

Mobile Imaging, Sensing and Tracking – Ethics (MIST-E): A Vision Paper
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Vision. We have rapidly entered the pervasive sensing era where researchers collect data ‘on-the-fly,’ in real-time and, subsequently design meaningful, personalized and adaptive health interventions. While the opportunities are fantastic, guidance to inform the responsible and ethical conduct of this research is lagging behind. The lack of relevant and responsive guidance is creating challenges for Institutional Review Boards (IRBs), researchers, consumers and research subjects alike. Our vision is to engage stakeholders as collaborators to design an empirically informed framework that promotes the responsible design and ethical review of research utilizing pervasive sensing tools. We believe this focus on the ethical, legal and social implications is critical to advancing transformative research generally speaking and, in particular on college student health.

Background. Mobile Imaging, Sensing, and Tracking (MIST) technologies are used in health promotion and disease prevention research. This research involves devices (e.g., mobile phones, wearable cameras, location logging devices, and skin sensors) that are worn, carried by and/or implanted in research participants to monitor behavior, activity, location, and assorted physiological and cognitive functions. A device may be programmed to interact with the participant to promote increased exercise or adherence to a medication schedule. Given the potential for improved individual wellness and decreased health care costs, the ethical and regulatory dimensions must be carefully considered. Researchers and ethics board members are independently questioning the ethical dimensions of this research. Common questions include: Does the consent form and process explain the technology using terms understood by prospective participants? Do participants understand the granular level of personal information collected about them? Do organizations have accepted standards for how sensitive information is collected, stored, and used? Are potential risks to privacy and limitations to de-identification understood by ethics board members? Under what circumstances should a bystander who is imaged or recorded by a research participant provide consent (e.g., home, office, public park, etc.)? When is it appropriate to share images and geo-location data? To explore these and other questions, we have initiated pilot studies to examine the ethical and regulatory implications specific to MIST device use in health research.

What we have learned is subjects may not fully understand the type/amount of personal data collected, IRB risk assessment is inconsistent leading to delays in approval, and researchers are uncertain about how to store/share these large data sets (e.g., imaging, audio and GPS coordinates). These concerns may be due to the novelty of MIST technologies. Our vision is to engage stakeholders (e.g., IRBs, researchers, subjects, bystanders) in discussion about: **(a)** meaningful informed consent, **(b)** risks identification and management strategies and **(c)** standards for MIST data sharing.

(a) Informed Consent: What an IRB finds to be an acceptable consent process does not always map to what may result in an informed research subject. We want to know what researchers and human subjects would identify as meaningful informed consent. We will then work with researchers and IRB members to bridge this gap, developing educational materials to facilitate an informed choice.

(b) Risk/Benefit: We don’t know stakeholders’ perspective on MIST risks/benefits. Are there privacy concerns? Is confidentiality an issue? How should risks be managed? If people who are not research subjects become part of the data (e.g., imaging, audio), what are stakeholder responsibilities?

(c) Data Management: Digital data creates storage and sharing problems – particularly when non-participants are recorded. Researchers recognize these data are potential sensitive, yet uniform best practices for managing them don't exist. Should they? We are looking to experts and stakeholders to clarify concerns around privacy and data confidentiality and provide guidance for management.

Solution. UC San Diego is at the forefront of pervasive sensing technology research. Advancing this field requires an informed and responsive regulatory and ethical review process. We know researchers spend valuable time negotiating with the IRB over concerns with no basis in fact. While this problem is not unique to MIST research, it needs to be addressed. Moreover, we have an opportunity to inform best practices by engaging with our stakeholder networks (i.e., Society for Behavioral Medicine, Health Data Exploration Network, Quantified Self, and Public Responsibility in Medicine and Research). By increasing awareness of the ethical dimensions of MIST research and developing a more relevant and efficient IRB review process, we hope to have greater access to programs and practices that influence health.

By participating in this invitational workshop, we can engage researchers as partners in the process of developing an ethical framework and learn from their experiences. Likewise, initiating collaborative projects that engage college students in connected health studies (i.e., Dartmouth Rhythm study) presents an opportunity to gather data directly from student participants to qualify risk, risk management and the informed consent process. We will use what we learn during the workshop to guide development of a focus group and survey that we will conduct with IRB members and analysts in November (PRIM&R meeting).

Proposer Credentials. Dr. Camille Nebeker is an Assistant Professor in the Department of Family Medicine and Public Health at UC San Diego, adjunct faculty in the Graduate School of Public Health at San Diego State University and an affiliated investigator with the UCSD Research Ethics Program. She has over 20 years of research and practice experience focusing on advancing ethical and responsible research through both academic and community-based educational initiatives. Dr. Nebeker's research has received support from the NIH, NSF and federal Office of Research Integrity. She is presently leading two projects that involve developing research competencies in front-line research support staff (Spanish and English speakers) who have received little or no formal academic research training, yet carry out key roles in the implementation of community-based research studies. Since 2013, she has led pilot studies designed to examine the ethical dimensions of mobile imaging, sensing and tracking technologies used in health-related research (also known as mHealth). Given this expertise in human research ethics and increasing familiarity with the ethical and regulatory challenges in the digital age, she is well qualified to contribute to this workshop.

Contributor. Dr. Weibel is research faculty in the department of Computer Science and Engineering (CSE) at UC San Diego. His research is in human computer interaction (HCI) with a focus on studying the deployment of technology in critical settings, in particular healthcare, mHealth, and public health. He is an affiliated faculty at the UCSD's Center for Wireless and Population Health System and the newly formed UCSD DesignLab and has 12 years of experience in studying, developing and deploying mobile, wearable and ubiquitous computing technology. As part of his work he develops novel methods to collect data in ecologically valid environments based on a range of cutting-edge technologies and devices.

Drs. Nebeker and Weibel have co-presented at several professional venues to increase awareness of the ethical and regulatory dimensions of mHealth research.