



Informed consent in online research: the need for new ways of addressing research subjects

Marc van Hoof, Guy Widdershoven

Department of Medical Humanities, VU University Medical Center, Amsterdam, The Netherlands

Correspondence to: Marc van Hoof. Department of Medical Humanities, VU University Medical Center, Amsterdam, The Netherlands. Email: m.vanhoof@vumc.nl; Guy Widdershoven. Department of Medical Humanities, VU University Medical Center, Amsterdam, The Netherlands. Email: g.widdershoven@vumc.nl.

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Introduction

Informed consent is an ethical and legal requirement for research with human subjects. In principle, informed consent can render actions morally permissible that would otherwise be wrong (1). The information requirement should ensure an understanding of what such an action entails in absence of control by others (2), respecting persons and their autonomy. However, a gap between theory and practice is evident. While investigators are responsible for facilitating forming an informed and independent decision by the subject, research shows that this is often not achieved in practice (3). Signed informed consent also is misused to serve the interests from sponsors and institutions in matters of liability (1).

Progress in online communication technologies have introduced new challenges as innovative types of research on a larger scale and in an international setting are technically possible. In a multipart review series *the changing face of clinical trials* published in *The New England Journal of Medicine*, such issues and innovative approaches to improving and expanding the informed consent process are discussed (4). In this contribution, we will go into some of the issues highlighted in the review series. We will show that the connections between business, internet technology and science leads to new ethical questions, both concerning recruitment of research subjects and validity of results, as data mining in the context of big data may reflect biases. We will argue that online research requires new ways of addressing research subjects, not only for achieving informed consent, but also for reflection on possible biases.

We will plea for a more active role of research subjects, both in entering the study, and in reflection on study design and study results.

Informed consent in the internet age

Grady *et al.* (4) observe that the classic interaction of informed consent is becoming outdated and does not always fulfill its purpose. The authors argue that new technologies such as interactive discussions, creative graphics, support for revisions and standardization might be beneficial in improving informed consent (E-consent) with regard to disclosure, understanding, voluntariness and authorization. However, the flexibilities gained with the increased freedom in location and time poses new challenges to tailor to the capacities of individual subjects and to verify their identification. The volatility of online contacts and information makes it easy to consent without achieving comprehension, similar to current online approval buttons and click-through agreements (4). The effort required for an informed consent procedure which aims to ensure an appropriate level of understanding (e.g., with a short online test or by asking subjects to explain the study) might counter previous troubles with informed consent and the volatility of 'tick this box for approval' behavior.

With regard to research in trials, Cummings and Rowbotham (4) argue that classical informed consent is obsolete, and hinders research as it physically ties subjects to research sites. Trials could be conducted entirely through the internet (Internet-based clinical trials) using biometrics

to ensure the participant identity and the combination of postal services and mobile nurses for specific study procedures. The authors showed that previously, short trials with many participants studying nutraceuticals and over-the-counter medication worked well, albeit sometimes with a low yield (<1%) of actual inclusion. McConnell and Ashley elaborate (4) that the mobile phone as a platform for online research adds the ability to continuously collect data (movement detection, cameras, microphones etc.). Advantageous is the large uptake of mobile phones globally, including the developing world, which is often left out in research leaving a significant selection bias. As an example of scalability, the authors show that a third-party software framework (ResearchKit Apple Inc., Cupertino, USA) was able to include over 70,000 participants in cardiovascular research using the mobile phone as a platform.

New connections between business, online technologies and science

Surveys have shown that people prefer to have a say in how their (online) data is used (5,6). Indeed, the moral force of consent is not unique to health care or formal research. Online communities and social networks currently monetize online activities of users which render data to be mined for commercial exploitation. One could argue this happens without the user's explicit informed consent (5). Few people actually read the terms and conditions of these social networks (7). This is especially relevant within the context that these networks intervene in the way information is presented in respect to an outcome [i.e., the expression of emotions online (8)]. In many ways, this could be considered behavioral science which closely resembles a classical randomized controlled trial. The difference being the absence of bells and whistles that accompany a formal trial in academia. These serve to protect research participants and the validity of results. In the publically known exemplary case of Facebook Inc., 700,000 social network users were not aware of being participants in such a study (8). This research was conducted by academics on data which was made available by this social network. The interventional experiment was already performed internally (9). In response to public outrage (10) that followed the scientific publication, the Editor-in-Chief of the corresponding journal judged in an Editorial Expression of Concern and Correction (9), that although it raised several ethical concerns, there was no obligation for a corporation

to abide by the US Department of Health and Human Services Policy for the Protection of Human Research Subjects or obtain an approval from an Institutional Review Board. Legal and ethical frameworks apparently have not managed to keep up with what is possible.

Big data can have big unforeseen consequences for subjects

New types of large scale data collections combined with powerful analytics (big data) pose new questions with respect to the informed consent of subjects for the intent and use of supplied data. Machine learning can be influenced by biases in data (11). An illustrative example can be found in the use of predictive policing to apprehend crime based on data with initial correlations between crime rates and the demographics of a community. Those situations are at risk for becoming a self-fulfilling prophecy as subsequent profiling might induce the development of stereotypes in a community. For example, by selectively arresting a selection of community members, based on a profile from available data, followed by higher sentences for the same sub community and then finally confirming initial prejudices about higher crime rates. Thus, a community is further stigmatized, and the rate of crime effectively increases (12). This clearly illustrates how individual interests in privacy can hold a complex relationship with an indirect and for individual's adverse outcome such as stigmatization. In the science of policing it can even lead to a higher chance of incarceration. It can hardly be expected that a layman can oversee such risks when consenting to the collection of privacy sensitive data. These matters [formal verification, validity and specification of data models (13)] require the expertise not only of field-specific experts, but also of ethicists and computer scientists.

The anonymous research subject and 'Big Brother' researcher

The internet is not a fully neutral, reliable, open or when necessary, shielded communication channel. Can we expect that subjects participating in online communication such as (private) chat rooms or online trials are sufficiently aware of associated risks? On the other hand, can researchers truly sufficiently assess and assure an online research setting in terms of truthfulness, validity and reliability of the data to be collected? For the researcher, having no or a limited form of direct human-to-human interaction (i.e.,

seeing a subject struggle with a questionnaire by means of facial expressions and vocal intonations) challenges the ability to monitor day-to-day research practices. The BlackBerry project (14) showed that despite formal and extensive informed consent, teenagers willingly gave up their privacy by consenting to full online surveillance in a trade-off for a mobile phone with a service plan paid for by the researchers. Researchers monitored to prevent only the most severe events (e.g., suicide) during this long-term experiment amongst these teenagers. Lead scientist Underwood (15) later discussed the 'digital harms' which were newly discovered in this study and similar research which were facilitated by these experiments. The combination of aspects of technology (anonymity, surveillance) for research and psychosocial behaviors asks for new types of expertise in reviewing such research in relation to informed consent in protecting both the quality of research and interests of the subject.

Using internet technology for fostering participation of research subjects

Informed consent in research implies duties for the researcher (providing information and asking for consent). Yet, informed consent is not necessarily a one-way street. Although not legally binding, it presumes an effort to commit to research from the subject as well. This protects research procedures and the validity of findings. In clinical research, patient loyalty to the physician who invites a subject to participate is relevant. The participation of patients in research involves an active role of the patient, going beyond merely being a source of data.

How can research subjects be adequately addressed in internet research, so that their engagement and active role are promoted? This clearly requires a contextual and appropriate online informed consent procedure. From an evidence based perspective, there is no solid evidence that new types of informed consent actually perform better in this respect (4). Intensive human-to-human contact is not easily replaced by online procedures. Therefore more research and development is needed (4) to address the merits and issues with new types of informed consent taking into account the preferences of subjects and stimulating their active role.

For clinical investigations, using internet technology creates an opportunity to tailor informed consent procedures to the level the individual wishes to be informed (16). The physician or researcher can play a

contextualizing role to assess the amount of information the subject would like to receive. When potential side-effect during an investigation arise, subjects could ask investigators to disclose more information about potential adverse events online or provide them with information for a correct interpretation. Once reported and if appropriate, research participants could even be given selective access to see if other participants have reported similar side effects to comply with the requirement to inform research participants of the latest developments in a clinical trial, where necessary.

New technologies can enable to engage research participants in later stages than what is now common. Instead of only providing data, research participants and online community members could participate actively in ongoing investigations. Participatory approaches in health care research (17) empower research subjects, considering them as stakeholders who can provide their motivations, preferences and opinions in relation to their own outcomes or those of others. Why should a subject only tick a box, when thinking aloud while completing a questionnaire provides a full audio recording full of deliberations? Using such technology can provide a wealth of information on procedures and motivations which were previously obscured by procedural limitations. Importantly, it allows for a concurrent in-depth validation as well. The option of an audio or video recording of informed consent, although troubled in some ways as outlined by Kang (4), might provide a way to provoke a subject to motivate their consent in relation to the information provided. This yields a proof of informed consent while providing biometric data which can assure proper identification of research subjects.

Conclusions

History shows that important steps in the regulation of research and development of informed consent occurred after-the-fact initiated by outside parties. There are signs that the same is true now for new types of research online. It should be investigated if classical methods of governing informed consent are up to the task at hand. One of the key conclusions from Grady *et al.* (4), that more research is needed about new paradigms for informed consent, should be taken up urgently. As outlined here, commercial parties are conducting such research and collecting data without ethical supervision already today, which creates new risks. Further investigation and reflection on how science is conducted and supervised online on a larger

scale is required to remain in pace with technological developments. External rules will not suffice to identify and counter the issues mentioned above. The scientific community itself should take seriously, both the challenges and opportunities involved in using new technologies. Difficult cases should be investigated and discussed openly. In such a process of reflection, all stakeholders should get a voice, including research subjects. Internet technology enables large scale processes of deliberation, including many users. Internet innovations in research clearly create ethical questions, but could also be helpful in finding answers, by fostering reflection and deliberation of all parties involved.

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