New Challenges for Research Ethics in the Digital Age

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Beyond IRBs: Ethical Review Processes for Big Data Research

We have rapidly entered an era where researchers collect data 'on-the-fly,' in real-time and, subsequently can design meaningful, personalized and adaptive health interventions. The technologies that we focus on in this paper include devices and apps that enable data collection via **M**obile **I**maging, pervasive **S**ensing, **S**ocial-media and location **T**racking (MISST) methods[1,2]. The MISST acronym describes the broad range of devices worn, deployed, carried or implanted to monitor or measure an individual's behavior, activity, location and assorted biological indicators (e.g., sweat, heart rate). In addition to measurement and monitoring, MISST devices are programmed to interact with the research participant or patient to promote, for example, increased exercise or adherence to a medication schedule[3–5]. While the opportunities are exciting, standards to guide the responsible and ethical conduct of this research are lagging behind creating challenges for Institutional Review Boards (IRBs) and researchers alike. Given the potential for improved individual wellness and decreased health care costs, the ethical and regulatory dimensions must be carefully considered.

This rapid acceleration of emerging technologies requires researchers and ethics review boards to become familiar with the functionality such that sufficient knowledge (i.e., technology and data literacy) informs the ethical design and conduct (researcher) and appropriate review and oversight (IRB). Currently, academic researchers and IRBs are expected to apply accepted ethical principles of the Belmont Report and adhere to federal regulations governing human subjects protections when planning, conducting and reviewing research[6,7]. Likewise, scientists have a social responsibility to carry out their research in keeping with the highest regard for integrity to ensure trustworthy results. Both the National Institutes of Health (NIH) and the National Science Foundation (NSF) require training in the "responsible conduct of research" (RCR) to instill the values that promote research integrity and uphold the public's trust of the scientific method [8,9]. Nevertheless, stakeholders must be responsive to advances in pervasive

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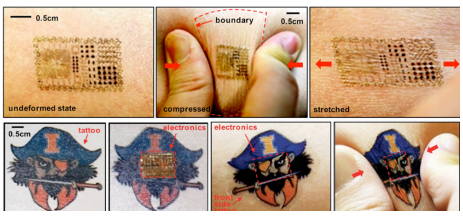
information and communication technologies, which are presently challenging researchers, regulators, ethicists and scholars to consider new ethical parameters [10]. While steps are being taken to advance responsible research practices in the age of big data [11–14], these efforts are occurring slowly and in silos. Moreover, while we have an opportunity to update the Common Rule that guides IRB practice through the recently issued Notice of Proposed Rule Making (NPRM),[15] regulations may not be the answer. In fact, regulations are likely too static to be responsive to the ethical challenges introduced by emerging technologies used in research.

MISST Use in Research

MISST technologies are used in a variety of observational and intervention research, and they introduce a range of ethical issues. In the following we detail the four sets of technology that identify MISST and discuss the related ethical issues.

Visual Methods. Digital technology is making it possible for researchers to qualify and quantify physical activity, diet and travel and the settings in which these occur. Increasing interest in studying "free-living" behavior "in the wild" will lead to increased use of visual methods. In one observational study, participants agreed to document their daily activities for one week using an outwardly facing camera that automatically takes a still image every 20 seconds during which time, approximately 30,000 images were recorded (see adjacent images) [16–19]. Although participants agreed to be in the study and wear the device while at the office, church, park etc., images captured include people who are not research participants. It is unclear what role, if any, the IRB should play in 'protecting' people who are captured in the data collection process, yet who are not research participants – people we call 'bystanders.' Due to perceived risk to bystander rights, we have learned that IRBs have either denied approval of studies or imposed burdensome requirements on researchers to secure approval (e.g., deleting bystander body parts from images).



Sensors. With epidermal electronics (see sensor/tattoo images below), coupled with smart phone transmission, and analytics in the cloud, health information can be captured continuously in real time [20]. With sensors, researchers can access real time data about a participant in remote locations. The positive impact is clear, but continuous feed of physiological data presents new considerations for protection of personal data, especially if not covered under HIPAA[21].Researchers report that IRBs appear unaware of potential risks associated with sensor technologies leaving it to researchers to advise them.

Social Networks. Researchers are using Facebook and Twitter, among other social media, to study trends, predict outbreaks, medication adherence, social behavior etc.[22–26]. IRBs are unsure about when end-users should know that their information is being used for research purposes, especially if it is already in the public domain, and when/if to require informed consent.

Tracking. Spatial data obtained via Global Positioning System (GPS) (image below) provides the opportunity for researchers to assess the context in which behavior is occurring, as well as to identify underlying spatial relationships such as clustering or transmission pathways [27–29]. Location data is specific down to the exact longitude and latitude at a specific point in time. These data present potential privacy and security risks for the participants who wear the devices, should the data security be compromised. In our pilot analysis, GPS data rarely received attention by our local IRBs suggesting a need to increase awareness of possible sensitivity of these data and identify appropriate data management strategies from among those being developed in other fields..

Commercial Sensing Devices. We are seeing an explosion of commercial devices that record and transmit personal health and potentially medically-relevant information. These products (see image) contribute to the 'grey zone' of ethical challenges for consumers as well as for IRBs and research participants. We know of IRBs that denied approval of a study that utilized a FitBit device, citing concerns with the End User Licensing Agreement (EULA) and data ownership.

Due to observations of a growing gap between researchers who are designing MISST studies and the IRB who review them, we initiated pilot studies to explore MISST related risks, acceptable risk management strategies, barriers to participation and experience of study participants [1,2]. Pilot studies focused on: 1) IRB/Investigator communications specific to protocol review[1], 2) rationale provided by study 'decliners', 3) participant experiences[2] and, 4) perceptions of members from underserved communities. Findings from the content analysis of IRB review determinations revealed inconsistent evaluations of study benefits, risks and risk management solutions[1]. In several instances, concerns about potentially sensitive data were not raised; likewise, the IRB imposed requirements to manage risk that had no factual basis and, actually resulted in greater potential risk to participants. Another study was designed to assess

participant experience after completing a study in which they wore a wearable camera, a location tracking device and an activity monitor. Results shed light on informed consent, bystander perspectives and privacy concerns [2]. Our conclusions suggest that IRBs, as presently constituted, may not have sufficient expertise to review research using emerging technologies and, may not have the expertise needed to evaluate MISST research protocols. Moreover, since much of the health data being captured by pervasive sensing methods may fall outside of HIPAA protections, clearly defined data management standards are needed to support practices that protect participant privacy and data confidentiality. Through these pilot studies, we have identified the following ethical, legal and social concerns.

Ethical, Legal & Social Concerns

A subset of ethical legal and social concerns percolating within the MISST ecosystem fall under three broad categories: **(i)** informed consent, **(ii)** bystander rights and **(iii)** data management. We frame these as potential research questions below:

(i) Informed Consent: A meaningful and authentic informed consent to participate should address:

- *Technological Literacy* – What information should be communicated during the informed consent process to effectively explain the technology? What terminology is most meaningful when making a decision? Do explanations address a broad cross-section of the community who may be asked to use a MISST device?
- *Cultural and Research Literacy* – How does cultural background, education and/or understanding of the scientific method influence one's ability to evaluate MIST and determine whether participation in a study is appropriate? How do we ensure that researchers understand the impact of culture on benefits, risks, privacy and confidentiality?
- *Privacy/Confidentiality* – What information should be conveyed to a participant to ensure understanding of the granular detail of personal information collected (e.g., mapping of individual movements via GPS, collection of images revealing illegal activity or collateral bystanders who may have privacy expectations)?

(ii) Bystander Rights: In addition to considering the ethical and regulatory implications specific to human research protections, the rights of a bystander**,** who may be imaged/recorded by a research participant, must be considered in the risk/benefit calculation. Should the IRB oversee protection of bystanders who are not research subjects? Under what circumstances should that protection be extended (e.g., home, bank, social function, office, public park, etc.) and, what form should it take (e.g., when/how should permission be obtained)?

(iii) Data Management: MISST technologies present new challenges for data sharing and management. Standards for sharing images and geo-location data within the research team and among external collaborators do not exist. New challenges are introduced when interdisciplinary standards for data sharing vary across individuals with a high threshold for protecting access to data (e.g. behavioral scientists) vs. a high threshold for sharing data (e.g., computer scientists) With technological advances, it is nearly impossible to completely protect data from identifying a research participant. Issues are associated with documentation of illegal behaviors captured by imaging or location logging techniques that may be reportable or which could be subpoenaed by legal authorities.

Next Steps: Designing a "learning" research ethics system informed by stakeholders

Mobile and wearable solutions are here to stay and will contribute to meaningful research – including the Precision Medicine Initiative[30] to better understand and, potentially prevent a number of chronic health concerns (i.e., cancer, obesity, heart disease). Yet, in a society with mounting concerns of surveillance and privacy, an ethical approach to MISST research is essential. Observations of the growing gap between academic researchers and IRBs as well as the apparent need for guidance to inform the growing number of research-active companies and not-for-profit organizations (most not bound by the Common Rule) prompted us to consider how to improve the ethical design and review of MISST research. We are now in the process of designing a system that we believe will support the MISST research community with an overarching goal of creating a dynamic "learning ethics system" to increase the effectiveness and efficiency of current research oversight practices.

We are designing a system to support access to relevant and dynamic resources with a goal of fostering the ethical design and review of studies using MISST technologies. Our design will involve a participatory approach that includes key stakeholders in research ethics, ethics review board affiliates, researchers (e.g., public health, information science, behavioral medicine, human computer interaction), and experts in privacy and technology design who will inform the MISST-E standards and the CORE design. This formative research will examine bidirectional and dynamic models of informed consent, risk identification and management strategies, data management protocols, and requirements for deploying a web-based system to support a dynamic learning ethics system.

Our plan is to gently disrupt what has become an ineffective research ethics system bound by rules and lacking in creativity. If successful, we believe that our approach could have a profound effect on counteracting persistent and growing challenges within the existing IRB system. We propose to introduce a stakeholder informed, pragmatic and timely shift in research oversight practice that could lead to a system in which researchers are empowered to build and

maintain a "learning ethics system." By engaging stakeholders in a collaborative design process, we expect to gain buy-in and cooperation from the collective research community thereby creating a solid structural foundation. This collaborative and stakeholder driven approach will also help to ensure that the system envisioned stays relevant for advancing technologies as they emerge.

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