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DEPARTMENT: PERVASIVE HEALTHCARE

Pervasive Healthcare IRBs and Ethics Reviews in Research: Going Beyond the Paperwork

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Ethics committee approval is often viewed as a necessary hoop to jump through before a research study can begin. However, when focusing primarily on the administrative burden associated with this process, researchers may miss the opportunity to use this process as a scaffolding for thinking critically about the risks and benefits of the research for participants.

Human subjects research is increasingly used in computing and engineering within the context of user centered design. Although many researchers in these fields may be new to working with human subjects, even the most seasoned clinical researchers struggle to think thoroughly through ethical considerations. Training in the responsible conduct of research with human subjects is often routine in academia, yet for many researchers, even those with a lot of experience working with human subjects, the process of thinking through ethical issues present in our own research may be overlooked. We often believe that usability and small pilot studies with participants is harmless. However, no matter how seemingly benign, technologies and research may involve risks that are not intuitive. In this article, we discuss thinking through the process of conducting user research with technology to identify implications around risks. To aid this discussion, we present a brief history of research ethics oversight committees and ways to work through understanding and communicating risks of technology-based research.

REGULATING HUMAN SUBJECT RESEARCH: RESEARCH ETHICS COMMITTEES AND INSTITUTIONAL REVIEW BOARDS

Adequate training in the responsible conduct of research is essential for public funding and is a basic fundamental requirement for approving the conduct of human research in the U.S.; however, training typically relies on self-paced training modules, where the level of understanding of ethical principles can vary greatly depending on how serious the learner is in learning the material. Moreover, without adequate research experience involving human subjects, learning to think through research risks can be difficult. Even experienced researchers often overlook important ethical considerations reinforcing the fact that this is a skill that requires years to hone. Although most people can likely identify gross violations of ethical standards, more unassuming research activities, such as small formative usability studies and small pilots may seem incredibly benign and risk free to researchers.

Research involving humans is typically subject to review by some type of ethics committee. Outside of the U.S., these are often known as Ethics Review Boards or Ethics Committees, whereas in the U.S., they are commonly referred to as Institutional Review Boards (IRBs). IRBs are formally designated groups that review and monitor research involving human subjects. IRBs often exist within research institutions, but independent IRBs also exist and can be contracted to regulate research originating from institutions and companies without their own. IRBs have the authority to approve, require modifications, or deny research protocols based on ethical concerns. The goal of an IRB is not to judge the quality of research proposed; rather they seek to protect the welfare of human research subjects.

IRBs have a long history in the U.S. From 1932 to 1972, the U.S. Public Health Service, in collaboration with Tuskegee University, conducted the Tuskegee Syphilis study.[1] This study sought to observe the effects of untreated syphilis in African American men, some of whom had syphilis and controls who did not. Participants with syphilis were not told of their diagnosis and despite promises of free medical care, adequate care

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was not provided. In 1972, a whistleblower leaked details on the unethical conduct of the study to the press. This led to major changes in U.S. law and regulation on the protection of human subjects, including the requirement of informed consent. The Tuskegee Syphilis study, along with other high-profile instances of unethical human subject research, contributed to the development of The Declaration of Helsinki, The Nuremberg Code, and The Belmont Report, which have shaped the ethical guidelines that our IRBs follow today, with the primary goal being to "do no harm."[2]

UNDERSTANDING RISK: MORE THAN JUST PHYSICAL HARM

Many researchers believe that their studies pose "no risk" to participants; however, most ethics committees acknowledge that no research study is free from risk. Risks may be minimal, but they are not nonexistent. Indeed, in our previous work, Huh-Yoo and Radar demonstrated that IRB members viewed the collection and use of digital data of today's technology as having added risk above and beyond that of nondigital data, citing additional concerns such as breaches of confidentiality, unintended collection of sensitive data, and unauthorized reuse.[3] Physical harm to a participant is the most obvious possible harm, but there are more to consider, including psychological, social, economic, and legal harm, as well as loss of autonomy and any forms of injustice documented as harms in the Belmont Report.[2] The Tuskegee Syphilis study shows evident physical harm and the systemic racism is inherent in the study premise and design. In the present time, when many of us are reflecting on how to be more antiracist in our own work, thinking about more subtle harms and risks is essential when considering the ethical issues inherent in our own work. As we develop and evaluate novel technologies, it is imperative that we think about how use of these products can influence a person and their physical self, as well as their behavior, psychological state, social standing, privacy, finances, and/or legal affairs.

To illustrate, in 2012, Facebook conducted a one-week study among randomly selected users to test the effects of manipulating algorithms that decide what to present on a user's newsfeed. Known as the Emotion Contagion Experiment, researchers manipulated users' news feeds to test, among other things, whether fewer positive posts in the news feed can lead to greater expressions of sadness by the user.[4] The researchers of this study did not obtain full IRB review and approval, nor did they engage in informed consent processes with those who received the experimental condition. This article received a lot of media attention and was strongly criticized for being ethically problematic due to its lack of informed consent. Moreover, the use of user-based data was seen by some as a violation of identity-based norms and an exploitation of the vulnerability of users who self-disclose on social media with no control over how their data are presented.[5] The study, published in the Proceedings of the National Academy of Sciences, even drew editorial comment explaining the reasoning behind the decision to publish the study, while acknowledging that it "may have involved practices that were not fully consistent with the principles of obtaining informed consent and allowing participants to opt out."[6] Facebook argued that they were within their rights to manipulate their service as specified in their Terms of Service, a point that many scholars have debated. Whether Facebook was within their rights to conduct this study is not for us to decide; however, it can be a useful case study to illustrate potential risks inherent in study design. Without informed consent, some users were unknowingly participating in an experiment with demonstrated effects on psychological state. Moreover, if the experimental condition had enough of an effect, it is possible that the intentionally suppressed positive posts could have affected the user's social standing among others and may have led to social and psychological harm.

BEYOND RESEARCH ETHICS APPROVAL: REFLECTING ON RISK

In formative technology development stages, ethics committee oversight may not be required, but we should still think through ethical issues inherent in our processes. What would seem to be "minimal risk" for testing (no greater risk than those risks encountered in daily life; a condition for IRB exemption in the U.S.) can generate risks that may not be minimal. In fact, we would argue that in the absence of IRB or ethics committee oversight, such as in formative development and small scale usability testing, thinking critically about ethical considerations in our work is even more imperative and our own assessment of risk is even more important. Without oversight, it falls to us as researchers to ensure that we take the full responsibility of protecting our human subjects from harm and mitigating risks to the best of our ability.

For instance, smart home devices are owned by many. Conducting usability testing on Amazon Alexa, a digital voice assistant, seems to pose minimal risk. However, if tested in the home, any bystanders who speak within its listening range may be recorded,

regardless of whether they agreed to participate in research using the device. Potential risks exist if Alexa were to capture mandatory reporting events (e.g., child abuse) or other sensitive information (e.g., undocumented residency status, illegal activity, etc.). Moreover, due to algorithmic recommendations based on users' input, the output from Alexa could unintentionally reveal private information to other household members. It is also important to consider the fact that information captured by Alexa is not under the researcher's ability to manage, control, or discard, and third party vendors that produce the device own the data (e.g., Amazon) and could be subpoenaed by the government or other interested parties. Even testing by members of the development or research team should be carefully considered, and depending on your IRB, could require its own approval process and informed consent.

The issues surrounding control are not uncommon. Novel technologies often involve complicated data flows that may involve third party vendors that are outside a researcher's control. Vendors often cannot or will not give clear answers to describe how information flows due to trade secrets, machine learning algorithms, and/or multiple third-party companies embedded in a technology. For example, if you are building a mobile app that incorporates Fitbit data via an API, your app relies on third-party data. The data you receive are not data you actually "own" and may change. Fitbit can change the way it collects and shares data at any time, which could affect your product and your research. When forecasting risks inherent to a new technology, including its design and evaluation, it is essential that all parties of the research project (e.g., researchers, participants, research institution, and funders) understand how the technology works, and to make sure that there are appropriate safeguards in place. When trying to understand these concerns, we must ask how does the data flow from the user and how is it reused with or without the user's consent? Is this ethical? Is this putting anyone at risk?

Having approval from an ethics committee is not sufficient to prevent unanticipated events from happening. Despite our best intentions, the fact remains that when working with new technologies, existing regulatory approaches may not fully address new risks to testers, study participants, and household members or bystanders. It is imperative that researchers have the skills and training to recognize problems as they occur, and to work with their research ethics committees to handle unanticipated situations in a responsible and ethical manner.

BEYOND GETTING A SIGNATURE: MITIGATING RISKS BY COMMUNICATING WITH PARTICIPANTS

Ensuring that participants understand the risks and benefits of a research study through the informed consent process is vital. Although there are instances where informed consent requirements can be waived, this decision should not be considered lightly. Careful planning and well-informed consent processes can mitigate risks involved in the research process, in the experimental and/or control conditions, in data collection and management, and in data analysis and reporting. Although these elements pertain to all research studies, those that involve technology tend to involve an added layer of potential ethical considerations as data are often collected or generated by the user and in the cases where the technology is created by a third party, ownership of the data is ambiguous.

The informed consent process provides an opportunity for researchers to communicate directly to participants about what their involvement entails, what risks are anticipated, and what steps are taken to mitigate risk. This process affords participants autonomy in deciding whether to participate in the study or not. However, when the study involves new kinds of technology that is unfamiliar to the participants, in addition to explaining study procedures, researchers need to make sure that the technology is explained in a clear, complete, and accurate way, in language the participant can understand. The informed consent process might be different depending on the tech savviness of the participant but should always be presented in a way that allows participants with a lower educational background to make an informed choice to participate. If participants have difficulties understanding how the technology works, or even the concepts of privacy, anonymity, and confidentiality, one of the core principles of ethical research–voluntariness–will be challenged.

A good informed consent process should adequately describe the technology used within the study and the anticipated risks and benefits of the technology and research process. This includes the data that will be collected by the study device and the study team, as well as how that data will not only be accessed by the researcher but also any involved third parties where data may flow. Often overlooked risks to communication include the fact that we may

accidentally collect information participants did not approve or know about, or as mentioned earlier, information about nonparticipants. Participants need to know what data is shared and with whom, as well as the fact that that data shared outside the research team may not be controlled.

REASONS TO STRIVE FOR ETHICAL RESEARCH CONDUCT AND OVERSIGHT

We as researchers have a moral and professional obligation to do our best to mitigate the risk of harm to the research participants. Although we may not be able to erase all potential harm, taking steps to ensure that participants understand the potential risks and benefits and the procedures we undertake to mitigate risk, is well within our control. However, there are many practical reasons beyond this obligation that support the need to subject our research protocols to ethics committee oversight. Statements on research ethics oversight or exemption are often required for publishing research results. In addition, proper ethics training and oversight are often a requirement of funding agencies. Grant review panels are tasked with judging whether proposals consider ethical aspects of their proposed studies and take appropriate steps to mitigate unnecessary risks. Failure to adequately address risks could make a difference in funding decisions. In industry, funders may be investors and consumers rather than grant agencies. In this case, subjecting research studies to ethics approval may not be required. Still, it is considered a best practice and is viewed as a strategy to mitigate corporate risk. In addition, many businesses and organizations outside of academia may not have internal ethics committees, thus contracting with an external IRB is an inexpensive way to ensure adequate research conduct. In the Facebook Emotion Contagion experiment, not only could the controversy affect investors and their willingness to invest in the company, but it may have affected users and their trust for the company.

It may be tempting to think about obtaining ethics committee approval simply as an exercise in routine paperwork. However, we can reframe the approval process as a way to think critically about risks as we prepare documents and scripts that appropriately describe the risks, benefits, and protections. This includes understanding the risks inherent in the technology and its use, as well as the risks inherent in the design of the research study, including how participants are identified and recruited, how they are informed about the risks and benefits of the research study and whether the incentives offered are coercive, what they are asked to do, what data are collected, and how that data are analyzed and reported.

CONCLUSION

In this piece, we unraveled the multifaceted processes of understanding and communicating risks of technology research that involves human subjects. Through focusing on the history and importance of IRB and ethics committee oversight, we highlighted the importance of going beyond our moral obligations to conduct ethical research and pointed out the practical and logistical reasons for adhering to research ethics review procedures. We urged the critical need to think proactively, rather than retroactively, of what risks we introduce to study participants, including potential physical, emotional, social, legal, and economic harms. We also examined how information flows to external entities outside of the research process need special consideration. Finally, informed consent can be reframed as a process beyond receiving signatures for formal, liability purposes. It is an opportunity to communicate risks to participants, and to put into place strategies to mitigate those risks.

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