

This is the pre-peer-reviewed version of the following article:

Larsen EP, Kolman JM, Rao AH, Masud FN, Sasangohar F. Ethical considerations when using a mobile eye tracker in a patient-facing area: case study of an intensive care unit (ICU) observational protocol. *Ethics Hum Res.* 2020;42(6):2–13. doi:10.1002/eahr.500068, which has been published in final form at <https://onlinelibrary.wiley.com/doi/epdf/10.1002/eahr.500068>

Ethical Considerations When Using a Mobile Eye Tracker in a Patient-facing Area: Case Study  
of an Intensive Care Unit (ICU) Observational Protocol

**ABSTRACT**

This case study describes the process of designing, approving, and conducting an investigator-initiated protocol to use an eye-tracking device in a healthcare setting. Participants wore the device, similar to eye glasses, in a front-facing manner in an intensive care unit, to study personnel gaze patterns, producing a visual record of workflow. While HIPAA-protected information was not the data of interest, a wide variety of such data is captured by this technique, and prospective consent of all people who might be incidentally videotaped was not feasible. The protocol therefore required attention to unique ethical considerations—including consent, privacy and confidentiality, HIPAA compliance, institutional liability, and secondary data use. The richness of eye tracker data suggests various beneficial applications in healthcare occupational research and quality improvement. Therefore, sharing the study’s successful design and execution, including proactive researcher-IRB communication, can inform and encourage similarly valuable, ethical, and innovative audio-visual research techniques.

**Keywords:** Health Insurance Portability and Accountability Act; Video-Audio Media; Fixation, Ocular; Intensive Care Units; Patient Rights; Health Personnel

## **INTRODUCTION**

Burnout is a growing concern throughout the U.S. workforce, but burnout in healthcare providers is of particular concern.<sup>1</sup> Burnout may be a contributor to the high turnover rate currently seen in critical care nursing.<sup>2</sup> At this time, the prevailing methodological approach to assessing burnout is reactionary, in the form of self-reporting survey tools.<sup>3</sup> We sought to gain proactive understanding of the triggers of stress, fatigue and ultimately burnout through analysis of physiological metrics and documentation of work context. In order to facilitate documentation of complex activities in an active patient care unit, we proposed the use of wearable technology in the form of a mobile eye tracker. The study methods described in this case study are detailed in a separate pending paper.

While convenient, the mobile eye tracker in particular poses several unusual ethical issues for use in patient-facing healthcare environments. The eye tracker itself consists fundamentally of four cameras that watch the subject's eyes, and a forward facing-camera that shows what the participant is seeing. In addition to the cameras, the mobile eye tracker also includes an onboard microphone. The data collected by a mobile eye tracker is comprehensive when assessing the actions and experiences of the subject, but will also potentially contain all of the designated protected health information elements identified in the Healthcare Insurance Portability and Accountability Act (HIPAA; cf. 45 CFR 160 and 164) for that healthcare worker subject's patients. In order to pursue this novel approach, the research team engaged with the institutional review board (IRB) in order to determine how we could conduct the study while protecting all participants and any incidentally-documented individuals or protected health information (PHI), as well as address any other ethical concerns raised by such a study design.

This paper presents the process the research team took in navigating ethical and logistical hurdles in order to effectively and ethically conduct the study with 28 nurses in a Cardiovascular Intensive Care Unit (CVICU). The investigators took the initiative to review not only the relevant scientific literature on their study concept, but also of the ethical literature on similar audio-visual study designs, in order to be well-informed of the issues which may be of concern to the IRB, patients, visitors, administration, and other stakeholders. A research assistant assembled an internal briefing on the ethics of AV research, modified and summarized in the following section. We then report on the approval and conduct of the research, as an example of the proactive and continuous measures, both previously employed in AV research as well as adapted to the needs of eye tracker studies specifically, that can facilitate future research using similar recording methods in patient-facing areas.

### **Background: AV ethics issues anticipated from literature**

Taking as given the overall framework of research ethics (e.g., the Belmont Report's principles of respect for persons, beneficence, and justice),<sup>4</sup> and regulatory implementation of these ethical values via the Common Rule (45 CFR 46) and HIPAA, the team reviewed studies specifically involving audio-visual (AV) research which explicitly discussed ethics and/or consent procedures. The general research ethics values and regulations, as well as layers of research accountability (seeking prospective IRB approval, adhering to institutional mission values, and maintaining the public trust) apply to AV research as to any other form of research. The literature confirmed, however, that AV recording modifies a number of standard considerations such as privacy, consent, and research risks.

Privacy, PHI, and research recordings. Video capture includes, but is not limited to, HIPAA identifier #17 ("full-face photographic images and any comparable images"),<sup>5</sup> as well as

any other aspect of sensitive or private health information (PHI) the participant happens to look at in the course of care. Facial capture or other signature elements (e.g., tattoos) in particular could readily identify the recorded person, and elements of the video record such as time-stamps also qualify (dates are PHI when related to care delivery).<sup>6</sup> Such PHI has been used, without a signed patient HIPAA authorization, for treatment, (internal) educational purposes, and, if properly de-identified, even in (non-research) publication; prior permission is not technically required by HIPAA, *per se*, for obtaining video recordings for these applications, but where such practices are routine, consultants advise institutions to establish prior authorization procedures.<sup>7</sup>

Real-time AV data recording has been used in “a broad range of medical settings” for research purposes<sup>8</sup> and for *in situ* clinical analyses in particular.<sup>14</sup> Researchers interested in communications, workflow, or ethnography praise AV data capture as far superior to observations, and even superior to verbal interview transcription, for the ability to record rich non-verbal, tonal, and situational cues unavailable by other data methods.<sup>9</sup> In a regulatory context, “collection of data from voice, video, digital, or image recordings made for research purposes,” can even qualify for expedited (“category 6”) IRB review on a minimal risk basis, barring additional interventions or risk factors.<sup>10</sup> However, research seeks to use PHI in a manner more than the “minimum necessary” for normal treatment or education, and hence this normally requires subject authorization.<sup>11</sup> Practical barriers and proposed exceptions to that authorization require careful consideration, as do other risk factors specific to AV protocols. Although our research team was initially concerned that privacy and confidentiality issues alone could make the ICU eye-tracker study an ethical non-starter, the existence of prior AV research in patient-facing areas changed the question from “whether” to “how” video research can proceed.

However, it also became evident that privacy and confidentiality were not the sole (or even most AV-unique) concerns to address.

Who is a subject? Who consents and authorizes? Weinger, et al. have given particular focus to the ethical issues and IRB review and approval process of their AV-research,<sup>12</sup> and they distinguish between the consenting *subjects* from *bystanders*. Subjects are, from their *methodological* point of view (but not a *regulatory* view – see below), those participants who are of direct interest to the research aims and from whom consent can feasibly be obtained, along with patients for whom the situation can feasibly allow consent and authorization. However, video research adds *bystanders*—healthcare workers, patients, guests, and others who incidentally and unpredictably appear in the tape in potentially identifiable fashion. The authors caution against the potential reflex reaction of IRBs to require consent from all of these parties, as this presents a “serious impediment” to potentially valuable research, as well as adding a disruptive element to an AV data capture method which can be otherwise “largely unobtrusive” to the clinical encounter.<sup>13</sup>

However, from a regulatory perspective, bystanders can also be regarded as research subjects, and so protections are warranted by default, while exceptions must always bear the burden of justification. This status should not be underestimated or misconstrued. A research subject is defined not by the objectives of the research (the “subject” of an investigator’s scientific interest) but by how the research-specific interventions or intrusions affect people (i.e., those who are “subjected to” the procedure). The Common Rule (45 CFR 46.102(e))<sup>14</sup> states, “*Human subject* means a living individual about whom an investigator ... conducting research (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or (2) Obtains, uses, studies,

analyzes, or generates identifiable private information or identifiable biospecimens.” Further, this section defines “intervention” as including “manipulations of the ... subject’s environment that are performed for research purposes.” Introduction of otherwise absent AV equipment and data recording in the clinical setting may count as such a manipulation of the bystander’s environment.<sup>15</sup> As these bystanders could arguably be regarded as subjects, any status which complicates the inclusion of subjects would also apply—e.g., minors taped without parental consent, or unconscious / incapacitated adults taped without their knowledge, which is a probable scenario for research in an uncontrolled ICU or trauma ward setting.<sup>16</sup>

Weinger et al.’s proposed alternatives to obtaining research consent and data authorization include prior ward-wide notification (e.g., verbal, posted); opt-out procedures, including rapid termination of taping, redaction of data upon request, and even complete termination in the event of objections; IRB-approved waivers of consent and of HIPAA authorization for bystanders; converting research studies to quality improvement (QI) projects to better represent study intent and avoid inapplicable regulations; and “complete and immediate de-identification of the videotapes and related data before review” as a protocol step.<sup>17</sup> These alternatives are not entirely distinct or exclusive; de-identification “at the earliest opportunity consistent with the conduct of the research” is one of the necessary criteria for a waiver of HIPAA authorization,<sup>18</sup> and researchers could present risk-minimization and notification procedures, along with secure handling and storage of data, when justifying a waiver of research consent to the IRB (i.e., when discussing whether 45 CFR 46.116(f)(3)(i) has been satisfied). Weinger’s team also used “blanket quarterly consents,” which, in their case of operating room (OR) taping, covered anesthesiologists who were not enrolled in the study but were likely to relieve study-enrolled anesthesiologists in the OR, and hence to appear on tape.<sup>19</sup> However,

investigators and IRBs may vary in their comfort-level with the very concept of “blanket” consent, which has been controversial (and complicated by recent regulatory revisions to the Common Rule at 45 CFR 46.116(d), a broad consent mechanism that institutions may hesitate to implement until further official guidance is issued, at least at the time of this writing).<sup>20</sup>

The likelihood of recording bystander information may also have been underestimated in prior studies. An ICU-specific study<sup>21</sup> claimed to have recorded only (consenting) ICU staff, with ethics approval (and termination / redaction of recording upon objection or withdrawal, in line with Weinger et al.’s recommendations). Study authors claimed that patients were not recorded, but neither the issue of incidentally captured patient information nor healthcare worker or visitor bystanders were discussed. Given that the data included audio records of clinician communication *in situ*, we found the details supporting this claim to be highly unlikely and insufficiently reported. Means of de-identification, if present, should have been reported for posterity.<sup>22</sup>

Of course, visuals of patients in normal video research can be prevented by limiting camera locations to closed-door briefing rooms or angled away from patient monitors, but this would be of little use to an ever-moving, participant-mounted eye tracker study set in patient areas for comprehensive observation. Given the dearth of prior research on mobile AV research in an ICU environment, the research team flagged the bystander issue (and potential solutions) on the cautionary assumption that patient and healthcare worker bystanders would, in fact, appear legibly within the visual record in uniquely unavoidable ways compared to studies involving more controllable spaces or stationary AV recording devices.

*Psychological risks to patients and bystanders.* Risks are not limited to breaches of privacy and confidentiality. The initial presence of filming technology or crews can alone be

unnerving in a clinical context where they would not normally be expected, though means of acclimation can be accounted for in the study planning and also occur naturally over prolonged exposure time.<sup>23</sup> Psychological harm can occur if bystanders are taped at moments of intimate medical crises or if sensitive topics are recorded.<sup>24</sup> In one case, a family member objected that his dying father was taped without consent; the objector took issue with the taping itself, independent of later use or disclosure protections (“even if footage ... had never aired”).<sup>25</sup> As a second harm in the same case, family members recognized the blurred face of the decedent when footage aired on television,<sup>26</sup> illustrating the valuable reminder that de-identification is not perfect and that re-identification risk has a broad scope (identifiable *to whom?*). The public’s idea of what counts as sensitive data or objectionable research use may be more stringent than anticipated by regulation and law, such that disclosure disrupts public trust even when data, specimens, or footage is supposedly rendered “unproblematic” through mechanisms like de-identification or blanket consent/notifications.<sup>27</sup>

*Legal risks to healthcare worker-subjects and the institution.* The implications of filming an adverse event,<sup>28</sup> or “unethical behavior” on the part of the healthcare worker-subject<sup>29</sup> are legally and ethically complicated, creating liability concerns well beyond HIPAA breaches for the healthcare worker-subject and the institution itself. The researcher may have a duty (*qua* researcher) to protect the healthcare worker-subject from harms of exposure occurring as a result of research participation, yet may also have a competing duty (*qua* institution member) to “blow the whistle” on misconduct, or to break confidentiality if compelled by subpoena.

Particularly regarding subpoena: regulations protecting human subjects’ data confidentiality and regulations granting subpoena authority for judicial purposes are not, in any obvious way, harmonized, across or even within relevant national jurisdictions.<sup>30</sup> Researchers

can fight subpoenas to protect their subjects, but at the same time are cautioned not to guarantee confidentiality against all government inquiry in the consent form—not even National Institute of Health (NIH) Certificates of Confidentiality are iron-clad in practice.<sup>31</sup> This is why methods of anonymous data capture (or at least of rapid de-identification and destruction of identifiers) have presented a lively topic in research on illegal activities such as sex work, drug addiction, and financial misconduct.<sup>32</sup> Risks would be too high, and trust from the target population too low, to recruit for a study which exposed the participant to severe criminal or civil liabilities, yet protection from such liabilities is uncertain as long as an identifiable record exists.

*Consent process and subject experience are different with video.* An empirical ethics study by O'Reilly et al.<sup>33</sup> had two relevant findings regarding the consent process for video (in a case where subjects were consented in closed sessions, which avoided bystanders). First, patients in taped therapy sessions were acutely aware that recording devices *record and retain* data, a circumstance which participants explicitly distinguished from (non-recording) listeners or research observers; patients seem to appreciate, in their level of concern, the greater capability of video to retain more details than an in-person shadowing observer (who may be exposed to the patient's PHI and may even take notes, but not to the same degree of detail or retention possible with an AV device). Consequently, this affected the consent process, as the recording technology had to accommodate requests from consenting subjects to hold certain conversations “off the record” versus “on the record” as a “negotiation,” more subtle and continuous than can be expressed by initial consent to participate or by a full-stop option to withdraw from the study entirely at any time. The second key finding was that, as the patient-participants become acclimated to video over longer footage sessions, they can forget the video is running if not periodically reminded, which is problematic if sensitive topics should come up.

These findings have implications when the research subject is a healthcare worker and patient bystanders are introduced, as both parties may benefit from the continual negotiation of video capture yet also be susceptible to acclimation. The researcher and even the healthcare worker-participant should therefore be trained to prompt involved patients periodically to verify continued consent as circumstances evolve (similar emphasis on the continual consent process has been expressed in video nursing research<sup>34</sup>). In short, while all good research consent is a study-long process of *continual* consent, this consideration seems especially important for AV research.

### **OBTAINING APPROVAL FOR EYE TRACKING STUDY**

In light of the prior efforts in AV-based research, the research team had several meetings with the IRB administrators. We found that the in-person meetings were useful in order to come to a mutual understanding of the requirements and reasoning behind the requests in the protocol that would otherwise be lost with an electronic submission and verbal descriptions alone. In particular, a video demonstration of the eye tracker, its mounting apparatus, a sample of its data output (using a mock participant from the research team), and proposed additional data collection methods to be correlated with the eye tracker data (including *in situ* observation and digitally monitored vital statistics, to be further reported in a forthcoming methodology paper), were presented at these meetings to ensure clarity.

The original intent of the project involved automated data reduction to remove videotaped identifiers shortly after collection, thus preventing their storage or handling by any human investigator. Censorship of AV footage was one of the protective strategies noted in the prior literature, and since the primary variable of interest involved only a “yes/no” value across the timeframe of recording (whether the participant was, or was not, looking at a device of

interest such as a monitor containing electronic health record output), this strategy was deemed consistent with at least the primary study objective to study the effects of technology on the healthcare worker (albeit obstructing some degree of study-relevant information, such as the type of monitor or interface in the participant's gaze, in the interests of patient protection). The study team had also hoped that by avoiding retention of PHI (despite initial exposure to PHI), the study might resemble Common Rule Exemption 2 for observational research involving no recorded identifiers (45 CFR 46.104(d)(2)(iii)). Exempt research would not be under the same regulatory pressure to obtain fully documented consent from potential bystanders; furthermore, automation to avoid any human eyes on the recorded output would also address subjects' awareness that retained recordings are importantly different than observer field notes.

However, this method proved not to be feasible with the varied ICU environment in question and given the practical limitations of coding such diverse object recognition capabilities (including various objects of interest at various angles of approach) into the eye tracker. Face-blurring software (as applied in other AV research case studies)<sup>35</sup> was likewise not compatible with the eye-tracking device and could not be expected to recognize the variety of PHI-displaying devices in an ICU. The technology could not do the job of a human analyst, and thus full video had to be retained to achieve study objectives. To transition from rapid reduction of the data stream to retention of the recorded video, researchers provided additional protocol revision and consulted with the IRB administrators. Through discussion and recognition of the limitations of the software, an initial pilot was planned to test out a protocol for manual de-identification and to further develop the methodology in general.

In a trial de-identification step, the process was found to be highly time intensive, requiring five to ten times the processing time as the eye tracker video duration itself, given in

part to the sensitive ICU setting, and in part to the nature of the eye-tracking footage to capture this setting naturalistically (i.e., controlled camera angles to avoid PHI were not an option). A step to de-identify data prior to analysis would thus require as many manual hands on the data, and with prolonged access, as to defeat the purpose of rendering a de-identified data set; proceeding directly to analysis would be faster and expose fewer personnel to the data. In addition, the de-identification would potentially obstruct information of interest to the study, as noted above, and even threatened to impact the stability of the analysis software. In light of this, upon a follow-up meeting with the IRB administrators, it was mutually decided that a HIPAA waiver was necessary to allow the retention of all collected information; the IRB in particular recognized that censoring the electronic displays, even if it had been feasible, would have greatly reduced the meaningful benefits of the study. With a HIPAA waiver, patient protection therefore derived from the means employed to protect the PHI-laden data rather than censor the data. In order to protect this data, the saved files were restricted to specific network users and designated to be accessed only on one particular computer (with further details of protection outlined in the design below).<sup>36</sup> The institution required Responsible Conduct of Research (RCR) training through the Collaborative Institutional Training Initiative (CITI)<sup>37</sup> for all staff of any discipline (e.g., clinical, engineering) of any level (trainee, PI, staff) involved in human subjects research.

These pilot runs of alternate protocols were ultimately experiments in themselves, testing both the technological limits and human workflow capabilities to determine the maximal degree of subjects protection and minimal degree of intrusion upon bystander parties, that could, or could not, “practicably be carried out” consistent with the study aims (cf. 45 CFR 46.116(f) and 45 CFR 164.512(i)(2)(ii)(B-C)). The study therefore proceeded not on assumption or interpretation of what could reasonably be done, but on experience. The aspects of study design

which follow benefitted from this extra effort, invested out of a shared prioritization for subject protections from the PIs, research staff, and IRB.

## **ETHICAL PROTECTIONS IN STUDY DESIGN AND CONDUCT**

### **Participant Recruitment**

In order to recruit participants, the research team engaged in several outreach sessions in the ICU. The study coordinator and staff met with the unit administration to find optimal times to reach the most potential participants, making ourselves known to the staff and explaining the study to all who were interested. The sessions enabled the research team to become familiar to the unit staff, both those eligible and interested in participating, and the rest of the personnel who would be around the active participants. Through these sessions the research team was able to demo the eye-tracking device, answer questions, and resolve confusion as to the nature and intent of the study.

Potential participants did inquire about whether the data collected would be used to assess quality of care or accuracy. In this situation and overall, the research team emphasized their disciplinary background as systems engineers, not healthcare providers. Due to this different background we were in fact not qualified to make any such judgment of medical care and would need a later follow-up session in order to truly understand what we were seeing. These interactions laid the groundwork for the follow-up sessions following a participatory ergonomics approach, in which the subjects are highly engaged in the research beyond the data collection phase to help drive improvement efforts.

While there was some lingering confusion, continual availability on the part of the research team allowed all staff to comfortably approach the team and resolve their concerns. After reaching a “critical mass,” the participants themselves actively began encouraging

participation within the unit to ensure the research captured a comprehensive scope of participants. This behavior demonstrated that participants understood the study was not designed to grade their own performance, but on the contrary to assess and improve aspects of the work environment.

The research team actively discouraged unit administrators and supervisors from recruiting participants, to ensure all eye tracker participants consented voluntarily. Instead, administrators were asked to connect interested potential participants with the study coordinator. Only members of the research team actively recruited and engaged with potential participants.

### **Consent**

The “active participants”—ICU nurse subjects wearing the research hardware—provided standard written consent to be engaged in the study. Consent for the remaining staff, patients and guests of the unit (representing the bystander issue identified in the literature above) was waived, but with measures in place to ensure protections. None of these bystander groups represented the focus of the study, and so their personal data was not utilized in analysis. Although the earlier pilot attempts to redact patient data from the data set had proven impracticable, the protective measures for data collection handling (see below), and absence of further plans to include bystander details in analysis or reporting stages of the project, were deemed sufficient not to interrupt the natural ICU environment under study with a full, written bystander consent requirement.

Bystanders to the study did have an ability to opt out of incidental participation and ask that their footage be deleted or that the active participant remove the eye tracker glasses. Information about these rights was disseminated in supplemental information available in the unit and explained to the engaged active participants, who in turn provided notice and verbal

explanation in particular to patients and guests upon entering each ICU room. Providing this opt-out notice was part of the initial orientation for participant engagement. Effectively this method incorporated the healthcare worker participants as partners with the research team to ensure a respectful approach.

We feel it is worth noting that, while these contingencies were considered and planned for, at no point did any patient, family member / guest, or the other staff in the space object to the eye tracker or activate any of the opt out contingencies.

### **Data Collection**

Data collection activities in the unit were successful and uneventful. The research team would arrive in advance of the participant shift start time and provide the consent forms and perform hardware setup around the participant's availability during the pre-shift huddle. During the setup, a script was utilized to ensure compliance and consistency, reminding participants about bystanders and other concerns that were included in the consent form and printed materials.

Confidentiality of participation was not feasible due to the obvious nature of the hardware worn—the eye tracker, though lightweight, has a blocky addition to the frame to house the recording device, seen in Figure 1,<sup>38</sup> which distinguished it readily from reading glasses. However, within the span of four participants, the unit had grown accustomed to the presence of the hardware and the research team. In some cases, patients and families that had spent extended periods on the unit also grew accustomed to the presence of the team and study, interacting with the participant, saying “Oh you get to wear the funny glasses today!” and asking questions of the research team. In part thanks to the outreach activities conducted, the project had significant support among the potential participant pool. In many cases nurses recruited their coworkers to

participate and worked to ensure we captured the depth and breadth of the nursing responsibilities in the ICU.

<<Fig.1 inserted here>>

We found that the movements of the participant occasionally disrupted the video recording. This required more interactions with the participant than we had originally planned in order to fix the recording device and/or its associated battery pack. In all situations, care for patients was the highest priority; no patient care activities were interrupted, and participant interactions occurred only during periods they self-identified to be available. Engaged participants wore the eye tracker for the duration of their 12-hour work shift, with the exception of their 30-minute lunch break, and any visits to the bathroom. Between the expected bathroom and lunch breaks, and occasional equipment malfunctions, participants physically wore the eye tracker between nine and eleven hours.

The team maintained a strict policy of no entry into patient room unless under specific invitation by the patient and nurse. The only anticipated scenario where that invitation would be offered was if the patient had asked questions about the study that the participant felt uncomfortable answering and wanted to defer to the research team. This anticipated event did not occur, and the patient and family bystanders were content with the answers provided by the nurses.

During data collection the research team maintained a minimal footprint and presence in the unit, often limiting to a single researcher monitoring data collection. Care was given to the fact that the research was ongoing in an active clinical environment and maintaining a minimally invasive presence in that space was a high priority.

During some events in the unit, we chose to proactively intervene and remove the obvious hardware from participants, particularly when dealing with the withdrawal of care from a patient. During the healthcare worker's initial conversations with the family and until after the act of the care withdrawal, researchers elected to remove the eye tracker in order not to complicate a sensitive situation with unusual equipment or recordings. These cases of researcher-initiated withdrawal of data gathering were preemptive and therefore did not burden subjects or bystanders with the need to actively express an opt-out request.

### **Data Storage, Access, and Dissemination**

Given the study's location (at a hospital with an established research institute), storage and access for video benefitted from the same infrastructure and procedures as for any other research involving identifiable information. Both physical and electronic spaces were already set up for compliance with the HIPAA Security Rule (e.g., locked and access-limited research spaces, password-protected computers, firewall-protected servers).<sup>39</sup> Upon completion of recording, the files were loaded onto a designated study computer and materials were archived to secured network drives. After verifying the transfer, the memory cards were wiped and stored ready for the next participant. Only one designated computer was given access to the saved files, and access was further restricted to specific members of the research team, as for any study involving identifiable data. The memory cards were reused throughout the study and stored securely with the rest of the equipment. Since there was no option available to format the cards in a way that would satisfy the requirements of HIPAA, the cards themselves will be physically destroyed after formatting a final time upon study completion.

Conference and journal materials related to this study and any related device usage demonstrations that were and will be disseminated involve either mock data or de-identified

samples (liberally censored with consideration of possible indirect re-identification or patients contextually identifiable by loved ones, as noted in the literature above) rather than identifiable study records. Any still images or video from this study intended for publication or dissemination will be reviewed and approved by the IRB before publication or presentation.

### **Creation of a Data Bank**

While reviewing the initial pilot recordings, the research team realized that there was an incredible wealth of information available in the recordings, unparalleled in any other institution. Utilizing the study records for a single project and then destroying them would be a significant underutilization of the effort in data collection—a case in which an otherwise-standard protective measure may undermine a substantive and long-lasting study benefit. Prior to the start of full-scale data collection, an additional amendment was submitted to the IRB to enable the secure retention of the raw data as a data bank. The consent form included consent for retention in the data bank. No participants refused participation due to the data bank clause indicating retention of the recordings. The data bank exists as part of the project protocol and as such is subject to annual review for compliance. As per the agreement with the IRB at the creation of the data bank, any projects looking to make use of the data bank would require separate IRB application and approval. Images were not copyrighted to the researchers and are not to be monetized, to avoid profiting from patients' or research participants' ICU experiences.

### **LESSONS LEARNED FOR FUTURE STUDIES**

Ethical data collections in an active care unit with an eye tracker are possible and can be successful. As we have encountered, such a study can even be met with positive support from the potential participant pool. We expected to encounter patients and guests who were

uncomfortable with the presence of eye tracking on their care team but found universal support for the study.

Lessons learned from this study and its approval process are limited to the contexts of the study. The study aims of the research were overt, not covert—the scientific aims of the study would not be furthered by obscuring the study aims from participants or bystanders, and so all parties were given transparent information and, in the case of the healthcare worker participants, fully informed consent; if an eye-tracking study involves covert study aims, additional considerations would apply.<sup>40</sup> Since no participant or bystander requested withdrawal of participation or data from the study, we also cannot speak to the actual logistics of carrying out the protective measure of removing said data, except that the software used was fully capable of processing selective video cropping / deletion as needed without compromising the licit portions of video feed.<sup>41</sup>

We attribute the successful IRB approval, efficient launch, and ethical conduct of this study in particular to several inter-related factors. First and foremost, as prior AV research investigators have noted, communication between researchers and the IRB, early and often in the design process, is essential “to determine what approaches will be feasible.”<sup>42</sup> IRB feedback was instrumental in improving study design. Second, all stakeholders involved were part of an institution with a patient-centered, value-driven culture which is frequently reinforced to all employees (e.g., at onboarding, twice-yearly refresher courses, and at unit-wide culture-building meetings and activities). Integrity, compassion, accountability, respect, and excellence, particularly as applied to patient and coworker care in service, safety, and privacy, have guided all stakeholders—the research teams, IRB, healthcare worker participants, and unit-level leadership—who allowed the study to proceed. Third, all parties recognized regulatory

requirements as a floor, not a ceiling, particularly where innovative data collection methods and emerging technologies are involved. HIPAA governs the use and disclosure of PHI, not the recording of PHI *per se*, yet patients in other cases have become upset at the prospect of being recorded,<sup>43</sup> and so our participants were trained to be transparent and allow bystanders an opportunity to opt out. Employing only IRB-approved informed consent and study notification procedures is required, but so too is adapting to emerging situations with a cautionary and protective mindset, such as removing data collection from events perceived as especially sensitive, private, and emotionally difficult, when (due either to acclimation or the stress of the moment) opt-out procedures and recording devices are furthest from participants' and bystanders' minds.

Lastly, the team was gratified to see a shared appreciation for the potential benefits of the study. In particular, we believe that because the ultimate goal behind the study objective was to improve healthcare worker wellbeing and address the sources of burnout, all parties involved were more willing to accommodate a study in this area of research. While there are significant concerns for protection of patient information, the benefits of being able to collect the kind of rich dataset that eye tracking can provide are certainly worth the effort. The ability to discern insights into the details of daily work tasks and execution with the minimally invasive collection from wearable devices can answer numerous work study questions as long as concerns for privacy of the participant and those incidentally recorded are considered.

## References

1. Maslach, C., S. E. Jackson, and M. Leiter, "Maslach Burnout Inventory Third Edition," in *Evaluating Stress: A Book of Resources*, ed. C. P. Zalaquett and R. J. Wood (Lanham, MD: The Scarecrow Press, 1997), 191-218; C. Maslach, W. B. Schaufeli, and M. P. Leiter, "Job Burnout," *Annual Review of Psychology* 52, no. 1 (2001): 397-422; L. Emanuel, et al., *EPEC-O: Education in Palliative and End-of-life Care for Oncology, Participant's Handbook, Plenary 1: Gaps in Oncology* (Chicago, IL: The EPEC Project™, 2005), at 19-20.
2. Gregory, S. T., and T. Menser, "Burnout Among Primary Care Physicians: A Test of the Areas of Worklife Model," *Journal of Healthcare Management* 60, no. 2 (2015): 133-148; National Academies of Sciences, Engineering and Medicine, *Taking Action Against Clinician Burnout: A Systems Approach to Professional Well-Being* (Washington, DC: The National Academies Press, 2019).
3. Gardner, R. L., et al., "Physician Stress and Burnout: The Impact of Health Information Technology," *Journal of the American Medical Informatics Association* 26, no. 2 (2019): 106-114; R. E. Khamali, et al., "Effects of a Multimodal Program Including Simulation on Job Strain Among Nurses Working in Intensive Care Units: A Randomized Clinical Trial," *JAMA* 320, no. 19 (2018): 1988-1997; S. P. Schwartz, et al., "Work-life Balance Behaviours Cluster in Work Settings and Relate to Burnout and Safety Culture: A Cross-Sectional Survey Analysis," *BMJ Quality & Safety* 28, no. 2 (2019): 142-150.
4. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Washington, DC: Government Printing Office, 1979).
5. Department of Health and Human Services, *Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule* (Bethesda, MD: National Institutes of Health, 2004), at 10.
6. Department of Health and Human Services, *Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule*, at 10; M. B. Weinger, et al., "Video Capture of Clinical Care to Enhance Patient Safety," *BMJ Quality & Safety* 13, no. 2 (2004): 136-144, at 143.
7. Shindell, R., "HIPAA Privacy & Security Compliance: Managing the Use of Photographs and Videos in the Wound Clinic," *Today's Wound Clinic* (blog), July 12, 2016, <https://www.todayswoundclinic.com/blog/hipaa-privacy-security-compliance-managing-use-photographs-and-videos-wound-clinic>.
8. Heath, C., P. Luff, and M. S. Svensson, "Video and Qualitative Research: Analysing Medical Practice and Interaction," *Medical Education* 41, no. 1 (2007): 109-116, at 110.
9. Carroll, K., R. Iedema, and R. Kerridge, "Reshaping ICU Ward Round Practices Using Video-reflexive Ethnography," *Qualitative Health Research* 18, no. 3 (2008): 380-390.

10. Office for Human Research Protections, “OHRP Expedited Review Categories (1998),” <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html>. [unpaginated]
11. Office for Human Research Protections, “OHRP Expedited Review Categories (1998).”
12. Weinger et al., “Video Capture of Clinical Care to Enhance Patient Safety.”
13. Weinger et al., “Video Capture of Clinical Care to Enhance Patient Safety,” at 142.
14. The 2018 Revised Common Rule definitions have been presented here; although our case study was initially discussed and approved prior to the full implementation of these changes, revisions were not impactful to the present case (we also anticipated the publicly available changes during pre-research preparations). For present purposes of discussion, we may assume the current, post-2018 wording throughout.
15. Some investigators have argued that highly indirect manipulations (e.g., of cluster-level implementation studies at the institutional policy level) are different, but these cases generally do not involve direct access to or prospective recording of PHI (or at least researchers can plausibly avoid receiving data in un-coded formats), so this debate may not apply straightforwardly to AV research. For discussion of indirect manipulations in other contexts, cf. C. A. Minami, D. D. Odell, and K. Y. Bilimoria, “Ethical Considerations in the Development of the Flexibility in Duty Hour Requirements for Surgical Trainees Trial,” *JAMA Surgery* 152 (2017): 7-8; N. Chiota-McCollum, “A FIRST-rate Oversight, and Other Problems with Studies of Medical Residents’ Work Hours,” *Bioethics Forum* (blog), February 23, 2016, [www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=7762&blogid=140](http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=7762&blogid=140).
16. Halimaa, S.-L., “Video Recording as a Method of Data Collection in Nursing Research,” *Sykepleievitenskap Omvårdnadsforskning [Nordic Journal of Nursing Research]* 21, no. 2 (2001): 21-26.
17. Weinger et al., “Video Capture of Clinical Care to Enhance Patient Safety,” at 142.
18. Department of Health and Human Services, *Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule*, at 14.
19. Weinger et al., “Video Capture of Clinical Care to Enhance Patient Safety,” at 142.
20. Rothstein, M. A., “The End of the HIPAA Privacy Rule?,” *Journal of Law, Medicine, & Ethics* 44 (2016): 352-358.
21. Carroll, Iedema, and Kerridge, “Reshaping ICU Ward Round Practices Using Video-reflexive Ethnography.”
22. The study took place outside of U.S. jurisdiction (Australia), but the local privacy rules in place are sufficiently analogous to HIPAA for the criticisms above to apply as instructive to a U.S. audience; cf. Office of the Australian Information Commissioner, “Health and Medical

Research,” July 19, 2019, <https://www.oaic.gov.au/privacy/the-privacy-act/health-and-medical-research/>.

23. O’Reilly, M., N. Parker, and I. Hutchby, “Ongoing Processes of Managing Consent: The Empirical Ethics of Using Video-Recording in Clinical Practice and Research,” *Clinical Ethics* 6, no. 4 (2011): 179-185; Halimaa, “Video Recording as a Method of Data Collection in Nursing Research.”

24. Weinger et al., “Video Capture of Clinical Care to Enhance Patient Safety.”; O’Reilly, Parker, and IHutchby, “Ongoing Processes of Managing Consent: The Empirical Ethics of Using Video-Recording in Clinical Practice and Research.”

25. LW Consulting, Inc., “Can Video in a Hospital Lead to a HIPAA Violation?,” January 23, 2015, <https://www.lw-consult.com/resources/medical-litigation-support/can-video-in-a-hospital-lead-to-a-hipaa-violation>. [unpaginated]

26. LW Consulting, Inc., “Can Video in a Hospital Lead to a HIPAA Violation?”

27. Cornelius, K., “HIPAA Myths and Social Media Violations” *OpenSesame* (blog). June 18, 2013, <https://www.opensesame.com/blog/hipaa-myths-and-social-media-violations>.

28. Weinger et al., “Video Capture of Clinical Care to Enhance Patient Safety.”

29. Halimaa, “Video Recording as a Method of Data Collection in Nursing Research,” at 23, 24.

30. Kolman, J. M., et al., “Conflicts among Multinational Ethical and Scientific Standards for Clinical Trials of Therapeutic Interventions,” *Journal of Law, Medicine, & Ethics* 40, no. 1 (2012): 99-121.

31. Mello. M. M., and I. G. Cohen, “Clinical Trials and the Right to Remain Silent,” *JAMA Internal Medicine* 174, no. 9 (2014): 1505-1506.

32. Hoang, K. K., “Keynote Address: Social Black Holes: The Ethics of Research on Illicit or Morally Compromising Market Actors,” presented at *Social, Behavioral, and Educational Research (SBER) Conference* (San Antonio, TX: Public Responsibility in Medicine and Research [PRIM&R], 2017), <https://www.primr.org/sber17/>; S. Carlberg-Racich, “Poster #14: Agency in Photovoice Research: Exploring the Lived Experience of Persons Who Inject Drugs,” presented at *2017 Advancing Ethical Research (AER) Conference* (San Antonio, TX: PRIM&R, 2017), <https://www.primr.org/aer17/>; D. Wolfe, “Moving the Needle: Strengthening Ethical Protections for People Who Inject Drugs in Clinical Trials,” *Journal of Medical Ethics* 44, no. 3 (2018): 161-162.

33. O’Reilly, Parker, and Hutchby, “Ongoing Processes of Managing Consent: The Empirical Ethics of Using Video-Recording in Clinical Practice and Research.”

34. Halimaa, “Video Recording as a Method of Data Collection in Nursing Research.”

35. Mackenzie, C.F., et al., "Video as a Tool for Improving Tracheal Intubation Tasks for Emergency Medical and Trauma Care," *Annals of Emergency Medicine* 50, no. 4 (2007): 436-442; Weinger et al., "Video Capture of Clinical Care to Enhance Patient Safety."
36. For a study with this level of sensitivity as well as expertise necessary in the eye-tracker software, access was especially restrictive even among the on-protocol research-credentialed staff.
37. Collaborative Institutional Training Initiative, <https://about.citiprogram.org/>.
38. Tobii AB, "Tobii Pro Glasses 2 Wearable Eye Tracker," <https://www.tobiipro.com/product-listing/tobii-pro-glasses-2/>.
39. Office for Civil Rights, "The Security Rule," September 10, 2009, <https://www.hhs.gov/hipaa/for-professionals/security/index.html>.
40. Miller, F. G., J. P. Gluck, Jr., and D. Wendler, "Debriefing and Accountability in Deceptive Research." *Kennedy Institute of Ethics Journal* 18, no. 3 (2008): 235-51; Council for International Organizations of Medical Sciences [CIOMS], World Health Organization [WHO], *International Ethical Guidelines for Health-Related Research Involving Human* (Geneva, CH: CIOMS, 2016), at 37-38.
41. Tobii AB, "Tobii Pro Lab - Software for Eye Tracking and Biometrics," <https://www.tobiipro.com/product-listing/tobii-pro-lab/>.
42. Weinger et al., "Video Capture of Clinical Care to Enhance Patient Safety," at 142.
43. LW Consulting, Inc., "Can Video in a Hospital Lead to a HIPAA Violation?"