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Consumer Informatics and Digital Health

Solutions for Health and Health Care

Springer

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ISBN 978-3-319-96904-6 ISBN 978-3-319-96906-0 (eBook)
https://doi.org/10.1007/978-3-319-96906-0

Library of Congress Control Number: 2018957137

This Springer imprint is published by the registered company Springer Nature Switzerland AG
The registered company address is: Gewerbestrasse 11, 6330 Cham, Switzerland

Chapter 17
Ethical Issues in Consumer Informatics and Online Content

John Wilbanks

Introduction

After the revelations of Edward Snowden, and the elections of 2016, ethical issues in consumer informatics and online content finally began to rise to the level of public consciousness. Yet, the vast majority of consumer informatics applications continue to ignore ethical issues in favor of business considerations such as low transaction costs and frictionless enrollment and engagement strategies.

Software developers typically focus on minimizing the ability of their potential users to understand how the data is captured, how it is processed, and who owns the data in the end. This culture supports a set of business models in software development that depend on post-hoc uses of data to bring in revenue—most of which are advertising or surveillance based.

The end result of this transactional approach to ethics is a sea of data captured about us as we use our digital devices, phones, and credit cards. This data moves about without our agency, and usually without any right of ours to scrutinize the system or flow. It also enables the emergence of a surveillance culture of government, in which the ability to sensitively profile any citizen is achievable with just a few clicks in key corporate databases.

However, early returns from data collection in regulated informatics—clinical observational research—indicate a path forward, where the same tools used to design software are used to design ethical interactions. Using ethnography, personas, user stories, and other tools of interaction design, we see a path that balances the data collection of contemporary digital technology with concepts of autonomy, informedness, and the treatment of users as citizens with equal rights to their data.

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M. Edmunds et al. (eds.), *Consumer Informatics and Digital Health*,
https://doi.org/10.1007/978-3-319-96906-0_17

State of Consumer Data: Endless Terms of Service and "Dark Patterns"

As our lives have moved more and more into digitally mediated spaces, we are subject to more and more interlocking contracts we sign in order to access technology—the terms of service. At the same time, the business models that fund the creation of that software has become more and more dependent on returns emerging from user data, rather than annual or lifetime sales models.

Two trends emerge from this context that merit exploration. First, the legal agreements surrounding technology have expanded in size and scope, and cover every scrap of software code that we touch over the course of a day. An average internet user would need to take 76 vacation days from work per year to read all the relevant privacy policies alone, ignoring all the terms of service![1]

Unsurprisingly, we have developed a culture in which we do not prioritize reading the legal agreement before we sign it when it comes to digital devices. A recent study called "The biggest lie on the internet" analyzed precisely this behavior. Reading an average privacy policy should take 30 min based on average reading speed, but instead took 73 s, where terms of service took 51 s yet should have taken 16 min (Obar & Oeldorf-Hirsch, 2016). As an additional sting, terms of service in this study included clauses advertising data sharing with the National Security Agency and potential employers, and requiring the donation of a first-born child in return for access.

In addition to the cultural pressure to click "Accept" without reading, physical differences exist when we read on screens versus in print: Web market research using eye gaze tracking finds that most users read half or less of the text on screen, that a vast majority scan text by skipping around the page, and only a small percentage read word by word (Weinreich, Obendorf, Herder, & Mayer, 2008).

A second trend emerges from the presence of savvy designers under pressure to maximize "engagement." "Dark patterns," which trick unsuspecting users into actions they would not normally choose, represent deceptive practices that interact with complex terms of service and privacy policies to trap users of consumer technologies in agreements that take advantage of their data (Brignull, 2013).

Dark patterns have a long history. A familiar pre-Internet example is the deceptive marketing practices of Columbia House mail order music, where participants were charged extremely high rates for music they did not want if they forgot to specify their choices. Known as negative billing, this dark pattern is nearly a 100 years old. Harry Brignull (2013) identified multiple types of dark patterns, including bait-and-switch, disguised ads, forced continuity, misdirection, and the roach motel, noting

[1] The Cost of Reading Privacy Policies: http://lorrie.cranor.org/pubs/readingPolicyCost-authorDraft.pdf. Researchers reviewed the top 75 websites on the Internet and found that the median length of their privacy policies was 2514 words. Then, they added another factor—how long it took an average person to actually understand what they were reading, which they found by giving simple comprehension questions to 212 study participants. http://techland.time.com/2012/03/06/youd-need-76-work-days-to-read-all-your-privacy-policies-each-year/.

their connection to longstanding heuristics of good design. Designers take these patterns and make them scalable, visually complex, and difficult to avoid.

The emergence of internet-connected hardware devices—also known as the Internet of Things (IoT)—represents a perfect marriage of abstruse terms of service, dark patterns, and the business models they support. Akin to Gillette razors of old, the hardware is sold at a loss, paid for by the evergreen flow of data.

Interestingly, there may be an opening as a result of the Internet of Things to begin addressing the twin issues of metastatic legal agreements and dark design patterns. The more intrusive the devices, the more difficult to maintain the ignorance of the user base—it becomes much easier to think about the question of what is happening with the information. And interestingly, these devices are increasingly contemplated as a component of ethically regulated observational research (Haghi, Thurow, & Stoll, 2017). For the first time, the convergence of dark patterns and lengthy agreements fall under the scrutiny of an established regulatory and ethical regime that cannot be easily avoided.

Ethical Issues in Regulated Research

The process of informed consent is essential to enhance participant autonomy when deciding whether or not to enroll in a regulated clinical research study. The informed consent doctrine (e.g., Murray, 2012) has evolved from disclosing the potential risks associated with medical treatment to include "all pertinent information enabling one to make a meaningful decision," a mandate that can be overwhelming to prospective participants.

As with online terms of service and privacy policies, a set of dark patterns in "traditional" informed consent processes deserves scrutiny. Multiple studies have reported significant issues with comprehension or "informedness" after traditional informing interactions before enrolling in studies and trials:

- IC forms are long and complex—more than 20 pages on average, requiring more than 1 h to read (Kass, Chaisson, Taylor, & Lohse, 2011).
- Nearly, 70% of informed consent interactions ended with the participant signing but not actually reading the entire consent form (Lavelle-Jones, Byrne, Rice, & Cuschieri, 1993).
- Even with careful implementation of consent protocols, only half of all those consented could accurately describe what was going to happen to them under that consent (Schultz, Pardee, & Ensinck, 1975).
- Nearly, all participants believed they understood the trials in which they had decided to participate, but only one in three could later describe the trial's goals (Daugherty et al., 1995).
- Only 40% of the patients claimed to ever read the consent form "carefully" and the legalistic structure and language was correlated to poor long-term comprehension of study goals and outcomes (Cassileth, Zupkis, Sutton-Smith, & March, 1980).

– Readability of IRB approved forms consistently falls short of IRB standards on readability (Paasche-Orlow, Taylor, & Brancati, 2003).

Taken together, these elements interact with the existing culture of lengthy agreements and dark design patterns to create a very compelling trap for regulated medical research as it moves into digital devices such as phones and IoT. Regulated research then represents a potential testing ground for designers, ethicists, and software developers to work together to create a novel set of light pattern for ethical interactions with devices and data capture. However, the interactions that will emerge from this grouping will be different than those created in nearly every other element of technology development. These are interactions that intentionally expose friction, rather than intentionally hide it.

Clues to these patterns exist. Reading comprehension does appear to increase with certain actions, with implications for assisting "informedness" processes in e-consent.

First, prioritization of certain paragraphs and key words on the screen or on subsequent screens positively correlates with retention (Lorigo et al., 2008).

Second, addition of pictures has been shown to slow down readers, lengthening eye-text fixation (correlated to the "on task" nature of a picture, with the belief that the cognitive effort to relate the pictures and the text together slows the reading) (Beymer, Orton, & Russell, 2007).

Third, shorter forms have also been connected to both improve comprehension and higher consent rate (Wager, Tooley, Emanuel, & Wood, 1995).

Last, there is evidence that informedness "decays" over time and is greatest at the moment of consent. E-consent might allow the study to scale in terms of enrollment but also removes the human-to-human interaction where a study staffer might intervene to address comprehension and capacity to provide informed consent (Lavelle-Jones et al., 1993).

At Sage Bionetworks, we worked with the Electronic Data Methods Forum (EDM Forum) at AcademyHealth to develop an eConsent toolkit to support the creation of some initial "light patterns" for consent into clinical research. First, we interviewed stakeholders in the EDM Forum's collaborative network, including ethicists, technologists, scientists, patient advocates, clinical data specialists, and more to understand their challenges and requirements.

We asked questions such as:

– What are your goals in patient-centered research? How do they inform your ethical procedures?
– What kind of data are you collecting, and how are you storing and syndicating it?
– Has the structure of informed consent documents ever prevented secondary data reuse? If so, how?
– At what point do you see informed consent as "kicking in" during patient-centered research? At collection of data? At entering a registry? At syndication of data to researchers?
– What are the implications of broad or open consent in your work? How do they connect with e-consent?

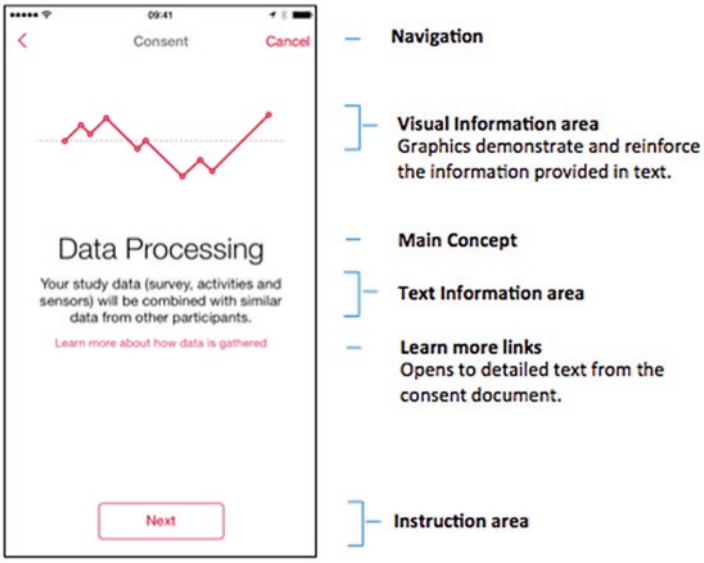

Fig. 17.1 Visual tier of consent screen shows the "data processing" concept

– Would you use a toolkit that provided prefabricated consent design and experience to enable your consent processes? What would you need to see out of that toolkit before you used or trusted it?

Emerging from these interviews, we created the Participant-Centric Consent Toolkit to help investigators create visual representations of consent forms. The visual representation draws on the implications of on-task pictures slowing reading comprehension, paired with clear, limited-length, large-font text, to increase comprehension (Fig. 17.1).

As we built the toolkit, we developed informal rules of thumb[2] for visual informed consent, including:

Use large icons related to the key study concept to occupy up to 30% of your screen;
Use 2–4 word text phrases describing the concept, to be placed underneath the icon to slow reading and fix attention on the concept;
Use text labels of less than 10 words, placed under the text slug;
Place no more than two links (other than "cancel") on the screen—one to learn more and the other to proceed to next screen; and.
Use simple, short text (less than 50 words) on secondary screens.

The visual representation takes a narrative form. Each screen displays an essential study concept, so that a succession of screens combines to describe the study's key features. Concepts cluster into classes such as research activities, data handling,

[2] Rules of Thumb. http://sagebase.org/pcc/participant-centered-consent-toolkit/rules-of-thumb/. Accessed October 19, 2015.

Fig. 17.2 Combined screens form a narrative layer atop an informed consent document

impact on participant life, participant rights, free will, and potential risks and benefits, issues to consider. Each concept screen has an on-task icon, a large-font "slug"[3] of one or two words indicating the concept, a text "label" of a sentence or two, and a "learn more" link. Clicking "learn more" generates a simple text screen whose navigation reverts to the main concept for reinforcement. When combined, the screens form a visual narrative that acts as an interface to the consent, to facilitate participant enrollment decisions (Fig. 17.2).

Benefits of Participant Centricity

All interactions that leverage digital devices exist in an attention economy (Goldhaber, 1997) that is not present in traditional clinical research. While it is significantly easier to recruit and enroll participants using these kinds of methods, retention and engagement become significantly more difficult. For most studies that use mobile devices, even consenting tens of thousands of participants does not yield large participation in data collection only a few months after enrollment. These samples are also not particularly representative, as early mobile studies show a significant bias towards young, male participants.

Taking a user-centered approach towards informed consent yields both an interface that is consistent with ethical obligations and existing regulations on human research, as well as indicating a path forward for general consumer data capture that

[3] "The keyword or slug (sometimes more than one word) clearly indicates the content of the story." *Associated Press: 2008 Stylebook and Briefing on Media Law,* ISBN 978-0-917,360-52-7, p.404

does not rely on misdirection and obfuscation. It is entirely possible to both craft short, readable text about clinical studies as well as to apply design resources to clearly reveal facts and details about clinical studies. It simply is a matter of willpower and time.

There may also be a degree to which this is a competitive advantage. In clinical research, moving to digital devices appears to increase enrollment, but does not lead to long-term and sustained engagement with the devices or the mobile apps (McConnell, Shcherbina, Pavlovic, et al., 2017).

The challenges of attempting mobile clinical studies include bias in selection, poor retention, self-reporting biases, and more (Chan, Wang, Tignor, et al., 2017). Thus, it is possible that mobile studies attempting to leverage dark patterns and complex agreements may suffer more attrition in their recruited participant base than studies leveraging intentional design.

Rigorous controlled experiments, as well as retrospective analysis, will be essential to understanding the subtle difference between unintended friction in consent design (which is undesirable) and friction working as designed to enhance participant informedness.

Emerging Trends and Future Directions: Nothing About Me Without Me

Consent, however, does not exist in a vacuum. It is deeply tied to the governance of the data that is collected. Traditionally, consent was obtained to extract the data from the individual, and that was the end of the relationship. Most of contemporary non-electronic consents reflect this transactional nature. However, participants in clinical studies have begun to demand a different social contract, one encapsulated in the phrase "nothing about me without me" (Delbanco, Berwick, Boufford, et al., 2001).

Nothing about me without me implies a relationship that is far more equal than the traditional asymmetric researcher to patient one. It must be addressed in consent, and its absence is often felt in consent interactions and clinical protocols that treat individuals as subjects. Designing study and technology governance that empowers the participant by giving them copies of their own data, easy ways to manage their study enrollment, research results, and the ability to directly contact the scientists running the study—these are all elements of participant interaction that must be addressed in contemporary clinical study. And, each of them impacts the consent design.

Meeting the participant community halfway can be complex. Most research institutions and funders do not have supporting structures that facilitate these new kinds of interactions. At a minimum, those running studies should give a full and complete copy of data back to every participant on demand. Designers should also ensure that the ability to withdraw, pause, and otherwise modify participation is easy to find within the user interface, rather than being buried at the bottom of complex nested menus.

In addition, our engagement with participants during our consent design process made clear that many participants want their data broadly available beyond the initial study that collects it. As participants become aware of the value of their data, more and more will demand giving the power to make that data broadly available.

In our own studies at Sage Bionetworks, we provide a "donate broadly" option to all participants. More than 70% of our enrolled participants elect to share broadly, and we launched data sharing in March 2016, in advance of our own data analysis publication (Wilbanks & Friend, 2016) and now have more than a 100 external data users actively analyzing the data. And, the "donate broadly" concept sits at the heart of the NIH's flagship Precision Medicine Initiative, where the AllOfUs Program will enroll participants specifically into a broadly shared data enclave intended to support the ongoing research and participant collaboration.

The nothing about me without me concept contains many possibilities, including making it simple for participants to download their data, or donate it to organizations that share on their behalf, or synchronize it with their accounts at companies that maintain other health data and services. These will become an essential element of participant engagement and study governance, and may begin to bleed over into consumer informatics and data capture as health and consumer trends begin to merge.

Summary and Conclusions

Informed consent sits at a crossroad. As data collection becomes more and more digital, informed consent can either adapt and become a design priority in the new world, or be treated as part of the one-click consumer agreement universe. Either way, the devices are coming—they simply represent too powerful of a data collection method, and too strong of an enrollment method, to stay out of the research space.

The early work on participant-centered consent represents simply the first step on a complicated journey towards designing rich interactions for clinical research and ethical individual engagement. We need a multiyear program to investigate the efficacy and desirability of various types of consent interactions, and a public effort to benchmark and evaluate these methods in different contexts with different populations. Without such an effort, it is very difficult to understand if an informed consent implementation is actually working or not. And, without such an effort being public, it will be easy for stakeholders to obscure the efficacy of their processes.

However, there remains a self-interest element to adopting ethical consent procedures beyond regulated research. As citizens are more and more bombarded with digital technology choices, those choices that present clear and ethical relationships over time may possess a sustained competitive advantage. Because the real challenge is not getting someone to install an application, or allow data collection. The

real challenge is working with someone to keep the application and data collection going over a long period of time, and to remain willing to perform study tasks in ways that provoke an understanding of health and wellness. Starting with a clearly ethical interaction is by far the best way to start that long-term, and we need free and open-source tools to support as many of those interactions as we can design.

References

Beymer, D., Orton, P., & Russell, D. (2007). An eye tracking study of how pictures influence online reading. In C. Baranauskas, P. Palanque, J. Abascal, & S. D. J. Barbosa (Eds.), *Human-Computer Interaction – INTERACT 2007. INTERACT 2007*, *Lecture notes in computer science* (Vol. 4663). Berlin, Heidelberg: Springer. https://doi.org/10.1007/978-3-540-74800-7_41

Brignull, H. (2013, August 29). *Dark Patterns: Inside the interfaces designed to trick you*. Retrieved May 11, 2017, from https://www.theverge.com/2013/8/29/4640308/dark-patterns-inside-the-interfaces-designed-to-trick-you

Cassileth, B. R., Zupkis, R. V., Sutton-Smith, K., & March, V. (1980). Informed consent—Why are its goals imperfectly realized? *The New England Journal of Medicine, 302*(16), 896–900.

Chan, Y. Y., Wang, P., Tignor, N., et al. (2017). The Asthma Mobile Health Study, a large-scale clinical observational study using ResearchKit. *Nature Biotechnology, 35*, 354–362. https://doi.org/10.1038/nbt.3826

Daugherty, C., Ratain, M. J., Grochowski, E., Stocking, C., EKodish, E., Mick, R., & Siegler, M. (1995). Perceptions of cancer patients and their physicians involved in phase I trials. *Journal of Clinical Oncology, 13*(5), 1062–1072.

Delbanco, T., Berwick, D. M., Boufford, J. I., et al. (2001). Healthcare in a land called PeoplePower: Nothing about me without me. *Health Expectations: An International Journal of Public Participation in Health Care and Health Policy, 4*(3), 144–150. https://doi.org/10.1046/j.1369-6513.2001.00145.x

Goldhaber, M. H. (1997). The attention economy and the net. *First Monday* 2.4. Retrieved May 11, 2017, from http://firstmonday.org/article/view/519/440

Haghi, M., Thurow, K., & Stoll, R. (2017). Wearable devices in medical Internet of things: Scientific research and commercially available devices. *Healthcare Informatics Research, 23*(1), 4–15. https://doi.org/10.4258/hir.2017.23.1.4

Kass, N. E., Chaisson, L., Taylor, H. A., & Lohse, J. (2011). Length and complexity of U.S. and international HIV consent forms from federal HIV network trials. *Journal of General Internal Medicine, 26*(11), 1324–1328.

Lavelle-Jones, C., Byrne, D. J., Rice, P., & Cuschieri, A. (1993). Factors affecting quality of informed consent. *British Medical Journal, 306*, 885.

Lorigo, L., Haridasan, M., Brynjarsdóttir, H., Xia, L., Joachims, T., Gay, G., … Pan, B. (2008). Eye tracking and online search: Lessons learned and challenges ahead. *Journal of the American Society for Information Science and Technology, 59*, 1041–1052. https://doi.org/10.1002/asi.20794

McConnell, M. V., Shcherbina, A., Pavlovic, A., et al. (2017). Feasibility of obtaining measures of lifestyle from a smartphone app: The MyHeart Counts Cardiovascular Health Study. *JAMA Cardiology, 2*(1), 67–76. https://doi.org/10.1001/jamacardio.2016.4395

Murray, B. (2012). Informed consent: What must a physician disclose to a patient? *Virtual Mentor, AMA Journal of Ethics 14*(7):563–566. Retrieved August 19, 2017, from http://journalofethics.ama-assn.org/2012/07/hlaw1-1207.html

Obar, J. A., & Oeldorf-Hirsch, A. (2016, August 24). The biggest lie on the Internet: Ignoring the privacy policies and terms of service policies of social networking services.In *TPRC 44: The 44th Research Conference on Communication, Information and Internet Policy 2016*. Retrieved May 11, 2017, from SSRN: https://ssm.com/abstract=2757466 or https://doi.org/10.2139/ssm.2757465

Paasche-Orlow, M. K., Taylor, H. A., & Brancati, F. L. (2003). Readability standards for informed-consent forms as compared with actual readability. *The New England Journal of Medicine, 348*, 721–726.

Schultz, A. L., Pardee, G. P., & Ensinck, J. W. (1975). Are research subjects really informed? *Western Journal of Medicine, 123*(1), 76–80.

Wager, E., Tooley, P. J., Emanuel, M. B., & Wood, S. F. (1995). How to do it. Get patients' consent to enter clinical trials. *BMJ: British Medical Journal, 311*(7007), 734–737.

Weinreich, H., Obendorf, H., Herder, E., & Mayer, M. (2008, February) Not quite the average: An empirical study of Web use. *Association for Computing Machinery Transactions on the Web. 2*(1)—also see study data reanalyzed at How Little Do Users Read? Retrieved October 19, 2015, from http://www.nngroup.com/articles/how-little-do-users-read/ Published May 6, 2008.

Wilbanks, J., & Friend, S. H. (2016). First, design for data sharing. *Nature Biotechnology, 34*(4), 377–379. https://doi.org/10.1038/nbt.3516