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

2010-11 Student Proposal Cover Page

Applicant Information

Applicant Name:	Elita Poplavska			Email:	Popl0017@umn.edu
Project Title:	"We get patients": Understanding the culture of patient recruitment organizations				
Department:	Pharmaceutical Care and Health Systems	College:	College of Pharmacy		
Home address:	2121 Garfield Ave	City & State:	Minneapolis, MN	Zip:	55405
Faculty advisor name:	Linda M. Strand	Email:	lstrand1@medsmanagement.com	☐ Not applicable	
Dept. Head's name:	Stephen Schondelmeyer	Dept. Head's email:	Schon001@umn.edu		
Dean's name:	Marilyn K. Speedie	Dean's email:	Speed001@umn.edu		

How did you hear about this funding opportunity? Through email notices

Funding

Total amount of funding requested: $6,378.99

Is funding available within your center or dept for this project? No

Executive summary (maximum 200 words)

Funds which include salary and research related expenses will be used to conduct ethnographic fieldwork—participant observation and interviews in the patient recruitment company as well as data analysis and writing a section of my PhD thesis during the summer of 2011.

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	☒ Application pending	Submitted on February 7, 2011
IACUC ☐ Yes ☐ No	☐ Application pending	N/A
Other ☐ Yes ☐ No	☐ Application pending	N/A

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.

Project title: "We get patients": Understanding the culture of patient recruitment organizations.

This research project aims to explore the process of professionalized patient recruitment for clinical trials. Patient recruitment organizations are private businesses that specialize in delivering human subjects to clinical research. These companies develop specific knowledge of various social, cultural, psychological, technological, and economic ways for convincing people to participate and remain in clinical trial studies[1]. The emergence of recruitment companies around 1990s is part of a tendency within the pharmaceutical industry to focus on outsourcing clinical trial research.

The clinical development process very much depends on the patient enrollment and retention in clinical studies. The data shows that 80 percent of the total clinical trials are delayed at least one month because of unfulfilled enrollment, and each day a drug is delayed from the market, sponsors can lose one million dollars in unrealized sales[2].

Certainly clinical research on human subjects is an important part of the process of developing new pharmaceuticals. In addition, in some cases—for patients like those who are diagnosed with cancer or orphan diseases—clinical trials provide hope to receive a treatment. Nevertheless, despite the obvious benefits of clinical research, it is essential to ensure participant protection by considering the risks and mistreatment they might face.

The Food and Drug Administration (FDA) has issued an information sheet that Institutional Review Boards (IRBs) use as guidance in the review process of recruitment materials[3]. However, these guidelines mainly refer to recruitment by mass media advertisement and do not discuss other recruiting or retention methods. New recruitment techniques have been used more frequently, such as reminders sent to patient's cell-

[1] Epstein, S. (2007) *Inclusion: The politics of difference in medical research*, The University of Chicago Press
[2] Fisher, J.A. (2009) *Medical research for hire*, Rutgers University Press
[3] FDA (2009) *Recruiting study subjects- information sheet.* Retrieved January 20, 2011 from http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm

phones, investigator speeches at local health fairs and brief posts on social networking sites[4]. Due to the lack of up-to-date guidelines, evaluation of various recruitment techniques for IRBs often is challenging[5].

Understanding the recruitment process is significant to ensure appropriate informed consent process. The informed consent is the main mechanism for the research subject protection and ensures that he or she fully understands the purpose of the clinical study and voluntarily agrees to participate. The "screening and consent visit" is when prospective participants receive an informed consent form and complete information about the study. However, the research shows that often the prospective participants make their decision to participate on the information disseminated by recruiters[6]. Thus, before having full information about the purposes, risks and benefits of particular research study.

There are discussions in academic literature about ethical issues of various recruitment techniques, but the interactions between potential clinical trial participants and professional recruitment enterprises that goes beyond the language of coercion and rational choice has not been fully assessed[7]. This proposed study will attempt to fill this empirical gap and analyze implications of applied recruitment strategies for research participants.

The purpose of this research is to address the following questions: How do patient recruitment companies work in order to meet a high demand for human subjects? How do

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[4] Anderson, D. L. (Ed.) (2004) *A guide to patient recruitment and retention.* Thomson Healthcare CenterWatch

[5] Office of Inspector General (2000) *Recruiting human subjects: Pressures in industry sponsored clinical research.* Retrieved January 20, 2011, from http://oig.hhs.gov/oei/reports/oei-01-97-00195.pdf

[6] Fisher, J. A. (2007) *"Ready-to- recruit" or "ready-to-consent" populations? Informed consent and the limits of subject autonomy.* Qualitative Inquiry, 13(6)

[7] Petryna, A. (2009) *When experiments travel.* Princeton University Press

they navigate ethical guidelines and regulations? And what ethical issues are involved in these practices?

Interdisciplinary contribution

By attempting to answer the questions stated above, this project will offer an innovative perspective on the use of different recruitment methods by these companies. Furthermore, by describing recruiters' values and attitudes toward regulations and ethical guidelines, I will attempt to shed light on factors that facilitate or hinder the patient recruitment process in the current research industry. This is a crucial piece of information for improving the ethical process of bringing new treatment options to the market. Clinical research – including the patient recruitment – plays a significant role in all healthcare professions. Health providers not only engage in these research processes, but also increasingly depend on the results of clinical trials in their daily practice.

By furthering a dialogue between regulating bodies and the practices in the "real world", this study will attempt to create suggestions towards a balance between effective recruitment and fair treatment of patients. Moreover, the results will certainly provide new insights for other research questions in this area, what has a potential impact in furthering the study of societal implications of the entangle of bioethics and health sciences.

Work plan

To answer proposed research questions, I will use ethnographic research methodology. Ethnography is used when there is little information known about the topic and when the researcher aims to gain a holistic understanding of groups' beliefs, values, attitudes and behaviors[8].

[8] Gordon, E. J. & Wolder Levin, B. (2008) Contextualizing ethical dilemmas: Ethnography for bioethics. In L. Jacoby, & L. A. Siminoff (Eds.), Advances in bioethics volume 11, Empirical methods for bioethics: A primer. Elsevier

The research design for this project will integrate multiple methods: field observations, interviews and a reflective journal. I will conduct participant observation in one patient recruitment organization in the Minneapolis- St. Paul area that has agreed to collaborate for this project (For the purpose of confidentiality I will not disclose the name of the company). The planned length of participant observation is six months. In addition, I will informally interview participants through the process of observations. After 3 months of observations I will conduct in depth semi-structured formal interviews with the company's employees.

To gain a broader perspective, I will also interview individuals who work in recruitment companies, outside the Minneapolis-Saint Paul area. It is estimated that 35 individuals will be formally interviewed. The entire ethnographic record will be analyzed as described by Germain (2001) and Fetterman (2010)[9]. The results will be presented in a comprehensive account.

Timeline

Spring 2011	Preparation for fieldwork. Development of theoretical framework for data analysis. Initiating participant observation. Preliminary data analysis.
Summer 2011	Participant observation and interviews. Data analysis. Finishing the chapter of literature review and theoretical discussion on ethics of patient recruitment for clinical trials.
Fall 2011	Completing participant observation and interviews. Conducting interviews in the recruitment companies outside the Minneapolis- St. Paul area. Finalizing data analysis. Writing thesis.
Spring 2012	Defense of PhD dissertation. Writing publications.

[9] Fetterman, D. M. (2010). *Ethnography: Step-by-step* (3rd ed.) Sage; Germain, C. P. (2001). *Ethnography the method in Nursing research: A qualitative perspective,* National League For Nursing

Biography

Currently I am PhD candidate with a major in Social and Administrative Pharmacy and a minor in Bioethics. Prior to entering graduate school in 2008, I earned Master of Science in Pharmacy from Riga Stradins University in my home country of Latvia.

My educational background in pharmacy as well as work experience in a research lab and a pharmaceutical company has influenced my choice of this particular research project. I am interested in the ethical aspects of medication promotion and ethics of clinical research as the knowledge about medications constitutes the bases of health care provider practices.

My research project for MSc degree focused on patient rights and pharmacist responsibilities in community pharmacies and was presented in the Annual Scientific Conference of Riga Stradins University. Also, I have presented a paper on pharmaceutical care practices in Latvia at the International Pharmaceutical Care Conference in Poland. During my graduate studies I have held positions as a teaching assistant for several courses, including Ethics in Pharmacy Practice and Pharmaceutical Care lab, and as a research assistant at the Peters Institute in the College of Pharmacy.

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	Instructions provided below.		**Requested funding**	**Matching/other funding**	
	Personnel costs	**Description & justification** **Salary = __hrs x ____ hrly wage**	**Amount**	**Amount**	**Source**
1	Your salary (stipend)	11 weeks of salary (20 h per week) at $ 19.45 per hour - Total: $ 4,279.00	$4,279.00	0	0
2	Other personnel				
3	Other personnel				
4	Other personnel				
5	**Personnel Subtotal**		$0.00	$0.00	$0.00
6	Speaker Honoraria				
7	Supplies & Services	Interview transcribing ($100 per hour* of recorded interview, estimated 20 hours of interviews**) * http://www.transcriptionstar.com/index.html ** This will not account for all interviews, but the funds will be used to transcribe early interviews to permit concurrent data analysis and collection that is crucial for rigor in ethnographic research.	$2,000.00		
8	Equipment	Olympus WS-500 Digital Voice Recorder, pricing from Amazon.com as of Jan 31st, 2011	$99.99		
9	Travel				
10	**Subtotal research supplies, equipment, travel, other**		$2,099.99	$0.00	$0.00
11	**TOTAL BUDGET**		**$6,378.99**	**$0.00**	**$0.00**

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.

2-4. Identify all other personnel to be paid from this grant including interpreters, travel guides, etc. and justify their salary by identifying the number of hours they will work and the hourly wage. What is the hourly wage based on?

6. For colloquia, identify the number of speakers and the amount of honoraria you will provide.

7. 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.

8. 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.

9. 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).