

PAPER

The impossibility of informed consent?

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Received 1 September 2014

Revised 26 September 2014

Accepted 23 October 2014

ABSTRACT

The problematic nature of informed consent to medical treatment and research, and its relation to autonomy, trust and clinical practice, has been addressed on many occasions and from a variety of ethical perspectives in the pages of the *Journal of Medical Ethics*. This paper gives an account of how discussion of these issues has developed and changed, by describing a number of significant contributions to these debates which provide examples of 'doing good medical ethics' over the 40 years of the *Journal's* publication.

THE IMPOSSIBILITY OF INFORMED CONSENT?

Awareness that informed consent is problematic, in theory and in practice, was already evident in the earliest editions of the *Journal of Medical Ethics*. 'Is the doctor to warn the patient of every conceivable complication and give her the statistical data? Is there such a thing as 'truly informed' consent?' asked an editorial¹ in September 1975, discussing a 'woman's right to choose' abortion. In the same issue, serious doubts about informed consent to participation in clinical research were raised in a paper by the British clinical pharmacologist JC Garnham.² This presented evidence that only 'medically trained people', and sometimes not even all of them, when recruited as subjects of non-therapeutic clinical research, demonstrated sufficient understanding of the implications of their voluntary consent for it to be meaningfully considered 'informed'. In the research context therefore, the paper concluded, 'informed consent' had 'little or no meaning'; and it went on to recommend that any request for consent to participation in clinical research should be preceded by information provided by the investigators, and by the registration of medical agreement to participation in the study by the potential subject's own or nominated doctor.

Garnham's paper further recommended that in order to prevent conflicts of interest, research ethics committees should be 'appointed on a geographical basis rather than by institutions'. A decade or so later a national system of such independent committees was set up in the UK, and their role in protecting the interests of research subjects perhaps partly superseded that envisaged by Garnham for the subject's own or nominated doctor. Many other aspects of informed consent however remained and remain contested philosophically and practically, and were to be addressed in the pages of the *Journal* from a considerable variety of different approaches. The following represent some significant contributions to these debates which provide examples of 'doing good

medical ethics' over the 40 years of the *Journal's* publication.

Surveying the scene: the law and ethics of informed consent to treatment and research

Two early and wide-ranging contributions on medico-legal and ethical aspects of informed consent were made in papers by judge Kirby³ of Australia in 1983 and paediatrician Silverman⁴ of the USA in 1989. Both agreed that a paternalist or beneficence-based approach, in which the doctor recommends a course of treatment to which the patient either consents or refuses, had properly been superseded by an approach based on respect for the autonomy or right to self-determination of the individual patient. Having spelt out the necessity for this latter approach in terms of the law of trespass and of negligence, Kirby admitted that informed consent was 'hard to define' and 'simply an ideal to which daily practice can only aim': it was 'impossible for the healthcare professional to impart... every facet of his knowledge and expertise involved in the decision... in the space of a 30-min consultation' to patients who 'vary enormously in their interest in and capacity to absorb information about medical procedures'. The 'degree of detail and information' to be provided nevertheless had now, in the view of the courts, to be determined not by 'the sole judgement of the medical profession itself' but by 'the patient's need to know and respect for the patient's autonomy'. Ultimately however, and for most doctors reassuringly, Kirby concluded, 'The fact that the patient gave an informed consent usually will not prevent him from suing; a warm relationship with a competent and caring physician usually will.'

Silverman's less reassuring paper, entitled 'The myth of informed consent: in daily practice and in clinical trials', was concerned to reconcile the standards and practice of informed consent in clinical practice and clinical research, particularly in the USA. While informed consent ('a modern American invention', first enunciated in a legal case in 1957) required doctors to 'disclose risks and alternatives of treatment' as well as the treatment's 'nature and consequences', there was little evidence, from studies of clinical practice, of doctors being aware that 'the consent-seeking routine was intended to allow patients to make a choice or state a preference about the treatment on offer': doctors still 'felt duty-bound to provide patients with an unequivocal recommendation for action' and thereby to 'minimise the uncertainties about 'best' treatment'. In clinical trials, by contrast, doctors seeking informed consent were now required to be explicit about the uncertainties which justified the



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To cite: Boyd K. *J Med Ethics* 2015;**41**:44–47.

need for a trial, but again there was little empirical evidence that this 'ritual' provided research subjects with either any additional protection from the risks of participation, or any increased respect for their autonomy: there was in fact considerable evidence that the majority of participants did not 'fully understand the implications of a formal clinical trial'. It was possible, moreover (a point also noted by Kirby), that the consent process might act as 'an effective social filter', selecting out 'for refusal those on the upper rungs of the social ladder' who were 'most likely to understand what is requested in the consent ritual', leaving among those consenting 'a disproportionate representation' of the 'socially disadvantaged'. This 'apparently irresolvable conflict between the ethical requirement that a patient must always be offered the best treatment known, and the equivocal choice in a comparative trial', Silverman argued, failed to 'satisfy the competing moral imperatives' of respect for autonomy, beneficence and justice. There was however no currently obvious way to 'conserve the spirit of informed consent without snuffing out the flame of responsible clinical study': only by 'experiment with various discretionary approaches' might it become possible to 'strike a balance among the competing interests'.

Fresh insights from psychiatry and philosophy

Despite Silverman's hopes for reconciliation between the standards for consent to treatment and for consent to research, this issue also was to remain and remains ethically contested. With respect to consent to treatment however, two further papers from the 1980s suggested different ways in which legal requirements might be reconciled with ethical principles and good medical practice. A 1987 paper by Dyer and Bloch,⁵ from the USA and England, offered insights from their own psychiatric specialty, while one of 1989 by surgeon and ethicist Gillett⁶ from New Zealand suggested a virtue ethics approach to the issue.

Writing against the background of recent legislative and legal developments in England (the Mental Health Act 1983 and the 1984 Sidaway case) Dyer and Bloch observed that while medical paternalism was no longer ethically acceptable, and it was necessary to respect the autonomy of a patient as a person with human rights, this could be very difficult if the autonomy of a patient was limited, for example by an acute psychotic condition or severe dementia. Deciding that they lacked capacity and needed to have their interests represented by a guardian or proxy on the other hand did not restore these patients' autonomy, and at worst could be an impersonal form of official paternalism. This dilemma or conflict between the principle of autonomy and the principle of paternalistic beneficence in relation to informed consent could be resolved however by introducing an ethical ideal even more basic than either—the fiduciary principle of partnership, in which the doctor decides not for but *with* the patient, a process dependent on the development of the patient's trust and one which while 'requiring mutual trust... particularly calls on the doctor to be trustworthy'. This ideal was exemplified in psychotherapy, for which a trusting relationship was essential if the goal of both partners—'to understand and clarify the motives of the patient'—was to be achieved: this however necessarily took time, meaning that informed consent 'occurs not once, but repeatedly...as a continuing process'.

This (later widely accepted) view of informed consent not as an act but as a process was shared by Gillett in his 1989 paper. This enquired (again against the background of the Sidaway decision) whether, especially in a legally disputed case, it was

possible to decide in retrospect if consent had been informed by what was 'of material relevance to a prudent or reasonable patient'. Given on the one hand the need for the consent process to be sufficiently informal 'to allow free communication' (often 'on a ward round or in a bedside conversation' with 'no detailed record of the conversation' in 'the medical notes') and given on the other hand the 'confounding effects of stress and illness' and the fallibility of memory, it could subsequently be 'difficult, if not impossible to reconstruct exactly what happened on an occasion where consent has become an adversarial issue'. In such circumstances, Gillett believed, it was helpful to consider the philosopher Peter Winch's 'analysis of retrospective moral evaluation'. Winch had argued that 'when the facts are unclear it may be that the best guide we have to the rightness of what was done is what a morally endorsable agent actually did as a participant in the situation'. In other words, was the doctor concerned 'a person of the requisite moral character who acted with an informed grasp of the situation'? Ultimately the only way for a moral spectator scrutinising the doctor's actions to answer these questions, was by trying to discover, possibly from others among his patients in similar circumstances, 'the known practice of the doctor concerned, as materially relevant to the present decision'. If enquiries into the doctor's 'track record' satisfied the observer that the doctor was 'a competent moral judge' who 'acted in accordance with adequate principles', then it should be accepted that his actions were 'likely to have been *the* right thing to do or perhaps *a* right thing to do in the situation'.

Informed consent requirements in changing contexts

Several papers from the late 1990s and early 2000s illustrate ethical arguments about how changing contexts and new developments in clinical practice and healthcare research may require different standards for informed consent. Some of these papers related to contemporary events such as the organ retention scandals in and around 2000,⁷ or to the acceptability of 'broad consent' for future research from the new biobanks.⁸ Others however were concerned with and developed themes discussed earlier in the pages of the *Journal*.

A 1998 paper by ethicist Hansson⁹ from Sweden and one of 2002 by health services researchers Cassell and Young¹⁰ from England, for example, returned to the issues discussed earlier by Silverman concerning different standards for clinical practice and for medical research, but also drew attention to a further relevant distinction between clinical trials and epidemiological or health services research. Noting a 'tendency today for the rule (of informed consent) to be applied too rigidly and with too little sensitivity to the values that are at stake in connection with different kinds of research protocols', Hansson proposed 'a model for balancing the quality of consent against other variables that are ethically important in different contexts'. Hansson's model balanced the quality of consent 'against the time that is available for the communication process and against the values that are at stake for the individual most directly concerned': where values vital for the person concerned ('integrity, health and well-being') were involved and ample time available (as in clinical trials), extensive informed consent procedures were required, but where time was short (as in medical emergencies) less elaborate procedures providing more limited information were sufficient; and in cases where there was no serious threat to the individual's integrity or confidentiality for example (as in epidemiological research seeking information that 'is not judged to be sensitive or socially stigmatising for any

individual'), simply making available information relevant to enable a right to refusal might be sufficient.

While agreeing that applying the same standards of informed consent in all healthcare and research contexts was ethically inappropriate, Cassell and Young criticised the single standard from a different angle with particular relevance to health services research in the National Health Service. Such research, into the organisation and delivery of healthcare, they argued, was ethically as well as practically necessary in order to 'equalise opportunities for health'. When time-consuming standards of informed consent designed for clinical trials were insisted upon by ethics committees, this could obstruct healthcare research by discouraging participation, allowing patients to opt out, and making health service research possible only with unrepresentative samples. This was especially inappropriate in the National Health Service, of which by its unique nature all UK citizens essentially were not consumers or patients but members, and as members had a common obligation to protect the equal rights of all other members—rights which were not respected if the organisation and delivery of healthcare, and organisational change in the health service, were not properly evaluated by health services research.

Calling autonomy to account

One of the most common assumptions about informed consent—that its ethical basis is respect for autonomy or the self-determination of the patient—was radically challenged in a 2003 paper by the Kantian philosopher O'Neill¹¹ from the UK, entitled 'Some limits of informed consent'. Among these limits, O'Neill observed, was that only competent patients could give informed consent; and even among them, this was practically difficult or impossible for those rendered vulnerable by illness or dependency, for relatives of patients who shared information about them with their doctors, or for individuals who would be affected by public health policies. Equally significant, was what O'Neill called the 'opacity' and lack of 'transitivity' of informed consent: a patient giving consent to a medical procedure might be unaware of all the possibilities that it might entail, including those to which they might not have consented had they known of them, yet spelling out in detail every last implication on a complex consent form could be confusing and counterproductive. Part of the problem behind all this, O'Neill argued, was the 'endlessly repeated but deeply obscure' claim that informed consent was 'the key to respecting patient autonomy'. This claim surely could not be correct since the choices protected by informed consent included those that were autonomous and 'choices that are timid, conventional, and lacking in individual autonomy'. The real ethical importance of informed consent rather, O'Neill continued, was 'to provide reasonable reassurance that a patient (research subject, tissue donor) has not been deceived or coerced', and this could be assured in practice 'by giving them a limited amount of accurate and relevant information and providing user-friendly ways for them to extend this amount (thereby checking that they are not deceived) as well as easy ways of rescinding consent (thereby checking that they are not coerced)'.

O'Neill's arguments were to be influential: set out at greater length in her 2001 Gifford Lectures, they included the claim that informed consent was 'generally important (inter alia) because it can make a distinctive contribution to the restoration of trust'.¹² Arguments by O'Neill and others in support of this claim however have more recently been challenged in a 2014 paper by ethicist Eyal¹³ from the USA. The argument that informed consent promotes trust in medical practice, Eyal

argues, while initially appealing, does not necessarily hold up for a variety of reasons: trust in doctors, for example, is not invariably desirable, especially if it is excessive, while on the other hand trust may actually be diminished, if overemphasising a need for trust or providing too much information makes patients, reasonably or unreasonably, suspicious. There may moreover be some circumstances in which patients have greater trust in doctors whom they believe in the future will act in their best interests rather than abandoning them to an informed refusal they might later live or not live to regret. Promoting trust, Eyal concludes, cannot be seen as the only reason for informed consent procedures which need to be supported by other reasons.

Two final papers from the *Journal of Medical Ethics* return to considerations of autonomy and in that context argue for further qualifications of, or constraints on informed consent. In their 1997 paper¹⁴ entitled 'Should informed consent be based on rational beliefs?',¹³ physician and ethicist J Savulescu from the UK and philosopher Momeyer from the USA argue that being autonomous 'may not require that one's choices and actions are rational' but 'it does require that one's beliefs which ground those choices are rational.' Being autonomous 'involves freely and actively making one's own evaluative choices about how one's life should go', but 'we cannot form an idea of *what* we want without knowing what the options on offer are *like*'. Applying these considerations to refusal of life-prolonging blood transfusions by Jehovah's Witnesses, Savulescu and Momeyer argue that the beliefs on which this refusal is based are 'irrational on at least two counts: their particular beliefs are not responsive to evidence nor are their interpretations of Biblical text consistent' either with other Biblical texts contradicting their beliefs or with 'the vast majority ... in the Judeo-Christian tradition'. While a Jehovah's Witness could still make an autonomous choice to refuse blood even if they accepted this irrationality and adopted 'relevant informed, rational beliefs', nevertheless as long as their beliefs remained irrational their autonomy would be in question. Savulescu and Momeyer emphasise however that they are employing the example of Jehovah's Witnesses, not to coerce Jehovah's Witness in particular, but simply to illustrate the more general argument that in seeking informed consent, doctors as also educators have a responsibility, if their patients hold irrational beliefs, not simply to inform and then 'abandon' them, but also to help 'patients to deliberate more effectively'.

Similar considerations have been addressed more recently in a 2014 paper by ethicist Levy¹⁵ from Australia, entitled 'Forced to be free? Increasing patient autonomy by constraining it.' Citing a variety of empirical psychological studies illustrating the 'fallibilities of human reasoning' (including 'myopia for the future', 'motivated reasoning' and 'biases' in 'assessing probabilities... exacerbated... under cognitive load'), Levy argues that 'Human beings are, under a variety of conditions, systematically bad reasoners, and many of their reasoning faults can be expected to affect the kind of judgements that they make when they are called upon to give informed consent'. Because such fallibilities 'threaten to undermine autonomy, but the purpose of securing informed consent is to protect and promote autonomy', he continues, 'we have good reason to redesign the informed consent procedure in ways that help to avoid these fallibilities, even if the redesign reduces the scope for individual decision making in the procedure'. There might, Levy concludes, be 'a case for introducing informed consent specialists', who would 'have the job of detecting cognitive illusions in patients and informing them if they are likely to be at work in their decision-making'.

While Levy's suggestion of these additional 'strangers at the bedside' seems a possibility less likely to be generally favoured than Savulescu and Momeyer's variation on the traditional educational role of doctors, these early 21st century papers suggest in medical ethics a possible rebalancing (as suggested by Hansson) of beneficence over autonomy. In a commentary on Levy's paper the US ethicist Caplan¹⁶ remarks 'What we need in healthcare is a bit more medical paternalism'. If that is going to be the trend, it will be important to weigh in the balance also from the 1970s and 1980s, on the one hand the concerns of Garnham and Silverman about consent to clinical trials, and on the other, in relation to clinical practice, the insights of Dyer and Bloch about the fiduciary principle of partnership, and of Gillett about virtue ethics.

Competing interests None.

Provenance and peer review Commissioned; internally peer reviewed.

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Consent for Biobank Donations High in US Survey

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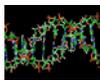
January 30, 2015

EDITORS' RECOMMENDATIONS



Mayo Clinic Biobank Begins to Elucidate Bipolar Disorder

Henrietta Lacks and the HeLa cell (or how to profit from someone else's cancer cells)



Largest Biobank in the US Poised to Advance Knowledge

DRUG & REFERENCE INFORMATION

Nonrhabdomyosarcoma Soft Tissue Sarcomas

Mixed Connective-Tissue Disease

Tissue Flap Classification

Biobanks are repositories of research gold, offering investigators virtually unlimited access to cells, blood samples, and other donated tissues for myriad research projects, including basic and clinical investigations and drug development.

But patients' willingness to donate tissue samples to research biobanks may hinge on how the information is presented to them, say medical ethicists.

Results of a survey of adults' attitudes toward tissue donation and informed consent show that when the question was framed broadly, using a "blanket consent" approach, more than two thirds of patients said they were willing to donate tissue samples to a biobank.

However, when confronted with specific, hypothetical examples of how their tissues might be used, such as research to make abortion techniques safer and more effective, fewer participants said they would be willing to give blanket consent, report Tom Tomlinson, PhD, from the Center for Ethics and Humanities in the Life Sciences, Michigan State University East Lansing, and colleagues.

One fourth of all participants in the survey said that the best option for consent would be a combination of blanket consent with an option to withdraw their approval if their tissues are being used in projects of which they disapprove, the authors report.

"As recruitment of donors becomes more widespread, such concerns may need to be addressed to moderate possible effects on donation rates," they write in a research letter [published](#) in the January 27 issue of *JAMA*.

Uninformed Consent

Rebecca Skloot, author of the best-selling book *The Immortal Life of Henrietta Lacks*, which deals with the consequences of human tissue research without donor knowledge or consent, tells *Medscape Medical News* that potential donors want to know where bits of themselves are going and how they might be used.

"What I hear from most people is that they want to know how their tissue is being used in research — some want to be able to find out more information about the study, some don't — and they want to be able to withdraw if they feel uncomfortable about it. And that is exactly in line with federal regulations regarding human subject research," she said.

The Immortal Life of Henrietta Lacks tells the remarkable story of how cervical cancer cells taken without consent or even knowledge from a poor tobacco farmer from Virginia became the HeLa cell line, the first immortalized cell line used in medical research. Henrietta Lacks died from cervical cancer in 1951, at age 31 years.

"Her cells were part of research into the genes that cause cancer and those that suppress it; they helped develop drugs for treating herpes, leukemia, influenza, hemophilia, and Parkinson's disease, and they've been used to study lactose digestion, sexually transmitted diseases, appendicitis, human longevity, mosquito mating, and the negative cellular effects of working in sewers," Skloot writes in the book.

But Henrietta Lacks' family was hurt and outraged when they learned from a *Rolling Stone* reporter in 1976 that HeLa cells (and other cell lines), in his words, "are swapped, traded, forwarded, begged, and borrowed among research institutions around the world."

In 1976, a small vial of HeLa cells could be purchased from a commercial laboratory for about \$25. A casual search of the Internet shows that now, in 2015, commercial laboratory supplies peddle HeLa-based cell cultures from about \$500 to more than \$1000.

Biobank Consent Survey

In the current study, Dr Tomlinson and colleagues surveyed participants in the GfK Knowledge Panel, a large-scale online panel based on a representative random sample of US adults aged 18 years and older, to gauge whether US adults would be willing to donate to a biobank and under what conditions.

The survey presented a description of a fictional biobank and asked participants to indicate on a 6-point scale their willingness to donate tissues under a blanket consent agreement and under seven potential research scenarios, including the aforementioned question about abortion, the use of tissues by for-profit firms to develop drugs, the use of animals as hosts for growing human organs for transplant, the creation of vaccines against biological weapons, or the use of the tissues themselves to create new biological weapons.

The authors received complete responses from 1599 (60.2%) of 2654 participants who received the survey.

Under the blanket consent condition, 68.0% of respondents said they were willing to donate tissues, but a significantly smaller proportion of respondents said they would agree under all but one of the hypothetical scenarios (range for 5 questions, 49.5% - 64.2%).

The single exception was a scenario in which donations could be used to "develop stem cells that have the donor's genetic code. These could be kept alive for many years. Scientists might use those stem cells to create many different kinds of tissues and organs for use in medical research." In all, 70.1% of respondents said they would be willing to donate under such a scenario.

When asked which of five informed-consent options they found most acceptable, 25.5% said blanket consent with option to withdraw was best, followed by plain blank consent (no donor control, 21.1%) and blanket combined with a caution that "[s]ome people may have moral, religious or cultural concerns about some kinds of research," giving them the option not to donate (19.7%).

Nearly half of all participants (45.0%) rated as the "worst" consent option real-time, specific consent for each use of the donated sample, in which the biobank contacts the donor to obtain consent whenever there is a research request for the tissues.

No Federal Rule

Skloot noted that in 1951, when physicians took Henrietta Lacks' cells without permission, and in 2009, when the first edition of her book went to press, there was no federal law requiring patient notification that harvested cells were being used in research. Still today, there is still no such law on the books; although a [proposed regulation](#) has been offered for public comment, it has languished without action for years.

"Where did those proposed regulations go? They were proposed years ago," Skloot said.

Although there is rigorous federal oversight of how intact human beings are treated in medical research, the rules applying to tissue research are far more lax. And what the consent scenarios described by Dr Tomlinson and colleagues fail to mention is that despite alleged privacy safeguards, research using donated tissues "could someday identify you and reveal personal information about you," Skloot added.

In 2013, researchers at the European Molecular Biology Laboratory in Heidelberg, Germany, sequenced and published the HeLa genome sequence, exposing the Lacks' family's genetic heritage to the world at large.

"This whole sequence could tell you whether she had the gene for early-onset Alzheimer's, which no one in the family wanted to know whether they had it or not," Skloot said. "The family didn't know that someone could use HeLa cells to do that, and really nobody did, because the technology didn't exist when they first took the cells."

In the 5 years since her book's publication, Skloot has toured and spoken on talk shows and at medical schools, research institutions, and countless other venues.

"What I hear across the board is that people want to donate, they understand why donating tissues is important for science. They want to be told, and they want to be asked how their tissues will be used," she said.

The study by was supported by a grant from the National Genome Research Institute. The investigators and Skloot have disclosed no relevant financial relationships.

JAMA. 2015;313:417-419. [Extract](#)

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Ampersand



Building Better Networks for Health Research

Posted: 07 Apr 2015 12:58 PM PDT



By Amy Davis, JD, MPH

Social media platforms such as Facebook, Twitter, YouTube, LinkedIn, and others have dramatically exposed new opportunities for conducting research and recruiting subjects. Although the application of these tools to the research enterprise has been cautious, they are used for a variety of purposes. Researchers are conducting observational studies of online behaviors and survey research; informing patient groups of relevant clinical trials; conducting community consultation in anticipation of emergency research ([Stephens, et al.](#)); locating subjects lost to follow up; and even designing studies through crowdsourcing public input. ([Thompson](#)) In addition, these tools are used by participants to learn about their diseases, to find emotional and practical support, to find clinical trials, and even to initiate their own studies. ([Moreno, et al.](#)) Social media websites have the potential to support the full spectrum of communication between researchers and the public more efficiently, cheaply, broadly, and deeply.

And yet these new communication tools have not made a significant impact on clinical trial participation. In fact, meeting enrollment timelines is on the decline to such an extent that one study estimates that 80% of trials fail to meet enrollment timelines, and 50% of them enroll one or no patients. ([Zamosky](#)) Moreover, only about three percent of cancer patients participate in clinical trials, and seniors represent only about one third of people volunteering for clinical trials, despite the fact that most studies involve drugs targeted at age-related diseases. ([Katz, et al.](#))

As a cancer survivor and a beneficiary of clinical trials that relied on the participation of many thousands of research subjects, these are very disturbing statistics. Treatment will not advance without human subjects research. Failure to recruit subjects derails research studies, wastes resources, and dangerously slows the progress of drug development and health improvements.

When you consider that 86% of Americans have access to the internet; that most of those users (58%) are on Facebook; and that 52% use at least *two* social media sites ([Pew Research](#)), you would think that social media would be a boon for solving the enrollment problem. But, you would be wrong; at least so far. It turns out that a very small percentage of drug sponsors, for example, use social media for recruitment purposes. They use these tools for marketing their products but not for research. ([Tufts Center for the Study of Drug Development](#))

So what's the problem? Why have researchers not found social media to be an effective or attractive strategy for recruitment? Studies suggest that researchers are reluctant to use social media for recruitment or other research endeavors due to a variety

of concerns. It is daunting to consider how to protect the integrity of research in an environment where there can be uncertainty about identity of respondents, potential for falsification of eligibility, ambiguity about data ownership, and challenges for protecting personal data.

Potential subjects, on the other hand, continue to fear being "treated like a guinea pig." Worries persist that clinical trial participation is risky to one's health, privacy and confidentiality, and social networking sites may not have the power to overcome or diminish (and indeed may exacerbate) these fears. ([Research America](#)) The data on who participates in clinical research bears this out. It is alarming that only a small percentage of Americans (16%) have participated, or have a family member who has participated, in a clinical trial. ([Research America](#)) More worrisome, is the statistic that 34% of Americans have not even heard of a clinical trial. ([Thompson](#))

Given these barriers, it is surprising to learn that a large majority of Americans (72%) say that they would consider participating in research if their doctors recommended it, suggesting, perhaps, that patients are more trusting of information coming from this source than from the internet. However, only 22% of patients surveyed report that they have discussed participation in a clinical trial with their health care provider. ([Research America](#)) Physicians don't seem to be talking to their patients about research. Similarly, patients who do participate in research don't talk about it afterwards, despite reporting that their experience had been positive. Study participants don't seem to recognize the importance of their contribution, or at least don't want to bring attention to it. ([CISCRP](#))

So to review: researchers are on the internet using social media; patients are on the internet using social media; researchers need more subjects; and patients are interested in participating research. However, the researchers and the patients are reluctant to find each other through this medium. Until technology and data collection systems improve to an extent where researchers feel more comfortable using social media platforms to seek out trial participants, maybe they should consider interacting with the public in an informal, yet informative manner. For example, Ken Getz, founder and chairman of Center for Information and Study on Clinical Research Participation (CISCRP) and director of sponsored programs, research associate professor (PHCM) CSDD, Tufts University School of Medicine, favors using social media for "engaging" more with patients rather than for recruitment. ([Wechsler](#))

What would increased "engagement" look like? Perhaps one vision would be more researchers active on social media sites, simply "chatting" about their work; asking questions about the experience of others who also conduct research or who have participated in research. Then the general public could "friend" and "follow" the scientists, the patients, and the research coordinators, and discuss the research that is ongoing, or is needed. ([Katz](#)) And what if these discussions were occurring not only on patient-focused websites like [PatientsLikeMe](#), [Inspire](#), and [ArmyofWomen](#), but on more mainstream sites such as Facebook, Twitter, and YouTube? Other possibilities are is physicians providing more information to their patients about relevant studies—not so much for the purpose of recruitment but for education and trial participants being encouraged to post, tweet, and blog about their experiences as research subjects. These kinds of conversations and collaborations do occur, and there are researchers and patients working on creating Facebook pages and Twitter hashtags that facilitate this communication. ([Thompson](#)) But perhaps if these conversations were more widespread, the percentages of people who know about clinical trials and who participate in them would increase.

The number of people who donate blood every year in the United States is over 9 million. ([American Red Cross](#)) The number of Americans who participate in clinical trials in a year is fewer than 3 million ([IOM](#)). Is there a way to tap into the evidently deep well of altruism that motivates blood donors for improving research participation? Perhaps mainstream social media has the power to do that.

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Establishing IRB Review Policies for Social Media Participant Recruitment and Retention Programs

Institution Bulletin vol 5, issue 1



As new technologies emerge, stakeholders must find ways to apply existing regulations and guidance to ensure appropriate IRB review and approval is obtained. This presents a huge challenge to independent and institutional review boards (IRBs) as they must develop their own written policies and procedures. This article focuses on the regulatory basis and considerations an IRB may want to contemplate when developing their own policies on reviewing social media recruitment and retention campaigns.

Defining the Scope of Social Media

Quorum Review has defined “social media” as “an interactive platform for electronic communications, used by groups of people to create, share, and exchange information.” Typically, these platforms are internet-based and allow users to interact with other users through a website or web application. Examples of social media usage in the context of clinical trials include:

- Facebook and Twitter advertising campaigns to recruit participants;
- A phone application (i.e., iPhone, iPad, or an Android platform based phone) that users download on their phone and use as an electronic diary;
- A Pinterest board where a clinical trial site can “pin” news articles, blog postings, and enrolling clinical trials; or,
- A Facebook “Fan” page for the study.

Although the forums and type of social media are distinct, the IRB’s review is based on the same fundamental principles and regulatory requirements.

Regulatory Basis

An IRB has “the authority to approve, require modifications in, or disapprove all research activities,” covered by IRB regulations.^[1] In addition, an IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects.^[2] To fulfill these responsibilities, the IRB is expected to review the methods and material that investigators propose to use to recruit subjects.^[3] The IRB must review advertising material to ensure that it is not unduly influencing and does not promise a certainty of cure beyond what is outlined in the informed consent document and protocol.^[4]

Although the FDA has issued draft guidance recently on social media and internet communications about medical products, this guidance is intended for the post-approval context instead of the research context. However, it can be useful in understanding the agency’s approach to the use of social media. As noted in a [previous article](#) by my colleague, Mitchell Parrish, the guidance titled *Internet/Social Media Platforms with Character Space Limitations – Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices* indicates that

...any recruitment of or advertising to research subjects through social media must still comply with applicable FDA regulations related to human subject research. This means adherence to 21 CFR §56 as explained in the FDA’s longstanding document titled, “Recruiting Study Subjects – Information Sheet, Guidance for Institutional Review Boards and Clinical Investigators” ([Recruitment Information Sheet](#)). This also means that some forms of social media,

such as Twitter, may not be appropriate to advertise certain clinical trials that require the dissemination of more complex information.

This may present a challenge to the IRB when asked to review campaigns where complex risk and/or benefit information is communicated to the potential participant. However, the basic tenets set out in the current regulations and guidance remains the same and can be applied to emerging technologies.

Review Standards

As noted in the *Recruiting Study Subjects – Information Sheet*, the IRB should review the information contained in an advertisement and the mode of its communication. This can be a challenge with social media campaigns, as the sponsor or site may have to initially submit unfinished campaign materials, such as storyboards, mockups, or wireframes to depict social media interactions, social media pages, or websites for review as well as the final product. Generally, the following types of material should be reviewed:



Recruitment

- Any direct advertising using social network ads, display ads, banner ads, rich media ads, paid search ads, and in-text ads;
- Any free form listing of study specific information including but not limited to a study description, contact information, and compensation designed to recruit participants;
- Any study specific websites or posts designed to recruit participants;
- Any publication or dissemination of study results with an intent to create interest in new research opportunities;

Communications (fixed)

- Any study specific websites or social media intended to serve as support for enrolled participants; or
- Any communications intended for study retention or advertising for future studies;

Interactions (free-form)

- Any study or site specific websites or social media that allows for user generated content;
- Any requests for the provision of identifiable private information (e.g., health) from potential participants or participants; and
- Any protocol study tools (applications or software) used to collect data for the research (e.g., an app that captures glucose or blood pressure readings, an app that interfaces with an implanted device, etc.).

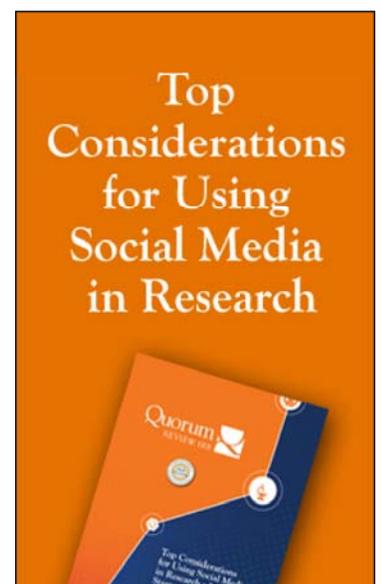
Quorum's social media policy sets the minimum acceptable submission for review as a printable final draft. This final draft may comprise the text and graphics that will be used only and does not have to be the final composition.

Additional Considerations

Review should be undertaken in accordance with the guidelines set out in the *Recruiting Study Subjects – Information Sheet* and the IRB's written procedures. In addition to the standard guidelines, the reviewer should try and account for any unique issues that may be unduly influential based on the proposed activity and the technology being used.

Interactive Social Media Programs

One of the most difficult parts in a social media program is managing interaction with participants. Where an investigator, sponsor, or participant will interact with another participant (i.e., through a Facebook "fan" page or an online message board), Quorum's social media policy typically requires development of a



written management/communication plan. The plan serves two prongs:

1. **Sponsor/site** – development of a plan allows a sponsor/site to define the scope of the plan, set out specific procedures tailored to the nature and frequency of interaction, and ensure the rights and welfare of research participants are protected.
2. **IRB** – the IRB can use the plan to evaluate the social media program and ensure it is not unduly coercive. Additionally, where social media will be used for retention of participants, the IRB can ensure the information given to participants is in accordance with the regulations and appropriate safeguards exist to protect the rights and welfare of research participants.



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Conclusion

IRBs need to consider a number of additional factors in developing review standards for social media and guidelines for social media plans. To help institutional boards in this effort, Quorum has developed a [whitepaper](#) describing many of the factors IRBs should consider.

[\[1\]](#) 21 CFR 56.109; 45 CFR 46.109.

[\[2\]](#) 21 CFR 56.107(a); 21 CFR 56.111; 45 CFR 46.109.

[\[3\]](#) FDA Information Sheet, [Recruiting Study Subjects](#). (1998).

[\[4\]](#) *Id.*

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