

PERSPECTIVE

Ethics in published brain–computer interface research

To cite this article: L Specker Sullivan and J Illes 2018 *J. Neural Eng.* **15** 013001

View the [article online](#) for updates and enhancements.

Related content

- [Informed consent in implantable BCI research: identification of research risks and recommendations for development of best practices](#)
Eran Klein and Jeffrey Ojemann
- [Ethical issues in neuroprosthetics](#)
Walter Glannon
- [Perspective](#)
Patrick Rousche, David M Schneeweis, Eric J Perreault et al.



IOP | ebooks™

Bringing you innovative digital publishing with leading voices to create your essential collection of books in STEM research.

Start exploring the collection - download the first chapter of every title for free.

Perspective

Ethics in published brain–computer interface research

L Specker Sullivan²  and J Illes¹¹ National Core for Neuroethics, University of British Columbia, Vancouver, Canada² Center for Bioethics, Harvard Medical School, Boston, MA, United States of AmericaE-mail: Laura_SpeckerSullivan@hms.harvard.edu

Received 6 June 2017, revised 14 September 2017

Accepted for publication 21 September 2017

Published 8 January 2018

**Abstract**

Objective. Sophisticated signal processing has opened the doors to more research with human subjects than ever before. The increase in the use of human subjects in research comes with a need for increased human subjects protections. **Approach.** We quantified the presence or absence of ethics language in published reports of brain–computer interface (BCI) studies that involved human subjects and qualitatively characterized ethics statements. **Main results.** Reports of BCI studies with human subjects that are published in neural engineering and engineering journals are anchored in the rationale of technological improvement. Ethics language is markedly absent, omitted from 31% of studies published in neural engineering journals and 59% of studies in biomedical engineering journals. **Significance.** As the integration of technological tools with the capacities of the mind deepens, explicit attention to ethical issues will ensure that broad human benefit is embraced and not eclipsed by technological exclusiveness.

Keywords: brain–computer interface, neuroethics, clinical ethics, informed consent

(Some figures may appear in colour only in the online journal)

The expanding world of BCI research

Brain–computer interface (BCI) research is one of the fastest growing areas of neural engineering (Daly and Huggins 2015) with the potential for commercialization across healthcare, research, and consumer markets estimated to be more than \$700 million. The target end users of BCI healthcare applications are adults and children in the longer term with sensorimotor disabilities, stroke, spinal cord injury, amyotrophic lateral sclerosis, locked-in syndrome, disorders of consciousness due to acquired brain injury, and other neurologic conditions. These are populations considered to be vulnerable in the context of medical research and BCI studies, in particular, can present unique challenges to participant consent, identity, and agency (Glannon 2015, Klein 2016, Klein and Ojemann 2016). The potential benefits of advancements with BCI might, in some contexts, outweigh risks, however, and the use of human subjects—both controls and affected individuals—in this context

is growing both in absolute numbers and in numbers of studies using invasive procedures (Specker Sullivan and Illes 2016).

Due in part to increasingly sophisticated methods for signal processing, the doors to a wide array of studies with human subjects have been opened. These include, for example, testing of communication paradigms and the development of prosthetic tools (Mak and Wolpaw 2009, Wolpaw and Wolpaw 2012, Rao 2013, Murphy *et al* 2015). The possible rationales for these forms of human subjects research are diverse, yet ultimately their justification depends on the social, scientific, or clinical value of the research. A rationale is the purpose or contribution of a study—it explains *why* the study is being done (this is in contrast to the permissibility of a study, which concerns whether it *can be done ethically*). Within human subjects research, rationales referencing human benefit are essential to ensure that human lives are not negatively affected for the sake of science alone. Henry Beecher, one of the founders of bioethics, famously wrote that ‘*an experiment is ethical or*

not at its inception; it does not become ethical post hoc—ends do not justify means’ (Beecher 1966: 372). Emanuel *et al* have detailed the questions that must be asked at the inception of clinical research with human subjects: Does the study evaluate an intervention that will improve health or well-being, or test preliminary data with the goal of producing such an intervention? Will it provide important knowledge about human biological systems (Emanuel *et al* 2000)?

In recent work (Specker Sullivan and Illes 2016) we reported high rates of the use of technological improvement as the motivating rationale—an important aspect of research ethics—for BCI research published in journals that focus on neural engineering, compared to more person-centered rationales, such as augmented communication or improvement of motor skills, in journals that have a more scientific or medical mission. Technological improvement rationales focus on how a study advances and refines the capabilities of a technological device. This is in contrast to scientific rationales that focus on the contribution of a study to human understanding, and to medical rationales that concentrate on the improvement of human well-being. Yet technological sophistication does not provide value independent of human benefit; technology is not an intrinsic good, but is valued instrumentally—for how it can be used. The absence of reference to instrumental value in articles reporting BCI research does not mean that BCI research has no human value, only that researchers choose not to report on it in their publications. While the reasons underpinning this trend are unknown, it is possible that inattention to questions of why technological progress has human value is a source.

Whatever the explanation, a statement describing the ethical rationale for a study—why it is justified—is an advanced step in research ethics, and one that not all published human subject studies are currently expected to satisfy. Indeed, most translational and clinical medicine journals do not require a rationale or justification statement that addresses the potential social or human impact of the results. Highly ranked peer-reviewed medical journals do, however, require a statement of informed consent, that at the most basic level, implies that participants or their surrogates gave autonomous acknowledgment that they understood and accepted the risks and benefits of the research in which they agreed to participate. While there are clear differences between ethical rationales and specific ethics protections—namely that the former concern the ethical *justification* of a study and the latter address its *permissibility*—they are similar in that they both aim to ensure that human subjects are protected, either from higher-order justifications that disregard the specific personal impact of clinical research, or from lower-order missteps that compromise subjects’ safety, privacy, autonomy, and other individual goods.

Informed consent may be particularly difficult in BCI research—especially when such research is invasive—given the unique risks that such research presents, and the difficulty subjects may have in imagining what these risks entail (Glannon 2015, Klein and Ojemann 2016). Risks and complicating factors of BCI that affect informed consent include: bidirectionality (Kellmeyer *et al* 2016), predictability of outcomes (Gilbert 2015), challenges of implantation (Klein 2016,

Klein and Ojemann 2016), and the possibility of hacking into one brain or connecting two (Trimper *et al* 2014). These risks raise ethical concerns related to accountability, autonomy, identity, stigma, agency, and privacy (Clausen 2008, Klein *et al* 2015). BCI research may also be difficult due to the challenges of establishing communication with subjects who have disorders of consciousness, such as those in a minimally conscious state or locked-in syndrome (Glannon 2015).

Here we report on the secondary analysis of the BCI studies, for which we quantitatively identified the presence and absence of ethics language in published studies of BCI research with human subjects, and qualitatively characterized ethics statements. We discuss the findings in the context of practical methods for ensuring that the ethics of translational human subjects research in emerging areas at the intersection of neuroscience and technological fields such as engineering are explicitly addressed in publications of research results and discussed in the field more broadly. Building upon arguments in favor of ethical reproducibility via transparent reporting in biomedical research and Henry Beecher’s seminal work on ethics and clinical research, we further address how including ethical content in peer-reviewed publications might enhance ethical research itself (Beecher 1966, Anderson *et al* 2013).

Ethics content in brain–computer interface research with human subjects

Database

We conducted a secondary analysis of 210 articles representing 217 studies retrieved from a customized search of two databases: the Web of Science database and the PubMed database. This data set was first used for a study of reported rationales (Specker Sullivan and Illes 2016).

As reported in our previous study, we used customized search algorithms to interrogate two databases in January 2016: the Web of Science database and the PubMed database. Eligibility criteria were the use of: (1) one or more iterations of ‘brain–computer interface’ or ‘brain machine interface’ and (2) human subjects. For the Web of Science, the search strategy for English articles in the core collection was: topic (topic = TS) (‘brain–computer interface’ OR ‘brain–computer interfaces’ OR ‘brain machine interface’ OR ‘brain machine interfaces’) AND TS = (‘clinical study’ OR ‘clinical trial’ OR ‘case report’ OR ‘in human’ OR ‘pilot study’ OR ‘feasibility study’ OR ‘safety study’). For PubMed, we used an advanced search strategy for English article titles with the following terms: (‘Brain–Computer Interfaces’[Mesh] OR ‘brain–computer interface’ OR ‘brain–computer interfaces’ OR ‘brain machine interface’ OR ‘brain machine interfaces’ OR bci[ti]) AND (Clinical Trial[ptyp]).

Full text articles available in either the University of Washington or University of British Columbia library system were retrieved for the period 2000–2015, a 15 years window corresponding to the first published study returned by the search strategy (not necessarily the first in-human brain–computer interface study), and the most recent as of January 2016. While studies of brain–computer interfaces with human

subjects were conducted prior to 2000, these studies were not included in the data set if they were not retrieved by the search strategy. This approach ensured that the composition of the data did not reflect our own biases about what constitutes a brain–computer interface.

Search returns were curated for duplicates and relevance. The final data set was used for the present analysis and one prior that was focused on reported study rationales (Specker Sullivan and Illes 2016). In the present analysis, we identified and characterized ethics language in BCI studies with the goal of assessing how far up the research ethics chain attention to ethical issues succeeds or fails. We used the presence and absence of ethics language related to human subject research as a proxy measure of those variables.

Analysis

Articles were classified deductively for type of journal by discipline or field of journal, and according to their stated mission. Using a refined analysis, the resulting journal sets were neural engineering ($n = 7$), biomedical engineering ($n = 3$), engineering ($n = 9$), neuroscience ($n = 13$), neurology ($n = 12$), science and medicine ($n = 13$).

Content analytic methods were then used to classify the ethics language in each article inductively, with ethics interpreted as any language in the paper that discusses protections and precautions taken for the use of human subjects. Ethics in the context of science and medicine is a broad category that includes the ethical character of the scientist or clinician (virtue ethics), duties and obligations that arise from clinical relationships (deontological ethics), and the contribution of the scientific or clinical practice to the good of stakeholders (utilitarian ethics). Within clinical research ethics, the protection of human subjects includes both deontological and utilitarian aspects. Our inclusion criteria were: statements related to the protection of human subjects. Our exclusion criteria were: statements not related to the protection of human subjects.

We did not use an *a priori* search term list to identify ethics language beyond the inclusion and exclusion criteria described above. Rather, each article was read thoroughly for any mention of, or reference to, protection of human subjects. The resulting inductive ethics categories were: informed consent, IRB approval, processes of consent, Declaration of Helsinki, remuneration, risk-benefit, and clinical trial number. Other terms that relate to human subject protections, such as ‘privacy’ and ‘conflict of interest’, did not appear in our data set.

Ethics content was all-or-none; a single mention of consent, for instance, counted as ethics language. Statements on informed consent were further specifically analyzed for level of detail beyond a mere statement that informed consent was obtained. For instance, a more detailed ethics statement might specify written as opposed to verbal consent, or might include an explanation of why a surrogate decision-maker was used. Level of detail was not assessed by the number of terms included in the ethics statement, but by the

additional information communicated beyond the mere fact that ‘informed consent was done’.

Finally, to interrogate the relationship between the analysis of ethics language and rationales specifically, we mapped the relationship between journal type and rationale type for presence or absence of ethics language. Multiple rationale types were possible for each study.

Presence of ethics language

We found ethics language in 76% (160/210) of the total number of articles distributed across primary journal types as follows: neurology 95% (38/40), neural engineering 69% (57/83), and biomedical engineering 41% (12/29). Neural engineering, biomedical engineering, engineering, and robotics journal articles have the fewest instances of ethics language.

In 81% of the sample with ethics language (129/160), the content consists of a statement of institutional ethics approval and informed consent only. In 56% of these (89/160), the content further includes a description qualifying informed consent: 14% (23/160) of articles mentions the Declaration of Helsinki, 11% specifies remuneration (17/160), 7% (11/160) describes the risks and benefits of the study, and 6% (10/160) includes a clinical trial number.

Cross-analysis with the rationale study yields a direct overlap between the engineering data sets for rationale and ethics language, with high rates of technological improvement rationales and low rates of ethics content, in contrast to related content in science and medicine journal sets (figure 1).

Technological improvement and the ethics of research with human subjects

Devices that read, interpret, and modulate neural signals of the human brain have emerged from the realm of science fiction and moved into reality (Attiah and Farah 2015). As the market for these devices grows, researchers from a wide range of disciplinary backgrounds seek to conjoin engineering and human translation in ways that increasingly push the boundaries of technological innovation.

This evolution presents both opportunities and challenges. On the one hand, interdisciplinary neural engineering work has the potential to bring significant positive impact to human disability and suffering on a large scale (Schneider *et al* 2012). On the other hand, engineers working in an interdisciplinary space are faced with the continuous challenge of wrestling with diverse understandings and definitions of the value of their work and the means to express it. The present results reinforce this assertion: reports of BCI studies with human subjects that are published in neural engineering and engineering journals are anchored in the rationale of technological improvement. Ethics language is often omitted. While some researchers may focus on the primary value of BCI research as the development of novel technological devices—and some journals may reinforce this understanding through their articulated missions—potentially risky research with human subjects requires more than technological innovation for ethical justification. At the

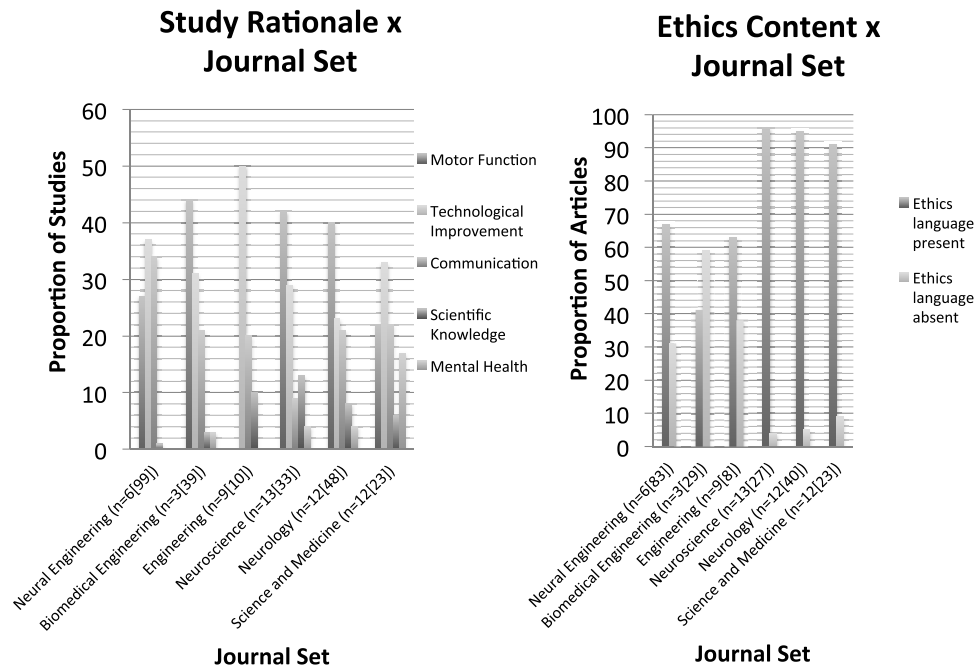


Figure 1. Study rationale and ethics content by journal set.

most basic level, translational research with human subjects requires robust informed consent in practice and evidence of these practices in study dissemination. Although a source of this ethics lacuna may be the attention to technological perfection, technological improvement and human values are different virtues. Looking through the lens of the ethical conduct of research as defined by statements such as the Declaration of Helsinki, the Belmont Report, and the TriCouncil Policy Statement from Canada (World Medical Association 2013, The Commission 1978, Canadian Institutes of Health Research 2014), we posit that any in-human study ought to address precisely where technological improvement and human values overlap for ethical justification (Goering and Yuste 2016); technological improvement alone without an attendant contribution to human values may be insufficient for justification.

Promoting ethics in translational neural engineering research

If the results here are telling, ethics capacities and reporting in BCI research can be improved. This goal will be met through two changes:

- (1) *Explicit reflection on the value, goals, and methods in human subjects study design.* This includes reflection on practices such as informed consent, subject selection, and trial design in published papers and group workshops, as well as the advancement of structured and unstructured ethics engagement activities with the public and with ethicists who specialize in neurological science and engineering (Specker Sullivan and Illes 2017).
- (2) *Openness and transparency about ethics practices in reporting.* Journals that publish engineering research aimed at human translation may consider requiring that authors explicitly include certain ethics content, such as information

about subject selection and informed consent processes, as well as additional details including conflict of interest, data integrity, and privacy before the articles can be published.

These two components of progress in ethics will reciprocally feed and inform each other. Publications offer opportunities for both, and the openness will further contribute to ethical reproducibility in study design and reporting. Reproducibility is a guiding principle of scientific practice: a study must be reproducible from the concrete features of study design shared in the methods. Likewise, ethical reproducibility promotes transparency about ethics methods in published studies such that future researchers can learn from and reapply these methods in their own research (Anderson *et al* 2013). Both the process of including ethics content in published papers (i.e. reflecting on and summarizing ethics methods) and the end result (i.e. disclosure of ethics content for other researchers to read) are significant. When published research does not contain comprehensive ethics content, no inferences ought to be made about the intent or ethical conduct of investigators, positive or negative.

Our proposals here further build on the argumentation of Henry Beecher's seminal 1966 article on ethics and clinical research (Beecher 1966, Jones *et al* 2016). Beecher analyzed published in-human research studies, and identified ethical issues. In many of these articles, the ethical issue was that consent was never mentioned, while in others, there was clear harm to subjects. Beecher's article garnered immediate attention and impacted American policy. In the article, he emphasizes not only that '*in the publication of experimental results it must be made unmistakably clear that the proprieties have been observed*' but also that '*the statement that consent has been obtained has little meaning unless the subject or his guardian is capable of understanding what is to be undertaken and unless all hazards are made clear. If this is not known this, too, should be stated*' (Beecher 1966: 372). In short, ethics

methods must be published and must be detailed enough to establish their effectiveness. Yet Beecher did not think that research ethics would be guaranteed by this ethical transparency in published papers; he suggested that the ‘*more reliable safeguard*’ is ‘*the presence of an intelligent, informed, conscientious, compassionate, responsible investigator*’ (Beecher 1966: 372).

Just over 50 years have passed since the publication of Beecher’s article, and there is still much to reflect on in research ethics. While Beecher stressed investigator virtue, his stipulation that ethics methods be transparently reported reflected his concern that the immense pressure on young investigators—to publish noteworthy research, to receive grants, to achieve tenure—could easily lead them to misguided decisions in their work with human subjects. We hypothesize that the allure of technological progress is an additional pressure currently exerted on investigators working at the intersection of science, medicine, and technology, although this remains the subject of future work. Nonetheless, the external pressures listed above do exist, and it is due to these external pressures that investigator virtue and regulations on research and publication go hand in hand—one mutually reinforces the other.

Regular habits determine the development of an ethical character—the source of investigator virtue (Aristotle 350BCE, Resnick 2012). When researchers share the ethics methods used in their studies and openly discuss the ethical dimensions of their studies, they create opportunities for reflection while aiding other researchers who are designing studies with similar considerations. This is not to say that ethics ought not play a role in training, education, grant writing, and other research activities; it should (Ramos *et al* 2017). Nevertheless, writing and revising papers for publication represent a substantial portion of the time and attention of researchers, and as such offer opportunities for reflection, both on efficient communication of scientific methods and contributions, and on effective communication of ethical methods and contributions. Such activities can simultaneously reinforce investigator habits and disposition, and contribute to ethical awareness and dialogue within the field as a whole.

The human brain is a complex organ that is central to the concept of what it is to live a human life. As the ability to integrate technological tools with the capacities of the mind deepens, explicit attention to ethical issues will ensure that broad human benefit is embraced and not eclipsed by technological exclusiveness in translational neural engineering research.

Limitations

While this study utilized two databases for study retrieval, the return of all BCI studies for clinical use with human subjects may have been limited by the constraints of indexing and categorization. Nevertheless, the results are based on a representative sample for analysis. Further, while bias can arise any thematic analysis, coding by two independent coders with complementary backgrounds in empirical and conceptual ethics mitigated this challenge.

Acknowledgments

This work was supported by a grant from the National Science Foundation (NSF Award #EEC-1028725) and the Vancouver Coastal Health Research Institute. JI is Canada Research Chair in Neuroethics. JI is also partly supported by the Kids Brain Health Network.

ORCID iDs

L Specker Sullivan  <https://orcid.org/0000-0002-2596-9059>

References

- Anderson J, Eijkholt M and Illes J 2013 Ethical reproducibility: towards transparent reporting in biomedical research *Nat. Methods* **10** 843–5
- Aristotle 350BCE 2000 *Nicomachean Ethics* trans. and ed R Crisp (Cambridge: Cambridge University Press)
- Attiah M A and Farah M 2015 Minds, motherboards, and money: futurism and realism in the neuroethics of BCI technologies *Frontiers Syst. Neurosci.* **8** 1–3
- Beecher H K 1966 Ethics and clinical research *New Engl. J. Med.* **79** 367–72
- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada 2014 Tri-council policy statement: ethical conduct for research involving humans
- Clausen J 2008 Moving minds: ethical aspects of neural motor prostheses *Biotechnol. J.* **3** 1493–501
- Daly J J and Huggins J E 2015 Brain–computer interface: current and emerging rehabilitation applications *Arch. Phys. Med. Rehabil.* **96** S1–7
- Emanuel E, Wendler D and Grady C 2000 What makes clinical research ethical? *JAMA* **283** 2701–11
- Gilbert F 2015 A threat to autonomy? The intrusion of predictive brain implants *Am. J. Bioethics Neurosci.* **6** 4–11
- Glannon W 2015 Ethical issues with brain–computer interfaces *Frontiers Syst. Neurosci.* **8** 136
- Goering S and Yuste R 2016 On the necessity of ethical guidelines for neural engineering research *Cell* **167** 882–5
- Jones D S, Grady C and Lederer S E 2016 ‘Ethics and Clinical Research’—The 50th Anniversary of Beecher’s Bombshell *New Engl. J. Med.* **374** 2393–8
- Kellmeyer P, Cochrane T, Müller O, Mitchell C, Ball T, Fins J J and Biller-Andorno N 2016 The effects of closed-loop medical devices on the autonomy and accountability of persons and systems *Camb. Q. Healthcare Ethics* **25** 623–33
- Klein E 2016 Informed consent in implantable BCI research: identifying risks and exploring meaning *Sci. Eng. Ethics* **22** 1299–317
- Klein E, Brown T, Sample M, Truitt A R and Goering S 2015 Engineering the brain: ethical issues and the introduction of neural devices *Hastings Cent. Rep.* **45** 26–35
- Klein E and Ojemann J 2016 Informed consent in implantable BCI research: identification of research risks and recommendations for development of best practices *J. Neural Eng.* **13** 043001
- Mak J N and Wolpaw J R 2009 Clinical applications of brain–computer interfaces: current state and future prospects *IEEE Rev. Biomed. Eng.* **2** 187–99
- Murphy M D, Guggenmos D J, Bundy D T and Nudo R J 2015 Current challenges facing the translation of brain computer interfaces from preclinical trials to use in human patients *Frontiers Cell Neurosci.* **9** 497

- Ramos K, Rommelfanger K, Greely H T and Koroshetz W 2017 Neuroethics and the NIH BRAIN initiative *J. Responsible Innov.* (<https://doi.org/10.1080/23299460.2017.1319035>)
- Rao R 2013 *Brain–Computer Interfacing: an Introduction*. (Cambridge: Cambridge University Press)
- Resnick D B 2012 Ethical virtues in scientific research *Account. Res.* **19** 329–43
- Schneider M J, Fins J and Wolpaw J R 2012 Ethical issues in BCI research *Brain–Computer Interfaces: Principles and Practice* ed J R Wolpaw and E W Wolpaw (Oxford: Oxford University Press)
- Specker Sullivan L and Illes J 2016 Beyond communication and control: towards ethically complete rationales for brain computer interface research *Brain–Computer Interfaces* **3** 156–63
- Specker Sullivan L and Illes J 2017 Models of engagement in neuroethics programs: past, present, and future *The Debate About Neuroethics: Perspectives on the Field's Development, Focus, and Future (Advances in Neuroethics Series)* ed E Racine and J Aspler (Berlin: Springer)
- Trimper J, Root Wolpe P and Rommelfanger K 2014 When ‘I’ becomes ‘we’: ethical implications of emerging brain-to-brain interfacing technologies *Frontiers Neuroeng.* **7** 4
- The Commission 1978 *The Belmont Report* (Bethesda, MD, United States)
- Wolpaw J R and Wolpaw E W 2012 *Brain–Computer Interfaces: Principles and Practice* (Oxford: Oxford University Press)
- World Medical Association 2013 Declaration of Helsinki *JAMA* **310** 2191–4