerns these goals raise for the attempt to create a rule of research misconduct to regulate the behavior of scientists. These sorts of goals, prevalent in shaping Tort Law, also affected the nature and kind of rules governing integrity in science and as a result, helped shape the role of ethics education.

Integrity and Theory: Delineating the Role of Rules

The fundamental goals to be reached by regulation or rules resulted in the creation of two distinct categories of unethical behavior related to the scientific process. Research misconduct is defined now by the federal guidelines as encompassing only FFP:

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest errors or differences of opinion. A finding of research misconduct requires that there be a significant departure from accepted practices of the relevant research community, and the misconduct be committed intentionally, or knowingly, or recklessly, and the allegations be proven by a preponderance of the evidence. (Federal Register, 2004).

Of course there is other problematic conduct related to the scientific process not covered by FFP. Such behavior is referred to as “questionable research practices: actions that violate traditional values of the research enterprise and that may be detrimental to the research process” (NAS, 1992). Questionable research practices include what is often referred to as misrepresentation of data, which is the failure to truthfully or objectively report data or results. Examples of misrepresentation include trimming (where one leaves out data that doesn’t support one’s hypothesis), cooking (where one designs experiments/tests to obtain results they already suspect will be positive), and fudging (trying to make results appear better than they are (Resnik, 1998)). These questionable research practices raise the same concerns as FFP with respect to integrity in research and the potential for harm such violations raise, yet the rule meant to help assure integrity in research does not include them. Why should this be? This should be, I will show, because attempts to formulate a definition that includes these other questionable research practices cannot be done in a way that successfully meets all of the general standards or goals of a rule mentioned above.

One way to include behavior that violates scientific methodology beyond FFP into the research misconduct definition is to adopt a definition that includes the “other serious deviations” clause (OSD); the claim that misconduct not only includes FFP, but also *other practices that seriously deviate from those commonly accepted within the scientific community for proposing, conducting, or reporting research.*² Earlier suggestions about how to define research misconduct that included this “other serious deviations” clause *may* have covered such questionable practices, thereby widening the culpability standard (the conditions under which a scientist may be considered guilty of failing to live up to the standards of methodology and hence, performing unethical science).

The debate over the inclusion of the “OSD” clause in the definition of research misconduct was unquestionably political. As Jennifer Kulynych (1998) explains, the debate over culpability “may serve to mask policy disputes between agencies over how and to what extent the federal government should intrude on the practice of science.” Inclusion of the “OSD” clause widens the culpability standard. Under such a definition, institutions responsible for upholding it would have to define what the standards of science are in order to determine whether a practice is a significant deviation from them. This gives government agencies great control over the scientific process and the scientists who engage in it. A more minimal culpability standard (in this case limiting research misconduct to FFP) significantly limits this control.

But this debate is not only a political one. It is also a theoretical one in that the clause seems to presuppose a more objective, rule-based view of the nature of the scientific method; there is an accepted, articulated and well-understood norm on which scientists generally agree and from which scientists might grossly deviate. Despite its seemingly normative implications, some, like Donald Buzelli (of National Science Foundation) (Buzelli, last accessed July 2006), claim that the “OSD” clause gives people charged with upholding integrity flexibility or discretion in determining culpability; it both widens and limits culpability in the appropriate ways. In other words, a rule including this clause seems to be more successful at reaching some of the aims of having such a rule in the first place than those that do not include the clause.

²From the Public Health Service (PHS) version.

One such aim is for the rule to act as a deterrent which makes society safer. A definition with the clause may initially seem to be more successful at reaching this aim because it widens culpability to include practices that do not necessarily fit into the FFP formula but which nevertheless threaten the integrity of science and (potentially) the safety and welfare of stakeholders. By widening the definition of misconduct in this way, scientists will be more cognizant of the way they practice science beyond merely FFP and thus the well-being of society and the scientific record will be better maintained. Another aim is for the rule to accord with community standards of fairness. Inclusion of the clause (worded as suggested) may meet such an aim in that it precludes conduct that is not “serious” from being subject to intense scrutiny and/or sanctions. Some actions, while unethical, are not serious enough to threaten the integrity of science (or to cause harm to other stakeholders).³ A definition that allows too much scrutiny of scientists’ behavior is surely not fair in that it undermines the professionalism and autonomy of the scientific community too much.

Yet not everyone agreed that including this phrase in the definition of misconduct would satisfy this goal. In addition, many argued that it fails to meet the third aim of a rule mentioned above; namely, that it be characterized in a way that enables it to be fairly and effectively administered. Although the “other serious deviations” clause was never meant to apply to novel ideas in science, many scientists argued nonetheless that the clause *could* result in “misconduct complaints [being] lodged against scientists based solely on the use of novel or unorthodox research methods” (NAS, 1992). The clause seems to project the idea that standard scientific methodology can be clearly expressed and is greatly understood. But this misguided view about the nature of the scientific process, many feared, might stifle the creativity that often lies at the base of important paradigm shifts in science. It may lead us to mistake innovation for unreasonable behavior. A classic example involves the sun centered model of the solar system. Copernicans were well aware of evidence that might seem to refute their view: the absence of detectable stellar parallax. If the earth really moves around the sun, then heavenly bodies should *not* seem fixed on the celestial

³This, too, is analogous to Tort Law, in that not all “unreasonable” behavior is subject to legal action or sanctions; only unreasonable behavior that results in harm.

background, but should appear at different relative positions from season to season. Such parallax could not be detected even by Tycho Brahe's sophisticated 17th century observatory. So to account for the experimental 'refutation,' Copernicus and his followers proposed the hypothesis that the stars were at practically infinite distance from the sun (resulting in practically infinitesimal seasonal angles of displacement). This ad hoc postulation is not consistent with the stricter sort of rules sometimes supposed to guide science. And it may have even seemed, at the time, to be counter to prevailing community methodology. Surely, though, we don't want a rule that can be used to stifle such innovative thinking. There is, many argue, a strongly creative aspect to concept formation, theory construction, and theory testing that does not follow specifiable and clearly articulated scientific methodology that the "other serious deviations" clause seems to presuppose.

Thus, we can see the debate about the nature of science (theoretical concerns) underlying the discussion of culpability in research conduct. Including this phrase seems to project the idea that there is some well-understood and clearly-defined scientific standard of behavior from which a scientist might deviate. Yet adopting a definition that projects this will create problems if science requires more creativity to thrive. If the norms of science cannot be so clearly articulated, the prospects of applying a rule that appeals to general methodology fairly and effectively are undermined. And the integrity and autonomy of the profession might also be undermined, as regulatory bodies (not the professionals) will determine whether behavior exemplifies creativity or a gross violation of scientific methodology. Thus, it seems, theoretical concerns (ideas about the very nature of science or the scientific method) preclude having a definition of misconduct that satisfies all three goals effectively. To the extent, in this respect, that the definition is fair to professionals and effectively applied/enforced, it is less effective as a deterrent. And to the extent that we widen culpability in the attempt to create a rule that is a more effective deterrent, success at reaching the aims of fairness and effective application is undermined.

Another source of debate about how to define research misconduct concerned the honest errors/differences of opinion clause (which is still part of the definition); *research misconduct does not include honest errors or differences of opinion*. Including this clause

forces us to focus heavily on the intentions of researchers in assessing their conduct, which establishes a narrow standard of culpability. If the definition includes this phrase, actions constituting research misconduct must have been taken with the intent to deceive. Including such a phrase about state of mind, in addition to being political, also has theoretical implications. There is inherent recognition in this clause that the norms of scientific conduct are not so stringent so as to disallow differences in interpretations of data. And they are not so simple and straightforward so as to disallow honest mistakes. In other words, the less stringently objective view of the scientific method makes it harder to “determine whether a person is falsifying or misrepresenting data or whether the move is a legitimate (though perhaps unorthodox) scientific practice. Since the line between deception and disagreement is quite fuzzy, the best way to distinguish between dishonesty and disagreement is to focus on the researcher’s motives” (Resnik, 1996). Thus, inclusion of this phrase helps the rule to achieve the aims of adherence to community ideas of fairness and ease of application.

But, many argued, as in the debate about the “other serious deviations” clause, we reach those aims at the expense of the aim of deterrence and society safety. Surely not all actions related to the scientific method that threaten the integrity of science and have the potential to harm are done with intent; with the desire to cause certain immediate consequences (Kionka, 2005). Some actions are done negligently; where no intent to cause harm was present at all, but rather the scientist was thoughtless or incompetent in that he paid no attention to the requisite standard of care that a reasonable scientist would heed. Failure to include negligence in the definition of misconduct limits its scope and thus undermines its effectiveness as a deterrent. Including negligence (not limiting misconduct to instances where intent can be proven) would result in making scientists more careful in proposing, engaging in, and reporting research. A scientist would be negligent if s/he was inattentive to standards of behavior that the prudent scientist would exemplify. This argument gets some impetus by examining some cases appealed under the proposed definition of misconduct endorsed by Public Health Service (PHS) which, due to the honest errors clause, seemed to limit culpability to intentionality.

Consider the case of Dr. Rameshwar Sharma, a researcher at the Cleveland Clinic Foundation, who submitted grant applications

to the National Institute of Health (NIH) that he later conceded contained erroneous information. (This case is recounted in Kulynich, 1998.) Such information gave the impression that he had research data that did not exist at the time the application was submitted which served to strengthen his application and increase his chances for funding. Although admitting that his application contained errors, Dr. Sharma drew on the honest errors clause as a defense; his errors, he claimed, were inadvertent typographical mistakes and did not constitute intentional misconduct. The Cleveland Clinic, agreeing with this interpretation of the PHS definition and seeing no way to prove intent, exonerated Dr. Sharma. But OSI officials disagreed, arguing that perhaps intentional misconduct could be inferred on the basis of a pattern of false statements and his failure to amend his application when the errors were first brought to his attention by a supervisee. Upon a finding of research misconduct by OSI, Dr. Sharma appealed. And lawyers meant to supervise the appeals process to assure it is fair suggested that OSI officials did not fully appreciate the difference between intentional and unintentional misconduct implied by the Public Health Service (PHS) definition. ORI officials (by this time OSI had been reorganized) then attempted to shift to a negligence standard of culpability, arguing that Dr. Sharma had breached his duty of care by submitting an application with such errors. But it was ruled that a definition that includes the honest errors clause did not allow for negligence as constituting research misconduct.

This seemed, to many, to be a problem with the PHS definition. To be more successful at the aim of deterrence, inclusion of negligent conduct seems warranted. After all, violations of standard protocol have the same potential to harm whether done with intent or not. Yet doing so has theoretical implications. As we have seen, negligent behavior requires an assumption of a clearly articulated and well-understood standard of care that should be recognized by all scientists. Expanding state of mind seems to indicate that the standards of scientific practice can be clearly articulated; there is some standard that all scientists should know, understand, and use to guide scientific choices. The nature of scientific justification and good scientific process is known and good scientists will understand it and are responsible for acting within it; ignorance of the method is no excuse. Surely, carefully proofreading grant submissions (and other scientific work) for typographical and other errors and,

indeed, failing to report errors once they are discovered, is part of the standard of care in science and thus, failing to do so constitutes negligence. And a definition that fails to cover such negligence seems to be seriously lacking in its effectiveness as a deterrent.

But adding negligence to the rule governing research misconduct would be problematic in other cases, particularly those dealing more directly with theory selection or other interpretations of data. It would be problematic for two reasons. First, most scientists, presumably, practice what they believe is good science with the best of intentions and yet, given the complexity of its method, honest errors can occur. Surely, we don't want a rule that allows us to accuse scientists of misconduct every time an error has occurred, claiming that they should have tried harder and been more aware of "true methodology." Such a standard would be too high. Moreover, disagreements among scientists do not even necessarily indicate possible error. Scientists can legitimately disagree about what constitutes adequate justification or interpretation of data. Thus, including negligence in the rule of research misconduct would require that we find some way of determining which actions are honest errors, which are legitimate interpretations of data or justification of theory selection, and which were the result of negligence. But this can only be done by appealing to some clearly articulated and easily understood community standard. In other words, to prove that some harmful act was the result of negligence, we would have to prove that the act was in violation of "usual or customary conduct or practice of others under similar circumstances" (Kionka, 2005). But if breach of usual or customary methodology is necessary for science to thrive, then including negligence in such a rule would have negative implications for scientists.

Clearly, any attempt to widen culpability to include states of mind other than intent will, given the true nature of scientific methodology, render the rule governing behavior of scientists too hard to apply fairly and effectively. Adding negligence will result in our trying to identify the distinction between scientifically significant errors, honest errors, egregious violations of standard theory selection or data interpretation, and legitimate differences of opinion. And this requires a more objective, clearly articulated, static idea of scientific methodology than anyone believes is possible.

The final definition of research misconduct clearly limits culpability by requiring proof that the scientist had the requisite level

of intent or a certain state of mind. But it tried to find a better balance between the three fundamental aims of a rule by adding a statement that misconduct might be alleged not only when committed intentionally (with the intent to cause harm), but also knowingly (acting with awareness that the conduct will likely cause harm) or recklessly (being conscious of the risk of harm and yet choosing to proceed in spite of such awareness). Such an extension of state of mind might cover cases like the Sharma case without overstepping its regulatory force. Failure to report errors immediately upon discovery surely constitutes reckless behavior. Deciding with the best of intentions that a data point is a true outlier (even if it isn't) is not.

What the Rule Leaves Out: What Role Education Must Fill

Because of the nature of scientific methodology and our understanding of it, a rule governing research misconduct (to the extent that we are cognizant of its fulfilling the aims of fairness and applicability) will be limited in fulfilling the aim of being an effective deterrent. As a result, the federal definition of research misconduct still leaves oversight of research conduct by the scientific community open to considerable controversy. It does so in several ways.

First, there is controversy over when behavior actually constitutes falsification and this is directly related to ideas about the nature of science itself. Determinations of falsification ("bad" data interpretation) cannot be made by looking at the definition alone. Thus, there are important questions as to how to apply this definition in practice, for behavior that at least lies on the border is somewhat prevalent among scientists. For example, in a recent poll published in *Nature* (Martinson et al., 2005), 15.3% of US scientists admitted to dropping observations or data points based on a gut feeling that they were inaccurate (behavior that some might think constitutes falsification) while .3% admitted to falsifying outright. By far, the most common accusation of misconduct that results in an investigation involves falsification. It accounted for 43% of all misconduct investigations by ORI between 1993 and 1997 (Office of Research Integrity, 1998). It is probably so high, in part, because sound scientific procedure defies explicit codification.

This concern was raised long before any attempts were made to explicate poor science in terms of a rule, in the case of Robert Millikan. (This explanation of the Millikan experiments excerpted

from www.onlineethics.org.) Millikan won the Nobel Prize in 1924, largely due to his experiments aimed at discovering the charge on the electron. Did all electrons have the same charge? Or did electrons come in a variety of charges? To measure the charge of the electron, Millikan observed ionized droplets of oil fall between two plates. The speed of the droplet depends on the charge riding on it. Based on his data, Millikan suggested that all electrons had the same charge.

Millikan wrote a series of articles on his experiments, which he believed exemplified irrefutable proof of the atomicity of the electron charge. Yet, an examination of Millikan's own articles and notebooks reveals that he exercised discrimination with respect to which drops he included in his articles. Sometimes he mentioned data he left out, and sometimes he did not. Of particular concern is the fact that in one article, presenting the most complete account of his measurements of the charge on the electron, Millikan states: *It is to be remarked that this is not a selected group of drops but represents all of the drops experimented upon during 60 consecutive days* (Millikan, 1913). However, Millikan's notebook shows that of 189 observations during the period in question, only 140 are presented in the article.

On the basis of these "discrepancies", Felix Ehrenhaft, of the University of Vienna, contested Millikan's findings. He claimed that he found "subelectrons" or electrons with charges of different values. Moreover, he claimed that Millikan's own data (data left out of the final analysis) confirmed this. This resulted in a long controversy over whether or not electrons had different charges.

This controversy makes an excellent case study because Millikan kept stellar notebooks. We can thus see what data was left out of the final analysis. Scientists and other scholars disagree on whether Millikan was guilty of unethical behavior in the treatment and presentation of his data. Some condemn Millikan for publishing a statement that is obviously at odds with what can be concluded from an uncritical examination of his laboratory notebooks. Others exonerate Millikan on the basis of a careful analysis and interpretation of comments on the data that appear in the notebooks. They assert that Millikan's claims that all drops were presented in the article refers to all of the data taken under those conditions when the apparatus was working properly. Some scientists "appear to permit Millikan much discretion in the use of his "scientific intuition" to decide which data to include or exclude. This latter view seems to

be guided by the principle that any scientist who consistently gets what turns out to be the correct answer is doing *good science*.”

As this case shows, scientists can rationally disagree about when it is appropriate to disregard data or whether the statistical analysis used was appropriate. Making judgments about such allegations of cheating require the very interpretive considerations (namely, ideas about proper scientific methodology or standards of behavior) I have argued is not properly placed explicitly in the definition of misconduct. Yet, clearly, successful application of this rule to possible cases of falsification seems to require some agreement on or explication of standards of data selection and interpretation. Indeed, the rule of research misconduct seems to tie these sometimes hard to determine acts to “significant departures from accepted practices of the scientific community.”

The second shortcoming of the rule of research misconduct, as I have shown, is that at least some science independent of FFP is not “good science” (in terms of method and hence in terms of ethics) and should be weeded out before it has a chance to negatively effect stakeholders. In fact, the results of the same study mentioned above, “suggest that U.S. scientists engage in a range of behaviors extending far beyond FFP” and that “to protect the integrity of science, we must look beyond FF and P to a wider range of questionable research practices.” For example, over their career, 15.5% of scientists polled admitted to changing the design, methodology, or results of a study in response to pressure from funding sources. Thus, although the definition of research misconduct must be limited to FFP for reasons I have discussed, promoting integrity in research requires that we encourage and discourage many behaviors that lie outside FFP.

Third, while honest error is not (and should not be) within the scope of scientific misconduct, error can be a very “serious offence, since it can yield the same consequences as dishonesty in that an honest mistake can lead to deception as easily as intentional fraud” (Resnik, 1996). Thus, while the federal definition of research misconduct is what it needs to be, it still leaves the scientific community with some gaps to fill. Successful implementation of the rule and future promotion of integrity rests largely in the hands of scientists.

It is precisely these gaps and limitations of the rule of research misconduct that the role of education is meant to fill. Thus, as I see it, ethics education needs to aim at three main

goals. First, it should augment the rule of research misconduct and other rules governing the behavior of scientists in research by educating scientists about them. Second, it should aim to help scientists to successfully apply the rule of research misconduct—particularly in cases of alleged falsification. Third, it should aim to augment the rule by focusing researcher’s attention on and understanding of other behaviors (those beyond FFP and errors) that affect the integrity of science and the safety and welfare of stakeholders. The question is whether the current approach to such education successfully meets those needs; is the current education (referred to as RCR) designed in a way that enables it to fulfill the roles I have just suggested it needs to fill? I believe that it does not and I will make a suggestion of how we might change the approach to ethics education so that it does.

As I see it, successfully reaching the second and third goals mentioned above requires a better understanding of the standards of scientific practice. To reach the second aim of successfully applying the rule of research misconduct to alleged cases of falsification, we must better understand the standards of practice of the relevant research community. To successfully reach the third aim, we must do the same as many practices that fall outside the scope of FFP are tied to scientific procedure and errors in scientific practice might be limited if scientists were more explicitly aware of their expectations and exercise due care in trying to reach them.

Augmenting the Role of Current Ethics Education

As was revealed in the discussion above, we cannot expect a rule to clearly articulate an agreed upon standard of scientific behavior in order to cleanly distinguish between good and problematic scientific practices. Yet a greater understanding of good scientific practice is necessary for upholding integrity and I believe possible. Even if no tribunal is appropriate for questionable scientific practices that lie outside FFP or even for making determinations as to what cases the definition is applicable, there may be good means of sensitizing scientists and science students. In any case, I will argue that it is time for scientists to begin considering their own “standard of care” as a means of augmenting the definition of research misconduct by augmenting the now often unsuccessful three Rs and that such a standard of care should be a fundamental aim of ethics education. What

I am suggesting has many similar qualities to the legal concept embodied in Tort Law of a standard of care; for example, in medicine. But it also has significant differences. For example, I am not suggesting it as a legal concept for science since I believe (and we can probably learn from medicine and from my discussion above) that regulation is much better, more effective, and efficient if it comes from within rather than without. Despite this significant departure, I believe that the analogy to law is quite helpful. All persons by law have a general duty of ordinary care; a Standard of conduct required by society for the protection of its members. Members of particular professions like medicine have their own standard of care: Standards of conduct required by society but defined and maintained by the relevant profession for the protection of those greatly affected by it. Similarly, I am suggesting that scientists have their own standard of care: Standards of scientific conduct required, defined, and maintained by the relevant scientific community for the protection of the research enterprise and those affected by it. And I suggest that scientists create, maintain and define this standard of care through more stringent, wider reaching, and deeper ethics education than is currently taking place.

National Academy of Sciences (NAS) suggests that the best way to assure scientific integrity is by integrating ethics into the education of scientists. I agree with NAS that ethics education is fundamental. But because I see that a major role of education as filling the gaps left behind by rules like that of research misconduct and because of the intimate connection between the nature of the scientific process and scientific integrity, any successful education will get scientists to think deeply about the very process in which they are engaged. Good ethics education, to successfully meet the goals described above, will foster discussion about the scientific process that will aim at increasing understanding of it. While there are often disagreements about theory justification, data selection, and other standard scientific practices, there is also profound agreement as to what counts as valid, sound research practices. Scientists must think deeply about these and articulate them to the best of their ability so that errors can be avoided to the greatest extent possible, determinations of true falsification can be made, and unethical behavior related to scientific practice but not encompassed by FFP can be monitored, discovered, and understood.

So while NAS and the federal government suggest that scientists be trained in several areas including responsible authorship, data

management, and mentoring, I believe that training in thinking about the scientific process itself is indispensable for starting to establish the hard to define norms needed to effectively implement the definition of research misconduct and assure scientific integrity beyond it. For example, current education stresses (or should stress) that researchers not make exaggerated claims about what their data supports. Surely, this is important for scientific integrity. Yet many training programs do not go deeply enough into this issue. Identifying what makes a claim exaggerated (or unjustified) depends on what constitutes adequate justification. And in science, justification is procedural. It is the outcome of a process. Thus, good ethics education will include discussion of the process to help scientists to better identify just what constitutes an exaggerated claim. It will, in other words, aim at establishing a wide-reaching but discipline specific standard of care. Scientists need to reflect more explicitly upon the methods for analyzing and resolving issues, and this includes focusing on and articulating the process in which they are engaged. Coupled with the holding of workshops that talk about the ethics of scientific practice in what is often a rule-based way (e.g., don't exaggerate your results, use appropriate statistical methods of analysis), this form of education would have the aim of getting at the heart of those rules by discussion of their theoretical underpinnings. This deeper understanding would aim at fostering the standard of care for the community. Discussion of how the scientific process justifies decisions about methodology, interpretation and theory choice needs to take place. While the creative aspect of science bars any clearly articulated, static standard of care, even the most ardent subjectivists in science believe that the scientific process has built-in, shared criteria on which to base decisions. These should be the focus of education.

Thus, more effective ethics education should involve discussion over the appeal to values or norms governing good scientific practice; those characteristics scientists seek in theories or the values good theory exemplifies. Among the shared values that influence theory choice in science are accuracy, scope, simplicity, and fruitfulness. These values, as Kuhn explains, "specify what each scientist must consider when reaching a decision, what he may or may not consider relevant, and what he may be legitimately required to report as a basis for the choice he has made" (Kuhn,

1979). Values like these help generate limits on what constitutes good theory choice in science. And yet recognizing the importance of these values does not result in rules too stringent, for scientists have great latitude in defining and ranking them.

Explicit discussion of these values and their influence on theory choice should be part of ethics education, but good education will not limit scientists by picking one interpretation or ranking as the supposed best. This would stifle creativity. Education should aim at gaining a better understanding of the scientific process and other standards of scientific behavior, but at the same time it should be stressed that creativity and values are part of the nature of science and thus the standard of care is neither wholly objective nor static. Ethics education should stress being open to alternative ideas and understanding that rival theories must be tested, that testing takes time, and this requires tolerance for diverging opinions.

Not only must the nature of ethics education be changed in order for it to fulfill its role, the scope of our current education must change as well. Most scientists (just as most doctors) “learn the various traditions, methods, and values of their practices in academic research groups” (Resnik, 1998). But because the procedures, treatments, and knowledge of disease in medicine are constantly changing and evolving, the medical community realizes that such education cannot end when graduation occurs. Likewise, since science and its methods are constantly evolving (especially in the newer disciplines), the education of scientists about what constitutes adequate justification and good sound procedure must continue beyond the academic setting. It must also encompass a wider range than within small academic laboratories. The kind of standard needed is a community standard; and although this will differ among different scientific disciplines, each discipline should itself continually work to define and redefine its own standard of care.⁴

Creating a standard of care enables a medical doctor to ask: “Is this treatment plan consistent with what the reasonable cardiologist would do?” In understanding the general duty of care, a person who is thinking of getting into a car after having a few

⁴This is important and likely necessary. Working for the Online Ethics Center, the author of this article visited several departments helping to lead workshops on research ethics. Great disparity was found among different labs within the same academic disciplines regarding the handling of many ethical issues.

drinks can ask: “Is this decision consistent with what a reasonable person would do?” Likewise, in aiming at a better understanding of the scientific process and hence the scientific community’s version of a standard of care, the scientist will be able to ask: “Does the claim I am making reflect the kind of judgment that a reasonable scientist in my community would look for?” Successful ethics education will go well beyond topics like the treatment of research subjects, the environmental effects of scientific practice, and FFP to include a focus on understanding how scientific justification and methodology can be controversial and when it is not.

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