Consortium on Law and Values in Health, Environment & the Life Sciences

2013-14 Student Proposal Cover Page

Applicant Information				
Applicant name:	Laura M Pigozzi		Email: Pigoz002@umn.edu	
Project title:	Examining the gap between a morally valid consent and a legally adequate consent ¿Entiende?			
Department:	Department of Writing Studies	College: CLA		
Degree program:	PhD Rhetoric and Scientific and Technical Communication	Faculty advisor name & email:	Dr. Ann Hill Duin ahduin@umn.edu	☐ NA
Dept. Head:	Dr. Laura Gurak	Dept. Head's email:	gurakl@umn.edu	
Dean:	Dr. Raymond D. Duvall (interim Dean)	Dean's email:	rduvall@umn.edu	

How did you hear about this funding opportunity?
☐ VIP email ☐ The Brief ☐ Advisor ☐ Dept. email/newsletter ☐ OVPR website ☒ Other

Funding

Total amount of funding requested: **$7000.00**

Executive summary (maximum 200 words)

This project examines the adequacy of the informed consent process to convey prescribed information to immigrant Latinos when being enrolled into clinical trials. Currently, it is unclear if meaningful consent can be given. The implication is this population may be participating in clinical trials they don't fully understand, or researchers may be bypassing them as participants for fear of ethical breaches. Including minorities in research is essential to eliminate health disparities and increase the generalizability of research results. This study uses grounded theory to situate it at the intersection of rhetoric and scientific and technical communication, intercultural communication, and bioethics.

Approvals

Check all appropriate approvals required for your proposal. Approvals must be obtained prior to receipt of funding. If you have applied for approval but have not yet received it, indicate that below.

IRB	☐ Yes ☐ No ☐ NA	☐ Application pending	
Other	☒ Yes ☐ No ☐ NA	☐ Application pending	Specify: This project is currently working under IRB #1210P22682. To add this additional video would not require a new submission, but rather a Change of Protocol submission. One Change of Protocol has already been approved to add more participants and additional sites. I don't anticipate any problems with this change request. The request is structured in two Parts.

Checklist

☒ The proposal is 1000 words or less excluding budget, biographies, references and citations.

☒ The proposal includes a work plan with a specific timeline using months or quarters to identify work to be done and completion dates.

☒ The proposal includes a 1-2 paragraph biography of the applicant and all co-investigators.

☒ The budget form is complete including the funds sought for this project, other pending applications for this project, and the amount/source of matching or other funds.

☒	The applicant's faculty advisor is copied on the application email. Professional students w/o advisors check NA.
☒	All necessary approvals are pending or received. This project is currently working under IRB #1210P22682. To add this additional video would not require a new submission, but rather a Change of Protocol submission. One Change of Protocol has already been approved to add more participants and additional sites. I don't anticipate any problems with this change request.

Examining the gap between a morally valid consent and a legally adequate consent ¿Entiende?

Introduction

This research project examines the adequacy of the informed consent process when members of the immigrant Latino community are recruited into clinical trials. This bioethics question is being explored using a multi-disciplinary lens, situating it at the intersection of bioethics, rhetoric, scientific and technical communication, and intercultural communication. Themes emerging through the grounded theory methodology weave together the literature and give direction to the next phases of research. This proposal introduces the research topic, describes the next steps, and explains the overall significance of the project.

Background

Clinical trials are stringent studies performed on human participants that examine the safety and efficacy of experimental therapies. Clinical trials must meet certain ethical and regulatory requirements that are grounded in the principles of the Belmont Report. The principle of respect for persons requires that prospective research participants give informed consent before they are enrolled in a trial.

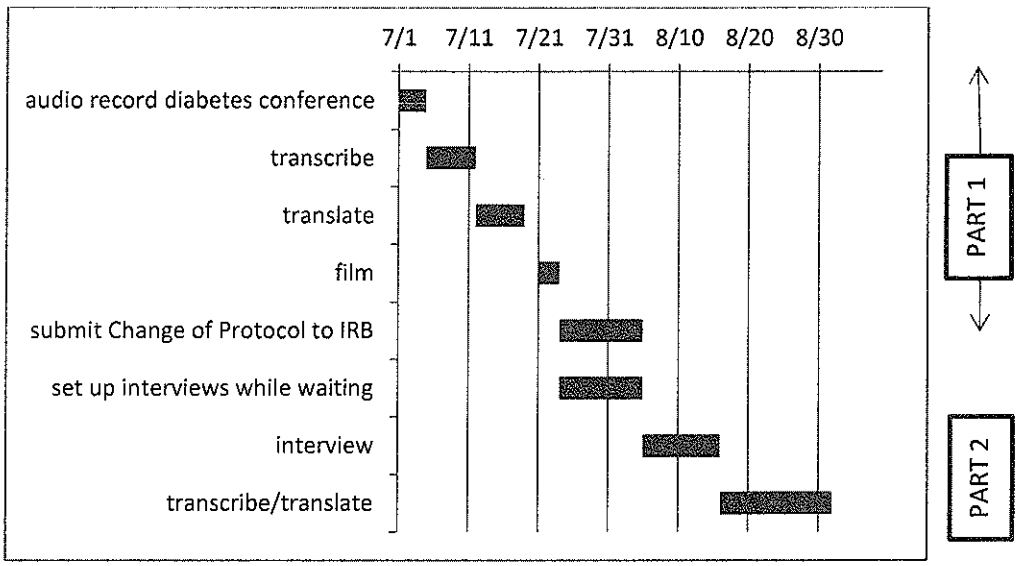
Philosopher John Kleinig (2010) notes that consent is a communicative act, and as such, "...there must be a convention whereby consent given is recognized as such" (p. 11). However, there is no algorithm to determine if the communicative act has been successful. Additionally, there are a number of barriers members of racial and ethnic populations may encounter, especially those with low English language skills. Even when the information is translated into the individual's native language, morally adequate consent may be difficult due to variables such as limited formal education, unfamiliarity with medical vocabulary and concepts, unfamiliarity with Western medicine, issues of power, and cultural factors. The result may be that this population are participating in clinical trials without providing meaningful consent, or researchers may be bypassing them as participants for fear of ethical breaches.

This study looks specifically at Latinos, the largest and fastest growing ethnic group in the United States, numbering 50.5 million, or 16.3% of the total population of the United States (Cohn, Passel, Lopez, 2011). Enrollment of members of racial and ethnic minority communities into clinical trials is necessary. Research that includes minorities works towards the elimination of health disparities and increases the generalizability of research results. Latinos have a high prevalence of diabetes, obesity (Cohn, Livingston Minushin, 2008), and hypertension (Vivo, et al., 2009). Having Latinos take part in research involving these and other health issues is essential since limited participation leads to limited data specific for this population. In addition, for some patients, inclusion in clinical trials represents an opportunity to receive new therapies not otherwise available.

Methods

Research participant populations are difficult to locate for consent research since the consent researchers must join an existing trial. The participants of the existing trial must then consent to both studies. Candilis and Lidz (2010) acknowledge the difficulty of joining existing clinical trials, "piggy-backing", to conduct consent research. The requirement that the potential trial participants be Latino with little English language skills made locating a trial even more complicated. To solve this dilemma, I chose the methodology of 'analogue patients', which will be referred to as 'analogue participants' in this study. Analogue participants are research participants who are asked to imagine that they are the

Work Plan



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Though I am proficient in Spanish, I am not a native speaker and am not confident that I can understand colloquial terms. To ensure I do not miss anything and to keep the conversation flowing, Elizabeth Nelson(see biography) joins me to conduct all interviews.

PI: Laura Pigozzi biography

I am trained as a mechanical engineer, with a bioengineering minor, and I have worked as an R&D engineer and as a technical writer. I have always had an interest in the biological sciences and medicine. My choice of Bioethics as both a Master's minor and a doctoral minor has reflected this engagement and has led to my interest in health communication. I designed and conducted a previous study which sought to understand how effectively available health materials communicated healthcare information, in the opinions of the immigrant Latina participants. I presented that study at a technical communication conference where it was well received. As a Latina myself I am familiar with the intricacies of communication with this population. My doctoral minor in bioethics coupled with my doctoral training in rhetoric and scientific and technical communication has led to an exploration of the communicative elements of the process of informed consent as the focus of my dissertation. While informed consent is relevant in a variety of settings, I am focusing on informed consent when used to enroll participants into clinical trials.

A description of this first research phase has been presented at the International Conference on Communication in Healthcare in Scotland and at the symposium Ethical Issues in Science Communication. The topic was received with great interest at both venues, with colleagues commenting on the uniqueness of the topic and the academic lens being employed. I strongly believe in research that demonstrates authentic engagement with community and I am committed to using a participatory research approach to bring forward the immigrant voice.

Interpreter, Translator: Elizabeth Nelson biography

Ms. Nelson, who is a native Texan from humble beginnings, received a Master's of Education (M. Ed.) in Human Resource Development and a minor in leadership from the University of Minnesota; she also holds a B.A. in Chicano Studies from the University of Minnesota. She lives in the Twin Cities area and has three teenagers. Elizabeth Nelson is the Office Manager and Human Resource contact of the TRIO Upward Bound (TRIO UB), a federally sponsored college preparatory high school program in the College of Education and Human Development (CEHD). She also serves as an interpreter for the Spanish speaking participants' family and is the Event and Scholarship Coordinator for the "Minnesota I Have a Dream Scholarship" in addition to preparing the United States Education Department Annual Performance Report.

A free-lance interpreter by trade, Ms. Nelson joined the University of Minnesota in 2007. Her public service as an interpreter for professional development sessions, conferences, and research focus on issues related to access and equity, concentrating on providing the meaning of the message from English to Spanish and vice-versa across differences of ethnicity, gender and class. Ms. Nelson is an affiliate and member of the National Association of Professional Women (NAPW) and Continental Who's Who, and International Women's Leadership Association (IWLA). She holds the NAPW 2013/2014 Woman of the Year Award, University of Minnesota Women of Color Tapestry Award 2012. She is a Ray G. Price Endowed Fellowship 2014 recipient, certified Meyers Briggs Type Indicator (MBTI) I & II practitioner, and is on the Minnesota Judicial roster of court interpreters.

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Budget for Student Proposals

Project Title: Piggozzi: Examining the gap between a mormally valid consent and a legally

	Instructions: Provide justification along with costs.		Requested funding	Matching/other funding	
	Category	**Description & justification**	**Amount**	**Amount**	**Source**
1	Your stipend	The graduate assistant rate in the Department of Writing Studies is $18.84/hr. I am	$4,350		
2	Speaker honoraria	___ speakers x $_____ honorarium			
3	Supplies & Services	Fees are for Elizabeth Nelson (see bio) for services in interpreting, translating, and transcription. Phase One: Video- 15 pages translation @ $30/hr = $450; Phase 2:	$2,500		
4	Equipment	$15 Cub Food Gift Certificates to thank interview participants for their time	$150		
5	Travel				
		Subtotal research expenses (2-6)	**$2,650**	**$0**	
	TOTAL BUDGET		$7,000	$0	

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Budget Guidelines

1. Stipend justification. You must justify the amount of stipend you are requesting by identifying the number of hours you plan to work on the project and the hourly wage used for research assistants in your department. Include fringe benefits.
2. For colloquia, identify the number of speakers and the amount of honoraria you will provide.
3. Supplies and services. List out all supplies and their estimated costs. Explain in line 7 or in the body of your proposal what the supplies will be used for.
4. Equipment costs are allowable only if the justification clearly shows that the equipment is necessary for the project. Include explanation of what will happen to equipment at completion of project.
5. Travel costs must include a description of the purpose of the travel, start and stop dates of travel, transportation costs, housing costs, and allowable per diem (use University rates found at http:// travel/umn.edu).