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# Utilization of research technologies within a local community hospital in Ann Arbor

Stephanie Otto

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Utilization of Research Technologies Within a Community Hospital in Ann Arbor Michigan

by

Stephanie Otto

Thesis

Submitted to the School of Health Sciences

Eastern Michigan University

in partial fulfillment of the requirements

for the degree of

MASTER OF SCIENCE

in

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Thesis Committee:

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### Abstract

Technology has the ability to change the way clinical trials are conducted. Technology utilization has expanded into research in the form of handheld smartphones, wearables, and social media. This project explored technologies and assessed which of those technologies are being utilized at a community hospital. A survey was designed, developed, and disseminated to principal investigators and co-investigators of research within the hospital. The results showed that few of the technologies included in the assessment are being utilized by the researchers at the hospital. The most popular technology category being utilized by the researchers is smartphone technology. This research could contribute to the knowledge about the utilization of research technologies to society, as well as to the operational directors of research within the community hospital, which could help reveal which technologies are most useful. This research could also aid in the assessment of technology utilization over time within the same hospital.

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## **Chapter 1: Introduction**

Technology is being incorporated into the design of clinical trials, and may be able to change the future of clinical research (Rosa, Campbell, Miele, Brunner, & Winstanley, 2015). There are different forms of clinical research, and clinical trials can be conducted differently. Clinical trials may be investigator sponsored, academic sponsored, or pharmaceutical industry sponsored. Trials may be conducted at a physician's office, a hospital, a university clinical research center, or a dedicated clinical research site. Research can include data collection, such as retrospective or observational studies, or interventions, such as medically inserted devices, patient-wearable devices, or pharmaceutical drugs. Additionally, research may include sponsor-funded (clinical trials), retrospective data collection, and investigator-initiated research.

Traditionally, clinical trials were executed using conventional methods, such as face-to-face recruitment and enrollment, administration of interventions, and data collection (Rosa et al., 2015). Newspapers and radio advertisements were used for participant recruitment. Follow-up assessments were conducted via mail or telephone, and data were collected using paper and pencil methods. Storage of the collected data took physical space. In the late 1980's and early 1990's, personal digital assistants (PDAs) were adopted into some clinical trials (Coons et al., 2014). These devices allowed temporary data storage on the device until the data could be uploaded to a central server. Electronic data capture (EDC) systems are now being used in the majority of clinical trials and significantly decrease the amount of paper needing to be stored. These EDCs can be monitored remotely, which allows sponsor companies and investigators to ensure data integrity without the additional expense of travel to each clinical trial site.



Advancements in electronic participant reported outcomes (ePRO) data collection have improved the accuracy and integrity of clinical trial data, which is why regulators encourage its use (Coons et al., 2014). Electronic capture of clinical trial source data is usually preferred over paper-based data collection. Improved protocol compliance, avoidance of secondary data errors, less administrative burden, and more accurate and complete data can be seen with the use of ePRO systems.

Another technology improvement in participant-reported outcomes is an emerging trend coined the 'Bring Your Own Device' (BYOD) approach. Participants use their own smartphone or internet-enabled device to complete field-based participant reported outcome (PRO) assessments. These devices can include smartphones, laptop and desktop computers, tablets, or internet-enabled televisions. Gwaltney et al. (2015) explored this trend in the use of personal devices for ePRO assessments and how they are implemented in clinical trials. The authors found that this departure from traditional methods can reduce costs, reduce training time, reduce study site burden, and keep study start-up times to a minimum.

Smartphone applications and use of smartphones in clinical trials can make support, information, and monitoring available almost constantly. One randomized clinical trial of a smartphone, called the Addiction–Comprehensive Health Enhancement Support System (A-CHES), showed that the use of a smartphone application designed to improve continuing care for alcohol use disorders may have significant benefit to participants (Gustafson et al., 2014). Multi-featured smartphones offered emotional and instrumental support any place and any time

study participants needed it. More recently, companies such as Apple and Google have expanded their technology into the research realm. On March 9, 2015, Apple (n.d.) presented its ResearchKit™, which is software designed for medical and health research. This software allows researchers to create apps for research utilization, and it works flawlessly with Apple's (n.d.) CareKit™, which is an open source framework that assists users in managing their health and connecting them to healthcare teams.

A very popular trend in research technology is using wearable data collection devices, such as a watch or bracelet. Google maintains a health company, Verily Life Science LLC, which in 2017 unveiled a watch that unobtrusively but continuously collects physiological data from participants (Regalado, 2017). This device can capture heart rate, movement data, electrical conductance of the skin, and electrocardiograms. This watch was developed as an investigational device to be used in clinical trials. Clinical wearable devices allow clinical trial participants ease of use and clinical site coordinators and principal investigators easy access to data. Wearable devices enable the collection of unobtrusive, frequent, and continuous data, which, as shown by Czaja, Gold, Bain, Hendrix, and Carrillo (2017), may be able to capture subtle changes in cognition and functional capacity as well. Wearable technologies in healthcare may also be able to offer personalized and remote care to pregnant participants for fetal monitoring, elderly participants for fall detection and prevention, and cuff-less and continuous monitoring of blood pressure. Wearable devices in healthcare are becoming increasingly popular for these reasons. The global healthcare wearable device market could reach revenues of 18.9 billion dollars by 2020 (Fassbender, 2016).

Just as the wearable healthcare technology market is expanding, enthusiasm for social networks as an avenue to reach more potential study participants has also been explored within

research settings. Social media can be used as an avenue to promote awareness of research activities and the results of research studies, and may also help industry sponsors by commercializing the results, which in turn bring bigger benefits and profits more quickly (Jaring & Back, 2017). Use of hashtags on social media can also be an avenue of tracking how many people are interested in the topic (Devitt, 2016). Some researchers are even considering recruiting study participants through social media and other online avenues. Gupta et al. (2015) found that the use of the internet provides a way to make communication interactive. Participants can be tracked at a granular level, and the use of online media for recruitment is more cost-effective, interactive, personalizable, and tractable when compared to offline media recruitment efforts. Social media sites offer a new way to recruit young participants into research.

Technological changes and the addition of social media utilization in research have the most implications for young people, as they are underrepresented in medical and population-based studies in the United States, and the addition of recruitment through social media could help to improve enrollment of these younger generations, thus improving representation of those generations in medical studies (Fenner et al., 2012).

Existing and emerging technologies can be extremely advantageous for clinical trials if they are recognized and utilized properly. Science and technology move very quickly, and the culture of communication has considerably changed in recent years, to a culture where potential research participants are surrounded daily with personal technology through devices and internet-based knowledge such as smartphones and social media. Internet-based communication and mobile technologies have become the norm for society and participants. As reported by Rosa et al. (2015), the world quickly went from interactive video games on a Wii™ system, to Siri™, a voice activated personal assistant, in the amount of time that it takes to design, implement, and

publish findings from a clinical trial. Technology can provide ease of use as well as higher quality data collection capabilities. The time has come when we must think about how we can make clinical trials more convenient for participants, and ensure they are active and engaged participants.

With all of the emerging and new technologies available for clinical trial use, it is pertinent that principal investigators are aware of these technologies. Principal investigators hold the responsibility for the proper conduct of research at a study site. Utilizing recent technologies may offer a way to lessen the workload and time spent on tedious tasks involved with the trial. Use of recent technologies may also engage both the principal investigator and the participant. Physicians' level of engagement can have significant effect on the overall success of a study and its components, such as participant recruitment and retention, follow-up, and quality of data collection (Zalay, Springer, Arts, & Eisenhauer 2018). New technologies can make clinical trials more appealing to participants because of the convenience. Mobile phone apps, wearables, and use of social media are just three new technologies that can help to reduce cost, improve enrollment, and collect new forms of data for some clinical trials.

### **Purpose of the Study**

The purpose of this study was to examine and measure the utilization of research technologies by clinical research principal investigators and co-investigators who have conducted research within the prior 24 months at a community hospital.

**Research Question**

Are clinical research investigators at a community hospital utilizing recent advancements in technology that can be applied to clinical research?

## **Chapter 2: Methods**

The study was submitted for review to the community hospital institutional review board (IRB) on January 3, 2019. The study received exemption status from the community hospital IRB on January 18, 2019. Following the list of abbreviations (Appendix A), is the hospital IRB approval letter (Appendix B). The study was then submitted for review to Eastern Michigan University (EMU) University Human Subjects Review Committee (UHSRC) on January 21, 2019, and received exemption status on January 23, 2019 (Appendix B). The survey tool can be found in Appendix C, followed by the researchers training documents in Appendix D.

### **Eligibility**

The population that was identified and used for this study included adult (18 years or older) clinical research principal investigators and co-investigators listed on a delegation of authority log within the last 24 months and who work under the direction of one of the three research departments within the community hospital. Excluded from this project were any research projects that were found to be in conflict with this project (deemed applicable by the operational directors of research) and any investigator who lacked comprehension of the English language due to the survey assessment only being available in English.

### **Sources of Participants**

The administrative assistant to the IRB was contacted at the community hospital prior to the launch of the research project in order to request assistance of the research project. The administrative assistant retains a list of principal investigators and co-investigators actively responsible for research conducted at the hospital. The administrative assistant was asked to forward study emails to the clinical research principal investigators with an embedded survey

link in order to maintain participant confidentiality. Subsequent contact with the principal investigators was through the administrative assistant and not the researcher. Emails were drafted and reviewed by the community hospital IRB. The first email introduced participants to the research topic, explained the intentions of the survey, and explained consent by participation. The email also contained the link to the survey assessment. Follow-up emails included a thank you for participation, as well as a reminder to those who had not completed the survey yet that there was still time to complete it, and the link to the survey.

### **Design**

The survey was designed and developed as a mixture of open and structured (fixed response) assessments (Appendix C). The opening page of the survey was the consent form. Participants who agreed to consent were then directed to the survey. Persons who chose to deny consent were thanked for their time and were not shown the survey. At the top of the survey, clear intentions informed participants of why the data were being collected and what the data were to be used for. Clear instructions on how to fill out the survey properly were also included. The survey consisted of brief questions and was estimated to take investigators less than five minutes to complete. The questionnaire used was not validated, but the survey was tested on nine people as a pilot to ensure all questions could be answered, which allowed the researcher time to make any necessary changes. The researcher made changes after the pilot phase to ensure good survey flow and participant understanding of categories and questions. The researcher included a statement to allow participants to skip any questions that made them uncomfortable as requested by the community hospital IRB and a full consent (by participation) as requested by the EMU UHSRC. The survey was voluntary.

The survey consisted of 10 questions and three major categories that were collapsed for ease of use. The participants were asked about three categories that included wearable data collection technology, smartphone data collection technology, and social media technology utilization in research. Each of these categories included multiple choice answers that supplied a specific type of technology that fit into that category.

The first four questions collected information pertaining to what role the participant had in clinical research, how long they had been engaged in research, and what type of research they were engaged in. The three categories focused on the technology that the participants had used in their current research studies. These categories were patient-wearable data collection technology, smartphone technology, and social media. Two questions assessed whether the participants felt well informed about recent technological advancements that can be utilized in research and whether they believe these advancements are helpful to research within the healthcare industry. A final open-ended question asked participants to list any other technologies they utilize in their current research that were not mentioned in the survey.

### **Risks and Benefits**

This was a minimal-risk study. No specific procedures, situations, or materials posed serious hazards to participants or personnel. The study was deemed minimal risk because, as with all survey research, there is always a small risk of breach of confidentiality pertaining to the survey responses. Data security measures minimized these risks, and there was no risk of disclosure of protected health information (PHI). Subject safety was ensured because no demographic information was collected with the surveys, and the surveys were returned in a fashion that did not correlate responses to any personally-linked email. In addition, the



researcher did not have access to any individual email addresses, and the administrative assistant to the IRB forwarded the emails with the survey link to the principal investigators and co-investigators. The online survey used a public URL in order to keep all IP addresses confidential. The survey link was a single, reusable, anonymous link that was unable to track identifying information of respondents. Minimal discomfort at answering the survey questions was considered another minimal risk, although unlikely. Participants were able to skip questions that may have made them uncomfortable.

There was no direct benefit to the principal investigators who participated in the survey. Benefits to society included understanding utilization of research technology within a community hospital. The operational directors of research within the community hospital could also find this knowledge beneficial.

### **Data Analysis**

The researcher, under the direction of Jim Pellerin, a statistics assistant for the EMU Graduate School, conducted all data analysis. Qualtrics® survey tool resources for data analysis were utilized. No protected health information (PHI) was collected or included in any data analysis. Missing data were not adjusted for in statistical analysis. Data were collected from the online survey tool and populated into a Microsoft Excel spreadsheet labeled with the individual variables for analysis. Non-parametric testing was conducted. Spearman's rho was used to measure the strength of association between variables. SPSS™ was used for analysis.

### Chapter 3: Results

The survey was disseminated to 105 PIs and CO-Is (researchers) at a community hospital. The survey was launched on January 25, 2019, and was available for participation until February 15, 2019. The survey contained 10 questions, and did not collect any demographic information to ensure participant confidentiality and anonymity. Of those 105 contacted, 29 (27.6%) PIs and Co-Is consented to participate in the survey, one respondent declined consent, and 75 recipients (71.4%) did not respond. Analysis conducted in this study included detailed analysis of the responses from 29 respondents.

Participants were asked to only complete the entire survey if they had been engaged in research within the prior 24 months. Participants who had not been engaged in research for the previous 24 months were asked to only complete the questions that asked them to assess how useful they feel research technology is to the healthcare industry and the question that asked how well informed they feel of research technologies (Questions 8 and 9 on survey; Appendix C). The number of responses to each question varied due to the design of the survey. Questions 3 through 7 included the option to select "all that apply," so we expected to see the number of responses vary from question to question. None of the 10 questions returned 29 responses. Figure 1 shows the dissemination and response to the survey, while Table 1 shows the number of responses to each survey question.

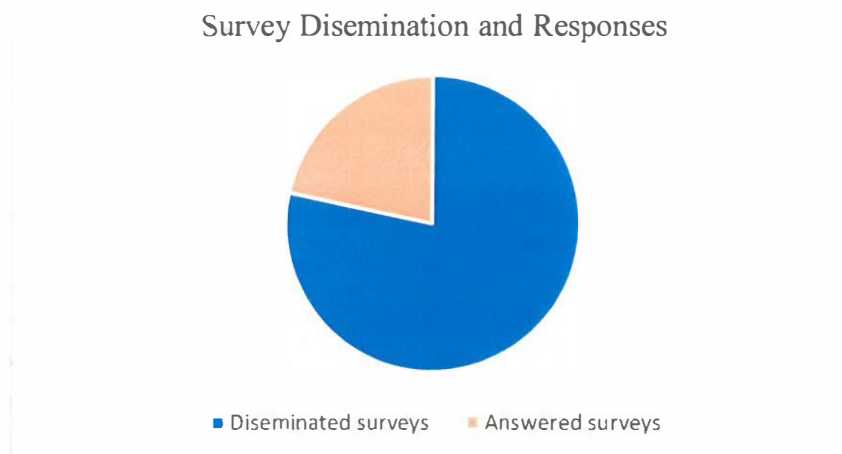


Figure 1. Survey dissemination and response.

Table 1

Survey Response Numbers to Individual Questions

Question Number**	Q1	Q2	Q3**	Q4**	Q5**	Q6**	Q7**	Q8	Q9	Q10
N*	25	22	28	23	22	23	21	25	25	4

\* N of responses = 29

\*\* Respondents allowed to select "all that apply"

The participants were asked if they had been engaged in research in the previous 24 months as a P.I., Co-I, or "not been engaged." Of the 29 respondents, 25 responded to this question. Of those, four (16%) had not been engaged in research in the prior 24 months and were asked to only complete survey that pertained to the respondents' perception of usefulness of research technologies, which asked them to assess how useful they feel research technology is to the healthcare industry and the question that asked how well informed they feel of research technologies (Questions 8 and 9 on the survey; Appendix C). The results showed that a little more than half of respondents were principal investigators (52%,  $n = 13$ ), and 32% ( $n = 8$ ), were

co-investigators engaged in research at the community hospital. Four (16%) respondents had not been engaged in research in the prior 24 months. Table 2 shows the sample characteristics of respondents surveyed.

Table 2

*Sample Characteristics*

Role in Research	Principal Investigator	Co-Investigator	Not Engaged in Prior 24 Months
N*	13 (52%)	8 (32%)	4 (16%)

\*N = 25 respondents

Participants were asked how long they had been engaged in research and had the following choices as answers: 1-5 years, 6-10 years, 11-15 years, 16-20 years, or more than 20 years. A total of 22 responses were analyzed for this question. The largest category of respondents had been engaged in research for 1-5 years, 40.9% ( $n = 9$ ). The next category showed 18.2% ( $n = 4$ ) of investigators had been engaged in research for 6-10 years, 13.6% ( $n = 3$ ) had been engaged in research for 11-15 years, 18.2% ( $n = 4$ ) had been engaged for 16-20 years, and 9.1% ( $n = 2$ ) of investigators had been engaged in research for 20 or more years. Figure 2 shows length of participant engagement in research.

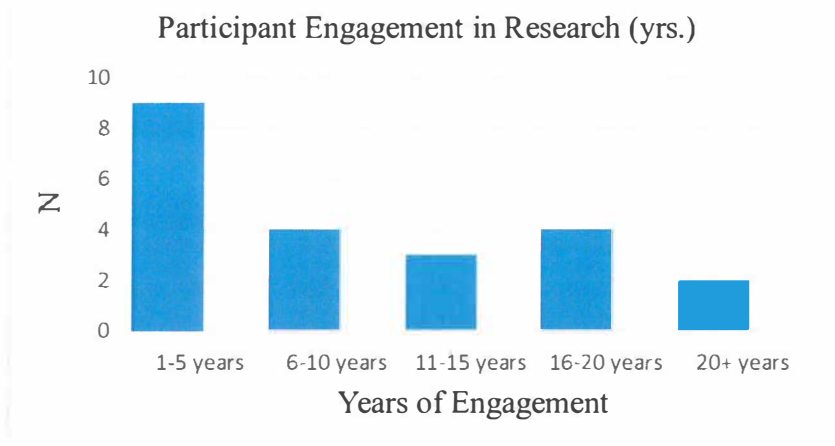


Figure 2. Participant engagement in research (yrs.).

Five categories were numerically coded to determine the mean. Codes were used as follows: 1-5 years was coded as "1," 6-10 years coded as "2," 11-15 years coded as "3," 16-20 years coded as "4," and 20 and up coded as "5." The mean was 2.36 ( $SD = 1.40$ ) which indicates that on average researchers who responded to the survey have been engaged in research between 6 and 10 years.

Participants were asked which category their most recent research falls under and were supplied these answer choices: pharmaceutical, medical device, retrospective or observational, "other," and "all that apply." As shown in Table 3, there were 28 responses to the question assessing which type of research participants are engaged in. Data showed that 17.9% ( $n = 5$ ) of the responses indicated engagement in pharmaceutical research, 10.7% ( $n = 3$ ) are involved in medical device research, and 57.1% ( $n = 16$ ) work with retrospective or observational research. Four respondents chose the "other" option and typed in responses. These responses were not analyzed for this question because the responses could have been captured by other questions further along in the survey.

Table 3

*Participant Category of Research Engagement 1*

Category**	Pharmaceutical	Medical Device	Retrospective or Observational	Other
N*	5 (17.9%)	3 (10.7%)	16 (44%)	4 (14.3%)

\*N = 28 responses

\*\*Respondents allowed to select "all that apply"

The next question again asked participants to select which category of research they were currently engaged in and supplied the following choices for answers: investigator initiated, industry sponsored (clinical trials), and "other," and could select "all that apply." This question collected 23 responses. Investigator initiated research applied to 78.3% ( $n = 18$ ) of responses, industry sponsored or clinical trials research applied to 17.4% ( $n = 4$ ) of responses, 4.4% ( $n = 1$ ), respondent was engaged in some other form of research as shown in Table 4. The one respondent who chose "other" as an answer choice for this question did not supply text to explain their choice, leaving the field blank.

Table 4

*Participant Category of Research Engagement 2*

Category**	Investigator Initiated	Industry Sponsored (clinical trials)	Other
N*	18 (78.2%)	4 (17.4%)	1 (4.3%)

\*N = 23

\*\*Respondents allowed to select "all that apply"

The participants were asked about how well informed of recent technological advancements that can be utilized in research they feel they are, to which 25 respondents supplied data. The selection of answers included: none, little, some, substantial and unsure. Of the respondents 8% ( $n = 2$ ) did not feel well informed of recent research technologies at all, while 24% ( $n = 6$ ) of respondents felt they were informed a little about recent technological advancements in research. Responses showed that 40% ( $n = 10$ ) feel somewhat well informed of advancements, while 28% ( $n = 7$ ) said they were well informed of the technological advancements (Figure 3).

Five categories were numerically coded to determine the mean. Codes were used as follows: none was coded as "1," little coded as "2," some coded as "3," substantial coded as "4," and unsure coded as "5." The mean, standard deviation, and variance of the respondents' selections for this question were reported as ( $M = 2.88, SD = 0.91, V = 0.83$ ).

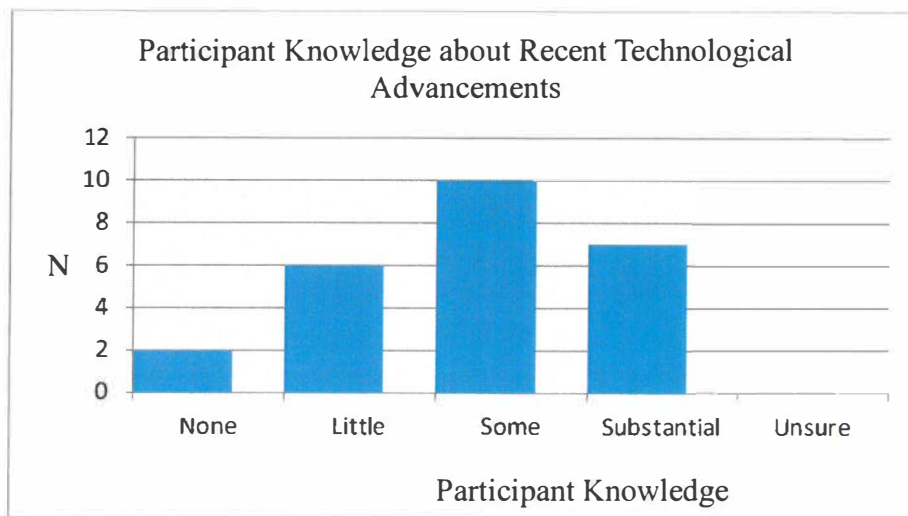


Figure 3. Participant knowledge about recent technological advancements.

The association between how well the participant felt informed of technology advancements and the amount of time they have been engaged in research was analyzed using Spearman’s rho ( $n = 22$ ). Using a significance level of 0.01, the correlation coefficient was 0.887, [ $r_s(22) = .887, p < .001$ ]. There is a strong positive association between the two variables. The relationship between the length of time a researcher has been engaged in research and how well they feel informed of recent technological advancements is also shown in Figure 4.

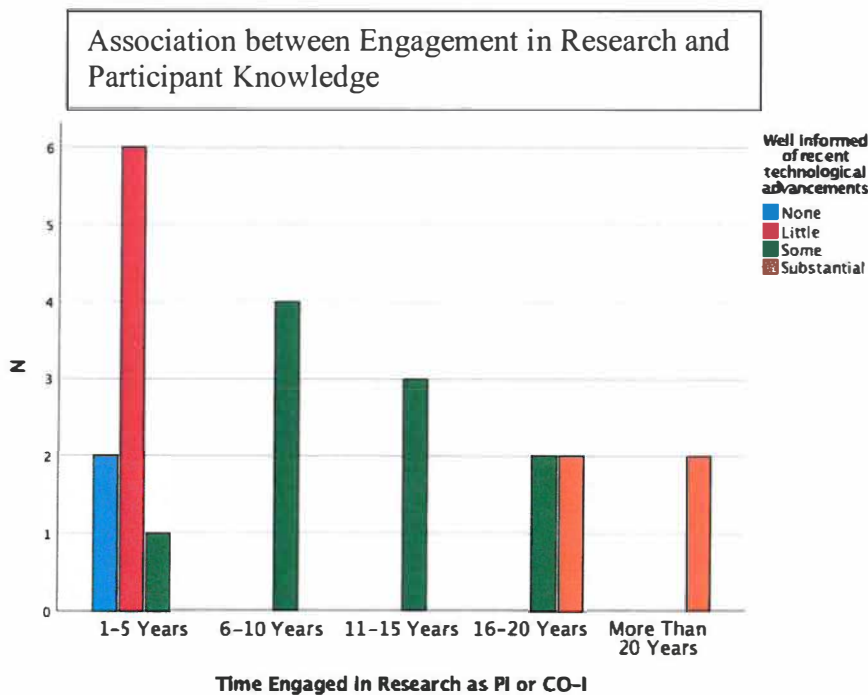


Figure 4. Association between engagement in research and participant knowledge.

The participants were asked if they believed that recent technological advancements are helpful to research within the healthcare industry, and participants were given these options for answer selections: none, little, some, substantial, and unsure. This question collected 25 responses. Responses showed that 52% ( $n = 13$ ) of participants believe that technology advancement are substantially helpful to research within the healthcare industry, while 36% ( $n =$



9) believe technological advancements are somewhat helpful. Results showed 8% ( $n = 2$ ) of respondents believe technological advancements only a little helpful, while one respondent believes that technology advancements are not helpful to research within the healthcare industry (Figure 5).

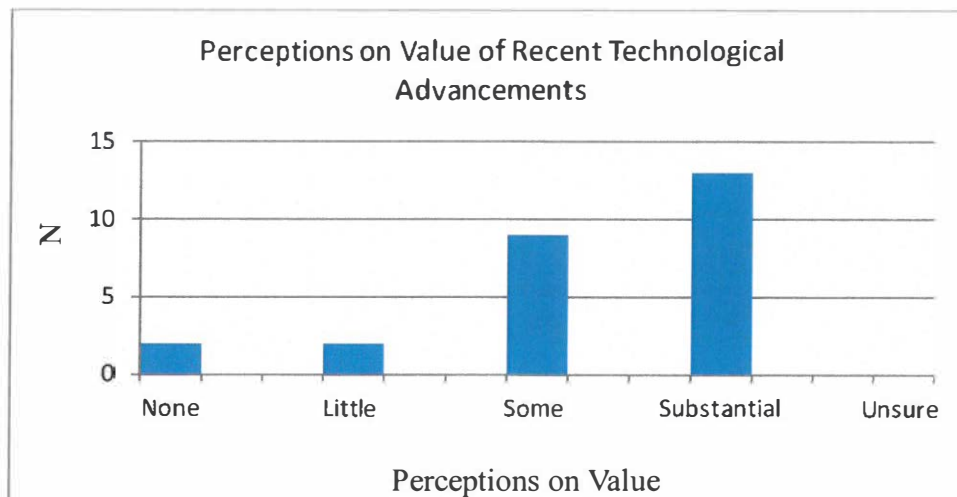


Figure 5. Perceptions on value of recent technological advancements.

The participants were asked which types of patient-wearable data collection technologies they use in their current research. Choices included smartwatches (e.g., Apple™ watch), fitness trackers (e.g., Fitbit™), and biosensor monitors (e.g., patches), and participants were asked to select "all that apply." A total of 22 responses were collected for this question. Responses showed 13.6% ( $n = 3$ ) use at least one form of patient wearable data collection technology in their current research. Fitness trackers are used by 9.1% ( $n = 2$ ) of all responses in their current research, and 4.5% ( $n = 1$ ) use an "other" form of patient-wearable data collection technology, which was described in text as a mobile phone app. The remaining 86.4% ( $n = 19$ ) of responses showed that they do not use a form of patient-wearable data collection in their current research,

and there were zero responses showing use of smartwatches or biosensor monitors for research as shown in Table 5.

Table 5

*Utilization of Patient-Wearable Data Collection Technology in Current Research*

Patient-Wearable Data Collection Technology**	Smartwatch	Fitness tracker	Biosensor Monitors	None	Other
N*	0 (0%)	2 (9.5%)	0 (0%)	19 (90.5%)	1 (4.8%)

\*N=22 responses

\*\* Respondents allowed to select "all that apply"

The relationship between how long a researcher has been engaged in research and which type of patient-wearable data collection technology they use in their current research was further explored. Fitness trackers were shown to be used by researchers that have been engaged in research for 1-5 years. All the other responses showed they were not using any type of patient-wearable data collection technology in their research regardless of experience levels. This relationships are shown in Figure 6.

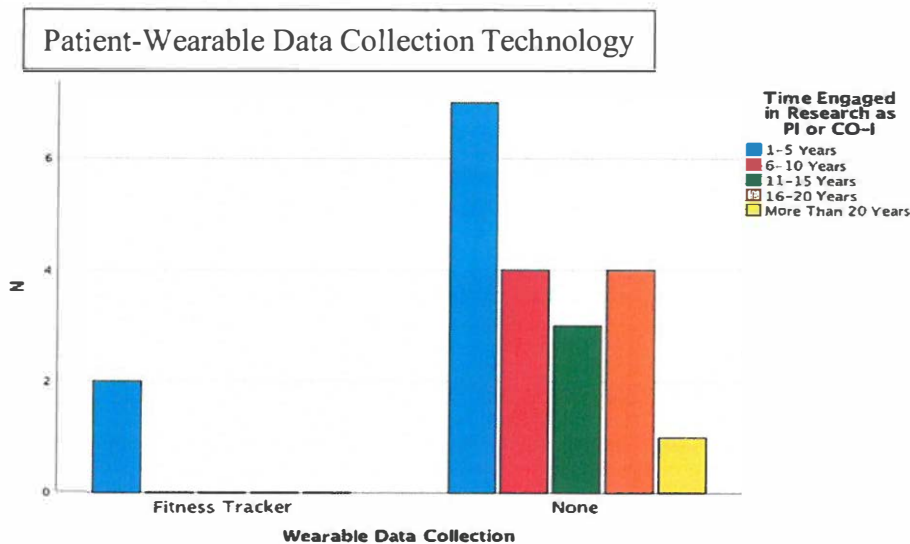


Figure 6. Patient-wearable data collection technology.

The participants were asked about which types of smartphone data collection technologies they use in their current research. The smartphone data collection technologies category included the following technologies: health/fitness applications, motion tracking sensor applications (e.g., step tracker), health assessments via smartphone, informed consent via smartphone, none, an open-ended "other" option for the participant to fill in if it pertained to their current research, and participants were allowed to select "all that apply." A total of 23 responses were analyzed for this question. Overall 30.4% ( $n = 7$ ) of responses use at least one form of smartphone technology in their current research, while 69.6% ( $n = 16$ ) do not use any form. A health/fitness app was used by 4.3% ( $n = 1$ ) respondent for research purposes, 8.7% ( $n = 2$ ) responses indicated current use of motion tracking sensor applications in current research, and 13.0% ( $n = 3$ ) of the responses currently utilize a smartphone to conduct health assessments with research participants. One participant (4.3%) utilizes a smartphone to supply the research subject with informed consent documents. Table 6 outlines the responses for the smartphone survey question. Figure 7 shows how long the participant has been engaged in research and what type of

smartphone technology they are utilizing. This figure shows that the researchers that have been engaged in research for the least amount of time are utilizing the smartphone technologies more than the researchers who have been engaged in research for longer lengths of time.

Table 6

*Utilization of Smartphone Data Collection Technology in Current Research*

Smartphone Data Collection Technology**	Health/Fitness App	Motion Tracking App	Health Assessments	Informed Consent	None	Other
N*	1 (4.3%)	2 (8.7%)	3 (13%)	1 (4.3%)	16 (69.6%)	0 (0%)

\*N = 23 responses

\*\* Respondents allowed to select "all that apply"

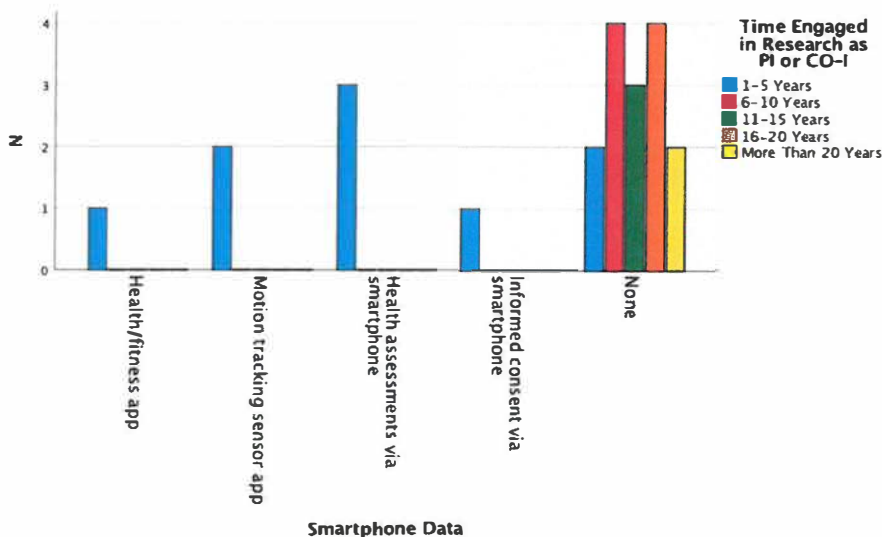


Figure 7. Participants' length of engagement and type of smartphone technology being utilized.

The final category asked participants about which type of social media they utilize in their current research. Options included use of social media to: recruit patients, supply

information to patients, advertise studies, supply health assessment surveys, use of social media in other ways and select "all that apply." Responses totaled 22 for this particular question. A total of 14.3% ( $n = 3$ ) of responses use at least one of these forms of social media to interact with their study participants. The majority 85.7% ( $n = 18$ ) do not use social media in their current research. Supplying research information to participants through social media was used by one respondent (4.8%), and one respondent uses social media as an avenue to advertise studies. None of the responses showed they are supplying health assessments to participants via social media, and only one response (4.8%) showed use of social media in their current research in "other" ways such as exception from informed consent (EFIC) compliance for emergency research (Table 7).

Table 7

*Utilization of Social Media Technology in Current Research*

Social Media Technology **	Recruitment via Social Media	Supplying Information vis Social Media	Advertise Studies via Social Media	Supply Health Assessments via Social Media	None	Other
N*	0 (0%)	1 (4.8%)	1 (4.8%)	0 (0%)	18 (85.7%)	1 (4.8%)

\*N = 22 responses

\*\* Respondents allowed to select all that apply

EFIC compliance refers to informed consent within emergency research. Emergency research involves human subjects who have a life threatening medical condition that necessitates urgent intervention and who, because of their condition, cannot provide informed consent. The FDA (2013) has developed regulations for this specific type of research, and these can be located in the Code of Federal Regulations (21 CFR 50.24). The regulations provide additional protections to these subjects as well.

The type of social media technology a participant uses was further analyzed against the length of time the participant has been engaged in research, and this relationship is shown in Figure 8. The researchers who have been engaged in research between 1 and 5 years are the researchers utilizing social media technology to both supply information to their subjects and to advertise their studies, while the more experienced researchers are not currently utilizing any form of social media in their research.

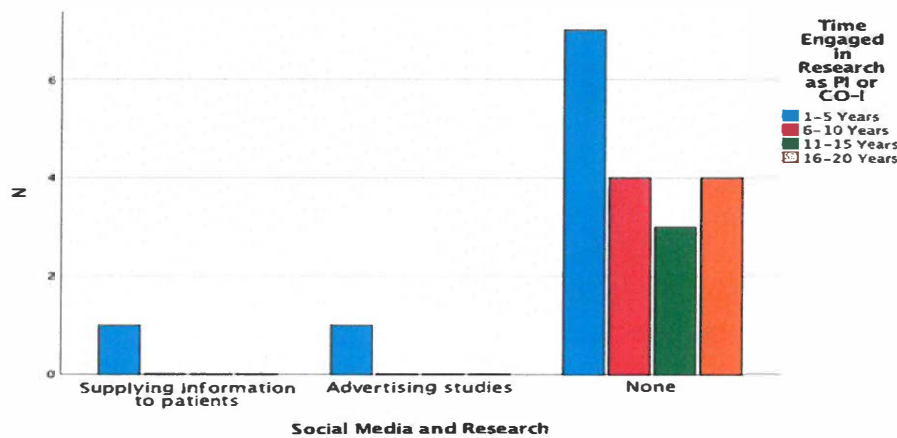


Figure 8. Length of participant engagement and type of social media use.

The final question in the survey allowed participants to share and explain any other type of technology they utilize in their current research, which was not previously reported in the survey. This question allowed an open-ended response to which participants could type up to 50 characters. The four responses collected included use of laptops, iPads, web-based data collection tools, and computers.

## Chapter 4: Discussion

In this survey, community hospital principal investigators and co-investigators of research were asked 10 questions, eight of which related to research technologies. The survey assessment was sent to 105 principal investigators and co-investigators that have been engaged in research within the prior 24 months, of which 29 responded. The objective of this research was to understand if certain research technologies were being utilized within the research studies conducted at the community hospital. The technologies examined were categorized as: patient wearable data collection devices, smartphone data collection technologies, and social media technologies. The responses showed that only some of the available technologies for research are being utilized within this community hospital. The participant's data indicated that the technology being most utilized within research studies at the community hospital are smartphone-related, followed by patient-wearable data collection technology; social media technology is the least utilized research technology.

The most utilized category, smartphone technology, included using health fitness applications and motion tracking sensor apps, providing informed consent to research participants via smartphones, and providing health assessments of research participants via smartphones. This category showed that 30.4% of responses indicated utilization of at least one form of smartphone technology in their current research and that the researchers that are utilizing this form of technology fall in the 1-5 years of experience category.

The social media category included recruiting through a form of social media, supplying information to participants through social media, advertising studies to research participants through social media, and offering health assessments to participants through social media. This

category of technologies showed that 4.8% of the responses utilize social media technology to supply information to their research participants. Another 4.8% of responses showed they utilized social media to advertise their studies, while 4.8% offered EFIC compliance to their participants via social media technology. Again, the researchers with 1-5 years' experience are the ones utilizing this form of technology.

The patient-wearable data collection category included the use of smartwatches, fitness trackers, and biosensor monitors such as patches. Fitness trackers were shown to be utilized by 9.1% of the responses collected, while the majority, 86.4% utilized none of the patient-wearable data collection technologies. The fitness trackers being utilized at the community hospital are being used by researchers with 1-5 years' experience.

The survey found that a positive association between the length of time the P.I. or Co-I was engaged in research and how well informed they were of the various research technologies available. This relationship was shown in a Spearman's rho correlation with a correlation coefficient of .887 with a significance level of  $p < .001$ . Missing data was not adjusted for in statistical analysis.

The way the survey was designed could have had the potential to influence participants' responses to the question that asked how well informed the researcher felt about recent technological advancements that can be utilized in research (Survey Question 8; Appendix C). The participants were shown the answer categories that directly pertained to recent research technologies, such as patient wearable data collection, smartphone and social media (Survey Questions 5, 6, and 7; Appendix C) before they received the question on how well informed they felt about these advancements. These could have reminded the researchers of recent



technological advancements or influenced the answers they supplied to that question that asked how well the participants felt they were informed of the technologies available.

The significant positive correlation between the length of time a researcher was engaged in research and how well informed they feel about the available technologies was expected and seen. The correlation showed that the longer the researcher was engaged in research, the more informed they felt they were about the available technologies to use in research. This suggests that the newer a researcher is, the less information they may be receiving about the advancements in research technology and presents an opportunity for education.

However, the data also show that the researchers who are the newest to research (1-5 years' experience) are the ones who are utilizing the more recent technologies, such as fitness trackers, smartphone apps, and social media. The researchers engaged in research the longest at the institution are not utilizing the technologies explored within this study. This may suggest that the methods being employed by the more experienced researchers are methods they are comfortable with and are known to work best for them, while the least experienced researchers are open to exploring the technologies as they begin their research careers. This may also suggest that the newer researchers are from a younger generation who may be more familiar with these technologies and probably use them more in their personal lives.

The survey results may not be generalizable to all hospitals and researchers due to the small sample size (low response rate). The results indicated that the most utilized technology at this particular community hospital is smartphone technologies, which included the using health fitness applications and motion tracking sensor apps, providing informed consent to research

participants via smartphones, and providing health assessments of research participants via smartphones.

The creation and dissemination of this survey may contribute to the knowledge of which research technologies are most utilized within an institution. This may help institutions to manage which studies to participate in, and which to decline based on the knowledge of their PIs and Co-Is. The survey can also assess how well informed the institution's researchers feel they are about the available research technologies, which may help the institution to educate researchers on available technologies. This survey could also be used as an assessment over time to see if an institution's P.I's and Co-I's utilization of technology changes over time.

### **Limitations and Future Research**

This study design is limited in the manner that it was only administered at one community hospital and may not be applicable to larger populations. In future studies, the online survey could be made available to more institutions to yield higher response rates. The type of hospital may also be a limiting factor, such as general, specialty, government, and university or academic medical centers. Results could vary from institute to institute depending on the kind of hospital surveyed. The survey assessment may also have generated a lower response rate due to it being survey research. Some of the answers to the research question could have been answered by gaining access to the study protocol records or IRB records, which would indicate which types of technologies were being used.

Another limitation of this study is that it did not include or mention telemedicine, which is the use of information technology and telecommunication to provide healthcare from a distance. Telemedicine is becoming very popular, and it could have been explored and included

in the assessment tool. Future studies may want to include use of telemedicine in clinical research within the assessment.

## Chapter 5: Conclusion

The objective of this research was to explore and assess what research technologies were being utilized at a community hospital. It had a focus on three main categories, including patient-wearable data collection technologies, smartphone technology, and social media technologies, that can be utilized in clinical research. The results show that few of the technologies explored through the survey are being utilized in the institution. The most utilized was smartphone data collection technologies. The survey found a positive correlation between the time a researcher has been engaged in research as a P.I. or Co-I and how informed they feel recent technological advancements that can be used in research. A positive association was also found between the length of time a researcher has been engaged in research and what category of research they are engaged in, when looking at pharmaceutical, medical device and retrospective or observational research. The data show that the researchers that have the least amount of experience in years are the ones that are utilizing the recent research technologies, while the more experienced researchers are not utilizing the recent technologies. Further research should include a larger survey sample as well as more than one institution.

## References

- Apple Inc. (n.d.).CareKit. Retrieved from <https://developer.apple.com/carekit/>
- Apple Inc. (n.d.).ResearchKit. Retrieved from <http://researchkit.org/>
- Coons, S., Eremenco, S., Lundy, J., O'Donohoe, P., Gorman, H., & Malizia, W. (2015). Erratum to: Capturing Patient-Reported Outcome (PRO) Data Electronically: The past, present, and promise of ePRO measurement in clinical trials. *The Patient-Centered Outcomes Research, 8*, (6), 571. doi:10.1007/s40271-015-0121-4
- Czaja, S., Gold, M., Bain, L. J., Hendrix, J. A., & Carrillo, M. C. (2017). Potential roles of digital technologies in clinical trials. *Alzheimers & Dementia, 13*(9), 1075-1076.  
doi:10.1016/j.jalz.2017.08.001
- Devitt, P. (2016). How to use social media to disseminate research findings. *Nursing Children and Young People, 28* (8), 20
- Fassbender, M. (2016, May 31). Clinical grade wearables market to reach \$18.9bn by 2020. Retrieved from <https://www.outsourcingpharma.com/Article/2016/05/31/wearables-market-to-reach-18.9bn-by-2020>
- Fenner, Y., Garland, S. M., Moore, E. E., Jayasinghe, Y., Fletcher, A., Tabrizi, S. N., . . . Wark, J. D. (2012). Web-based recruiting for health research using a social networking site: an exploratory study. *Journal of Medical Internet Research, 14*(1) doi:10.2196/jmir.1978
- Gupta, A., Calfas, K. J., Marshall, S. J., Robinson, T. N., Rock, C. L., Huang, J. S., . . . Patrick, K. (2015). Clinical trial management of participant recruitment, enrollment, engagement, and retention in the SMART study using a marketing and information technology

(MARKIT) model. *Contemporary Clinical Trials*, 42, 185-195.

doi:10.1016/j.cct.2015.04.002

Gustafson, D. H., McTavish, F. M., Chih, M., Atwood, A. K., Johnson, R. A., Boyle, M. G., . . .

Shah, D. (2014). A smartphone application to support recovery from alcoholism. *JAMA Psychiatry*, 71(5), 566. doi:10.1001/jamapsychiatry.2013.4642

Gwaltney, C., Coons, S. J., O'Donohoe, P., O'Gorman, H., Denomey, M., Howry, C., & Ross, J.

(2015). "Bring your own device" (BYOD). *Therapeutic Innovation & Regulatory Science*, 4(6), 783-791. doi:10.1177/2168479015609104

Jaring, P., & Back, A. (2017). How researchers use social media to promote their research and network with industry. *Technology Innovation Management Review*, 7 (8)32-39.

Retrieved from <http://timreview.ca/article/1098>

Mahmud, A., Zalay, O., Springer, A., Arts, K., & Eisenhauer, E. (2018). Barriers to participation in clinical trials: A physician survey. *Current Oncology*, 25(2), 119.

doi:10.3747/co.25.3857

Regalado, A. (2017, April 14). Verily's health research watch is super discreet but knows

everything about you. MIT Technology Review. Retrieved November 11, 2018, from

<https://www.technologyreview.com/s/604198/googles-verily-unveils-a-health-watch-for-research/>

Reychav, I., Beeri, R., Balapour, A., Raban, D. R., Sabherwal, R., & Azuri, J. (2019). How

reliable are self-assessments using mobile technology in healthcare? the effects of

technology identity and self-efficacy. *Computers in Human Behavior*, 91, 52-61.

doi:10.1016/j.chb.2018.09.024

Rosa, C., Campbell, A. N., Miele, G. M., Brunner, M., & Winstanley, E. L. (2015). Using e technologies in clinical trials. *Contemporary Clinical Trials*, 45, 41-54.

doi:10.1016/j.cct.2015.07.007

Tognetti, A., & Carbonaro, N. (2018). Special issue on “Wearable technologies.” *Technologies*, 6(4), 102. doi:10.3390/technologies6040102

U.S. Department of Health and Human Services, Food and Drug Administration. (2013).

*Guidance for institutional review boards, clinical investigators, and sponsors exception from informed consent requirements for emergency research.* Retrieved from

<https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm249673.pdf>

APPENDICES



## Appendix A: List of Abbreviations

EMU: Eastern Michigan University

P.I.: Principal Investigator

Co-I: Co- Investigator

IRB: Institutional Review Board

FDA: Food and Drug Administration

PHI: Protected Health information

DOA: Delegation of Authority

EDC: Electronic Data Capture

ePRO: Electronic Participants Reported Outcomes

BYOD: Bring Your Own Device

PDA: Personal Digital Assistant

UHSRC: University Human Subjects Review Committee

EFIC: Exception from Informed Consent

Appendix B: IRB Approval Letters

January 18, 2019

Stephanie Otto

Dear Ms. Otto:

On behalf of the [REDACTED] Institutional Review Board, expedited review was conducted on January 18, 2019 for the following:

**Project Entitled:** Utilization of Recent Research Technologies within [REDACTED]

**NHSR-19-786 was assigned for IRB tracking purposes.**

**The IRB determined the project does not meet the definition of human subjects research and therefore 45 CFR Part 46 does not apply. No further correspondence is required.**

The [REDACTED] IRB operates in accordance with Good Clinical Practice Guidelines and applicable laws and regulations. If there is any aspect of the policies and procedures about which you would like further information please visit the [REDACTED] IRB website at [REDACTED]. Failure to comply with [REDACTED] policy is in violation of federal regulations and could result in withdrawal of approval and/or funding for your project.

Sincerely,

[REDACTED]  
IRB Administrator

Eastern Michigan University Mail - UHSRC-FY18-19-175 - Initial: Initial - Exempt

Page 1 of 1



Stephanie Otto <otto1@emich.edu>

**UHSRC-FY18-19-175 - Initial: Initial - Exempt**

human.subjects@emich.edu <human.subjects@emich.edu>  
To: jrowan3@emich.edu, otto1@emich.edu

Wed, Jan 23, 2019 at 11:42 AM



University Human Subjects Review Committee

Jan 23, 2019 11:42 AM EST

Stephanie Otto  
Eastern Michigan University, School of Health Sciences

Re: Exempt - Initial - UHSRC-FY18-19-175 Utilization of Research Technologies within a local community hospital

Dear Stephanie Otto

The Eastern Michigan University Human Subjects Review Committee has rendered the decision below for Utilization of Research Technologies within a local community hospital. You may begin your research.

Decision: Exempt

Selected Category: Category 2 (i) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording). The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

Renewals: Exempt studies do not need to be renewed. When the project is completed, please contact human.subjects@emich.edu.

Modifications: Any plan to alter the study design or any study documents must be reviewed to determine if the Exempt decision changes. You must submit a modification request application in Cayuse IRB and await a decision prior to implementation.

Problems: Any deviations from the study protocol, unanticipated problems, adverse events, subject complaints, or other problems that may affect the risk to human subjects must be reported to the UHSRC. Complete an incident report in Cayuse IRB.

Follow-up: Please contact the UHSRC when your project is complete.

Please contact human.subjects@emich.edu with any questions or concerns.

Sincerely,

Eastern Michigan University Human Subjects Review Committee



**Waiver of Documentation of Consent**

- "Waiver of documentation of consent" means that consent is obtained from the participants, but is done via verbal consent or by a consent document without the signature lines (commonly referred to as an 'informational sheet'). This option is useful if you are conducting an Internet survey or telephone research or other types of minimal risk research.
- You will need to document in the research record or other location that a consent process took place.
- The consent process should include the required elements of consent. If you would like to exclude or alter the elements, please also complete the *Alteration of Consent* form.
- In order to qualify for waiver of documentation of consent for some or all of the participants, the research study must:
  - **OHRP-regulated** research- meet EITHER the 1<sup>st</sup> or 2<sup>nd</sup> requirement below [see 45 CFR 46.117(c)]
  - **FDA-regulated** research- meet the 2<sup>nd</sup> requirement below [see 21 CFR 56.109(c)(1)]
- Need help?

<b>Waiver of Documentation of Consent</b>	<i>Consent will be obtained, either verbally or with an Info Sheet</i>
---	--

**Title of Research Project: Utilization of Recent Research Technology**

Which method will you use?

- Verbal consent\*-- Please submit a verbal script
  - Consent document without signatures obtained / informational sheet
- \*Note that the IRB may still require that written information is given to some or all of the participants (info sheet).*

Indicate the documentation that will be used to note that consent took place: *The protocol or departmental procedures should indicate how and where to document the consent discussion (such as in a progress note, study file or research record).*

- Progress note
- Study file
- Other

Please indicate the status of the research study:

- New Project Application is being submitted – *please complete the informed consent section of the application, describing the consent process that will be used.*
- Study has been approved – *please attach or describe below the consent process that will be used:*

Choose <u>either</u> the 1 <sup>st</sup> or the 2 <sup>nd</sup> option, below, for OHRP-regulated research; Choose the 2 <sup>nd</sup> option only for FDA-regulated research; Complete both a) and b) for the chosen requirement:
--

- 1<sup>st</sup> Requirement (OHRP only)**

- a) The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality and privacy. Explain how your study meets this criterion. *Please note: the IRB may decide to require that the researcher provide the participants with a written statement about the research (information sheet/consent form without signature lines).*

AND

- b) Each participant will be asked whether the participant wants documentation linking them with the research (*i.e. sign a consent document or provide evidence that they gave consent for the study*), **and** the participant's wishes regarding documentation of consent will govern.

I will comply with this requirement

OR

**2<sup>nd</sup> Requirement (OHRP &/or FDA)**

- a) The research presents no more than minimal risk of harm to participants. Explain how your study meets this criterion. *Minimal risk means that "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests"*

**This is a minimal-risk study. There are no specific procedures, situations, or materials that pose serious hazards to patients or personnel. The study is minimal risk because as with all survey research there is always a small risk of breach of confidentiality pertaining to the survey responses. There will be data security measures in place to minimize these risks. There is no risk of disclosure of protected health information (PHI). Subject safety will be ensured through complete lack of the collection of demographic information with the surveys. There will be no identification through the survey, and surveys will be returned in a fashion that does not correlate to any email. The survey tool offers anonymous responses by not recording any personal information and removing all contact association, so the researcher will not have access to the email addresses of respondents. Qualtrics is also known for their recognized standard for proactive risk management, ISO 27001 ensures information security best practices in asset management, access control, cryptography, and network security. In addition, I personally will not have individual emails, and will have the administrative assistant forward out the emails with the survey link to the P.I.s and Co-I's. I will only have access to the results of the surveys which are anonymized. Minimal discomfort at answering the survey questions is another minimal risk although unlikely. Participants may skip questions that may make them uncomfortable.**

AND

- b) The research involves no procedures for which written consent is normally required outside of the research context. Explain how your study meets this criterion.

**The study will only include a survey assessment in which consent is given through participation. Mention of consent through participation is included in the email in which the survey link will be embedded as well as the survey itself.**

## Appendix C: Survey

**Research Technology Utilization****Consent Form**

Project Title: Utilization of Research Technologies within a local community hospital  
Principal Investigator: Stephanie Otto, Graduate Student [REDACTED]

**Purpose:** The purpose of this research study is to examine and measure the utilization of research technologies of the Principal Investigators and Co-Investigators at this institution.

**Study Procedures:** Participation in this study involves completing an online survey. It should take between 3 and 5 minutes to complete the survey.

**Types of Data Collected:** We will ask questions about your involvement in research and what types of technology your research may utilize. We will not ask for any demographic or personal information. We will not collect any identifiable data.

**Risks:** The primary risk of participation in this study is a potential loss of confidentiality. Some of the survey questions may make you feel uncomfortable. You do not have to answer any questions that make you uncomfortable or that you do not want to answer.

**Benefits:** You will not directly benefit from participating in this research. Benefits to society include understanding utilization of research technology within a community hospital.

**Confidentiality:** We will keep your responses confidential by using a code to identify your information. Your responses will be stored in a password-protected computer website. We will store your responses for three years after the project ends. The principal investigator and the research team will have access to the responses you provide for research purposes only. We may share your responses with other researchers outside of this institution and outside of Eastern Michigan University. If we share your information, we will remove any and all identifiable information so that you cannot reasonably be identified. De-identified information will be transferred by email. The results of this research may be published or used for teaching.

**Compensation:** There is no compensation for completion of this survey.

**Contact Information:** If you have any questions about the research, you can contact the Principal Investigator, Stephanie Otto at [REDACTED]

[REDACTED] For questions about your rights as a research subject, you can contact the Eastern Michigan University Office of Research Compliance at [REDACTED]

**Voluntary participation:** Participation in this research study is your choice. You may refuse to participate at any time, with no penalty or loss of benefits to which you are otherwise entitled. You may choose to leave the study at any time with no loss of benefits to which you are otherwise entitled.

**Statement of Consent:** I have read this form. I click "I consent" below to indicate my consent to participate in this research study, and will be directed to begin the survey. I click "I do not consent" below to indicate my choice to not participate in this research study, and will be directed to exit the survey.

I consent (1)

I do not consent (2)

**Thank you for participating in this survey!**

**Intentions:** This survey has been designed to collect information pertaining to the utilization of recent research technologies. This information and subsequent analysis will be included as part of a Clinical Research Administration Master of Science degree thesis. No personal or otherwise identifying information is required and all responses will be kept anonymous. By answering the following questions on the survey, you will be providing consent to participate.

**Survey Instructions:** Please answer all of the questions based on your personal experience. Certain questions require a single response while others ask that you select all that apply. You may skip questions that make you feel uncomfortable.

Q1 I have been engaged in research within the last 24 months as a: Principal Investigator or Co-Investigator:

- Principal Investigator (Please complete all remaining questions)
- Co-Investigator (Please complete all remaining questions)
- I have not been engaged in research in the last 24 months (please complete only questions 8 and 9)

Q2 I have been engaged in research as a P.I. or Co-I for:

- 1-5 years
- 6-10 years
- 11-15 years
- 16-20 years
- 20+ years

Q3 My most current research falls under the following category(ies): Select all that apply

- Pharmaceutical
- Medical device
- Retrospective or observational
- Other (please specify) \_\_\_\_\_

Q4 My most current research falls under the following category(ies): Select all that apply

- Investigator initiated
- Industry sponsored (Clinical Trials)
- Other (please specify) \_\_\_\_\_

Q5 My current research utilizes all of the following patient **wearable** data collection technologies: Select all that apply

- Smartwatch (e.g. , Applewatch)
- Fitness Tracker (e.g. , Fitbit)
- Biosensor monitors (e.g. , Patches)
- None
- Other (please specify) \_\_\_\_\_



Q6 My current research utilizes all of the following **smartphone** data collection technologies:  
Select all that apply

- Health/fitness app
- Motion tracking sensor app (e.g. step tracker)
- Health assessments via smartphone
- Informed consent via smartphone
- None
- Other (please specify) \_\_\_\_\_

Q7 My current research utilizes **social media** for the following: Select all that apply

- Recruitment
- Supplying information to patients
- Advertising studies
- Health assessment surveys
- None
- Other (please specify) \_\_\_\_\_

Q8 I feel well informed of recent technological advancements that can be utilized in research.

- None
- Little
- Some
- Substantial
- Unsure

Q9 I believe that recent technological advancements are helpful to research within the health care industry.

- None
- Little
- Some
- Substantial
- Unsure



Q10 Other than the technologies listed above, please inform us of any other technologies you utilize in your current research projects, and any other type or research you are engaged in, if not mentioned above (50 characters or less).

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## Appendix D: CITI Certificates

### COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM) COMPLETION REPORT - PART 1 OF 2 COURSEWORK REQUIREMENTS\*

\* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Stephanie Olio (ID: 5330094)
- **Institution Affiliation:** Eastern Michigan University (ID: 1788)
- **Institution Email:** solio1@emich.edu
- **Institution Unit:** Socd
- **Phone:** 7342771978

- **Curriculum Group:** Social & Behavioral Sciences: Responsible Conduct of Research
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - RCR
- **Description:** This course is for Investigators, staff and students with an interest or focus in Social and Behavioral research. This course contains text, embedded case studies AND quizzes.

- **RecordID:** 18484006
- **Completion Date:** 25-Jan-2016
- **Expiration Date:** N/A
- **Minimum Passing:** 80
- **Reported Score\*:** 89

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Responsible Conduct of Research (RCR) Course Introduction (ID: 1522)	25-Jan-2016	No Quiz
Research Misconduct (RCR-Basic) (ID: 16604)	25-Jan-2016	5/5 (100%)
Data Management (RCR-Basic) (ID: 16600)	25-Jan-2016	5/5 (100%)
Authorship (RCR-Basic) (ID: 16597)	25-Jan-2016	4/5 (80%)
Peer Review (RCR-Basic) (ID: 16603)	25-Jan-2016	4/5 (80%)
Mentoring (RCR-Basic) (ID: 16602)	25-Jan-2016	5/5 (100%)
Using Animal Subjects in Research (RCR-Basic) (ID: 13301)	25-Jan-2016	4/5 (80%)
Conflicts of Interest (RCR-Basic) (ID: 16599)	25-Jan-2016	4/5 (80%)
Collaborative Research (RCR-Basic) (ID: 16598)	25-Jan-2016	4/5 (80%)
Research Involving Human Subjects (RCR-Basic) (ID: 13566)	25-Jan-2016	5/5 (100%)
Responsible Conduct of Research (RCR) Course Conclusion (ID: 1043)	25-Jan-2016	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at [www.citiprogram.org/enh/7f3aa509b5-535a-4f6a-af08-563bd58b1b31-18484006](http://www.citiprogram.org/enh/7f3aa509b5-535a-4f6a-af08-563bd58b1b31-18484006)

Collaborative Institutional Training Initiative (CITI Program)  
Email: [support@citiprogram.org](mailto:support@citiprogram.org)  
Phone: 888-529-5929  
Web: <https://www.citiprogram.org>

**COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)  
COMPLETION REPORT - PART 1 OF 2  
COURSEWORK REQUIREMENTS\***

\* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements

- Name: Stephanie Ono (ID 5759297)
- Email: [REDACTED]
- Institution Affiliation: [REDACTED]
- Institution Unit: [REDACTED]
- Phone: [REDACTED]
  
- Curriculum Group: Good Clinical Practice Course (GCP)
- Course Learner Group: Same as Curriculum Group
- Stage: Stage 1 - GCP
- Description: This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.
  
- ReportID: 20672663
- Completion Date: 31-Aug-2016
- Expiration Date: 30-Aug-2020
- Minimum Passing: 85
- Reported Score\*: 96

**REQUIRED AND ELECTIVE MODULES ONLY**

	DATE COMPLETED	SCORE
[REDACTED]	31-Aug-2016	No Quiz
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices (ID 1350)	31-Aug-2016	3/3 (100%)
Overview of New Drug Development (ID 1351)	31-Aug-2016	5/5 (100%)
Overview of ICH GCP (ID 1352)	31-Aug-2016	3/4 (75%)
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID 1354)	31-Aug-2016	3/4 (75%)
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID 1355)	31-Aug-2016	3/3 (100%)
Investigator Obligations in FDA-Regulated Research (ID 1356)	31-Aug-2016	5/5 (100%)
Managing Investigational Agents According to GCP Requirements (ID 1357)	31-Aug-2016	5/5 (100%)
Overview of U.S. FDA Regulations for Medical Devices (ID 1358)	31-Aug-2016	3/3 (100%)
Informed Consent in Clinical Trials of Drugs, Biologics, and Devices (ID 1359)	31-Aug-2016	4/4 (100%)
Detecting and Evaluating Adverse Events (ID 1360)	31-Aug-2016	4/4 (100%)
Reporting Serious Adverse Events (ID 1361)	31-Aug-2016	4/4 (100%)
Audits and Inspections of Clinical Trials (ID 1363)	31-Aug-2016	5/5 (100%)
Monitoring of Clinical Trials by Industry Sponsors (ID 1362)	31-Aug-2016	5/5 (100%)
Completing the CITI GCP Course (ID 1364)	31-Aug-2016	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing Institution identified above or have been a paid Independent Learner.

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**CITI Program**  
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**COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)**

**COMPLETION REPORT - PART 2 OF 2  
COURSEWORK TRANSCRIPT\*\***

\*\* NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Stephanie Otto (ID: 5759297)
- **Email:** [REDACTED]
- **Institution Affiliation:** [REDACTED]
- **Institution Unit:** [REDACTED]
- **Phone:** [REDACTED]
  
- **Curriculum Group:** Good Clinical Practice Course (GCP)
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - GCP
- **Description:** This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training Identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.
  
- **Report ID:** 20672663
- **Report Date:** 13-Jan-2017
- **Current Score\*\*:** 96

**REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES**

	<b>MOST RECENT</b>	<b>SCORE</b>
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices (ID: 1350)	31-Aug-2016	3/3 (100%)
Overview of New Drug Development (ID: 1351)	31-Aug-2016	5/5 (100%)
Overview of ICH GCP (ID: 1352)	31-Aug-2016	3/4 (75%)
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID: 1354)	31-Aug-2016	3/4 (75%)
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID: 1355)	31-Aug-2016	3/3 (100%)
Investigator Obligations in FDA-Regulated Research (ID: 1356)	31-Aug-2016	5/5 (100%)
Managing Investigational Agents According to GCP Requirements (ID: 1357)	31-Aug-2016	5/5 (100%)
Overview of U.S. FDA Regulations for Medical Devices (ID: 1358)	31-Aug-2016	3/3 (100%)
Informed Consent in Clinical Trials of Drugs, Biologics, and Devices (ID: 1359)	31-Aug-2016	4/4 (100%)
Detecting and Evaluating Adverse Events (ID: 1360)	31-Aug-2016	4/4 (100%)
Reporting Serious Adverse Events (ID: 1361)	31-Aug-2016	4/4 (100%)
Audits and Inspections of Clinical Trials (ID: 1363)	31-Aug-2016	5/5 (100%)
Monitoring of Clinical Trials by Industry Sponsors (ID: 1362)	31-Aug-2016	5/5 (100%)
Completing the CITI GCP Course (ID: 1364)	31-Aug-2016	No Quiz
Saint Joseph Mercy Health System (ID: 12711)	31-Aug-2016	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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 Phone: 888-529-5929  
 Web: <https://www.citiprogram.org>

## **Xu Zhang**

404-661-2526, xzhang.ga@gmail.com

8181 Fannin St, #328, Houston, TX, 77054

### **SUMMARY OF QUALIFICATIONS**

- Extensive experiences in trial design and trial proposal/protocol development
- Expertise in causal inference, propensity score, model validation and calibration, cost-effective analysis, variable selection, multi-state model, diagnostic test evaluation, analysis of time-to-event data and longitudinal data
- Profound knowledge in statistical/big data/machine learning methodologies
- Proficiency in SAS, R and STATA

### **WORK EXPERIENCES**

#### **Associate Professor, 2016 – present**

University of Texas Health Science Center at Houston, Houston, TX

- Perform univariate, stratified and multivariable analyses of various types of data; implement variable selection using the forward stepwise and LASSO methods; validate and calibrate models.
- Conduct size/power calculations and write statistical analysis plans for proposals of clinical trials, observational studies and experiments.
- Performed univariate and multivariable analyses of survival endpoints including single, composite surrogate and dynamic endpoints; defined the novel dynamic endpoint for post-transplantation outcome in leukemia patients by creating the multi-state model.
- Taught Categorical Data Analysis to a class of 40+ students; delivered the lecture about Bayesian Network.

#### **Associate Professor, 2013 – 2016**

Department of Data Science, University of Mississippi Medical Center, Jackson, MS

- Developed statistical components of single-arm and randomized two- or multi-arm phase II clinical trials with binomial, time-to-event and continuous endpoints; determined sample size and power based on multiple endpoints; wrote statistical analysis plans for the primary and secondary endpoints.
- Implemented group sequential methods using the error spending function in trial design; estimated probabilities of stopping at stages and the expected number of enrollment; implemented the sequential probability ratio test (SPRT) to define the safety stopping rule.
- Served as member of Institutional Review Board; reviewed and critiqued clinical trial proposals and protocols; clarified the statistical concepts in protocols to the board.
- Collaborated with radiologists to evaluate accuracy and reproducibility of continuous markers as well as dichotomous and ordinal diagnostic tools.
- Conducted cost-effective analysis (CEA) to compare surgery versus surveillance strategy for patients with Bosniak III renal cyst; created the multi-state models for estimating gender-specific lifetime; calculated quality-adjusted lifetime and cost based on Medicare reimbursement rates; evaluated and interpreted the incremental cost-effectiveness ratio (ICER).

- Explored genomic data such as Gene Expression Omnibus (GEO), the Cancer Genome Atlas (TCGA) and EMBL-EBI to screen for or validate genes predictive of cancer genesis/progression; programmed with R/Bioconductor to correlate multiple genes or associate genomic markers with survival outcomes.

### **Assistant Professor, 2005 – 2012**

Department of Mathematics and Statistics, Georgia State University, Atlanta, GA

- Conducted methodological researches on competing risks, adjusted survival, adjusted cumulative incidence and length-biased sampling.
- Collaborated with researchers in nutrition to analyze national survey data (NHANES) to examine trend of vitamin D in US population.
- Directed student to perform principal component analysis (PCA) on dietary intake data and associate dietary factors to vitamin D deficiency; collaborate with biologists to cluster marine animals using the multidimensional scaling (MDS) method.
- Taught at both undergraduate and graduate levels including Elementary Statistics, Biostatistics, SAS Programming, Multiple Regression, and Longitudinal Data Analysis; wrote comprehensive and qualifying exams; contributed to the curriculum development; directed five students to write theses and dissertation.

### **Statistician, 2003 – 2005**

Department of Mathematics and Statistics, Georgia State University, Atlanta, GA

- Served as key statistician on projects studying effects of hospital and surgeon volumes on survival using the Medicare-SEER linked database; implemented propensity score to control for the imbalanced distribution of characteristics in arms; employed the frailty model to adjust for correlation of clustered data.
- Analyzed the Medicare claim database (5% random sample) to study healthcare disparity.

### **EDUCATION**

PhD in Biostatistics, 2005, Medical College of Wisconsin, Milwaukee, WI

MS in Applied Statistics, 2001, Northern Illinois University, DeKalb, IL

BS in Economics, 1995, Northern Jiaotong University, Beijing, China

### **PUBLICATIONS**

**Selected from a total of 76 peer reviewed publications:**

**(Citations as first/corresponding author 300+; Citations as second author 800+; Total citations 2400+)**

1. Zhang X, Loberizab FR, Klein JP, Zhang MJ (2007). A SAS macro for estimation of direct adjusted survival curves based on a stratified Cox regression model. *Computer Methods and Programs in Biomedicine* 88, 95-101. [Citation: 170; referenced by SAS/STAT manual]
2. Zhang X, Zhang MJ (2011). SAS macros for estimation of direct adjusted cumulative incidence curves under proportional subdistribution hazards models. *Computer Methods and Programs in Biomedicine* 101, 87-93. [Citation: 63]



3. Zhang X, Zhang MJ, Fine JP (2011). A proportional hazards regression model for the subdistribution with right censored and left truncated competing risks data. *Statistics in Medicine* 30, 1933-1951. [Citation: 44]
4. Zhang X, Akcin H, Lim HJ (2011). Regression analysis of competing risks data via semi-parametric additive hazards model. *Statistical Methods and Applications* 20, 357-381.
5. Zhang X (2012). Nonparametric inference for inverse probability weighted estimators with a randomly truncated sample. *Journal of Data Science* 10, 673-691.
6. Zhang X (2013). Comparison of restricted mean survival times between treatments based on a stratified Cox model. *Bio-Algorithms and Med-Systems* 9(4), 183-189.
7. Zhang X (2015). Nonparametric inference for an inverse-probability-weighted estimator with doubly truncated data. *Communications in Statistics - Simulation and Computation* 44, 489-504.
8. Zhang X, Li J and Liu Y (2017). Inference for probability of selection with dependently truncated data using a Cox model. *Communications in Statistics - Simulation and Computation* 46:1944-57.
9. Qi L, Zhang X, Wang L, Sun Y, Zhao Y (2018). Weighted estimators for additive hazards models with missing covariates. *Annals of the Institute of Statistical Mathematics*, <https://doi.org/10.1007/s10463-018-0648-y>
10. Liu Y, Li J, Zhang X\* (2017). Analysis of dependently truncated data in Cox framework. *Communications in Statistics-Simulations and Computation* 47:1677-95.
11. Zhang X, Jiang Y, Zhao Y, Akcin H (2018). Nonparametric estimation of a cumulative hazard function with right truncated data. In *Frontiers of Biostatistics and Bioinformatics*. Springer.

**Complete list of publications can be found at**

<https://scholar.google.com/citations?user=sVwptR4AAAAJ&hl=en>

**AWARDS AND PROFESSIONAL MEMBERSHIPS**

- Director's Award, Division of Statistics, Northern Illinois University, 2001
- Student of the Year, Division of Biostatistics, Medical College of Wisconsin, 2003
- American Statistical Association, 2001 – Present
- International Chinese Statistical Association, 2008 – Present
- Invited session organizer at ENAR 2015 and ICSA 2016
- Referee for *Journal of the American Statistical Association*, *Biometrics*, *Statistics in Medicine*, *Lifetime Data Analysis*, *Journal of Biopharmaceutical Statistics* and etc.
- Guest editor of *New Advances in Biostatistics*, special issue of *Journal of Probability and Statistics*, 2017-2018

**TECHNICAL SKILLS**

- Software: SAS, R, STATA, R/Bioconductor, GraphPad
- Programming Languages: R, MySQL, Python