Electronic Informed Consent in Mobile Applications Research

John T. Wilbanks

Electronic Informed Consent (eIC): Regulatory Considerations

Electronic informed consent sits inside a multi-decade process in the United States to convert diverse types of physical, paper contracts into virtual documents that can be "marked" and "signed" electronically. For this paper I will use the term "electronic signatures" for this legally centered concept, to distinguish them from "digital signatures," which are primarily concerned with cryptographic mechanisms.

Starting with commercial websites in the late 1990s, a variety of previously analog contracts moved online with associated uncertainty as to in what conditions the signatures of parties were binding. The US Congress reacted by passing the Electronic Signatures in Global and National Commerce Act ("E-Sign")[1] signed into law by President Clinton on June 30, 2000. Since then, 47 US States, the District of Columbia, and the US Virgin Islands passed a uniform piece of legislation implementing electronic signatures in their boundaries, with the remaining three states (NY, WA, and IL) passing non-uniform legislation with similar goals.[2]

Informed consent for research is documented on a written statement from the researcher to the participant, creating an interaction where the participant can understand the research, and make a recordable choice to enroll. Since at least the Camp Lazear yellow fever experiments[3] these documents explain what the participant deserves to know and a place where they can sign.[4] This structure became formal after a series of atrocities at home and abroad, and led to international and national regulation on the conditions under which research would be conducted.[5] Electronic informed consent (eIC) for research thus needs to fulfill both the legal and technical realities of a valid electronic signature, as well as fulfill the covenant between researcher and participant to disclose essential facts about the study.

The primary regulator of electronic signatures for research is the Food and Drug Adminstration (FDA), which describes standard process to evaluate electronic records and signatures to be "generally equivalent to a handwritten signature executed on paper."[6] eIC systems also need to capture and record dates of consent[7] and provide a signed copy of the informed consent to the participant.[8] But as a gateway to regulated research, the eIC is additionally subject to regulations governing traditional informed consent, plus additional electronic specific regulations above and beyond signature validity.

First, the eIC "must contain all elements of informed consent required by the Department of Health and Human Services (HHS) and/or FDA regulations[9] (see box 1). Additionally, in interventional trials, the FDA requires that the participant also has the right to opt out of the electronic process and request a paper-based consent form. Specific eIC guidance indicates the consent form must state that "significant new findings developed during the course of the research that may affect the subject's willingness to continue participation" be provided electronically as well (a concept not unique to eIC, but uniquely enabled due to the electronic medium and thus explicitly called out).[10]

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Box 1

Mandatory Elements of Informed Consent

All regulatorily compliant informed consent includes certain essential elements, in easily understandable language,[11] as per the National Human Genome Research Institute: [12]

- Voluntary Participation
- Purpose of Research
- Description of the Procedures
- Risks
- Confidentiality
- Potential Benefits
- Financial Considerations
- Withdrawal from Research
- Alternatives to Participation
- Explanation of Resources Available in Case of Injury
- Contact Information

eIC further illuminates where the traditional "human to human" informed consent conversation is difficult to translate into electronic form. For example, verifying the identity of study participants becomes far more complex in eIC and FDA guidance (this mandatory verification diverges from general HHS guidance to apply a risk-based approach to identity validation in minimal risk research under the Common Rule).[13] Another area where technology introduces complexity is in the conversation between participant and study coordinator: the traditional interaction makes it easy to ask and answer questions, an opportunity that has to be purposefully designed into an electronic context. The joint FDA-OHRP[14] guidance here notes that studies should have a method for questions to be asked and answered, but does not proscribe or require methods. The guidance also notes that informedness is a complex topic and notes that eIC "may" use a variety of methods such as multimedia and teach-back to attempt to increase and/or assess informedness.

Of course, these regulations only attach to researchers who perform research in a regulated context. The Common Rule does not apply to the individual using eIC to study herself, or her family, or her community, or even a community unknown to her to which she has no ties and therefore may feel no ethical obligation. Nor does the FDA guidance.[15] Thus, the only binding US federal consent regulation for the "unregulated" researcher using a mobile phone to study humans are related to obtaining a valid digital signature under E-Sign and the uniform state legislation. Interestingly, app store submission requirements can create a form of soft regulation that can require some form of consent akin to that required by statute, but only if the app stores find sufficient motivation to do so from the broader cultural and political environment.[16]

eIC: Design and Interface Considerations

Within eIC, all the elements of informed consent where people spoke to people now require interfaces and designs on screens. In addition to added cost (the cost of in person interaction having been implicit), these interfaces require very different skills to build and deploy than the skills found in traditional research settings, specifically human-computer interaction (HCI), user experience design (UX), and the translation of bioethical principles into software systems. The HHS and FDA regulation and guidance anticipated this transition and suggests directions for eIC interfaces: IRBs are explicitly tasked with reviewing everything from novel methods to studying materials usability to monitoring version control over time.[17]

In the 2010s, stakeholders began to focus on these "human to human" functions. In 2013, the Electronic Data Methods Forum (a project funded by the Agency for Healthcare Research and Quality, through Academy Health) funded a Sage Bionetworks project[18] in "portable" informed consent[19] for data donation. That project evolved into a "participant centered design" group, aiming specifically to address questions of how to plausibly inform participants in a fully electronic informed consent process. The design work built on research showing that screen reading is often a "scanning" or "skimming" process compared to print reading, as well as on work demonstrating that users frequently sign complex legal agreements without reading (e.g., copyright licenses, terms of service, privacy policy to inform designs for eIC.)[20]

In its initial form at Sage, participant centered design focused on the creation of screens that described the key concepts of the research study using small amounts of large-font text combined with semantically relevant iconography. An additional quiz module was added — questions that covered key concepts like therapeutic misconception, voluntariness, and key goals of the research — to assess basic (yes/no) comprehension of essential concepts conveyed (later moving to use these questions as a teach-back method rather than an evaluation).[21] Sage released an open source Participant-Centered Consent Toolkit[22] (updated in 2018 as the Elements of Informed Consent Toolkit)[23] comprised of an icon library, annotated sample protocols, "walkthroughs" of eIC informing processes for use by in-house designers, and more. The first wave of apps to feature the consent process included Sage's mPower app developed to study Parkinson's disease, which enrolled more than 16,000 participants.[24]

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Apple incorporated significant elements of the initial toolkit into consent-related templates of its ResearchKit framework in 2015.[25] Google did not release its own research app framework for Android, but the community-led ResearchStack open source project replicates nearly all of its key functions including informed consent.[26] The adoption and dissemination of UX elements in these toolkits (and the implicit endorsement of at least Apple's app store) may help incent researchers of all types to use design to communicate key IC concepts.

The move to eIC also opens up new fronts for researcher misbehavior in enrollment. User interfaces that abstract key elements of the consent form can also obscure or downplay key elements.[27] Designers in consumer technology regularly use "dark patterns" to entice users to subscribe, spend money, share data, or otherwise make choices without full understanding.[28] These patterns may correlate with higher "engagement" numbers[29] — for unregulated researchers, higher enrollment numbers — and thus may be attractive to developers who do not need to worry about regulation, although recent legislation introduced in the US Senate attempts to close that loophole.[30]

These app frameworks further accelerated the adoption of eIC, with more than 30 research apps[33] launched in 2015-2017 from academic medical centers, nonprofit organizations, patient groups, and pharmaceutical companies.[34] Nearly all of the first adopters of eIC frameworks conducted research in regulated contexts. However, given the cost and complexity of implementing eIC frameworks, it is possible that many unregulated app developers to come will simply choose to state clearly that they are not subject to either HHS or FDA regulations, and implement typical consent and privacy policies from consumer technology.

These consumer technology policies operate under a completely different framework from informed consent for regulated research: the Fair Information Practice Principles (FIPPs). Although they contain the word "consent," the definition is quite divergent in the consumer context, and consent is tied to "notice," and there are few regulatory requirements to achieve notice and consent. Online services frequently require a simple consent via users clicking a button to indicate they have been given notice and agree to whatever terms the site or app proposes, despite evidence that many of those who attempt to read the terms only skim the text.

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Box 2

What Is essential or Informed?

There is little consensus on either what informedness means,[31] or on what kinds of information are "essential" for participants to understand. Research has noted that expert groups reach one definition of "essential" information in an ideal context, but even the same expert group will redefine essentiality when faced with participants failing to correctly answer questions.[32] Thus, even as we change mediums, and who is doing research is opening up as never before, we still don't have consensus within the research community about informedness or what is essential for participants to "know."

eIC in an Evolving Research Ecosystem

Apple and Google do not maintain formal lists of mobile research apps (or if those apps are in regulated research or not), but a 2016 review of consent in 24 of these mobile research apps found wide variation in how informed consent processes implement the eIC guidance, including an element not anticipated by the

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guidance — easy, rapid, and widespread sharing of data beyond the initial study.[37] Data sharing can take many forms, from "open" data that can be downloaded and redistributed without restriction to a vast array of methods for collaboration,[38] and it can be difficult to fully inform participants of risks given that many risks will be emergent from the distribution itself. This onward sharing opens up another set of requirements for IRBs and for researchers to contemplate, and for eIC to address as part of an ongoing relationship with the participant.

Sharing liberalized data from electronically mediated research can also mean returning participant-level data to the participants themselves. This is a powerful, broad, medical data trend, driven by patients[39] and increasingly supported by policy.[40] This kind of data return in research is often held up as a form of returning value, although research indicates this is not always clear to all participants.[41] Others have called for a deeper process of acknowledgement of participants in this context,[42] but a larger study found that while respondents highly valued genetic results on medical response, predicting disease, and information about clinical trials and data use, the information of value varied widely across demographic variables.[43]

This sharing potential for data from mobile devices offers new complexities in how data are analyzed, and perhaps more importantly, re-analyzed. A multi-case study found that the text of the consent documents does not always keep up with the technology, so that studies originally intending to use Global Positioning System (GPS) data tracking participant movement expanded to include Global Information System (GIS) data. Two cases of this particular expansion transformed data that can easily be obscured by simply tracking total movement regardless of location into data that could be tagged directly to elements on a map, vastly increasing the potential for re-identification with no attempt to reconsent. [44]

This growth in implementation at the industry level masks the complexity of enrolling and retaining participants, which has long-term implications on app design and thus on informed consent. While these are not novel risks and exist in traditional studies, eIC allows for the entrance of scale and speed far beyond traditional consent.

Wearable devices in turn connect to mobile phones, and themselves represent other data collection technologies that may be leveraged for research. This can create a daisy chain of contracts (e.g., Privacy Polices, Terms of Service, Terms of Use) for commercial terms of service that a participant has to accept in order to join a study, which proliferate with every new measurement tool added over time. Each of these contracts holds the potential to complicate or counteract informed consent[45] and analysis of their terms indicates no meaningful commitments to privacy.[46] These contracts are notably long, densely written,[47] and rarely read.[48] Various groups have in reaction released open source iconographic labels for privacy policies,[49] nutrition labels for apps,[50] standard design "patterns" for good privacy policies,[51] and AI-enabled privacy policy interpreter software.[52] However, the current state of practice seems little impacted by these efforts to improve understandability, directly countervailing the informing requirement of informed consent.

As a further conflation, there may even be reasons to obscure some forms of data collection and analysis in order to generate more accurate observations of "natural" behavior.[53] These interacting pressures may increase the attractiveness of dark patterns to researchers who find significant drop-offs in mobile research studies after enrollment. And the desire to understand how participants, wearable technology, and the environment may further lead to an expansion of dark patterns from people's online behavior into people's relationship to their increasingly digital environment. For example, a person's mobile phone might send a signal to wireless sensors in a grocery store, or to a large display nearby, which might in turn change their behavior to deliver a personalized advertisement. The resulting dark patterns are explained by proxemics theory[54] and may form new vectors for risk, harm, and particularly re-identification.

eIC: Growth and Issues of Scale

eIC is gaining adoption quickly. A 2017 industry survey projected years of 30% compound annual growth of eIC in the pharmaceutical and biotech industry, with more than 80% of the industry projected to implement eIC by 2020. Notably, 76% of survey respondents wanted to build in-house (i.e., without relying on external vendors) and 80% said they want to deploy eIC to replace? supplement? traditional on-site informed consent.[55]

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retaining participants, which has long-term implications on app design and thus on informed consent. While these are not novel risks and exist in traditional studies, eIC allows for the entrance of scale and speed far beyond traditional consent. For example, a traditional cohort study like the Framingham Heart Study has enrolled over 15,000 participants across six cohorts over 55 years.[56] Leveraging eIC and an enrollment app, the AllofUs Research Program explicitly designed along the Framingham format[57] enrolled 283,000 participants in 18 months.[58] Early data on retention from these app-based studies show significant challenges: the Stanford My Heart Counts study enrolled more than 50,000 participants, but saw only around 10% actually complete physical tasks, with a "marked dropoff in the initial 7 day monitoring period."[59] A more systematic review found similar drop-offs persistently across more than 100,000 mobile participants, with stronger engagement predicted by either physician referral or payment than any existing design approaches.[60]

As with traditional consent, the ways in which study data are analyzed represents a vector for both benefits and harms. But as with enrollment, the sheer scale of systems that embed eIC creates different pressures on data analysis. Data analysis — or data science — as practiced in unregulated technology depends deeply on experimental processes relabeled as "A/B testing" by which companies study their customers.[61] But, as with unregulated mobile research, much data science falls largely outside traditional biomedical ethics and some data science practitioners choose to reject regulation outright.[62] Human psychology also comes into play here: research reports that for at least some portion of the population, people find being part of an experiment to define a better policy worse than either no-evidence policy alone.[63] eIC thus sits inside a larger cultural landscape of *data science* that is in constant flux, and is subject to the rapid evolution of how data is analyzed outside the clinical context.

Beyond data science, eIC must also grapple with the larger environment. Data collected from Facebook powered a variety of misuses in the 2016 election,[64] increasing public awareness and sensitivity to data science. But this public awareness is deeply contextual; studies of tweets about the scandals in countries tied to high levels of "power distance" show a greater acceptance of authority, and a larger blame on individuals, than in countries with low levels of power distance.[65] Data are being used and arguably misused in areas to automate hiring practices, with known racist and misogynist outcomes due to legacy training data.[66] Immigration enforcement in the United States is actively seeking social media data and other data to target undocumented immigrants,[67] and aiming to collect genetic data from detained immigrants.[68] Meaningful eIC for both regulated and unregulated research should describe these risks and the processes and policies in place to mitigate them.

eIC embedded into unregulated mobile research also risks interacting with the long-running use of the internet to profit from false health information. From nearly the beginning of the web, through to today,[69] hucksters have used technology to advertise fake cures for cancer and other diseases.[70] It is not a big jump from using Facebook to using an eIC framework built on standard apps to "healthify" what is actually a commercial data grab, or towards marketing a look-alike unregulated research app to support false health claims.

The expansion of communication to screens in eIC represent a challenge for consent anticipated in the FDA/HHS guidance. [71] How might one best describe a research study so that a prospective participant can make an informed choice, in the absence of a research coordinator? This textual challenge interacts with the requirements for eIC, resulting in a new set of costs and skills needed to launch a study. Of perhaps greatest concern, there is an explicit risk of transferring already seen dark patterns in electronic engagement to eIC, weighing participant enrollment over participant informedness. Regulated researchers, at least, have the intersecting incentives of the research institutions whose norms and structure at least create "strong incentives to protect research participants from harm and to engage with potential participants to develop trust regardless of what regulations require."[72] However, when unregulated researchers apply a model derived from modern consumer A/B testing like Facebook, but in an app that looks and feels like clinical research, the essential drive to inform may be lost from eIC.[73]

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