

A Multi-Case Study Of Research Using Mobile Imaging, Sensing And Tracking Technologies To Objectively Measure Behavior: Ethical Issues And Insights To Guide Responsible Research Practice

Camille Nebeker, EdD, MS
School of Medicine, UC San Diego

Rubi Linares-Orozco, BA, MASc
UC San Diego

Katie Crist, MPH
UC San Diego

Abstract: Introduction: *The increased availability of mobile sensing technologies is creating a paradigm shift for health research by creating new opportunities for measuring and monitoring behavior. For example, researchers can now collect objective information about a participant's daily activity using wearable devices that have: 1- Global Positioning System (GPS) to capture location; 2- an outwardly facing camera to document environmental and social context; and, 3- an accelerometer to measure activity levels. While these technologies may offer more accurate means of measuring and understanding behavior, they introduce potential privacy and data security risks for participants as well as for bystanders. The aim of this study was to describe potential risks and risk management strategies in studies using visual imaging and location logging (GPS) data collection methods.*

Methods: *Eight Institutional Review Board (IRB) research protocol applications that included visual imaging and/or GPS data collection methods were identified. Each research protocol application and IRB determination letter was analyzed with the a priori themes of identification of risks (e.g., privacy concerns, data security) and risk management strategies (e.g., disclosure, firewalls) associated with each device.*

Results: *Visual imaging was proposed in four of the eight studies. GPS was included in all eight studies. Geographic Information System (GIS) technology was proposed in all but one study to improve analytics. The findings reveal that: 1) IRBs are grappling with how to consider the rights of bystanders who may be imaged by virtue of being near a research participant; 2) IRBs may not be sufficiently aware of potential risks associated with collection of location data should a data breach occur; and, 3) while research plans incorporated consistent descriptions of each device and associated potential risks, IRB determination letters revealed inconsistent perception of potential study risks.*

Conclusions: *This paper sheds light on ethical issues when using visual imaging and location logging technologies in research. We have exposed concerns and presented management strategies. Questions remain as to whether the risk management strategies are effective and, under what circumstances researchers and IRBs should consider location logging as sensitive data. Empirical research is needed to inform guidelines to enhance the ethical design and conduct of research involving visual imaging and location logging.*

Keywords: *research ethics, pervasive imaging, wearable camera, location logging, GPS, human subjects*

Introduction

To objectively measure health behaviors (e.g., physical activity, sedentary behavior, and diet), researchers are increasingly turning to mobile imaging, sensing and tracking devices to record and/or intervene with health behaviors (Cole-Lewis & Kershaw, 2010; Doherty, Kelly, Kerr, et al., 2012; Kerr, Marshall, Godbole, et al., 2013; Kumar, Nilsen, Abernathy et al., 2013; Krishna, Boren, & Balas, 2009; Jankowska, Schipperijn & Kerr, 2015). This research involves devices (i.e., smart phones, wearable cameras, GPS, skin sensors etc.) that can monitor activity, location, and assorted physiological functions (Ibid). By understanding behavior in context, researchers can design interventions utilizing individual data that more accurately reflects exposure and risk and thus, may be more effective at promoting health (Kumar, Nilsen, Abernathy et al., 2013). While technology may improve measurement accuracy and increase the ability to develop and deliver more personalized interventions, the granularity of the data collected also introduces unique potential risks regarding participant privacy and confidentiality should data security be compromised. To advance this important and innovative research in a responsible manner, researchers and ethics board members must be prepared to effectively evaluate and mitigate risks to both participants and bystanders who may be included in the research record by virtue of their proximity to a research participant (Cox, Drew, Guillemain et al., 2014; Kelly, Marshall, Badland et al., 2013).

Since there is little empirical evidence to guide the ethical conduct or review of research involving mobile imaging, sensing and tracking, what we are calling "MIST" methods, researchers may find the IRB protocol development and review process to be challenging. Likewise, IRB members may be unfamiliar with these technologies prompting confusion about what actions are necessary and appropriate to enhance human subject protections. For one group of researchers, inconsistent IRB review outcomes led to a meeting with the lead author, an IRB member, to discuss the application of federal regulations and ethical practices designed to enhance research participant protections. The meeting objective was to discuss ethical challenges associated with visual imaging and location logging methods used in their studies. These challenges focused on informed consent (i.e., how much detail to include?), rights of bystanders (i.e., the camera will capture people who are not study subjects) and data management (i.e., how should images or location information be stored? when and how can imaging data be shared and with whom?) and led to the planning of several pilot studies designed to explore these challenges. The study reported here involved a review of IRB documents (e.g., research protocols, IRB determination letters) to examine how the local IRB considered risks and risk management strategies associated with visual imaging and location logging methods.

We selected visual imaging because of the likelihood for a non-research participant to be included in the research record and location logging because of the potential threats to privacy. This paper describes: 1) how visual imaging and location logging devices were used in research studies, 2) what concerns and risk management strategies were identified, and 3) suggestions for responsible research practices using location-logging and visual imaging methods.

Measuring Activity in the Built Environment

Researchers are using imaging and location logging methods to objectively contextualize participant activity. Data collected from the SenseCam wearable, automated camera (Vicon Review v1.0), a Global Positioning System (GPS) tracking device (Qstarz BT100X), and activity monitors (Actigraph GT3X+) provide researchers with information about participant activity in the context of their daily lives including the intensity and duration, location and the social and environmental context in which participants are active. A description of these devices follows:

Visual Imaging Methods

The use of visual imaging methods in research is not new (Cox, Drew, Guillemin et al., 2014). In fact, the social sciences have used photography and drawings to document ideas, the environment and abstract phenomena for years (Ibid). Digital imaging has made it possible for researchers to document travel, physical activity and nutrition by having research participants wear an outwardly facing camera on a lanyard around their neck (Doherty, Kelly, Kerr, et al., 2012; Doherty, Kelly, Kerr, et al., 2013; Kerr, Marshall, Godbole, et al., 2013; Oliver, Doherty, Kelly, et al., 2013). The automated, wearable camera has multiple sensors including a thermometer, a passive infrared sensor, and a light sensor so that it will take a picture when one of these elements has changed (See Figure 1). The purpose is to capture first person point-of-view images that provide rich contextual data, matched by time stamp to behaviors of interest (Figure 2). The automatic imaging generates up to 3,000 images per day. Image data on the device is encrypted so that the content is not viewable to anyone outside of the research team. These images are later coded and analyzed to qualify and quantify behaviors in the settings in which the behaviors occur, for example, walking outdoors with others.



Figure 1. SenseCam used to capture first person point of view



Figure 2. Image captured by SenseCam demonstrating the participant perspective

Location Logging Methods

For health applications where location is of interest (e.g., understanding environments where individuals are physically active, monitoring dementia patients' locations, measuring spatial components of disease transmission), the emergence of GPS as a research tool offers the opportunity of objectively linking health outcomes or measures to specific geographic coordinates. According to PubMed citations, studies using GPS have more than tripled between 2007 and 2013 (52 in 2007, 182 in 2013). Spatial data provides the opportunity for assessing context in which behavior is occurring, as well as identifying underlying spatial relationships such as clustering or transmission pathways.

The GPS device used in activity measurement studies is the size of a small pager and worn on a participant's belt (see Figure 3). Geographic Information System (GIS) software can provide context to the GPS data providing details about the environment (e.g., density, restaurants, green space, etc.). Metrics derived from the combined GIS and GPS data can be associated with health outcome data allowing researchers to answer specific questions about the relationship between environment and health. For example, researchers can identify whether most physical activity occurs near the participant's home or in a nearby park to establish relationships between differing environments and activities. Likewise, researchers can identify the actual activity (running, sitting), social context (other people present) and environmental conditions (sun or rain).

Participants wear the GPS device on a belt around their waist (See Figure 3), which generates data showing location throughout the day; however, for the studies evaluated, the devices do not allow for real time transmission of data. An image showing a sample of GPS traces is in Figure 4.



Figure 3. Wearable GPS

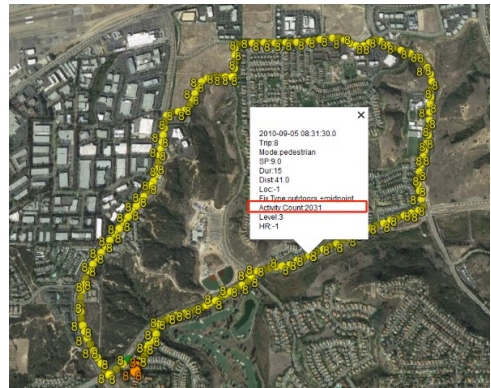


Figure 4. Example of GPS traces

Ethical Challenges

Given the relative novelty, yet growing interest, in using MIST devices to record behaviors, we sought to describe concerns being raised by both researchers and IRB members. An overarching goal was to identify issues as well as strategies that can be used by researchers and IRB members

to enhance the ethical design, review and implementation of research involving wearable sensors. This case study focused on imaging and location logging data collection methods due to the documented challenges for researchers and IRB members. The wearable camera automatically takes a picture at approximately 20-second intervals of what is in view of the participant. This method raises concerns about participant privacy as well as the rights of bystanders who are in the vicinity of the research participant and who are likely to be imaged (See Figures 5 and 6).



Figure 4. Participant point of view in an office setting



Figure 5. Participant point of view in a public setting

Questions associated with the visual imaging method of data collection include: 1) under what circumstances should a research participant disclose that the device is recording (i.e., at home? meeting friends for lunch? during a conference or meeting?); 2) how should data be handled that contains images of non-participants?; 3) at a time where surveillance is round the clock, should images be treated as sensitive data?; and, 4) what is the researcher's obligation to report illegal behaviors recorded by the device?

GPS data is granular and provides exact longitude and latitude at a specific point in time. While providing fantastic opportunities for researchers, this data may present significant privacy and security risks for the participants who wear the devices if the data security is compromised. For example, sports tracking applications (i.e., Strava (see: <http://www.strava.com>), Endomondo (see: <https://www.endomondo.com>)) are worn by cyclists and joggers to map exercise routes using GPS. The data identifies the route (e.g., where the activity started) as well as the temporal characteristics of when that activity started and stopped and mobile app users often share their routines with others. This disclosure can facilitate crime (Stottelar, Senden & Montoya, 2014) and led police in the UK to warn cyclists to check their smart phone privacy after suspecting thieves used GPS information to track down and steal 370 bicycles (Strege, 2013). Examples like this demonstrate the potential risk posed by GPS data collected for health research, and the profound need to discuss the sensitivity and required protection of GPS data. As noted, visual imaging and location logging are not new technologies; however, they are relatively new methods being used in social and behavioral sciences research studies to replace self-report or observation.

Methods

Since this study was exploratory in nature we conducted a multi-case analysis approach (Yin, 2009). The case study method is useful for exploring contemporary issues within real-life context and requires that decisions be made a priori to guide the study design including selection of cases and units of analysis (Meyer, 2001). For this study, we collaborated with local researchers and identified eight research studies that included visual imaging and/or location logging methods as our cases. The units of analysis were perceived risks and acceptable risk management strategies specific to the two devices across the eight studies. Each research record included the following source documents: 1) a research plan, including informed consent content, prepared by the researcher, 2) initial review determination correspondence prepared on behalf of an IRB, 3) the investigator response to a review determination, and 4) the IRB response to the researcher.

Each study protocol or “case” was printed and independently reviewed by two authors (CN and RO). The process for document review involved reading each study source document entirely. This was followed by a second review that included highlighting of content that specifically addressed visual imaging and GPS use. Concurrent with highlighting text, analytic memos were recorded for each study protocol prior to initiating review of the next case. Case details and analytic comments were recorded in a Microsoft Excel® spreadsheet and a Microsoft Word® document. Notations included a description of the study design, participant characteristics, review dates, device type, risks, benefits and risk management strategies identified by the researcher to initiate IRB review and stipulations determined by the IRB to secure approval. Themes and patterns were identified based on frequency of appearance across protocol reviews and discussed by the authors to ensure consistency in individual coding and agreement in interpretation. Discrepancies were resolved through additional review of the data and discussion between the study authors. Project managers responsible for development and management of a specific research study were consulted when needed for clarification.

Results

The eight cases evaluated shared a common purpose of assessing lifestyle behaviors, the environmental context and the relationship to health. All included the use of GPS to record location coordinates and time data about a participants’ location and accelerometry to measure physical activity and sedentary behavior. Four studies proposed to have participants wear a camera to capture specific behaviors (i.e., sitting watching television, running in a park) as well as environmental context (e.g., indoor/outdoor, weather, greenery). Five studies requested approval to include GIS to increase contextual knowledge of the location data. Study participants included both children and adults ranging in age from 6 to 102. With one exception unrelated to the imaging and GPS/GIS methods, studies involving the automated, wearable camera and/or location logging devices were determined by the IRB to present no greater than minimal risk of harm to research subjects. Table 1 identifies the study design, device use and participant age range.

A description of each case follows along with a summary of the IRB review determination specific to the visual imaging and GPS components of each case. Studies reviewed in this analysis were grouped and coded by the person identified as “principal investigator” or PI and numbered

Table 1. Description of cases analyzed and IRB concern specific to the devices of interest.

ID	Study Design	Camera	GPS	GIS	Participants	Age	IRB	Concern
A1	Observation	N (w)	Y	Y	Adults	40-75	Camera	Bystander privacy
A2	Observation	Y	Y	N	Minors/ Adults	6-102	None	
A3	Group RCT	N	Y	Y	Older Adults	65+	GIS	Participant consent
B1	Observational	Y	Y	Y	Hispanic Adults	18+	Camera	Bystander privacy
B2	RCT	N	Y	Y	Adults	21-60	GPS	Data security
C1	RCT	N	Y	N (w)	Women	21+	GIS	Participant consent
D1	Prospective Cohort	Y	Y	N	Adults	18+	None	
E1	RCT	N	Y	Y	Women	50+	None	

Y=Yes; N=No; (w) indicates device withdrawn from research plan after initial IRB review

sequentially (e.g., studies A1-A3 represent three studies being conducted by the same investigator). There were five different PIs for the cases included in this analysis; however, one investigator with interests in objective measurement of physical activity was involved in all studies accounting for the consistency in how elements of the study plan (e.g., informed consent, risks, benefits, risk management, etc.) were communicated across each case study.

1. Study A1 was a cross-sectional observational study proposing that where people spend their time may correlate to their risk of cancer. The study would also compare static and dynamic GPS/GIS measurements. A total of 700 adult participants would wear two activity monitors and a GPS device (waking hours) for seven days. A subset of 50 participants would wear a SenseCam to explore whether “social interactions & social behaviors from person view images are more strongly related to ... cancer risk factors than self-reported social environment measures.” Risks were described as minimal. The research plan did not describe risks associated with visual imaging. An excerpt from the research plan describing risks, risk management and the protocol for data management follows:

“Potential Risks. Subjects may experience 1) anxiety or embarrassment related to answering questions about one’s health or to the measurement process; 2) concern for privacy related to divulging personal information on the survey or loss of confidentiality if a computer is accessed by an unauthorized person; 3) participants may experience discomfort or a sense of loss of privacy as a result of revealing their exact location while wearing the GPS device for seven continuous days. GIS analysis will enrich the contextual understanding of participants’ movements. This increased knowledge of the surrounding environment may provide more information about participants’ habits and behaviors that they may wish to keep confidential; 4) discomfort from wearing any of the devices.”

“Risk Management Procedures and Adequacy of Resources. Participants will be informed that all responses and data collected from the GPS device will be kept confidential within the research team, and that no material that could personally identify them will be used in any reports or publications from this study. It will be explained to the subjects in clear terms, both verbally and in the written consent form, that their precise whereabouts for the entire time period the GPS device is worn will be known by the research staff. Any potential risks of embarrassment or privacy due to GIS analysis is mitigated by developing environmental measures and indices from the GIS analysis that solely deal with physical activity and eating habits. No other environmental measures that may be indicative for other behaviors will be created. Additionally, environmental measures created from the GIS analysis will be used in statistical modeling at the group level only, and will not be individually mapped or visualized for publication purposes.”

“Privacy and Confidentiality Considerations Including Data Access and Management. We have established an extensive protocol to protect participants’ privacy. We will keep informed consent statements and participant data in separate locked file cabinets so that individuals are not easily connected to the study results. All sensor data will be stored on a firewall and password-protected project server at the [university]. All subject records and data will be stripped of individual identifiers following data collection. We will assign each person a study ID and all records will be coded with the study ID rather than personal identifiers. The code that links the study ID and the name will be stored in a separate place than the data file until all of the measurements are complete. At that point, the personal information will be destroyed and all analyses will be conducted with the data set that has no personal identifiers. All data will be kept in locked cabinets at the study office, accessible only by investigators and project staff. Participants will also be told about the confidentiality procedures and that they have the right to refuse to answer questions or to terminate their participation in the study at any time. Finally, participant data will not be sold or exchanged with anyone and data sharing as per NIH requirements will be performed within strict protocol-driven procedural guidelines.”

Review Outcome. Upon review of this study, the IRB determined that additional detail specific to the SenseCam was necessary citing potential legal concerns and bystander rights to privacy. No concerns were voiced specific to the use of GPS or GIS. Other comments were limited to minor clarifications of the study plan. In response, the investigator addressed the IRB concerns; however, in lieu of providing additional information about the camera, the sub-study portion of the protocol in which the SenseCam was proposed was withdrawn.

2. A2 was an observational study to validate machine-learned classifiers of sedentary behavior and physical activity using data collected with an accelerometer and GPS. A total of 210 participants would represent three age groups that include youth age 6-17; adults age 18-55; and older adults age 65+. Over a three-day period, participants would complete a survey and wear two accelerometers, one GPS device and one SenseCam. Risks were described as minimal. Risk management included choices to not participate and options for removing the devices during the study. Extensive detail was provided for instructing the participant about when and where to remove the camera, when to use the privacy options and under what circumstances the participant

should request permission to wear the camera. Likewise, details were provided regarding steps taken by the research team to protect participant privacy and data confidentiality. Excerpts specific to risk and risk management strategies proposed by the researcher follow:

“Potential Risks. Risks to participants in this study are considered minimal. However, there is a possibility of some physical, psychological, social, economic and legal risk. Physical risks include a chance of physical injury if a device bruises the participant as a result of an incidental fall. Psychological risks include embarrassment or anxiety over the type of images being captured about daily life. Social or economic risks include a possibility of being teased or ridiculed by peers for wearing the devices or being socially excluded; or as a result of a breach of confidentiality of personally identifiable data. Economic or legal risks include researchers finding out that a participant has engaged in an illegal behavior (e.g., shoplifting, grievous bodily harm) from the image capture.”

“Risk Management Strategies and Adequacy of Resources. They [Participants] will also be asked to remove the camera or cover the lens in environments where camera phones are not permitted (locker rooms, public restrooms, etc.). Finally, participants will be given an opportunity to delete any images they do not wish to be seen by researchers prior to the files being stored for analysis...”

Review Outcome: The IRB determination letter did not identify any concerns related to the GPS or SenseCam methods. The research was approved pending the correction of minor inconsistencies within the research plan and consent forms.

3. A3 was a group randomized control design involving retirement community sites. The study objective was to evaluate the efficacy of an intervention to increase minutes of physical activity among older adults. Participants, 320 men and women who are 65 or older wear an activity monitor and GPS device 12-hours per day over 7-days. Risks were described as minimal and include the potential for embarrassment if privacy was breached. Study risks were managed by recognizing the sensitivity of the location data and emphasizing practices to securely store location data. The study was later modified to include GIS to enhance the analysis of the GPS data. The investigator explained that GPS provides information about “where participants walk” by providing coordinate and time data. By adding GIS, the “analysis will enrich the contextual understanding of participant’s movements.”

Review Outcome: The IRB approved this study noting no concerns for the use of GPS. When the study was modified to include GIS the IRB asked the investigator to modify the consent form to include this new analysis or to provide “justification for not informing subjects.” The investigator explained that the approved consent form included an appropriate description of granularity of location detail collected using GPS and that GIS analysis was consistent with this explanation. The researcher expressed concern that re-contacting participants to obtain consent was an added burden that did not equate to added participant protections and may result in participant confusion rather than added clarity. The IRB responded by accepting the researcher’s rationale and approved the request to add GIS analytics without requiring additional contact with former study participants.

4. B1 was a validation study involving 40 adults who identify as Latino adults. During this seven-day study, participants would wear a visual imaging device called a Vicon Review, a GPS to log location and an accelerometer to record activity level. In addition, participants completed two phone interviews and one written survey. The risks, risk management strategies and practices to enhance privacy and confidentiality were nearly identical to those described in study “A2” (see above).

Review Outcome. The IRB determination letter cited concern for non-participant privacy and concluded that there was “not a reasonable balance of risks to the subjects and the people they encounter to the research value of the information about personal level activity for a specific population” and “could not reach a final determination concerning this protocol.” After several communications between the investigator and IRB in which concerns over image capture of bystanders and potential breaches to confidentiality are discussed, the study was approved. The consent form and research plan were modified to include additional risks and limits to confidentiality.

The following language was included in the Research Plan, in addition to exact text used in case A1 (see above) to describe privacy and confidentiality practices:

“Privacy and Confidentiality Considerations Including Data Access and Management.

In order to protect the confidentiality of third parties, we treat all data with the same data security measures as PHI data. As image data is annotated by research staff, images that show places where a reasonable expectation of privacy is accepted (i.e. banks, restrooms, locker rooms, hospitals, and medical and treatment center) will be deleted. After image data is completely annotated, the image files will be destroyed and only the annotations will be used in data analysis.”

The following language was included in the informed consent document to describe study risks and confidentiality of data.

“Potential Risks. The risks involved in this study are minimal. Participation in this study may involve some physical discomfort to you from wearing the devices. You may also experience discomfort or a sense of loss of privacy as a result of revealing your location and daily activities for seven days to researchers or answering survey questions. You may feel discomfort wearing the Vicon Revue because it takes images of what you are doing throughout the day. You are free to remove the camera at any stage, and there is a privacy button you can press to stop the camera recording for 4 minutes. Also you will be able to review the images and delete any you do not wish researchers to see. You can discontinue participation at any time. There may also be concern for privacy related to revealing personal information or the loss of confidentiality if an unauthorized person accesses device data. There may also be some unknown risks that are currently unforeseeable.

Images captured by the Vicon Revue device that show instances of assault and abusive conduct, including abuse or neglect of children, elderly or dependent adults will be reported along with contact information.”

“Confidentiality. Research records will be kept confidential to the extent provided by law. Research records may be reviewed by the [university] Institutional Review Board

and the [funding agency]. All responses and data collected from the devices will be kept confidential within the research team, and no material that could personally identify you will be used in any reports or publications from this study. Your data will be stored appropriately in locked cabinets and on a secure computer server in order to minimize the risk of loss of confidentiality. All information collected for this research that is stored on our secure computer will be identified by subject ID number only. Results of this study may be reported in scientific journals, meeting, and news media. None of these reports will use your name or use data that can point to any person who took part in the study. Strict security measures will be taken to insure that none of these procedures results in release of any information you provide us.

Several aspects of the procedure are designed to safeguard your rights and privacy as a participant. The Vicon Revue is equipped with two methods to deactivate the camera at any time, should you want your activities to remain private (i.e., certain places, times, or situations). The two methods are:

- 1) The Vicon Revue has an ON/OFF button for complete deactivation (off) or reactivation (on).
- 2) The Vicon Revue has a “DO NOT DISTURB” button, which will put the camera into “DO NOT DISTURB” mode. In this mode, the camera will remain on but absolutely no images will be taken. The Vicon Revue will stop taking pictures for 4 minutes, and will alert you with a beep 15 seconds before it starts taking pictures. You may press the “DO NOT DISTURB” button again to reset the “DO NOT DISTURB” mode to last for another 4 minutes. You may also reactivate the Vicon Revue from “DO NOT DISTURB” mode at any time by pressing the manual shutter button.

In addition, should you want any images to be deleted that were accidentally taken (e.g. during a time when you would have preferred the Vicon Revue to be off but forgot to turn it off), you will be able to note the time in a small notepad, which we will provide to you. As soon as you return to the measurement office, you will have the opportunity to privately review and delete any images prior to them being seen by research staff.

Furthermore, several aspects of the procedure are designed to ensure the rights and privacy of other people who may appear in the images captured by Vicon Revue. These include:

- 1) You must deactivate the Vicon Revue when you are at, or in, any of the following list of places or situations.
 - a. Place/Situations:
 - i. Any restroom
 - ii. Any changing room, locker room, etc.
 - iii. Doctor’s office
 - iv. ATM or bank
 - v. Wherever/Whenever anyone requests deactivating

- 2) You *may not* use the Vicon Revue in private locations, such as a home, without the permission of other people in that location.
- 3) A reference card will be provided for you to carry around while wearing the device. This includes:
 - a. a prepared statement to read to anyone with questions or concerns about the Vicon Revue; “I am participating in an experiment on daily activities and the environment. This is a digital camera that automatically captures low-resolution still images throughout the day, which will later be used to describe my behavior and environment. It does not record audio or full-motion video. Any images captured will not be made public in any fashion and will only be seen by the researchers. If you would prefer, I can turn off or temporarily deactivate the camera, and/or make a note and have the images just taken deleted without anyone seeing them. I can also provide contact information for the researchers.”
 - b. Contact information for the investigators (email, address and phone number)
- 4) A small notepad in which to note periods of time for images that you want deleted.
- 5) In order to protect your privacy and the privacy of others who may appear in the images, the images will not be released to you under any circumstances.”

5. B2 was a randomized controlled trial (RCT) involving 300 adult participants to test a text message intervention for weight loss. Both English and Spanish-speaking men and women between the ages of 21-60 are eligible to participate. The study was modified to include a GPS device to assess physical activity in a subsample of participants who would wear the device for seven days at two time points. Several months later, the study was modified to include GIS analysis. The description of study risks, risk management strategies and practices to enhance privacy and confidentiality were nearly identical to those described in study “A3” (see above).

Review Outcome. The IRB expressed concern about the “potential legal implications associated with the use of GPS” and asked the investigator to revise the informed consent document to address limits to confidentiality. The consent form was revised to include the following detail, which was accepted by the IRB:

“If you are part of the sub sample study, there is a slight chance that you may find the GPS device uncomfortable to wear. You may decline to participate or stop wearing the device at any time. You may also experience discomfort or a sense of loss of privacy as a result of revealing your exact location for one week to the researchers. However, the GPS unit does not tell us what you are doing, who you are with, and generally does not track your location when you are inside a building. We will only know the location of your activities after you return the device. If you do not want us to track certain locations you visit, you can turn the GPS device off during this time. All responses and data collected from the GPS device will be kept confidential within the research team and will not be shared unless required to by law, and no material that could personally identify you will be used in any reports or publications from this study.”

6. C1 was a randomized control trial (RCT) involving 234 non-diabetic, obese adults designed to assess three dietary approaches in behavioral weight loss intervention. To objectively measure physical activity, participants agreed to wear a GPS and an accelerometer for seven days and a heart rate monitor for three days. Several years after the initial approval, the PI requested a modification to add GIS analysis. The description of the study risks and risk management strategies were similar to descriptions noted in other cases.

Review Outcome. Specific to the modification to add GIS analysis, the IRB requested that the investigator revise the informed consent document to address the additional risk that is described as “obtaining more knowledge about the environments the participant moves through.” The investigator responded in a manner consistent with those found in Cases A3 and B2; however, the IRB insisted that the consent form be revised. The investigator responded with additional information to clarify that the “GIS measures will improve these analyses, but do not alter the data that have been collected from the start of the study or its use in answering the proposed questions.” The investigator goes on to write that “The current consent form adequately addresses the issue of potential risk of loss of confidentiality ... addition of secondary analyses does not increase the current risk.” Several additional communications occur between the IRB and investigator concerning revisions to the informed consent document specific to GIS risk disclosure including a request for a waiver of written consent citing “substantial burden and difficulty” of contacting 185 participants who have since completed participation. The investigator also cited other studies that have received approval to conduct this secondary analysis without re-consenting subjects. The most recent communication revealed the investigator withdrew the request to include GIS analysis.

7. D1 was a prospective cohort study involving an older adult population. The study was modified to include a pilot to test the use of devices to objectively assess movement in this population. Participants were asked to wear the Vicon Review camera, a GPS device, and an accelerometer. Risks were described as minimal and descriptions of risks and risk management are consistent with other cases described previously.

Review Outcome. The pilot study is approved with no concerns expressed by the IRB.

8. E1 was a RCT involving 340 post-menopausal women. The study was modified to include a GPS, GIS and an accelerometer to examine the relationship between obesogenic environments and physical activity, sedentary behavior and body mass. The potential risks and risk management strategies were similar to those reported in other cases noted. The consent form was amended to reflect the changes.

Review Outcome. The IRB requested minor procedural clarifications and the pilot study was approved as proposed upon receipt of the investigator’s response.

Synthesis of Results

The use of MIST technologies will make observation of day-to-day behavior and activity knowable through objective means rather than by self-report methods. There are a number of new ethical and regulatory challenges introduced by the use of wearable sensing devices in behavioral health research as noted in the case study summaries. Likewise, there are challenges in how researchers,

IRBs and participants communicate to ensure the research is designed and conducted in a socially responsible manner. This study is novel in the elucidation of protections that researchers and IRB have agreed upon and use to guard research participants and unwitting bystanders from the overreach of the new mobile sensing research methodologies.

In this study, we provide results of a multi-case analysis to better understand the perceived risks and strategies used to mitigate risks that were found acceptable at one institution. With this snapshot, we are able to confirm that the use of sensing technologies to objectively measure physical activity are introducing unique issues for consideration. From our review of these eight studies, we have learned that the primary concerns with visual imaging methods focused on the rights of bystanders who may be imaged and well as concerns for participant privacy. Specific to location logging, we learned that the use of GPS did not prompt concern; however, when combined with GIS the IRB response was variable with respect to the IRB review outcomes.

Three main themes were identified that may contribute to enhanced protections of human subjects including: 1) methods to enhance informed consent; 2) precautions to respect the rights of bystanders; and, 3) considerations for data management. Procedures found to be acceptable to the PI and IRB of record are described below. We are continuing to collect evidence to determine whether strategies designed to enhance informed consent and mitigate participant and bystander risk are effective. It is important to recognize that findings associated with this case study analysis are limited to research protocols that included visual imaging and GPS measurement devices being used to measure activity. These studies occurred within one organization and received review by one of five of the organization's IRBs.

Informed Consent, Control and Transparency

The principle of 'respect for persons' is demonstrated through the process of obtaining the informed consent from an individual considering participation in research (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Belmont Report, 1979). The IRB-approved studies consistently indicated that participants may experience a loss of privacy while using location logging and imaging devices. To mitigate the threats to privacy associated with both devices, participants were informed that they could remove the device when desired, a practice intended to give the research subject more control over their participation. An example from an approved consent form is noted in B1 above.

With the imaging device, two methods were approved for safeguarding a participant privacy. First, the privacy setting on the camera was described during the informed consent process with instructions for the participant to press the privacy button when privacy was needed (e.g., banking, bathroom, gym, etc.). Second, the research staff could delete images captured by the device that the participant wanted omitted (e.g., when the participant forgot to use the privacy button). Approved studies also included a procedure whereby participants were given a small notepad to record the time and date of a private image so that research staff could easily locate the images to delete. Likewise, upon completing the study, participants had the option to privately view the images exported to the study computer and were able to delete images without restriction. While this strategy may compromise the data record, the value of giving participants control was prioritized.

To decrease the likelihood that participants would encounter a negative response from a bystander who may be imaged, potential subjects were asked to confer with family and cohabitants prior to enrolling in the study. Likewise, the participant was instructed on how to respond to an individual who preferred not to be recorded. Within the consent form, participants were told of limitations to confidentiality, including the requirement for researchers to report illegal and reportable incidents recorded by the camera.

Rights of Bystanders

The imaging methods used to measure activity in context captures what the participant sees and will include images of persons who are in the vicinity of the participant. These ‘bystanders’ will be included in the research record by virtue of their proximity to the participant. Since the research is not about the person in the image, that individual is not considered a human subject (45 CFR 46.101). However, two IRB determination letters revealed concerns about bystander rights. One IRB determination letter stipulated that the camera be removed from the study design to protect the rights of the bystander (non-participant) and considered the risk to the bystander as being greater than potential study benefits. Another asked that images irrelevant to the study goals be obscured using a blurring technique. However, to blur images would involve outsourcing of services thereby introducing increased risks of a data security incident. Likewise, blurring techniques may compromise data quality making environmental context difficult to interpret.

Approved research plans included procedures for the participant to obtain permission from a bystander when there was an expectation of privacy (e.g., at someone’s home) and included a reference card containing a brief explanation of the study should a bystander inquire about the device (see study B4). If upon learning about the study, a bystander does not want her/his image included in the research record, the research participant is instructed to remove the device or activate the privacy button on the camera and record the time and date of the interaction so that any images captured during that timeframe may be deleted.

Data Storage, Access and Sharing

Data confidentiality was a notable concern for both researchers and IRBs specific to information collected via imaging and tracking methods. Steps taken by the investigators to protect privacy involved: 1) configuring the camera to encrypt images so that if downloaded, images cannot be viewed; 2) limiting access to images recorded to members of the research team who were authorized to unlock the device; 3) storing data on a password protected secure server consistent with approved University security standards; 4) limiting GIS analysis to environmental measures of physical activity and eating habits; 5) not matching GPS coordinates with protected health information (PHI); and, 6) not linking GPS coordinates to participant information such as gender or age. Approved protocols also described required data management and confidentiality training for those on the research team who have access to participant information.

Data sharing protocols were briefly discussed within the cases analyzed. Questions remain regarding how and under what circumstances should location and imaging data be shared with colleagues who are not members of the immediate research team. Because these studies are occurring in multi-disciplinary environments, it is important for both researchers and IRBs to

recognize that the standards for sharing data within a research group can vary considerably as team members may have diverse conventions for data sharing.

Discussion

Our document analysis revealed ethical and regulatory concerns associated with two MIST technologies used in research. It is clear that both researchers and IRBs are exploring somewhat uncharted territory with respect to risk assessment and related strategies to mitigate risks to participants. How and whether the IRB should consider the rights of a bystander emerged as a new challenge when determining risk of harm and balancing potential harm with benefits. This is particularly noteworthy as the charge of the IRB pertains specifically to human subjects as defined in 45 CFR 46 and, while respect for others is important, it is unclear whether the IRB has a role in evaluating risk to bystanders. If IRBs will be charged with protecting bystanders, clear guidelines are needed to assist IRBs to navigate this expanded scope of responsibility.

The visual imaging method used to obtain participant point of view perspectives is increasing in popularity. In 2013, the 4th International SenseCam Conference was held in California drawing researchers from across the globe interested in utilizing visual imaging technology for research purposes. Recognizing the ethical challenges associated with visual imaging in research, an ethical framework was proposed to guide this work (see Kelly et al., 2013). For the most part, research included in this multi-case study adhered to these ethical guidelines, demonstrated via the informed consent process, risk management strategies and recognition of the rights of bystanders. Whether these procedures are effective is not yet known.

The lack of IRB concern for studies involving GPS location logging methods was surprising. The GPS traces captured during study participation includes the exact longitude and latitude at specific points in time, which can present rather significant privacy and security concerns for researchers and IRBs to consider when evaluating research. GIS software is used to contextualize the GPS data (e.g., is activity or lack thereof occurring at a park? or an office?). Interestingly, while use of GPS independently did not receive much attention, when coupled with GIS concerns were raised during IRB review. While understanding the context may appear rather innocuous, these data could be considered sensitive if data security is breached. Since GPS tracking is a feature of technologies used in daily life (e.g., smart phone, automobiles), it may appear undeserving of added scrutiny or, perhaps there is a lack of IRB sensitivity to the potential risks introduced if location data are not adequately protected. Research is needed to better understand GPS use in research and what may increase risk (e.g., characteristics of participants) and mitigate risks (appropriate data security). Likewise, it is important that IRB members become familiar with best practices for securing data generated from GPS.

During our review of the literature, we found no published guidelines to inform the ethical design of research studies that utilize GPS/GIS tracking methods. Michael et. al (2006) proposed an emerging ethical framework when GPS is used for other purposes (e.g., tracking patients, criminals, employees); however, the ethical issues of surveillance and human rights do not transfer directly to research studies in which participation is voluntary. Procedures to enhance the ethical conduct of GPS/GIS in the studies reviewed may represent an emerging ethics for researchers

and IRBs to evaluate and build upon. At a minimum, participants should receive information about how GPS/GIS is used, what the data reveal (e.g., include examples of GPS traces when obtaining informed consent) and limitations to the de-identification of these data. The primary risk associated with GPS is the potential for unauthorized access to data. To reduce the risk of a data breach, IRBs and researchers may benefit from working with data security experts to identify best practices for encrypting, storing and sharing of location data.

In conclusion, MIST technologies may be a game changer in the battle against a number of chronic health concerns. Yet, in a society with mounting concerns of surveillance and privacy, researchers and IRB members are obligated to explore new and complex ethical issues to ensure this research advances in an ethical and socially responsible manner. This paper sheds light on issues being raised by IRB members and researchers around risk assessment, informed consent, bystander rights and data management when using visual imaging and location logging technologies. While we have exposed concerns and presented management strategies, many questions remain including, for example, the role of an IRB in considering the non-participants or 'bystander' rights or whether the procedures to enhance human subject protections are effective. The amount of personal identifiable information and health information collected via mobile technologies is beyond what researchers and IRB members have navigated in the past and, in many cases extends into a grey zone outside of existing regulatory structures (e.g., HIPAA). Clearly, this is an area in which research stakeholders have a vested interest and one that is ripe for empirical research to inform best practices and guidelines.

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Camille Nebeker, EdD, MS

Assistant Professor, Behavioral Medicine
Department of Family Medicine and Public Health
School of Medicine, UC San Diego
9500 Gilman Drive, La Jolla, CA 92093
Email: nebeker@ucsd.edu
Telephone: 858-534-7786
Fax: (858) 534-4642

Rubi Linares-Orozco, BA, MASc

Health Policy and Law, Graduate Student
UC San Diego

Katie Crist, MPH,

Public Health, Graduate Student
Department of Family Medicine and Public Health
UC San Diego

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