Prototype to Patient Treatment: Dialogue on Safety, Regulation, Privacy, Security, and Acceptability for Wearable Medical Devices

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A Workshop Report

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Executive Summary

Emerging technologies, such as wearable medical devices, can raise important societal concerns about regulation, privacy, safety, security, and acceptability. If left unresolved, these issues may stymie important technologies from reaching patients or result in unforeseen physical or emotional harms. It is not enough for early-stage research and development to generate fundamental knowledge and optimize technical operations without addressing societal issues, explicitly. Thus, **organizations from across the medical device *innovation ecosystem* must work together to explore, deliberate, and negotiate topics that extend beyond technical functionality.** Knowledge needs to be exchanged among these organizations about new technical capacities (and limitations) and societal needs (and constraints) for wearable medical devices to emerge and enhance human health and well-being.

The Engineering Research Center for *Advanced Self-Powered Systems of Integrated Sensors and Technologies* (ASSIST) is researching novel prototypes of wearable medical devices that support health monitoring and treatment delivery. ASSIST leaders recognized the need to go beyond technical research and to explore the broader societal issues of risk, regulation, safety, security, and acceptability. On October 25, 2016, ASSIST brought together experts from academic and industrial research, healthcare administration, and federal agencies to facilitate dialogue across the innovation ecosystem among stakeholders that too often remain 'siloed' and disconnected from one another. The workshops objectives were to identify, prioritize and make key recommendations to address the challenge areas of safety, regulation, privacy, security, and acceptability. The workshop was designed to spark creativity, generate empathy, elicit complex issues, and explore alternative solutions.

The workshop yielded three key outcomes, including:

1. Create an **opportunity to collaborate in a low-risk setting and build relationships** with others from disparate sectors and organizations.
2. **Identify complex, cross-cutting, and inter-dependent issues** associated with the development of wearable devices before prioritizing key issues and making recommendations for each challenge area.
3. Identify at least **one key recommendation for each challenge area**:
   Security: Expand the Digital Millennium Copyright Act to include an exemption for medical devices, making it legal to reverse engineer and identify critical vulnerabilities in devices.
   Safety: Systematically identify who is legally responsible for each specific aspect of a device's functionality when wearable medical devices are integrated into patient care.
   Acceptability: Funding agencies need to move beyond technical feasibility measures for success and incentivize integration of knowledge and preferences from users, patients, payers, caregivers, and ethicists.
   Privacy: Acknowledge that ownership is multifaceted and reflect that in consent forms and policy documents, which need to be communicated in uniform, understandable language.
   Regulation: Create a secondary mechanism (in parallel to Phase III FDA approval) for novel wearable devices to be reviewed and approved by Medicaid and Medicare payers for use by lower-income patients. This addresses the issue of 'trickle down' innovation where wealthy patient reap rewards from innovation far sooner than lower-income patients.

The ASSIST Center is now well-positioned to facilitate on-going dialogues that pursue the five cross-cutting topics among organizations involved in medical device innovation.

1.0 Introduction

In 2012, the National Science Foundation awarded an Engineering and Research Center to North Carolina State University, University of Virginia, Florida International University, and Pennsylvania State University to drive transformation in the domain of health informatics enabled by advances in nanotechnology (NSF Award #1160483). That award founded the Advanced Self-Powered Systems of Integrated Sensors and Technologies (ASSIST) Research Center to create next generation sensing and monitoring devices that operate without traditional batteries to support patients, caregivers, doctors and medical researchers. The ASSIST Center concentrates their efforts, primarily, on two systems:

(i) **Health and Environmental Tracker (HET):** an ultra low-power device with extended battery life as a platform for different sensors to measure physiological and biomarkers in a non-invasive manner and to monitor toxins in the patient's environment to enable data correlation across multiple platforms to enable a sophisticated picture of human wellness.

(ii) **Self-Powered Adaptive Platform (SAP):** a self-powered wearable platform that measures critical vital parameters on the body continuously, autonomously, and vigilantly, leading to long-term wellness management.

The ASSIST Center harnesses interdisciplinary knowledge to create prototypes of novel, wearable biomedical devices that support health monitoring and medicine delivery critical to patient health. These innovation challenges are enormous, but the fundamental science and early stage engineering feats are only the first part of the journey. For example, much work remains for wearable, battery-free devices to clear the regulatory hurdles to be declared "fit for use" in patient treatment. Furthermore, as more and more wearable devices enter the market, there are concerns for the safety, security, and privacy of the exchanges between device-generated data, healthcare networks, and the patients, nurses and doctors. Research and development of the fundamental knowledge, technical operation and technical systems integration alone are not sufficient to address the broader societal questions that surround these novel devices.

Thus, the ASSIST Center sought to bring together colleagues from diverse academic disciplines, across multiple federal agencies, private corporations (large and small), and healthcare providers to address key issues that will be confronted when seeking to use wearable medical devices. The workshop's purpose was to bring together experts in fundamental science and engineering with experts in regulation, risk, safety, security and acceptability to enable wearable devices to be successful and achieve their role in wellness management. The workshop sought to initiate conversations between groups of stakeholders, creating new lines of intellectual inquiry and shared learning by all parties associated with wearable devices.

This report reviews the design and outcomes of an interactive workshop built to support creative thinking, relationship building, and knowledge sharing between persons with diverse expertise. The intent is for this report to disseminate those outcomes back to all participants (limited to about 50 people in the room) and other interested parties.

2.0 Workshop Design

The workshop was held just outside of Washington, DC at the Natcher Conference Center at the National Institutes of Health in Bethesda, MD on October 25, 2016. The workshop was scheduled to coincide with the IEEE Wireless Health 2016 conference and was an official pre-conference

event. The location was selected to reduce the expense for personnel in federal agencies that have authority for funding, regulating, and standardizing wearable medical devices. The site afforded easy access to insurers, law firms, business consultants, and healthcare advocates working in the surrounding metropolitan area. That did not preclude people from attending from across the nation, including participants from San Francisco, San Diego, Los Angeles, Boston, Philadelphia, Chicago, Indianapolis, and other regions of the country.

Participants

Over 150 persons from federal agencies, industry, healthcare providers, academia and advocacy organizations were invited, and 49 persons registered for the event not including the facilitators and co-facilitators, see Table 1. Participants were assigned seats to achieve a mix of academic, government, industry, and healthcare at each table. *This workshop report reflects the discussions and knowledge of these participants and is not a definitive statement of the state of the art or practice in mobile healthcare technologies (mHealth)*. Further, it must be noted that there were no participants present from NIH's Office of Behavioral and Social Sciences Research (OBSSR) and thus, their knowledge and research efforts, though relevant, are not significantly represented.

Sector	Secondary descriptors
Academic Research (17 persons)	Nano-scale science and engineering (10) Human and societal dimensions (5)
Federal Government (17 persons)	National Institutes of Health (5) National Science Foundation (2) Department of Defense (2) Food and Drug Administration (2) National Institute of Standards and Technology (1) Government Accountability Office (1)
Industry (6 persons)	Large Corporations (4) Small to medium enterprises (1) Consultants (1)
Healthcare (5 persons)	Hospital Administration (2) Healthcare Research (3)

Table 1. Participants by sector and secondary descriptors. Note: A full list of participants is included in Appendix A.

Workshop Goals

The specific goals of the workshop as introduced to the participants were:

1. Foster opportunities to share experiences and expertise,
2. Consider alternative perspectives,
3. Explore issues critical to the field, and
4. Prioritize and discuss potential solutions and strategies to key issues.

Supplementary Materials: A quick note

There are additional supplemental materials, attached, that reflect the notes collected from the co-facilitators and share details about each activity. The supplemental materials are intended to share the origins of the ideas that are synthesized in the main body of this report. They have been rendered anonymous (all participant names removed), yet are not edited for grammar.

3.0 Opening Plenary

Dr. Veena Misra (PI-ASSIST Center Director) introduced the technologies under development at the ASSIST Center and their technical capacities and limitations, see Figure 1. Dr. Misra's presentation gave an overview of the healthcare crisis facing the nation and the state of wearable devices on the market. She highlighted the limited functionality and poor battery life (energy storage) among current and near-market products and the imbalance between the supply of and demand for energy harvesting and storage solutions. Misra shared information about the range of signals and outputs and value of long-term health monitoring that the ASSIST Center seeks to enable through research into three cases: respiratory health, cardiovascular health, and glycemic index management. For each use case, Misra gave an overview of the technologies that ASSIST was developing and the potential for their application for supporting patient care. The fundamental enabling technologies being developed by ASSIST researchers include an ultra-low power electronic chip, flexible nanowire sensors, and energy efficient radio and data transmission and receiving devices that are Bluetooth® compatible. What follows are two paragraphs describing the technologies under development at the ASSIST Center that both rely upon the Self-Powered Adaptive Platform (SAP). Undergraduates at University of Virginia prepared 1-page briefing documents for each technology for participants to review and for use later in the workshop, see Supplemental Material A: Briefing Sheets.

Figure 1. Dr. Veena Misra addresses the participants during the opening plenary.

Testbed 1: Health and Environmental Tracker (HET) for Patients with Asthma

The first testbed that the ASSIST Center has been working on is the HET, which relies upon an ultra-low power wearable system that monitors the ozone concentration in the user's environment, user's heart rate, respiratory rate and wheezing in order to identify conditions that cause asthma exacerbations. The aim is to one day be able to predict conditions that spark an asthma attacks and alert users in time to prevent those occurrences from happening and causing harm.

According to the U.S. Centers for Disease Control and Prevention, asthma affects more than 24 million people in the United States. Asthma patients currently rely on inhalers to deal with their symptoms, which can include often-debilitating asthma attacks. The goal is to design a wearable device that tracks the patient's wellness and provides them with information that helps to predict asthma attacks. This would allow users to take steps to prevent the onset of asthmatic responses to the environment by providing advanced warning when they enter an environment that may trigger an asthma attack and allow patients to change their activities or leave that environment.

The HET consists of an ultra-low power patch that adheres to the chest, a wristband, and external self-powered spirometer that the patient breathes into several times a day to measure lung function. All these devices demonstrate power consumption levels that are in the sub-milliwatt levels by using nano-enabled novel sensor technologies, resulting in a long battery life (which means it needs to be charged less often). The device is designed to harvest power from the Self-powered Adaptive Platform (SAP) from thermal radiation and motion of the human body. This device is currently in the prototype stage, and data collection is underway to validate the underlying models. Researchers began testing the HET on a small user population in the summer of 2016.

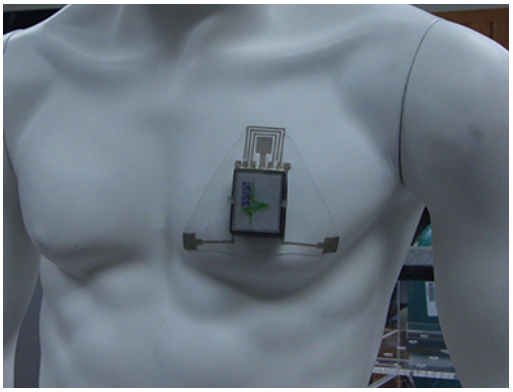


Figure 2. HET prototype affixed to a mannequin to demonstrate the size and positioning on a patient's body.

Technology Testbed 2: Wearable Sensors for Long-Term EKG and EMG Monitoring using SAP

In one testbed research program, ASSIST researchers are working on a self-powered wearable sensor capable of detecting electrophysiological signals such as electrocardiography (EKG) or electromyography (EMG). These detection methods are typically only used in a hospitals to monitor the electrical activity of a patient's heart and muscles, respectively. Commercially available sensors use "wet electrodes" that conduct electrical signals through an electrolytic gel placed between the sensor and patient's skin. Yet, commercially available products are ill suited for long-term monitoring, since the conductive gel dries out, patient's skin can become irritated, and the sensor's accuracy is not stable.

Researchers are experimenting with silver nanowires to create highly conductive and elastic conductors. The technology consists of nanowires integrated into a stretchable polymer that is placed into contact with the patient's skin in the form of a wristband. The stretchable nanowire polymer conforms to the patient's skin, providing even and accurate sensing, even when the patient is in motion. Additionally, the nanowires are highly conductive, which is how they are able to maintain high signal quality without the use of wet electrodes. For self-powering, ASSIST researchers have developed wearable and flexible nano-enhanced thermo-electric generators to convert the user's body temperature to electrical energy to power the system by using the SAP.

The goal for Technology Testbed 2 is to offer higher quality EKG and EMG data collection while ensuring efficacy, efficiency, and portability for the patient. Communication between the device, patients and their doctors remains undetermined insofar as how the data is transmitted, where data is stored, who has access to it. The device may be used to diagnose patients for a particular condition, but that application has not been clearly decided upon. This device is still in its preliminary stages of development, thus answers to the questions regarding data transmission, storage, access and diagnosis can inform future iterations in the devices design.

Figure 2. EKG and EMG data collection prototype with images of the nanosilver wires that conduct electrical signals from the skin to the device mounted on a wristband.

3.0 Activities

After the plenary, all the participants were invited to engage in hands-on, interactive activities to promote shared learning. Each table had an assigned facilitator (Drs. Foley, Asare, Delborne, Odumosu, and Barker) with responsibility to lead the activities and a co-facilitator, an undergraduate from either Bucknell University or University of Virginia with responsibilities for supporting the activities and taking notes. What follows is a review of the activities.

Activity 1: Creativity, play, and relationship building

Asare asked everyone to write down as many uses for a brick as they could. The goal was to spark creativity, create an environment for inviting and sharing diverse perspectives, and encourage the participants to become familiar with one another through a playful task. Participants spent a few minutes creating their lists, turned to a neighbor at their table, and compared their lists to generate even more ideas. Participants further introduced themselves to their neighbors before sharing their creative uses for a brick.

Figure 3. Participants readily engaged in the first set of activities.

Foley then introduced the second part of this activity that drew from Lego SeriousPlay®. The co-facilitators spilled Lego® bricks across the tables in a disorderly fashion, and participants instinctively reached into the piles even before Foley could offer the formal instructions to build a tower in the next two minutes. The facilitators and co-facilitators at each table worked to build their own towers, and any hesitant participants soon joined in. After 2 minutes, everyone was encouraged to look around at the different towers built. This seemingly ridiculous task created an environment of shared play in which participants could build without judgment and it was implicitly understood that the facilitators were working alongside the participants. This set the tone for the continued high-levels of engagement in the workshop activities. Participants were instructed to build a medical device and further prompted to address three key questions: What does it do? What is it designed to treat? Who needs this device?

Activity 1: Outcomes

Each table nominated one person to share the medical device that they had built, five of those devices are shared in Table 2.

What does it do?	What health conditions does it address?	Who needs this device?
Combo device, you insert your figure, blow, and eye scanning can all happen at once. Potential implications for marijuana/drug testing, understanding the limits of operability with legalized marijuana.	Monitoring, maybe for substance abuse	Substance Abusers, Law enforcement, Parents
Bracelet for patients with Alzheimer's, alert with GPS for wandering patients, speaker that alerts user and transmits to caregiver. Accelerometer to power by motion.	Alzheimer's	Alzheimer's patients
Self-adjusting orthotic that adjusts and grows with your foot provides support and steps back as you heal. "Sensible shoes" could be the product name.	Plantar Fasciitis	Patients with plantar Fasciitis
Wearable monitor with multiple sensors -bacterial- viral-radiological-chemical. The device constantly harvests information on environmental condition. The device communicates with other devices in the nearby area and then the signal is boosted for satellite uplink.	This offers a means for persons that may experience health complications to monitor (in real-time) their exposure to harmful situations or environments.	Soldiers, miners, environmental remediation professionals.
Wearable device placed in inner ear with microphone and audio sensors for directionality of the sound. Patients can wear it without having to explain multiple times why, because it cannot be seen.	For patients with hearing loss this device offers a very low profile and reduces social stigma associated with hearing aids.	Persons with complete or partial hearing loss.

Table 2. Medical devices built during the Lego SeriousPlay® exercise. Note: Participants defined health conditions more broadly than regulatory agencies do and included aspects of social stigma and air monitoring, which are related to health conditions or potential health complications.

The first example, i.e. the breathalyzer for marijuana and another one for substance abuser more generally, blurred the lines between legal enforcement and medical health. The last device described in the table brought up notions of the 'veil of secrecy/privacy' around medical conditions and how norms in the United States place a higher value on "hidden" devices that do not reveal that a person has a medical conditions, e.g. ultra-low profile hearing aids and biomarker stress sensors for persons with anxiety. Asare reinforced a few early takeaways: who you include and exclude will inform your definition of the problem, inform the solution and ultimately shape the technological design. The activity afforded everyone an opportunity to design devices and **identified tangible issues that arise from the design of novel medical devices.**

Activity 2: Technology Role-Plays

The next activity invited participants to engage in a role-playing exercise that focused on a specific technology and asked the participants to speak for a character that was created for this workshop, see Figure 4. Participant received a character card and a 1-page briefing document about the technology to prepare for the role-play, see Supplemental Material A: Briefing Sheets.

The role-play activity was initiated by Foley, who welcomed everyone to the fictitious "National Technology Assessment Center" in Washington DC. The participants were told this was an annual forum and this year's forum was hosted at the National Institutes of Health with a focus on wearable medical devices. Foley then turned the activity over to the facilitators and the characters seated at each table then introduced themselves.

Chelsea Thomas

Age: 9
Sex: Female
Ethnicity: Black
Hometown: Buffalo, New York
Occupation: Homeschooled

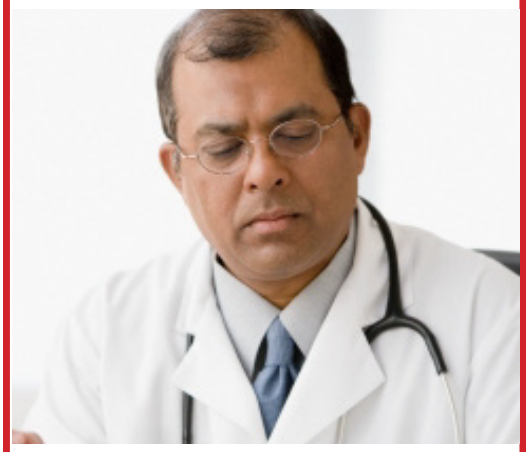
Chelsea was diagnosed with a heart condition as a young child. Currently she is stable, but she is behind in school and still suffers health complications. Her parents think this device would cut down on the hospital visits. While Chelsea received treatment in the hospital, the monitors constantly reported her heart rate and other important numbers to the doctors. This device could be useful to help monitor her and alert her parents to issues as soon as possible. Special rule: After introducing herself, Chelsea can only ask questions.

Amy Sherwood

Age: 41
Sex: Female
Ethnicity: White
Hometown: Durham, North Carolina
Occupation: Unemployed (full-time caregiver)

Though she had originally planned on returning to work after the birth of her second child, as she had with her first, she decided to stay at home after her son, Logan, (now 9 years old) was diagnosed with a heart condition. She highly values her son's health and doesn't want anyone to treat him as a research subject. She does want to keep him healthy, however, and the doctors are telling her about a trial program that may afford her son more freedom. She thinks the sensors could let doctors know what his body is doing.

Vinay Malhotra



Age: 53
Sex: Male
Race/Ethnicity: Asian (Indian)
Hometown: Bangalore, India
Occupation: Physician

Born in India, Vinay came to the US as a young a man and has established a well-respected medical practice in Florida. He also works in a research hospital and occasionally teaches classes at the medical school. He finds the US system of medical care inefficient and believes that data from wearable sensors networks could help him diagnose patients more effectively. He also thinks this data should be made public in some way, to promote new discoveries. Vinay's daughter runs on the track team Michelle coaches.

Michelle Sanchez

Age: 56
Sex: Female
Race/Ethnicity: Hispanic
Hometown: Pensacola, Florida
Occupation: High school coach

Michelle had complications from sports injuries when she played in college, and thinks sensors and other monitoring medical devices may have aided her recovery. She thinks this device might help her keep her players healthier and to train them better, especially in the heat of the summer when elevated heart rates can indicate over-heating. She is interested in looking at data from her players in real time, and making coaching decisions accordingly. Vinay's daughter runs on the track team Michelle coaches.

Figure 4. Four character cards used at the red table that focused on EKG/EMG monitoring devices. Note: Supplemental Material B: Character Cards offers a full set of character.

Table	Green	Red	Blue	Gray	Yellow
Technology	Monitor to prevent risk of falling (TEMPO)	EKG / EMG Monitor	Artificial Pancreas	Gait Tracking Device	HET or Health & Environmental Tracker
Character 1	Henry Lee, 8 months	Chelsea Thomas, 9	William Hoffstader, 5	Barbara Holmes, 58	Paul Brewer, 23
Character 2	Marcus Henderson, 33	Amy Sherwood, 41	Susan Lischner, 31	Anton Moretti, 29	Marcus Henderson, 33
Character 3	Nolan Thompson, 59	Vinay Malhotra, 53	Sharon Fleming, 46	Albert "Al" Miller, 75	Sharon Fleming, 46
Character 4	Vincent Castillo, 34	Michelle Sanchez, 56	Lisa Johnson, 43	Amy Sherwood, 38	Gael Ramos, 50
Character 5	Paul Brewer, 23	Anton Moretti, 29	Gael Ramos, 50	Vinay Malhotra, 53	Chelsea Harding, 50
Character 6	Carol Lynn, 85	Scott Campbell, 58	Simon McCallum, 41	Michelle Sanchez, 56	Horace Green, 66
Character 7	Barbara Holmes, 63	Robert Hudson, 86	Rosa Morales, 27	Lena Murphy, 41	Beth Stanley, 36
Character 8	Li Jun, 19	Sofia Flores, 13	Albert "Al" Miller, 75	Beth Stanley, 36	Scott Campbell, 58
Character 9		Marcus Henderson, 33	Amy Sherwood, 41	Scott Campbell, 58	Lena Murphy
Character 10		Susan Lischner, 31			
Facilitator	Marcus Johnson	Maria Suarez	Randy Harrison	Roberta Burfect	Brian Stevenson

Table 3. Role-playing set up. Table color, technology, character names and age and facilitator card names.

What ensued was an energetic exchange that lasted for well over the thirty minutes allotted. At each table, the characters introduced themselves by stating their "name," giving a bit of background, and sharing their interest in the workshop. The facilitators then asked each character about their hopes for the technology and how it could support them directly or those they care about. The role-playing activity evolved into an "in-character" conversation, during which the facilitators only intervened when the conversation started to either cycle or stagnate. The activity **offered an opportunity for low-risk relationship building** via playful exchanges.

Embracing the role-play, participants started to create richer narratives for their character. For example, some created new pets or family members, while others created 'origin stories' for their character. Many built upon the basic text provided on their character card to express more complex values and preferences than explicitly written on the character cards. Some participants realized that their characters were 'related' to other characters at the table by marriage, parentage (mother-daughter/father-daughter), or were connected as employee-employer, coach-athlete. In those cases, participants drew upon their lived experience in those types of relationships and expressed feelings and emotions that went far beyond the prompts offered. For example, when one participant that played the Vinay Malhotra character, shown above in Figure 4, realized that his daughter ran track for Michelle Sanchez's character the participant drew upon their experience as a parent of a student-athlete. For details on the characters' hopes, concerns and additional issues see Supplemental Material C: Character Statements.

Further, this activity **generated a list of societal issues relevant to specific medical devices**. The list of concerns generated in the role-playing were written on large note cards and affixed to an easel positioned near each group. After the role-playing participants were asked to draw upon their own expertise and each table generated additional issues that were not raised in the role-playing portion of this activity.

Activity 3: Categorizing and prioritizing issues

Participants were asked to take each note card and place it on one of five pre-determined poster boards: Privacy, Security, Safety, Regulation, and Social Acceptability. For many participants this exercise was straightforward, while others insisted on generating additional categories. Three categories were generated: Ethics, User-Design, and "Who? & For What?". The later two were placed next to each other, and the individuals that had created those categories engaged in a robust discussion on the definitional boundaries of those categories. A total of 119 note cards were grouped within the eight categories by the participants (see Supplemental Material D: Identified concerns by category). A few participants who were passionate and felt confident in their expertise took ownership of certain categories and worked to group note cards into topics. The facilitators were comfortable with the participants self-organizing to create categories.

After lunch, the workshop resumed with two brief exercises intended to address two different priorities: Who is responsible for ensuring of the safety, security, privacy, regulation, and social acceptability for wearable medical device? And what are the highest priorities issues for wearable medical devices? Participants at each table addressed the question of how responsibility shifts across the phases of innovation by force ranking a list of eight stakeholders: Academic researcher, Caregiver/nurse, Clinician/doctor, Funder, Hospital Administrator, Manufacturer, Patient/Patient Advocate, and Regulator (FDA). While engaging in this activity, participants expressed that the simple forms did not give enough context, nor were the eight stakeholder categories specific enough, and thus were not meaningful. Embracing a collaborative spirit, a few participants re-

created the exercise and shared their thoughts on how to better probe this question. Thirty-one participants completed the original activity, and the outcome from that exercise is shown in Supplemental Material: E. The results of this "failure" will inform the redesign of a short interactive interview protocol and questionnaire that will be administered at a later time.

The question of "what are the highest priorities" was addressed by a process of voting for the issues and concerns that were generated in earlier activities. Participants were given three mini-stickie notes, each representing one vote. The additional category of ethics was considered alongside privacy, while user design, and "Who? & For What?" were considered as part of social acceptability. **Voting resulted in three issues prioritized by the participants for further discussion**, see Table 3.

Security	**Safety**	**Privacy (+Ethics)**	**Regulation**	**Social Acceptability (+User design & Who? & For What?**
Reliability of data security	Reliability of device functionality	Who owns the data?	Regulatory pathway determination	Behavior Changes
Who can see/use the data?	Testing in different populations for risks based on user group	Minority rights and plain language	Approval by payers (Medicaid / Medicare)	Just because we can, doesn't mean we should
Automation versus self-control	Interoperability: How do all the pieces connect?	Unauthorized releases	Consumer confusion: medical devices and commercial devices	Social Justice

Table 3. Prioritized issues by category. Note: The brief names for the priority issues are elaborated upon in the following section and are used as a point of reference.

Activity 4: Problem definitions, solutions, strategies and tactics

Having prioritized the top three issues for each category, each table was assigned a category for further discussion. The participants discussed the following questions:

1. *How is this problem defined and who is harmed?*
2. *What tactics/strategies are available to address the symptoms or root causes?*
3. *What solution option(s) hold promise to ameliorate the problem?*

This activity yielded well-rounded descriptions of the highest priorities and a suite of solutions for two to four issues, summarized below. The groups prepared seven-minute presentations and then engaged in plenary discussions. What follows is the synthesis of the conversations with an emphasis placed on the ideas that arose in the group presentations. We should note that what is shared here are not the definitive statements on each of the issues, but what each specific group of participants discussed based on their background and experience. Certain viewpoints are missing, and the proposed "solutions" are worth considering, yet have not been rigorously assessed.

A. Security

Security––Issue 1: **Reliable security**

The problem of reliability was defined as fundamentally challenged by detecting and assessing threats, and the inability to simulate threats and attacks, especially in an era of growing cyber-security threats to medical health systems. Further, there is a lack of awareness or notification for bombardment tactics used by hackers, such as DDOS attacks. The problem extends to a lack of clear responsibility for security initially and how that changes overtime through

software updates. The negative effects can include direct physical harm to the patient and financial harm to the healthcare providers and corporation that maintain the data servers.

What tactics/strategies are available to address the symptoms or root causes?

Tactics to address this include 'distress' signals from the device to notify the patient, caregiver or healthcare system of an attack. There is a need to isolate unsecured data transmission systems from larger healthcare systems and records management. There is a need to create positions of Data Safety Officer within each major hospital's healthcare administration to handle remote and wearable devices that are entering the patient care setting.

Potential solution(s) that hold promise to ameliorate the problem?

Conduct threat assessments, scenarios, and mock attacks to test the device and broader system's reliability. Consider creating data transmission protocols for medical devices that are not connected to nor do they communicate with the global internet. A key takeaway from the security group was to **revise the Digital Millennium Copyright Act to address an exemption for medical devices** to allows for the identification of vulnerabilities in devices.

Security––Issue 2: **Who can see or use the data and for what purposes**

Data security and sharing may negatively affect employment opportunities, political aspirations, loss of independence (incarceration), or insurance coverage.

What tactics/strategies are available to address the symptoms or root causes?

Data security and the extent to which the data is shared is a decision that must be made by patients after reviewing terms and agreements in informed consent documents (issues of informed consent are taken up in later sections). The Health Insurance Portability and Accountability Act (HIPAA) contains privacy rules that allow for data share without the completion of "data use agreements", if the dataset is rendered anonymous (or de-identified). There is a need for more transparency to disseminate the value of data and afford persons that generate the data an opportunity to more directly benefit from the commodification of their data (e.g., an open market) and to execute transfers in a secure and contractual manner.

Potential solution(s) that hold promise to ameliorate the problem?

There is a need for more transparency, and better communication and education about how federal policies address security concerns regarding who has access to data and how data is shared among patients, healthcare providers and other interested parties.

Security––Issue 3: **Automation versus self-control**

The security issue of automated responses may result in inaccurate or false data that prompt reactions that harm the patient. The problem can arise when devices do not afford people a means to intervene in the operation of the device. This disempowers patients and caregivers.

What tactics/strategies are available to address the symptoms or root causes?

The direct solution is to ensure that the device is designed in a manner for the "operator", whoever that is determined to be, to retain power to make conscious decisions when the measurement context or other signals conflict with the route automated response by the device.

Potential solution(s) that hold promise to ameliorate the problem?

Further, internal monitoring systems that are intrinsic to the device design might also support the analysis and interpretation of the proper operation in relation to the patient's condition. **A patient's physiological responses need to be understood as valid basis upon which action can be taken that may run counter to the device's programmed operation**.

B. Patient safety

Patient safety––Issue 1: **Identifying legal responsibility for lack of reliability**

Negative effects are not limited to patients, but extend to manufacturers, insurers, healthcare providers, and caretakers who could all suffer financial or emotional losses in the event of device failure. The conversation centered around means to identify legal responsibility and hold accountable specific entities for the design, manufacture, and monitoring of a device's continuous functioning, The reliability of the device also needs to be considered within a larger healthcare system and the integration of data transmission and retrieval is vital to proper functionality.

What tactics/strategies are available to address the symptoms or root causes?

Failure modes need to be identified, defined, and cataloged as acceptable or critical for the device functionality in accordance with FDA's standards on Medical Device Reporting. Solutions and strategies to combat reliability issues could be in terms of diagnostic software, failure alarms, self-testing, calibrations, confirmation of proper systems integration, and manufacturer specifications for pre-test devices prior to deployment. Further, patients and care providers need to be trained on identifying failure modes and understanding their range of responses to failure notifications or alarms.

Potential solution(s) that hold promise to ameliorate the problem?

Comprehensive user guides, training, and internet-enabled resources might serve to support benchmarks for reliable performance, monitoring, and repair (or replacement) of wireless medical devices. Patients would then be about to support the identification of reliability issues, e.g. intermittent service, calibration, or breakage. This would enable user facilities, importers, or manufactures to benefit from patient and doctor reported issues and thus launch a Medical Device Report (MDR) following 21 CFR 8 Subpart A 803. In this way the issue would be identified early and may ensure more reliable operation and prevent harm.

Patient Safety––Issue 2: **Pre-deployment testing among diverse populations**

The problem was defined in terms of the statistical algorithms that hide differences between the actual users and the sample of the population subjected to the pre-approval testing. Misleading findings can arise when data is not understood as context-dependent (a sample of a particular population). There is no verification (and thus no accountability) that best practices for sampling a diversity of sub-groups that comprise the patient population are followed when companies conduct pre-approval testing of novel devices. The primary groups harmed are patients from diverse backgrounds for whom no pre-testing data is available to verify the efficacy of the device (or identify potential harms).

What tactics/strategies are available to address the symptoms or root causes?

Solutions need to focus on ensuring that samples are representative of the patient population. While this may incur higher costs for companies in the pre-approval testing phase of device development, it would offer more direct evidence of efficacy for sub-populations that are

often underrepresented in the data. Datasets generated from pre-approval testing need to be described in a manner that is understandable and transparent to caregivers and offers direct information about the efficacy of the device or treatment for specific sub-population. There is a need to create mechanisms that hold companies accountable for adhering to testing protocols that ensure a representative population is sampled. This may require increased incentives (or other measures) to recruit underrepresented populations to participate in pre-tests.

Potential solution(s) that hold promise to ameliorate the problem?

The datasets generated in FDA's pre-approval testing need to be de-identified and then made available in a centralized repository, regardless of the funding source (private or public) and regardless of the test's outcome. **A third-party organization needs to be commissioned to curate a dataset, report discrepancies, and track post-deployment issues and recalls.**

C. Acceptability

Acceptability––Issue 1: **Behavior change**

There is lack of attention paid to the fact that the connection between sensors, monitors, and managing health, largely depends upon changes in patients' behavior in response to the information offered by the devices. This was discussed within the KAP (knowledge – attitudes – practice) framework that demonstrates these three factors all precede behavior change. Two levels of behavior change are important to consider: i. getting patients to wear/use the device; ii. altering their behavior in response to the information provided by the device. Patients can continue to suffer from the symptoms of chronic diseases when behavior change is underemphasized or ignored.

What tactics/strategies are available to address the symptoms or root causes?

The issuance of wearable devices needs to accompany a behavior change management plan and the patient needs to understand that the device is simply a tool to support changes that will benefit their health. It is unclear if private industry manufacturing devices fully understand the implications and connections between devices and behavior change. Similarly, it is unclear if the motivations and incentives to change are understood in a manner that can enable devices to support improved health for people with different backgrounds.

Potential solution(s) that hold promise to ameliorate the problem?

Funding agencies need to directly support social and behavioral research, regardless of their connection to basic or applied research. The NIH's office of Office of Behavioral and Social Sciences Research (OBSSR) works to support basic and applied research with social science research. The participants at the workshop, none of whom was from NIH-OBSSR, expressed a need for social science research that can address the motivations and values of diverse patient populations alongside the development of the devices. This goes beyond technology assessments that incorporate patient's values to understanding the dynamics that are affecting motivations to change behavior. A paucity of research leaves open questions of beliefs, attitudes, tensions, self-efficacy, and skills or competencies to induce healthy behavior change. End-user knowledge integration is needed to support the device design and efficacy testing.

Acceptability––Issue 2: **Just because we can, doesn't mean we should**

This issue was defined as the unquestioned belief that novel wearable devices will yield positive outcomes. More is research is needed, beyond "market assessments" that focus on profitability from potential patients and payers, to explore questions such as, will the device have negative effects on the patients and their caregivers. Harm includes both wasted resources (continuing to invest public monies in research that demonstrates little or no societal value) and by creating devices that are costly, yet offer little or no benefit to the patients. Measures of research success need to account for more than papers, patents, and conference presentations to include changes in health conditions.

What tactics/strategies are available to address the symptoms or root causes?

When there is little evidence that public health gains or harms are identified, there needs to be a mechanism to alter or cease further funding without that decision negatively affecting the careers of the program officers that initially supported the research. Further, stopping or curtailing research in specific areas should not be considered 'anti-science' or 'anti-progress', but rather needs to be understood as part of the research portfolio that has not yielded the expected positive outcomes (beyond published papers and patents).

Potential solution(s) that hold promise to ameliorate the problem?

Major research investments in wearable devices need to be accompanied by social science research that can address normative questions of "should we" proceed. This will build capacity to explore and recognize negative unintended consequences and respond adaptively as new information is gained, including curtailing research activities.

Acceptability––Issue 3: **Social justice**

There are systemic challenges to reaching underserved populations and designing devices for minority and under privileged communities. 'Trickle down' medical device design does not justly distribute health benefits; rather it privileges wealthier populations, leaving out poorer minority populations. This can be traced to a utilitarian ethic, i.e. the most good for the most people. However, that leaves aside diseases that disproportionately affect minority populations.

What tactics/strategies are available to address the symptoms or root causes?

There are no quick solutions to this problem, though the Orphan Drug Act might offer a starting point to consider diseases underserved by medical devices and incentivize research in those areas. Public health funding needs to recognize which populations are not being served and how to address those high-risk sub-populations, especially for minority or low-income patients.

Potential solution(s) that hold promise to ameliorate the problem?

Federal payers (Medicaid and Medicare) need to be included in the existing priority setting processes for research funding for technical and non-technical solutions to public health problems, especially to address the high-risk populations they serve. This would follow a model born from the Department of Defense where innovation is derived from operational and warfare needs. For example, persons living in low-income communities have a higher probability of being chronically exposed to air-borne toxins, and thus have a higher likelihood of suffering from asthma. If wireless, wearable devices are part of a solution to this public health crisis, then how do low-income communities gain access to the internet (or other data services) needed to ensure that the device will function properly in their community?

D. Privacy

Privacy––Issue 1: **Who owns the data?**

The problem was succinctly identified as conflicting interests in more than one domain: i. commercial versus research interests and ii. healthcare uses versus patient's rights to non-disclosure of sensitive information. The patient's right to privacy, as defined by HIPAA, is vulnerable to unintentional or unauthorized uses. This can also harm researchers that spend time and effort to collect data, only to have it released prior to earning their own rewards, often in the form of publication. Further, private companies might be financially harmed by costly lawsuits if data privacy policies are unclear.

What tactics/strategies are available to address the symptoms or root causes?

Clearer policies, particularly which reward transparency in data usage, are needed. Another strategy involves shifting from a single ownership model of data to a legal mechanism that accounts for multifaceted ownership (or co-ownership). Data collection, storage, uses, and transfers need to be clearly articulated prior to data collection and amended prior to changes in ownership, possession and use. This demands a rethinking of the rights and responsibilities of all the parties involved in a manner that makes explicit the terms of agreement in an understandable manner (no small feat).

Potential solution(s) that hold promise to ameliorate the problem?

The primary recommendation that addresses many facets of data privacy is acknowledge **ownership is multifaceted and reflects the alternative uses for data in consent forms and policy documents**.

Privacy––Issue 2: **Minority Rights and Plain language**

A majority of patients read at a 4th to 8th grade level and the disclosure and consent forms are written in language that is far more complex. Harms occur when information is masked by legal jargon and efforts toward due diligence to ensure patients comprehend the terms of the consent form are not made, let alone achieved. As clinical trials demand that patients from diverse age groups, ethnicities, and gender (for example), there is a need to understand the data privacy issues that arise for those different populations and their different concerns. Case law has afforded patients with rights that may override consent forms or other contracts, which exposes numerous parties to legal responsibility.

What tactics/strategies are available to address the symptoms or root causes?

One solution entails ensuring freedom of choice, fair representation for the patient and not pressuring potential patients to consent to data release forms. Liaisons are needed to both translate languages and to facilitate discussions about types of data collection and how the patient's data might be used for research, healthcare, or other, private interests. While it is important to conduct pre-clinical and clinical tests with diverse patient populations, it is equally important to understand and find ways to respect different needs or desires around how data is handled. There needs to be a patient advocate who reviews a multitude of options for handling and sharing a patient's data prior to release. Aggregated data offers a work around that can also make the problem more complex, as data is bundled and transferred without qualifiers or individual markers indicating patient's stipulations for data privacy and handling.

Potential solution(s) that hold promise to ameliorate the problem?

Language needs to address what the patient is giving up and what they are receiving in return. **The creation of standardized language (or templates) might support a set of shared best practices that can be iteratively reviewed, refined and improved.**

Privacy––Issue 3: **Unauthorized data releases**

There is a growing cultural assumption in the U.S. that personal data will be hacked and there is minimal concern about the growing number of unauthorized data releases. However, it is unclear if the malaise will remain constant or if expectations for data privacy will shift. This issue warrants attention and review and revision of the HIPAA regulations as data storage and transmission continue to be released through unauthorized channels.

What tactics/strategies are available to address the symptoms or root causes?

HIPAA regulations need to address questions of: i) how do healthcare or other organizations disclose unauthorized releases? ii) How do patients and other parties store or transmit data in a manner that does not infringe, ostracize, or otherwise violate a person's right to privacy? iii) Can use agreements, contracts, or permissions be structured in a manner that anticipates unauthorized data releases? iv) How can we protect those people that opt-in with one set of assumptions, which are undermined by unauthorized releases?

Potential solution(s) that hold promise to ameliorate the problem?

Identifiable data may need to be stored on 'offline' servers that require tertiary authorization codes and physical access to locations where de-identified data (names, social security numbers, addresses) are stored. Further**,** mechanisms for matching de-identified data with identifying information should have appropriate authorization procedures that prevent unauthorized users' ability to aggregate datasets.

E. Regulation

Regulation––Issue 1: **Disconnects between the regulatory review processes**

There is a regulatory gap between FDA and federal payers (Medicaid/ Medicare). After phase III approval by FDA, there is no mechanism to alert and initiate a secondary approval process by federal payers (Medicaid/Medicare). This means that a device can be approved for use, but not approved for coverage and thus low-income patients cannot afford the device without insurance reimbursement. This secondary gap in the approval process results from the lack of a formal process by which the federal 'payers' (Medicaid/Medicare) provide a listing and reimbursement conditions for the use of novel devices. That listing usually informs coverage by private insurers and stipulates the conditions of treatment under which the device can be delivered to the patient.

What tactics/strategies are available to address the symptoms or root causes?

A recommendation to address this challenge is to create a working committee (or intra-agency task force) with the Department of Health and Human Services to identify recently approved devices and evaluate them for coverage by the federal 'payers'. This would allow patients that are dependent on insurance to receive up-to-date care and inform the private insurance industry with a clear mechanism for approval and disapproval.

Potential solution(s) that hold promise to ameliorate the problem?

Create a mechanism (parallel to FDA approval in Phase III) for wearable devices to be reviewed and approved by the Center for Medicaid and Medicare (CMS) for use by patients. A mechanism for FDA to directly communicate technical specifications, clinic trial results, and identified patient populations to the National Coverage Determination at the Center for Medicare and Medicaid Services' s (CMS). This will remove the burden from manufacturers for re-entering this information and may better align the CMS process with FDA's approval efforts so beneficial wearable devices can be covered for use by patients are covered by CMS.

Regulation––Issue 2: **Recognition for regulatory pathways**.

The underlying challenge is a lack of capacity within small and mid-size businesses to foresee the regulatory pathways for devices invented by companies with federal support. Innovators rarely recognize the importance about learning these regulations in the early stages of design, and thus the NIH and DOD educational resources on regulatory pathways largely under utilized. By not understanding what their design decisions will mean in terms of the FDA regulatory framework, innovators risk having to redesign the device later on in the process, thereby deferring device approval. However, it is primarily important to recognize that, while academic researchers often see device approval as the end goal in technology development, the universal aim is to provide patients with a safe, effective, and potentially life-saving device as efficiently as possible.

What tactics/strategies are available to address the symptoms or root causes?

The NIH Centers for Accelerated Innovation (NCAI) program and other parallel programs in DOD need additional support to more effectively engage with innovators and support their design efforts with information and consultative services about the regulatory process. The NCAI program (within NIH) provides companies that received SBIR (Small Business Innovation Research) funds with educational resources to advance medical devices and diagnostics to market through the regulatory process.

Potential solution(s) that hold promise to ameliorate the problem?

Require companies that receive federal funding to state and justify the regulatory pathway that their wearable medical device will follow prior to commercialization. This will allow for an initial pre-evaluation and can be reviewed by persons in the NCAI office. An intra-agency working group within the Department of Health and Human Services might best address the cross-agency issues between funders, regulators and payers. Further, an inter-agency working group that draws in the Department of Defense, National Science Foundation, Department of Commerce including the National Institute of Standards and Technology may be required.

4.0 Participant Reflections

In order to increase the response rate for participant reflections, time was allotted at the end of the workshop for participants to complete feedback forms (32 of 49 forms were completed). The forms asked about what was learned, enjoyed, what should be changed, who was missing, and what are the future needs to maintain this dialogue and move innovation forward.

Highlights from feedback forms:

- Nine participants were excited to learn about how ASSIST works to (re)design their prototypes in a manner that draws upon the solutions offered in the workshop.

- The most frequently mentioned lesson learned (8 participants) was, as one person put it succinctly, there are multiple perspectives to "problems that don't fit in neat boxes" and another stated as, "barriers between technology developers and clinicians" continue to challenge the innovation ecosystem of wearable devices.
- Quite a few respondents (7) felt that federal funding and regulatory agencies should form working groups to address each issue or at least fund further "training workshops."
- The participants appreciated the "interaction with diverse groups" and the opportunity to network and "exchange ideas with intelligent people" from other disciplines and sectors.
- What was clear is that the room was full (too overflowing) and that lead to the number one complaint about the need for, "a bigger room with windows", shared by 9 people.
- Another positive attribute of the workshop was the creative, highly engaging exercises that generated a strong connection between the members of the group.
- The workshop did not accommodate every viewpoint, nor did it draw in the knowledge and expertise from every single key stakeholder. Participants felt the following stakeholders needed more representation: providers (4), insurers (4), low-income patients (3), end-users (3), doctors (5), Payers, e.g. CMS (2), security professionals and white-hat hackers (2), venture capitalists and angel investors (1), students (1), first responders (1) and more private sector firms (2).
- Many participants (4) stated that they learned about the advanced prototypes under development at ASSIST, while others (7) stated that the workshop gave them an enhanced understanding of the non-technical issues that affect wearable medical devices, including three people that highlighted how social justice and inclusion are critical challenges.

While for some, the breadth of the workshop was "eye opening and well-organized", others (4) expressed a desire for the workshop to be more focused on one specific topic with attention to a narrower set of goals. Those comments accompanied calls from (5) participants for "less fun … more work" and "more plenary talks". Undoubtedly, the workshop design challenged the traditional, speaker-oriented, model, and it is understandable that the design challenged the traditional workshop models.

5.0 Concluding Thoughts and Takeaways

Societal issues may inhibit innovative wearable devices from supporting positive public health benefits if they remain ignored or inadequately addressed. Organizations from multiple sectors must find ways to enumerate these issues and orchestrate their responses among healthcare provider networks, large industry, entrepreneurs, governmental research funders, regulators, payers, and academic researchers. This report reflects a small step toward building such a coordinated network, identifying key issues, and articulating potential strategies and solutions.

Academic researchers and entrepreneurs, like those working at the ASSIST Center and others around the world, are developing prototypes that demand re-thinking how wireless, battery-free, wearable devices can positively affect acute and chronic diseases. Along with these devices arrive a set of critically important issues pertaining to:

- modes of failure and the outcomes of technical or cyber-security failures;
- patient safety and integration with established standards of care;

- regulatory approval by both FDA and by federal payers, i.e. Medicaid and Medicare; and
- issues of social justice and acceptable outcomes for all persons seeking healthcare.

Participants called for greater dialogue that is more inclusive of the stakeholders involved, beyond those in the room. The conversations and information sharing that took place and the energy and enthusiasm in the room signaled that there is a clear need for this type of cross-sector exchange. The participants shared their perspectives and understanding of these issues, which does not infer that every perspective and every domain of knowledge on healthcare was addressed at every table or represented in each conversation. This highlights the need for knowledge to be produced that is shared throughout the innovation ecosystem in formats that is usable to diverse decision-makers. Critical to the delivery of public health outcomes from the initial phases of research and development is the need for engagement with experts from other sectors and across numerous federal agencies. Yet, there are few forums that support genuine and meaningful interactions that result in shared learning and there is a need for ongoing knowledge exchanges among the broader community with vested interests in wearable medical devices.

There is a need to expand dialogue on the modes and mechanisms of data transfer and security protocols to safeguard patients and healthcare information networks from unauthorized security breaches. The legal barrier to reverse engineer devices in an effort to identify vulnerabilities is hampering the efforts of 'white hat' hackers to identify critical vulnerabilities.

There is a need for **the creation of a shared consent form for data release** and online and in person patient advocates to support the freedom to choose for all patients. There is a need for a **discrete repository to securely store and disseminate patient data**, and serve as the host for datasets that conform to agreed upon standards of data collection.

An intra-agency working group in the Department of Health and Human Services (DHHS) might best address the cross-agency issues between funders, regulators and payers. Further, an inter-agency working group might best support identifying issues and proposing solutions to these issues by creating dialogue among the DHHS, Department of Defense, National Science Foundation, and Department of Commerce.

Appendix A: Participant List

Participant list is in alphabetical order by last name with given title and organization at the time of the workshop. Note: Facilitators and co-facilitators are identified in parenthesis.

Philip Asare (Facilitator)
Assistant Professor
Electrical and Computer Engineering
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Susan Barker (Facilitator)
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Clem Bezold
Founder and Chairman of the Board
Institute for Alternative Futures

Casey Boutwell
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North Carolina State University

Alper Bozkurt
HET Testbed Leader, ASSIST Center
Associate Professor of Electrical & Computer Engineering
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Michael Cheetham
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National Institute of Biomedical Imaging and Bioengineering (NIBIB)
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Loriana Demirciyan (Co-facilitator)
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Emre Ertin
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Annette Gardner
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Associate Professor of Global Health
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Jen Healey
Senior Research Scientist
Intel

Susan Hoffman
Director: IRB for Health Sciences Research
University of Virginia

Georgia Holko
Contractor, Defense Threat Reduction Agency (DTRA)

Hayden Huang
Senior Engineer
Government Accountability Office (GAO)

Mike Jaffe
Consultant & Advisor
Cardiorespiratory Consulting, LLC
Paul Jones
Senior Software/Systems Engineer
Food & Drug Administration (US)

Rajinder Khosla
Senior Technical Advisor, ASSIST Center
North Carolina State University

John Lach
Professor and Chair, Charles L. Brown Department of Electrical and Computer Engineering
University of Virginia

Heather Lewis
Vice President - Anesthesia and Surgical Suites; Associate Chief Quality Officer
Geisinger Health System

Rubi Linares-Orozco
Sr. Research Compliance Analyst
University of California-San Diego Health, Research Compliance Program

Victoria Lindsey (Co-facilitator)
Undergraduate, University of Virginia

Caitlin Mahoney (Co-facilitator)
Undergraduate, Bucknell University

John McNeill
Professor & Associate Department Head
Electrical & Computer Engineering
Worchester Polytechnic Institute

Ember Melcher (Co-facilitator)
Communications & Event Coordinator, ASSIST Center
North Carolina State University

Todd Merchak
Biomedical Engineer,
Extramural Science Program NIBIB
National Institutes of Health

Veena Misra
Director, ASSIST Center
Distinguished Professor of Electrical and Computer Engineering
North Carolina State University

Wendy Nilsen
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National Science Foundation

Pearl O'Rourke
Director of Human Research Affairs
Partners HealthCare System Inc.

Tolu Odumosu (Facilitator)
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Department of Engineering & Society
University of Virginia

Andrew Omidvar
Vice President
Enterprise and Government R&D
Philips Healthcare

Claire Ortiz
Chief Executive Officer
Ortiz Industry

Mehmet Ozturk
Deputy Director, ASSIST Center
Professor of Electrical & Computer Engineering
North Carolina State University

Mark Poler
Director of Anesthesiology Informatics, Technology & Research
Geisinger Health System

Emma Price (Co-facilitator)
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Keith Roper
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Jennifer Yttri
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