



## Discussion forum

# Principled research ethics in practice? Reflections for neuroethics and bioethics

John R. Shook<sup>a</sup> and James Giordano<sup>b,c,\*</sup>

<sup>a</sup> Philosophy Department and Graduate School of Education, University at Buffalo, Buffalo, NY, USA

<sup>b</sup> Neuroethics Studies Program, Pellegrino Center for Clinical Bioethics, Georgetown University Medical Center, Washington, DC, USA

<sup>c</sup> Department of Neurology, Georgetown University Medical Center, Washington, DC, USA

In his objecting to methods employed by Institutional Review Boards (IRB), Jonathan Baron (2015) argues for a strict utilitarian approach – the only ethical system that he regards as actually ethical and systematic. Baron states that utilitarianism can and must: (1) consider only the actual goals of individuals affected, and (2) apply “best informed judgments” about probabilities of achieving those goals, and in these ways, prioritizes “equal sympathy for our fellow beings.” By implication, he adds, any other decision procedure(s) can be seen as duplicative, ignorant and/or unethical. Baron argues that IRBs too frequently impose unnecessary harms, not merely because they introduce inefficiencies out of ignorance, but mainly because their principled demands cannot meet utilitarian standards.

As directly relevant to neuroscientific and neurological research, the field, theories and practices of neuroethics are important to consider in light of Baron's assertions against bioethics. It is the case that neuroethics cannot be satisfied by the received tradition of medical ethics given new challenges from emerging neuroscientific techniques and neurotechnologies. Medical ethics has been dominated by Western medicine's normative notions of the “Moral Individual,” what counts as “Standard Health,” and concerns for the “Autonomous Patient” (MISHAP). In light of medicine's track record, its virtue ethics eventually had to achieve some compromise with deontological demands of legal rights and utilitarian management of scarce resources (Baker, 2013; Emanuel et al., 2008; Stark, 2012). Compromise and mutual adjustment can be intelligent, so long as it goes deeper than compartmentalized oversight. Bioethics can seek a more unified theoretical basis,

and neuroethics should partner in that effort, since neuroethics should neither dutifully “apply” received ethical theories one by one, nor consider itself solely as a dimension of medical ethics (Shook & Giordano, 2014).

Baron (2006, 2015) has little patience for bioethics. For judgments upon medical research, Baron expects “medical decision analysis” (MDA) to serve as the properly utilitarian methodology. However, this expectation isn't wholly consistent with his generic definition of utilitarianism: neither the subjects of research, the researchers, nor the many who may be affected by research are fully taken into account by MDA. Subjects of medical research have a variety of achievable goals besides those relating to disease, physiological and psychological functioning, reducing pain, forestalling death, and so on. Researchers are not only seeking professional goals of advancing biomedical knowledge and improving the lives of current and future patients, they are also pursuing career, status and personal goals. Furthermore, depending upon the research, many currently living (and future) persons will have interest in the progress of research. Why should the non-health goals of research subjects, the personal and professional goals of researchers, and the vital interests of so many other persons be arbitrarily left out of account? Does MDA fallaciously violate utilitarianism?

We do not believe that generic utilitarianism can guarantee ethically satisfactory results, either. It does stand ready, perhaps more so than any other ethical theory, to sacrifice the interests (and even the lives) of medical research subjects, depending on circumstances and probabilities. Baron isn't committed to that result; he could argue that rule utilitarian

\* Corresponding author. Neuroethics Studies Program, Pellegrino Center for Clinical Bioethics, and, Department of Neurology, Georgetown University Medical Center, 4000 Reservoir Road, Washington, DC 20057, USA.

E-mail address: [james.giordano@georgetown.edu](mailto:james.giordano@georgetown.edu) (J. Giordano).

<http://dx.doi.org/10.1016/j.cortex.2015.03.017>

0010-9452/© 2015 Elsevier Ltd. All rights reserved.

considerations should protect research subjects and patients from large risks and harms by evaluating broader research goals or public interests. Lessons learned from hard experience teach that act utilitarian judgments can differ from case to case, are sometimes able to sacrifice the few and the vulnerable for the sake of the many, and can often be counter-productive in the long run. Researchers are not immune from hubristic rationalizations imposing huge risks upon others in the name of science and imagined benefits for future generations. As a result, the willing participation of subjects, and public approval towards medical research, may both be diminished, which is far from an optimal long-term outcome.

Even if “best judgment” upon a particular case's merits do lean toward requiring great sacrifice, we are restrained by evidence from past tragedies, and by the “known unknowns” that are fostered by research – and particularly that which engages cutting-edge neuroscience and technology – on voluntary subjects, even if restraint isn't generated by sympathy toward the subjects themselves (Giordano 2014). Rule utilitarian's distinctive advantage over act utilitarianism, as noted by R. M. Hare (1981), is its capacity to factor in the fallible and finite intellectual resources of deliberators, and to give due respect to the wisdom of inherited principles as valuable information unobtainable by a lone living generation.

That said, let's agree, again for the sake of argument, that MDA's principled exclusion of broader goals of biomedical researchers, and long-term health interests of the public, is warranted by these sorts of rule utilitarian considerations. Yet, the public surely has meritorious goals besides the pursuit of improved health, quality of life, and prolonged life, and subjects themselves have various goals besides those that are intrinsically related to health. Generic utilitarianism should factor in those interests, producing another rule utilitarian result that matters such as dignity, autonomy, coercion, and privacy cannot be ignored. Does MDA include rules restricting medical research that unduly risks or harms these individual values? Apparently not; this too does not bode well for generic utilitarianism.

Here, let us consider Baron's example of protecting privacy. Is his complaint that IRBs shouldn't be trying to protect privacy so much because MDA wouldn't protect privacy to such an extent? Or is his claim that MDA would do a better job of protecting privacy? If the former, why should MDA enjoy privileged, utilitarian status, since MDA is inherently unable to fully factor in the actual goals of individuals' privacy? If the latter, then Baron's claim that MDA can best determine how to protect privacy on a case-by-case basis could be seen as a relapse into act utilitarianism, as his example displays.

These are not the wholly objective, factual matters that Baron depicts. How much risk to privacy is acceptable, and how much risk is worth trading for other values, is a highly normative and perspectival matter without solution by reduction to any set of facts, deduction from some intricate formula, or resolution by consultation among only like-minded researchers. Similarly, what counts as coercive manipulation is a complex matter that is not always easily or uniformly not reducible to what strikes a researcher in a wealthy country as coercive. The vulnerable are susceptible to kinds of inducements, intimidations, and coercions that can often be (almost) inconceivable to those of relatively

privileged status (Hawkins & Emanuel, 2008). Rule utilitarianism can handle better-informed evaluations of harmful and disrespectful treatments of persons no matter their place in the world. That is why well-informed and duly sensitized deliberations by rule utilitarianism often support principled rules that are nearly indistinguishable in real-world practice from inviolable moral principles and human rights.

We opine that Baron's stance needs rule utilitarianism to prevent generic utilitarianism from yielding unethical decisions, and to prevent act utilitarianism from justifying hasty, ill-informed, and parochial decisions. Concession to rule utilitarianism carries obligations to respect the way that it cannot simply approve case-by-case judgments made by professionals bearing special interests and statuses. Indeed, rule utilitarianism warrants civic structures and institutions protecting a large set of principled priorities, even as it continues to foster reasoned debates over how precisely to rank their priority and handle potentially burdensome – if not harmful – trade-offs.

Biomedicine's promulgation of its own professional ethics and set of virtues is laudable. Yet, we believe that these ethics and virtues are inadequate in many ways, and unenforceable by the profession alone. Medicine and medical research should not be at liberty to do as it deems best unless and until halted by legal inquiries and/or injunctions; the many egregious violations of human welfare and dignity within living memory bear witness to this fact. The medical profession cannot ensure that full knowledge of ethical standards is universal across the profession, much less any of its sub-professions such as biomedical research. To be sure, there is not even profession-wide agreement about which ethical standards take priority, or what they mean in real-world situations. Amalgamations of moral platitudes, vague guidelines, and legal requirements, such as the American Medical Association's Principles of Medical Ethics, do not constitute serious ethics in theory, nor ensure compliance in practice.

Biomedical research is too complex and multi-faceted to be asked to comply with short guideline lists, yet, despite significant attempts (see for example, Cahn & Markie, 1998; MacFarlane, 2008; and for review, Resnik, 2012), it lacks a sophisticated virtue/role ethics. Furthermore, its rule utilitarian drive to maximize overall health for people in general (whether current patients or not) will invariably clash with other utilitarian principles. For example, the rule utilitarian protection of the independence and autonomy of persons will not consistently cohere with a rule utilitarian drive to maximize health. The obstructionism which Baron laments isn't just the fault of deontological decrees; the collision of parallel utilitarian rules is sufficiently obstructive.

Rule utilitarians needn't agree among themselves after all their calculations of long-term expected utility, because decisions must first be made about what counts as relevant benefits and harms. Is the way that many of the vulnerable may die in the service of greater public health for coming generations going to count as an increase to the positive-value of their lives, or as a negative-value denigration of persons into mild servitude? Does the way that the vulnerable can be mildly coerced or under-informed count as a serious harm to persons, to be weighed in? Expecting formulaic calculations to speedily resolve research ethics cases is to wield prejudged answers.

But this is by no means a clear victory for rule utilitarianism. Rule utilitarianism in theory will at best produce systems of inter-related priorities that are irreducible to simplistic laws, while its application to individual cases will take the form of formulaic dictates that are insensitive to nuance and context. Still, such systematicity and rigidity provide two significant utilitarian benefits. First, researchers will have to learn about, and duly follow, many ethical guidelines while planning research, rather than relying on vague platitudes or haphazard advice from other researchers. Second, only “on the ground” and *de facto* enforcement of ethical principles during the planning and conducting of medical research is sufficient to ensure that many important rule-utilitarian goals are simultaneously satisfied, or at least not egregiously ignored and violated. This Ethical Research Control (ERC) is necessitated by strictly utilitarian expectations.

Biomedical research should be truly experimental and visionary. Yet the ongoing regulation of all aspects of medical research, whether for immediate practicality or eventual preparedness, is simultaneously important. Rule utilitarian trade-offs are necessitated by compromises between separate rule-utilitarian priorities and principles. Yes, biomedical research will be somewhat slowed and occasionally obstructed, and lives may be lost that could have otherwise been saved. By contrast, those “optimized” act utilitarian verdicts of the sort posed by Baron might appear to be more clean and clear-cut, but this is because only a few people (or perhaps even a single individual) is setting the rules and keeping score. Let us not forget that utilitarianism can devolve into narrow concerns that fail to acknowledge or respond to the richness of context(s). Tempering this possibility involves full considerations of such contexts and the effects that trade-offs will exert upon the various strike- and share-holders of any decision(s) that are made.

We support Baron's legitimate concerns about deleterious ways that IRBs in practice can fall short of satisfactory ERC expectations. However, we do not believe that this warrants abandoning ERC for a simple MDA alternative. Biomedical research serves – and can achieve – a host of potential goods, both as a scientific enterprise and as a constituent and contributory domain of the field and practice of medicine. Certainly, it can produce new knowledge and methods to mitigate and/or prevent disease and the effects of trauma. Thus, it can benefit both current and future patients. In this way, it is also a public and social good. As such – and as a facet of medicine, biomedical research is both directly and indirectly yoked to obligations for authenticity and non-wastefulness (May, 2003).

Research also affords individual goods that are of professional and personal value to researchers. Each and all of these goods must be acknowledged in deliberations over the scope and conduct of a study. The multidisciplinary constituency of an IRB reflects the diversity of perspectives necessary for the tasks of evaluating the benefits, burdens, risks, harms and conduct of a research endeavor. Medical researchers alone cannot execute such monitoring and decisions, notwithstanding impressive borrowed formulas, for the utilitarian reasons described. As Baron notes, medical research cannot reliably fulfill its aims when overtly external academic or

legalistic monitoring is adversarially or inefficiently executed. ERC should be conducted responsibly and visibly, accessible to the public eye and democratic deliberation, as a process continually undergoing evaluation and adjustment. Respect for the cultural diversity of human self-understandings, and its inquiries into our robust capacities for moral self-reflection, lends an optimistic boost to neuroethics – and by extension, bioethics (in broader contexts) as improvable and publicly responsible fields (Giordano, 2011; Giordano & Olds, 2010; Shook, Giordano, & Galvagni, 2014).

We support Baron's views that IRBs must be open to additional and improved methods of ethical deliberation and that decision-analyses should be pragmatic and prudent. Biomedical researchers should have a contributory role in the elaboration of ERC and the improved performance of IRBs; as should lawyers, ethicists, and to some extent, the public, and this contribution should reflect insights to the pitfalls of both excessively narrow internalization (e.g., as subject to the “pushing forces” borne of self-serving interests, whether from science or scientists) and diffusely broad externalization (e.g., as subject to inappropriate external pull or constraints, from economic markets, politics, etc.). Systematic rule utilitarianism can't assign monitoring to any single profession such as medicine or law, or an interdisciplinary field like neuroethics and/or bioethics. Rather, we claim that the current pace, applications, and extent of biomedical research – and particularly that in the neurosciences – is such that the professions have little choice but to work together. If they cannot, statutes written by politicians will be the default enforcer without moderation from the expertise and wisdom of the professions responsible for the scope, tenor and effects of the research undertaken.

---

## Acknowledgments

This work was supported in part by the William H. and Ruth Crane Schaefer Endowment, the Children's Hospital and Clinics Foundation; and funding from the Pellegrino Center for Clinical Bioethics of Georgetown University Medical Center (JG).

---

## REFERENCES

- Baker, R. (2013). *Before bioethics: a history of American medical ethics from the colonial period to the bioethics revolution*. Oxford: Oxford University Press.
- Baron, J. (2006). *Against bioethics*. Cambridge, MA: MIT Press.
- Baron, J. (2015). Some fallacies of human-subjects protection, and some solutions. *Cortex*, 65, 246–254. <http://dx.doi.org/10.1016/j.cortex.2014.11.004>.
- Cahn, S., & Markie, P. (1998). *Ethics: history, theory, and contemporary issues*. Oxford: Oxford University Press.
- Emanuel, E. J., Grady, C., Crouch, R. A., Lie, R. K., Miller, F. G., & Wendler, D. (Eds.). (2008). *The oxford textbook of clinical research ethics*. Oxford: Oxford University Press.
- Giordano, J. (2011). Neuroethics: interacting 'traditions' as a viable meta-ethics. *AJOB-Neuroscience*, 2(2), 17–19. <http://dx.doi.org/10.1080/21507740.2011.559922>.

- Giordano, J. (2014). The human prospect(s) of neuroscience and neurotechnology: domains of influence and the necessity – and questions – of neuroethics. *Human Prospect*, 4(1), 1–18.
- Giordano, J., & Olds, J. (2010). The interfluence of neuroscience, neuroethics, and legal and social issues: the need for (N)ELSI. *AJOB-Neuroscience*, 2(2), 12–14. <http://dx.doi.org/10.1080/21507740.2010.515964>.
- Hare, R. M. (1981). *Moral thinking: its levels, method, and point*. Oxford: Oxford University Press.
- Hawkins, J. S., & Emanuel, E. (Eds.). (2008). *Exploitation and developing countries: the ethics of clinical research*. Princeton, NJ: Princeton University Press.
- MacFarlane, B. (2008). *Researching with integrity: the ethics of academic inquiry*. London and New York: Routledge.
- May, W. F. (2003). Contending images of the healer in an era of turnstile medicine. In J. K. Walter, & E. P. Klein (Eds.), *The story of bioethics: from seminal works to contemporary explorations* (pp. 149–164). Washington, DC: Georgetown University Press.
- Resnik, D. B. (2012). Ethical virtues in scientific research. *Accountability in Research: Policies And Quality Assurance*, 19(6), 329–343. <http://dx.doi.org/10.1080/08989621.2012.728908>.
- Shook, J. R., Galvagni, L., & Giordano, J. (2014). Cognitive enhancement kept within contexts: neuroethics and informed public policy. *Frontiers in Systems Neuroscience*, 8. <http://dx.doi.org/10.3389/fnsys.2014.00228>. article 228.
- Shook, J. R., & Giordano, J. (2014). A principled and cosmopolitan neuroethics: considerations for international relevance. *Philosophy, Ethics, and Humanities in Medicine*, 9. <http://dx.doi.org/10.1186/1747-5341-9-1>. article 1.
- Stark, L. (2012). *Behind closed doors: IRBs and the making of ethical research*. Chicago: University of Chicago Press.

Received 16 March 2015

Reviewed 20 March 2015

Revised 23 March 2015

Accepted 23 March 2015