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Utilization of Opt-out Registries in Emergency Clinical Research

Samkeliso Mawocha

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Utilization of Opt-out Registries in Emergency Clinical Research

by

Samkeliso C. Mawocha

Thesis

Submitted to the College of Health and Human Services

Eastern Michigan University

in fulfillment of the requirements

for the degree of

MASTER OF SCIENCE

in

Clinical Research Administration

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March 15, 2011

Ypsilanti, Michigan

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Abstract

Background: Emergency clinical research aims to study and develop new treatments for acute injuries and illnesses such as stroke, traumatic brain injury, seizures, and meningitis. While the regulations require that researchers provide information about ways in which individuals wishing to be excluded from a study may indicate this preference, they do not require emergency clinical research investigators to provide specific resources to members of the public who may wish to opt out of the research.

Objectives: We investigated the methods which potential research subjects at a Midwest US university community might use to opt out of emergency clinical researcher. The primary aim of this research was to determine the method which potential emergency research subjects would prefer to use to opt out of emergency clinical research (e.g. by being listed online in a registry, by wearing a bracelet, or through direct communication with the research team).

Methods: Students and staff at Eastern Michigan University in Ypsilanti, Michigan, were asked to respond to an online survey.

Findings: 218 respondents participated in the survey. The data showed that 43.1% of respondents preferred to opt out by talking to the study team in person, while 39.2% of study respondents preferred opting out online.

Conclusions: We identified methods which members of a selected population preferred to use to opt out of emergency clinical research. Further studies in larger populations are needed to investigate whether different groups prefer different opt out methods for emergency clinical research.

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Chapter 1: Introduction and Background

According to the National Center for Health Statistics, there were roughly 124 million visits to hospital emergency departments in the United States in 2008 (NCHS, 2011). Rapid interventions must be implemented by paramedics in the field or by physicians in the Emergency Department where there is a narrow window of opportunity in treating damage from injuries and illness.

Sometimes, there are no effective treatments that have been shown in clinical trials to reduce morbidity and mortality, or shown to improve outcomes in survivors of these injuries. Emergency clinical research aims to study and develop new treatments for acute injuries and illnesses such as stroke, traumatic brain injury, seizures and meningitis. This type of research is important because it addresses an unmet medical need, and the potential to create new pharmacological therapies or improve current drugs or modes of treatment is great.

In the Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Emergency Clinical Research is defined as “a planned clinical investigation that requires prior written FDA authorization to proceed and involves subject(s) who are in a life-threatening situation for which available treatments or in vitro diagnostic tests are unproven or unsatisfactory.”

Federal regulations contain specific Human Subject Protection requirements pertaining to Emergency Clinical Research, found in 21 CFR 50, 56, 312, and 812 (United States Food and Drug Administration, 2006). Revised federal regulations for Emergency Clinical Research became effective November 1, 1996. 21 CFR 50.24 provides an exception from the standard requirement to obtain informed consent from each subject, or from the subject’s legally

authorized representative, prior to enrollment in the study (Exception from Informed Consent, or EFIC). These additions to the Code of Federal Regulations were necessary because Emergency Clinical Research involves a particularly vulnerable population: persons with life-threatening conditions who can neither give informed consent nor actively refuse enrollment. Since the Exception from Informed Consent policy was instituted in 1996, seventy-seven studies containing requests for exemption from informed consent have been submitted to the FDA. Out of this number, about forty-two were granted permission to be conducted using EFIC (Center for Drug Evaluation and Research, 2010).

Emergency clinical research is fundamentally different from other types of clinical research, in which potential subjects and their families have the opportunity to consider participation over longer periods of time. Studies involving EFIC are further complicated since, in most cases, the potential subjects cannot be prospectively located in order to ask their consent, or “opt-in.” For example, in a hypothetical study using a novel drug to treat severe burns, it is not logistically feasible for researchers to identify and contact every potential subjects in a given community in which the emergency clinical research is to occur. Therefore, before emergency clinical research using EFIC may be initiated, 21 CFR 50.24(a)(7)(i) states that Community Consultation, a two-way dialog between the researcher and members of the community in which the research will take place as well as the community already affected by the condition being studied, must be conducted. Community Consultation means providing the opportunity for discussions with, and soliciting opinions from, these two types of community: 1) the geographical community from which the study subjects will be drawn, and 2) the disease-related community or people affected by the condition being studied.

As described in the FDA Guidance for Exception from Informed Consent (2006), , Community Consultation provides the opportunity for clinical investigators to:

- “(1) Inform the communities that informed consent will not be obtained for most (or all) research subjects prior to enrollment,
- (2) Inform the communities about all relevant aspects of the study, including its risks and expected benefits,
- (3) Hear the perspective of the communities on the proposed research, and
- (4) *Provide information about ways in which individuals wishing to be excluded may indicate this preference*” (numbering and emphasis added by author).

It should be noted that Community Consultation does not mean “community consent.” This is a common misconception among researchers and the community. The Code of Federal Regulations further require Public Disclosure, which is dissemination of information from the research team to the community about the emergency clinical research in a way that allows the researchers to make a reasonable assumption that the communities are aware of the research prior to the beginning of the study, while the research is being conducted, and once enrollment has concluded and results are available. The Institutional Review Board (IRB) must also be satisfied that the community is aware of the risks and expected benefits, and the fact that the study will be conducted, with no considerable objection. Per the FDA’s EFIC guidance (2006), *“Public Disclosure should also include suggestions as to how individuals who do not want to participate in the research can communicate this (e.g., by use of medical identification bracelets or necklaces).”* IRBs are required to review plans and materials for Community Consultation and Public Disclosure, and determine whether they are adequate. During the conduct of the study, FDA guidelines state that the protocol must provide that first respondents should examine, as

time permits, “*easily accessible sources of information for evidence that may be related to that individual's willingness to participate in research*” The guidelines include examples such as an individual's medical identification bracelets or necklaces (Emphasis added by author).

Statement of the Problem

While the regulations require that researchers provide ways in which individuals wishing to be excluded from a study may do so, there is not a gold standard and one particular opt-out method over another is not mandated. The opt-out method(s) used for a particular study is at the discretion of the researcher and IRB where the trial will be conducted. A review of the PubMed.org website (the MEDLINE database of citations, abstracts, and full text articles on life sciences and biomedical topics) reveals that no published research has been undertaken to describe or to assess opt-out registries or other opt-out options in emergency clinical research.

Purpose of the Study

In this study, we considered several methods individuals could use to opt out of emergency research studies. The primary aim of this research was to determine the method which potential emergency research subjects would prefer to use to opt out of emergency clinical research (e.g. online in a registry, by wearing a bracelet, or through direct communication with the research team).

Significance of the Study

Findings in this study might offer suggestions for best practice methods for researchers to provide opt-out resources to members of the public who wish to exercise that right. This research may be useful as a guide in the development of new opt-out methods or the improvement of

current processes. Information from this research could be useful for researchers attempting to decide how to direct resources in future studies.

Chapter 2: Research Design and Methodology

Sample Selection

The population of interest for this study was adults (older than 18 years) attending or employed by Eastern Michigan University (EMU) in Ypsilanti, Michigan. There are 22931 students enrolled at EMU and 681 faculty members (EMU Institutional Research and Information Management, 2010). Each person has a university-issued email address with the domain name @emich.edu. Demographic profiles including gender, age, and race of the EMU population are provided in Appendices B-E.

An electronic survey was initially sent via SurveyMonkey™ (<http://www.surveymonkey.com/>) to 3162 randomly selected emails of EMU students and faculty in the EMU Eagle Mail directory between December 10, 2010, and February 9, 2011. An example email is provided in Appendix F. A second reminder email was then sent two to three weeks after the initial email, between January 7 and February 24, 2011. An example reminder email is provided in Appendix G. Email recipients who had opted out or who had previously responded to the initial survey were filtered out. Email addresses that were returned as undeliverable were also filtered out, so that the survey was successfully delivered to 2902 recipients. The survey is provided in Appendix H.

Human Subjects Protection

Prior to initiating this research, we submitted a Request for Approval of Research Involving Human Subjects to the Eastern Michigan University College of Health and Human Services (CHHS) Human Subjects Review Committee (HSRC). This research contained minimal risk, and no Protected Health Information was collected. The HSRC approved the research on December 1, 2010. A copy of the approval letter is provided in Appendix A. An informed

consent document, which explained the purpose of the research, was included on the first page of the online survey. Participants were given an opportunity to decline participation and exit the survey, or electronically sign consent and proceed to the survey. Each demographic question within the survey had a “Prefer not to respond” option.

Data Collection

The sample consisted of 20 questions (including 8 demographics and socio-economic status questions). The survey took less than 15 minutes to complete. Categorical responses were available for demographic and personal characteristic questions, which were modeled after previously validated scales used by the Pew Internet and American Life Project. Two survey questions contained an “It depends” option, which required a free text entry. An electronic survey was selected as the method of distribution for this survey for two main reasons:

1. Costs associated with paper and postage was eliminated.
2. The readily accessible email addresses in EMU Eagle Mail directory provided a select sampling frame, allowing a non-probability sample and statistical inferences to be made provided there were sufficient responses.

Chapter 3: Presentation and Analysis of Data

Two hundred and eighteen individuals responded to the survey; therefore the overall response rate was 7.5%. Two hundred and nine individuals completed the survey: one hundred and twenty-seven individuals responded to the initial email; and ninety-one responded to the second email. Nine individuals opened the survey but declined to electronically sign the informed consent document on the first page and were therefore force exited out of the survey. Selected respondent characteristics are provided in Table 1.

Table 1

Respondent characteristics (N = 209)

	N	%*
Age distribution (years)		
Less than 18 (excluded from analysis)	1	0.5
18-44	171	83
46-65	32	15.5
66 and older	2	1
Chose not to provide/skipped question	3	1.4
Gender		
Female	135	65.5
Male	70	34
Chose not to provide/skipped question	3	0.5
Race		
American Indian or Alaska Native	2	1.0
Native Hawaiian/other Pacific Islander	1	0.5
Asian or Asian American	6	2.9
Black or African American	23	11.2
White	158	77.1
Other (biracial or multi-racial)	7	3.4
Chose not to provide/skipped question	4	1.9
Occupation		
Full time student	99	48.3
Part time student	50	24.4
Not currently a student	56	27.3
Chose not to provide/skipped question	4	1.9
Education		
Grade 12 or GED (High school graduate)	7	3.4
College 1 to 3 yrs (Some college)	69	33.7
College 4 yrs or more (College graduate)	129	62.9

*percents do not always add up to 100 due to rounding.

Approximately 11% of respondents indicated that they would opt *themselves* out of emergency clinical research, while nearly 43% were not sure (Table 2). Respondents who indicated “It depends” (13.9%) were asked to provide more information in an open-ended text box. These responses are discussed further below.

Table 2

Response to opting self out of emergency clinical research (N = 209)

	N	%*
Response to opting self out		
Yes	22	10.6
No	69	33.2
Did not know	88	42.3
It depends	29	13.9
Chose not to provide/skipped question	1	0.5

*percents do not always add up to 100 due to rounding

One concern identified during analysis was the number of respondents who did not know or who were not sure whether they would opt out of emergency clinical research. During an in-person interview, respondents’ understanding of questions can be accessed and any unclear information can be further explained by the interviewer, if necessary. However, the format of a web-based survey does not allow such an assessment of the respondents’ understanding of information.

Those respondents who answered “Yes” or “It depends” to the question of whether they would personally opt out were then asked *how* they would prefer to opt out of emergency clinical research. Approximately 43% preferred to do so in person by talking to the researchers; 39.2% preferred going online to opt out; and nearly 4% would opt out by wearing a bracelet for the duration of the study (Table 3).

Table 3

Preferred method for opting out of emergency clinical research (N = 51)

	N	%*
Preferred method for opting out		
In person, by talking to the study researchers	22	43.1
Online	20	39.2
Wearing a bracelet for the duration of the study	2	3.9
Did not know	5	9.8
Other method	2	3.9

*percents do not always add up to 100 due to rounding

Table 4

Response to opting family members out of emergency clinical research (N = 209)

	N	%*
Response to opting family members out		
Yes	27	13
No	54	26.1
Did not know	100	48.3
It depends	26	12.6
Chose not to provide/skipped question	2	1

*percents do not always add up to 100 due to rounding

Thirteen percent of survey respondents indicated that they would opt their *family members* out of emergency clinical research. Most (48.3%) were not sure what they would do or did not know (Table 4). In an effort to better understand the reasons *why* an individual would opt out of emergency clinical research, respondents who answered “It depends” to the question of whether they would personally opt out were asked to provide more information in an open-ended text field.

Five general themes or concepts were derived independently from each of the open-ended text entries by two reviewers. Where there was disagreement, a third reviewer was used to arrive at a consensus. An example of an open-ended entry read: “It depends on the type of research, my condition, what the research involves [sic] and the risk involved.”

The concepts identified in Table 5 illustrate several reasons why an individual might wish to opt out of clinical research.

Table 5

Concepts that would impact respondents' decision to either participate or opt out of emergency clinical research

n = number of times particular concept was referenced in open-ended responses

	n	%
Concept		
Perceived risk/benefit ratio	10	28.6
Other treatment options	6	17.1
Severity of medical condition	7	20
Needed more information or context about emergency clinical research or specific study	11	31.4
Research did not conflict with belief system	1	2.9

N = 35, total number of coded concepts within 29 responses.

Table 6 contains the five major themes or concepts derived from open-ended responses from respondents who indicated “It depends” to the question of whether they would opt *family members* out of emergency clinical research. One example of an open-ended entry read: “Everything will depend on the chances of survival by taking the alternative action. If the alternative doesn’t promise survival I think I will go ahead an [sic] accept the emergency clinical research, after all I’ve got nothing to loose [sic] but everything to gain if the treatment works.” Another example read: “on the age of a parent what type of quality of living.”

Table 6

Concepts that would impact respondents' decision for family member to either participate or opt out of emergency clinical research

n = number of times concept was referenced in open-ended responses

Concept	n	%
Perceived risk/benefit ratio	11	37.9
Other treatment options	2	6.9
Severity of medical condition	4	13.8
Needed more information or context about emergency clinical research or specific study	5	17.2
Wishes/attitudes of family member	6	20.7
Opinion of other family members	1	

N = 29, total number of coded concepts within 26 responses.

Generally, the concepts identified were similar in respondents' decision to opt self or family out of emergency clinical research. The perceived risk/benefit ratio was a commonly cited factor in response to both questions. Notably, respondents indicated that their decision depended upon receiving further information about emergency clinical research or details about the specific research that would be done.

Table 7

Cross-tabulation of opting out self and opting out family members (N = 51)

	Opt out self	Opt out self
	Yes	It depends
Response to opting family member out		
Yes	10 45.5%	1 3.4%
No	6 27.3%	1 3.4%
Did not know	5 22.7%	6 20.7%
It depends	1 4.5%	21 72.4%
Total (N)	22	29

Cross-tabulation of the survey data showed that 45.5% respondents who opted themselves out of emergency research indicated that they would also opt out their family members. Approximately 72% of respondents who indicated “It depends” to opting themselves out also indicated “It depends” for opting out family members.

Table 8

Cross-tabulation of opting out self by sex (N = 50)*

	Opt out self	Opt out self
	Yes	It depends
Sex		
Female	13 61.9%	21 72.4%
Male	8 38.1	8 27.4
Total (N)	21	29

*One respondent skipped this question

Most (61.9%) respondents who indicated that they would opt themselves out of emergency research were female. Also, 72.4% of respondents who indicated “It depends” to the question of whether they would opt themselves were female.

Table 9

Cross-tabulation of opting out self by race (N = 50)*

	Opt out self	Opt out self
	Yes	It depends
Race		
American Indian/Alaska Native	1 4.8%	0 0%
Native Hawaiian/Other Pacific Islander	0 0%	1 3.4%
Asian	0 0%	0 0%
Black or African American	7 33.3%	3 10.3%
White	11 52.4%	22 75.9%
Other (biracial or multiracial)	0 0%	1 3.4%
Total	21	29

*One respondent skipped this question

Most (52.4%) respondents who indicated that they would opt themselves out of emergency research - or answered, “It depends” 75.9% - self-identified as White.

Chapter 4: Discussion and Conclusion

Discussion

In this study, we identified the method which some members of a selected population preferred to use to opt out of emergency clinical research. Only 10.6% of respondents in this survey indicated that they would opt out – while about a third (33.2%) indicated that they would be willing to participate in emergency clinical research. In a 2009 study of community attitudes towards emergency research and EFIC, the researchers found that survey respondents generally supported the concept of emergency clinical research. This finding has been shown in other studies of public attitudes towards emergency research (Biros, 2009).

Data from this survey showed that 43.1% of respondents preferred to opt out by talking to the study team in person. We believe that the first likely time point for this interaction would be during the community consultation process prior to the beginning of the study. The data also showed that 39.2% of study respondents preferred opting out online.

A larger sample size would allow statistical inferences to be made about whether different demographic groups preferred one opt out method to another. The ability to generalize results was one goal; however, the response rate for this survey was 7.6%, and the survey responders should not be considered representative of the population. One drawback of email surveys is that unknown addresses are intercepted by SPAM filters and relegated to recipients' Junk email folders. Potential respondents may have valid concerns about privacy and confidentiality, given the proliferation of data-harvesting programs on the internet, and therefore choose to not respond to an email survey.

Because of these and other issues, email survey response rates vary widely. For example, in an online survey of affirmative action using students at the University of Michigan, the response rates were 41.5 percent (excluding partial completions) and 47.1 percent (including partial questionnaires). In a Detroit Area Study conducted at the University of Michigan in early 1999 the response rate was only 4.8% (Couper, 2000). As with other types of surveys, non-response does present a great challenge. Further research needs to be conducted on non-response rates in online surveys specifically. This research could identify conditions under which low response rates on Web may still yield useful information and provide more data on how to improve online response rates.

Though the proportion of respondents in this research who indicated that they would opt out of emergency research is not significant, there are important practical observations for research teams to consider when planning emergency clinical research. These plans should include resources to track individuals who may not wish to participate in the research.

Within a registry, researchers would record the relevant data on those individuals who contact them wishing to opt out, for the duration of the study. Prior to each enrollment, researchers would check the name of the patient against this registry to ensure that they had not opted out. Data from this survey indicate that most individuals who wish to opt out of research want to do so by speaking to someone. This interaction should be an opportunity for the researchers to provide more information and hear out any concerns or correct any misconceptions that the individual has. A study website should be an additional consideration, as it would provide a resource for individuals to obtain more information about the study. The website would also provide a public registry where those who wished to could opt out. Since the online site would require individuals to enter personal and identifying information such as their

full name and date of birth, the researchers would need to plan to provide a secure, encrypted site. Therefore, the effort to build, maintain, and monitor security within this online database would need to be part of the study budget. Education of the research team would need to be conducted throughout the study to ensure that each enrolling researcher was trained to follow the steps prior to enrolling a subject. The opt-out process should not only be a part of Public Disclosure and made available during the Community Consultation process, but also throughout the conduct of the study.

In this survey, 74.1% of survey respondents indicated that they had access to internet for more than 8 hours a day, or unlimited access. A recent study by the Pew Internet and American Life Project found that though 79% of Americans use the internet, some members of the public do not have daily or frequent access to the Internet. It is unlikely that these potential research subjects would know about an online option to opt out, nor would they be able to opt out since they did not have access to the internet. An alternative method is for the research team to provide a wristband or bracelet for those who wish to opt out. The bracelet would state “Study Name – Declined” and the individual would have to keep the bracelet on their person at all times during the study enrollment period. Only 3.9% of respondents indicated a preference for the bracelet option in this survey. However, researchers should consider having bracelets available as an additional option to potential study subjects. The registry could also be utilized to track individuals who had requested and received a bracelet to prevent them from being enrolled in the research again, should they present to an Emergency Department without a bracelet. One caveat for researchers is that individuals who choose the wristband/bracelet option may not wish to be placed in a registry at all. For example, they may have concerns about their personal data being included in a registry. Therefore, it would be imperative that researchers first seek permission to

enter these individuals into the opt-out database. An alternative policy that researchers can adopt at the outset of the study is that the responsibility falls onto the individual who chooses the bracelet option, who must wear the bracelet at all times.

In each of the opt-out methods above, the study teams should make it clear that opting out confers no guarantee that they will not be enrolled into a study. For example, if they are brought to an Emergency Department without adequate identification (passport, driver's license, or other state-issued ID) to check against the opt-out registry, or without the bracelet, they could still be enrolled in the study. In this survey, 48.8% of respondents reported that they had experienced a medical emergency that required a visit to an Emergency Department in the past five years. Survey techniques can reach a broad population but may be susceptible to responder bias. For example, it is possible that previous emergency department visits increased the likelihood that this particular group would respond to this survey. Also, 65.5% of the respondents to the survey were female and 77% were White. In a study of survey response and non-response at a selective liberal arts college, Porter and Whitcomb (2005) demonstrated that female students responded to surveys at higher rates than male students. Several studies in survey literature indicate that there are certain characteristics associated with survey participation and survey response, namely being female, White, more affluent or having more academic achievement and social engagement. Therefore, the selection of respondents from a university community of students and staff makes it difficult to generalize to the general population. Studies in larger populations and using other methods, for example by mail survey, are needed to investigate whether different groups prefer different opt out methods for emergency clinical research.

Conclusion

The autonomy of human subjects is regarded as a tenet of clinical research. A small proportion of individuals may not wish to participate in emergency clinical research. The utilization of opt out registries is one way that researchers can safeguard that autonomy, thereby building public trust in the research enterprise.

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Appendix A – College of Human Health Services Human Subjects Review Committee

Decision Letter



COLLEGE of HEALTH & HUMAN SERVICES
www.emich.edu/chhs

December 1, 2010

Samkeliso Charmaine Mawocha
c/o Irwin Martin
Eastern Michigan University
School of Health Sciences
Ypsilanti, Michigan 48197

Dear Samkeliso Charmaine Mawocha,

The CHHS Human Subjects Review Committee has reviewed the revisions to your proposal entitled: "Utilization of Opt-Out Registries in Emergency Clinical Research." (CHHS 11-004).

The committee reviewed your proposal and its revisions and concluded that the risk to participants is minimal. Your study is approved by the committee.

Good luck in your research endeavors.

Sincerely,

A handwritten signature in blue ink, appearing to read "George Liepa".

George Liepa, Ph.D.
Chair, CHHS Human Subjects Review Committee

**Appendix B – EMU Student Enrollment by Race/Ethnicity, Gender and Level; Quick Facts
– Fall 2010, Official Record (Snapshot date: 01/15/2011)**

	UG MEN	UG WOMEN	UG UNK	GR MEN	GR WOMEN	GR UNK	TOTAL
Race							
American Indian/Alaska Native	39	62	0	14	17	0	132
Asian	188	222	0	41	80	1	532
Black or African American	1475	2354	3	191	510	2	4535
Hispanic/Latino	203	259	0	37	61	0	560
Native Hawaiian/Other Pacific Islander	8	15	0	1	7	0	31
Nonresident Alien	176	158	2	223	223	1	783
Race/Ethnicity Unknown	608	747	25	99	180	4	1663
Two or More Race	47	93	2	6	15	0	163
White	5198	6660	10	1227	2077	8	15180
Total	7942	10570	42	1839	3170	16	23579

**Appendix C – EMU Student Average Age; Quick Facts – Fall 2010
OFFICIAL RECORD (Snapshot date: 01/15/2011)**

	Avg. Age
Level	
Undergraduate	24.27
Graduate	33.23
Total	26.18

Appendix D – EMU Faculty Profile by Race - Fall 2009

	Count	Percent
Race		
American Indian/Alaska Native	5	0.7
Asian	35	9.5
African American	50	7.3
Hispanic/Latino	10	1.5
Native Hawaiian/Other Pacific Islander	0	0
White	551	80.9
Total	681	100.0

Appendix E – EMU Faculty Profile by Gender – Fall 2009

	Count	Percent
Gender		
Female	327	48
Male	354	52

Appendix F - Survey Email

To: [Email]

From: smawocha@emich.edu

Subject: EMU Graduate Student Research Project

Body: Hello, my name is Samkeliso Mawocha and I am a student in the Master of Science in Clinical Research Administration program here at EMU. I am conducting a survey as part of my Master's research project, and your response would be greatly appreciated.

Here is a link to the survey:

<https://www.surveymonkey.com/s.aspx>

This link is uniquely tied to this survey and your email address. Please do not forward this message.

Thank you for your participation!

Please note: If you do not wish to receive further emails from me, please click the link below, and you will be automatically removed from this mailing list.

<https://www.surveymonkey.com/optout.aspx>

Appendix G – Survey Reminder

To: [Email]

From: smawocha@emich.edu

Subject: EMU Student Research - Reminder - Please Read!

Body: Good Afternoon,

Two weeks ago you received an e-mail with my graduate research survey about Emergency Clinical Research. Emergency Clinical Research is a special type of medical research which is approved by the FDA for people who are experiencing a life-threatening emergency (such as a stroke, a brain injury, or a seizure).

I'm emailing again because I would deeply appreciate your opinion and thoughts regarding this concept. Completing this short survey will take you no more than 10 minutes.

Here is a link to the survey:

<https://www.surveymonkey.com/s.aspx>

Thank you very much for your time and for your opinion!

Sam Mawocha

Master of Science in Clinical Research Administration candidate

College of Health and Human Services

Eastern Michigan University

Please note: If you do not wish to receive further emails from me, please click the link below, and you will be automatically removed from this mailing list.

<https://www.surveymonkey.com/optout.aspx>

Appendix H – Survey

1. EASTERN MICHIGAN UNIVERSITY RESEARCH SUBJECT INFORMED CONSENT

WHAT AM I BEING ASKED TO DO?

You are being asked to participate in a research survey. Your participation is voluntary, which means you can choose whether or not you want to participate. If you decide to participate you will be asked to electronically consent below, and then you will proceed to the survey. If you decline to consent you will exit out of the survey.

WHAT IS THE PURPOSE OF THIS SURVEY?

The purpose of this survey is to determine which method potential emergency research subjects prefer to use to opt out of emergency clinical research.

HOW LONG WILL COMPLETING THE SURVEY TAKE? HOW MANY OTHER PEOPLE WILL BE IN THE STUDY?

The survey will take approximately 15 minutes to complete. About 380 students, staff and faculty at Eastern Michigan University will be asked to complete the survey.

WILL I HAVE TO PAY TO COMPLETE THIS SURVEY?

No.

WILL I BE PAID FOR COMPLETING THIS SURVEY?

You will not receive money for completing this survey.

CAN I LEAVE THE SURVEY BEFORE IT ENDS?

You are free to leave the survey at anytime. You can click the 'Exit this survey' link at the top right of any page.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS?

There are no known risks with completing a survey. You may not get any benefit from being in this survey. The information that we get from this survey may help us to understand how best to create opt out registries for emergency research.

HOW WILL MY PRIVACY BE PROTECTED?

SurveyMonkeyTM will not collect your IP address. Data on the website is securely transmitted with SSL encryption. Please read more information about privacy at http://help.surveymonkey.com/app/answers/detail/a_id/3950

Results of the study will be posted to the EMU Library's Digital Commons web site <http://commons.emich.edu>

No personal identifiers will be included in the publishing of the research results.

WHO CAN I CONTACT WITH QUESTIONS, CONCERNS OR COMPLAINTS?

This research protocol and informed consent document has been reviewed and

approved by Eastern Michigan University CHHS Human Subjects Review Committee for use from to . If you have questions about the approval process, please contact Dr. George Liapa (734)487-0077, Chair of the CHHS HSRC
chhs_human_subjects@emich.edu

*****YOU CAN PRINT A COPY OF THIS PAGE FOR YOUR RECORDS AND REFERENCE*****

- Yes, I consent to participate in this survey (click Next to
- No, I decline to participate (click Next to exit the survey)

2. On an average day, how often do you have access to the Internet (e.g., at home, at work, other locations such as a public library)?

- Not at all
- Less than 2 hours a day
- More than 2 hours, but less than 8 hours a day
- More than 8 hours a day or unlimited access
- I don't know/I'm not sure

3. Do you ever go to web sites that provide information or support for people who are interested in a specific medical condition?

- Yes, always
- Yes, most of the time
- Yes, sometimes
- No, never
- I don't know/I'm not sure

4. Have you ever volunteered or participated in any medical research study or clinical trial?

- Yes
- No
- I don't know/I'm not sure

5. In the past 5 years, have you ever had a medical emergency that required you to visit an Emergency Department?

- Yes
- No
- I don't know/I'm not sure

Emergency research is a type of research for people who are in a life-threatening situation that has no known or proven treatment. Emergency researchers study and develop new treatments for injuries and illnesses such as stroke, traumatic brain injury, seizures and meningitis.

Often, there is very little time to treat the damage from these injuries; so treatment must be given very quickly by paramedics at the scene, or in the ambulance on the way to the hospital, or by doctors in the Emergency Department. Sometimes, because of the injuries, the researchers cannot explain the emergency research to the injured person or get permission (consent) to give them the study medicine. Instead, the researchers look for the injured person's legally authorized representative (LAR), usually a family member, to consider their wishes. Sometimes, an LAR is not available quickly. In this situation, the injured person can be included in the emergency research using a Food and Drug Administration (FDA) approved process for emergency situations called Exception from Informed Consent (EFIC).

6. Had you ever heard of emergency clinical research before this survey?

- Yes
- No
- I don't know/I'm not sure

7. Do you make medical decisions for YOURSELF?

- Yes, always
- Yes, most of the time
- Yes, sometimes
- No, never
- I don't know/I'm not sure

8. Do you make medical decisions for any of YOUR FAMILY MEMBERS (i.e. children, elderly parents)?

- Yes, always
- Yes, most of the time
- Yes, sometimes
- No, never
- I don't know/I'm not sure

A potential method to opt out of emergency clinical research is to use an online Opt-Out Registry. An online Opt-Out Registry is a database on the internet that contains the names of people who do not wish to be included in a specific clinical research study.

Researchers must not enroll anyone who is listed in the Registry. Anyone can add their name to the online Opt-out Registry at any time if they do not wish to participate in the emergency clinical research. Placing your name into the Opt-Out registry does not guarantee that you won't be enrolled in the emergency clinical research. For example, if you are brought to an Emergency Department without identification such as a driver's license, passport, or other state-issued ID, you could still be enrolled in the study.

Another potential method to opt out of emergency clinical research is to wear a wristband or bracelet that says "Study Declined". You would have to keep the bracelet on AT ALL TIMES while the study is open.

Yet another potential method to opt out is to contact the study team directly, by telephone or in person, to let them know that you do not want to participate in the study.

9. Have you ever used an online Opt-Out registry to opt out of emergency clinical research before?

- Yes
- No
- I don't know/I'm not sure

10. Have you ever used an Opt-Out bracelet or wristband to opt out of emergency clinical research before?

- Yes
- No
- I don't know/I'm not sure

11. Would you opt yourself out of, or choose not to participate in emergency clinical

research?

- Yes
- No
- I don't know/I'm not sure
- It depends. Please explain:

12. If you answered 'Yes' or 'It depends' to the previous question, how would you prefer to Opt-Out of emergency clinical research?

- In person, by talking to the study researchers
- Online
- By wearing a bracelet for the duration of the research study
- I don't know/I don't remember
- By using another method. Please specify how:

13. Would you Opt-Out your family member(s) from emergency clinical research (i.e. children, elderly parents)?

- Yes
- No
- I don't know/I'm not sure
- It depends. Please explain:

Please complete this next portion of the survey to help us better understand who our survey takers are. Please DO NOT include your name in any of your responses.

14. What is your age?

- Less than 18 years old
- 18-45 years old
- 46-65 years old
- 66 and older
- Choose not to provide

15. What is your sex?

- Female
- Male
- Transgender
- Choose not to provide

16. What is your ethnicity?

- Hispanic or Latino
- Non-Hispanic
- Choose not to provide

17. What is your race?

- American Indian or Alaska Native
- Native Hawaiian or Other Pacific Islander

- Asian or Asian American
- Black or African American
- White
- Other (for example, biracial or multi-racial)
- Choose not to provide

18. Are you currently a student?

- Yes, a full time student
- Yes, a part-time student
- No, not currently a student
- Choose not to provide

19. Are you currently working?

- Yes, working full time
- Yes, working part time
- No, currently unemployed
- No, currently retired
- Choose not to provide

20. If you selected 'Working full Time' or 'Working part time' in the previous question, please select annual salary range:

- Less than \$30, 000 per year
- Between \$30,000 and \$49,999 per year
- Between \$50,000 and \$74,999 per year
- More than \$75, 000 per year
- Choose not to provide

21. What is the highest level of education you have completed?

- Never attended school or only attended kindergarten
- Grades 1 through 8 (Elementary)
- Grades 9 through 11 (Some high school)
- Grade 12 or GED (High school graduate)
- College 1 year to 3 years (Some college or technical school)
- College 4 years or more (College graduate)
- Choose not to provide

