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## The Lived Experience: Pulmonary Arterial Hypertension and Intravenous Prostaglandin Therapy

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THE LIVED EXPERIENCE: PULMONARY ARTERIAL HYPERTENSION AND  
INTRAVENOUS PROSTAGLANDIN THERAPY

By  
Phyllis D. Boone

A THESIS

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## ABSTRACT

### THE LIVED EXPERIENCE: PULMONARY ARTERIAL HYPERTENSION AND INTRAVENOUS PROSTAGLANDIN THERAPY

By

Phyllis D. Boone

A descriptive phenomenological study was proposed to obtain a subjective description of the experience of living with intravenous prostaglandin treatment for pulmonary arterial hypertension. It was intended to determine what kinds of elements are common to the experience with study participants, to develop an aggregate structure of the experience from the individual descriptions of it, and add to what is now known about this phenomenon. It was anticipated that the stories told by the participants could help to determine how nurses can assist future patients to live optimally within the confines of a palliative treatment for this incurable illness.

Unfortunately, no participants responded to recruitment efforts by the researcher. However, the current state of nursing science about the experience of having pulmonary arterial hypertension was synthesized, and the utility of phenomenological exploration for nursing practice was discussed. Finally, the barriers to recruitment for researchers following the Health Insurance Portability and Accountability Act Privacy Rule were examined and approaches to overcome these barriers were determined.

## Dedication

To my mother, who wanted her girls to have an education in order to support themselves, “just in case.” I think I’ve done that, Mom. I know you would be happy.

## Acknowledgements

So many people have supported me along this journey. I would not have been able to complete this endeavor without the love and support of my husband or without the inspiration of our sons and their families. My sister provided the encouragement I needed. Their faith in me did not waver.

I also want to recognize the guidance and support that the members of my thesis committee and my academic advisor, Dr. Brintnall, have provided. I have learned so very much from all of them! Without their enthusiasm, I could not have put all of this together.

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## CHAPTER 1

### INTRODUCTION

Pulmonary arterial hypertension (PAH) group 1, as defined by the World Health Organization (WHO) in 2003 (Simonneau, Galie, Rubin, Langleben, Seeger, & Domenighetti et al., 2004), is a progressive, life-threatening and incurable disease. The idiopathic and familial variants of PAH in group 1 (Appendix A) are uncommon, but affect 50,000 to 100,000 people in the United States. Of these, women are diagnosed at 2 to 3 times the rate of men (Simonneau, et al.). The patient with idiopathic PAH is typically a young woman of childbearing age (Traiger, 2007). The remaining members of this group are of all races and ages. Their disease can be inherited, a result of connective tissue diseases, human immunodeficiency virus, and congenital heart disease. It can also result from the use of anorexigens, and methamphetamine and cocaine abuse (Rubin & Hopkins, 2007).

The pathological manifestations seen in the pulmonary arterioles of patients with WHO classification Group 1 PAH include medial hypertrophy, intimal proliferation, concentric laminar fibrosis and plexiform and thrombotic lesions (Rich, 2000; Widlitz, McDevitt, Ward & Krichman, 2007). This arteriolar remodeling causes hemodynamic changes. In a healthy adult, the normal mean pulmonary artery pressure (mPAP) ranges from 10 to 17 mmHg and pulmonary vascular resistance (PVR) ranges from 60 to 100 dynes/sec/cm<sup>5</sup> (Swearingen & Hicks-Keen, 2001). For the adult with PAH, the mPAP,

measured during right heart catheterization (RHC) is greater than 25 mmHg at rest and greater than 30 mmHg with exercise. The PVR increases to greater than 120 dynes/sec/cm<sup>5</sup> (Rubin & Hopkins, 2007). These sustained increases in mPAP and PVR lead to right heart failure and death within 3 to 5 years from diagnosis if there is no pharmacologic intervention (Eells, 2004; Rubin & Hopkins, 2007; Sitbon, Humbert, Nunes, Parent, Garcia, Hervé, et al., 2002; Traiger, 2007). The hemodynamic changes affect day-to-day functioning of these patients, who experience progressively worsening cognition (White et al., 2006), shortness of breath, fatigue, liver congestion, peripheral edema and death (McPhee & Papadakis, 2008).

The New York Heart Association (NYHA)/WHO functional classification tool for PAH (Appendix B) is used to assess and classify the functional status of this patient population. This assessment tool is used on initial consultation and at all subsequent visits to the health-care provider (Rich, as cited in Traiger, 2007). It helps to clarify and classify the diagnosis of PAH as well as to assess treatment efficacy (Traiger, 2007).

Patients with severe PAH who have reached NYHA/WHO functional Class III or Class IV and remain in those classifications despite conventional treatments with oral vasodilators are considered for intravenous (IV) prostacyclin treatment (Depta & Krasuski, 2008; Roncesvalles, Lee, Camamo & Priestley, 2008). While the prostacyclins epoprostenol and treprostinil have significantly prolonged the lives of these patients (Barst, et al., 1996; MCPhee & Papadakis, 2008; Sitbon, et al., 2002), those taking these drugs may suffer numerous side effects. The side effects include jaw spasm, headache, flushing, rash, nausea and diarrhea. Over time, they might experience side effects that include musculoskeletal pain, a blotchy-red rash, impotence, thrombocytopenia, and

ascites. Finally, if patients receive doses that are too high for an extended period, high-output cardiac failure can result (Traiger, 2007). Furthermore, epoprostenol has an elimination half-life of less than 6 minutes (Roncesvalles et al., 2008). This means that if epoprostenol is stopped abruptly for any reason, the patient will experience sudden increasing symptoms including rebound pulmonary hypertension, cardiovascular collapse, and death (Barst, et al., 1996; Roncesvalles et al., 2008; Traiger, 2007). The newer IV drug treprostinil, with an elimination half-life of 2-4 hours was developed to minimize the rapid decline associated with abrupt discontinuation of epoprostenol. Treprostinil is recommended as an alternative treatment for patients in NYHA/WHO functional Class IV (Roncesvalles et al., 2008).

In addition to the side effects listed above, patients needing IV prostacyclin must also contend with maintaining an implanted catheter, an infusion pump, continuous drug administration, storage and availability, infusion maintenance and emergency contingency plans. Given the drug side effects and the demands of treatment, the decision for treatment with either drug is made with the patient, family and healthcare providers based on the severity of the patient's disease, the support available at home, lifestyle considerations and patient preference (Traiger, 2007). Patients needing IV treatment must be motivated, educated and well supported throughout their experience with this treatment.

### Background

Since 1995 much research has been done to evaluate the physiological impact of IV prostaglandin therapy on patients with PAH. These remarkable medicines, especially epoprostenol (Flolan®) (Barst, et al., 1996; Sitbon, et al., 2002) and its analog drug

treprostinil (Remodulin®) have shown an ability to improve functional capacity and survival in these patients. They are prescribed either as a bridge to lung transplantation or as palliative treatment for this incurable illness (Simonneau, et al., 2004). The drugs dilate the pulmonic and systemic vasculature and inhibit platelet aggregation (Depta & Krasuski, 2008; Eells, 2004; Flattery, Pinson, Savage & Salyer, 2005; McPhee & Papadakis, 2008; Roncesvalles et al., 2008; Traiger, 2007). They are now a main-stay in the treatment of functional Class III and Class IV PAH. But to date little research has been completed to determine how the complex and precise drug administration regimen, the monitoring requirements, and the demands of managing side effects when using these drugs impact the physical, emotional, and social well-being of these patients.

Nursing has always held a caring attitude with respect to others and their health and illness concerns. Trusting nurses on this account, patients have historically told nurses what is relevant or meaningful to them during times of illness and its treatment. As nurses listened to their patients, they recognized that the experiences of patients share some similarities. Nurses then realized that this knowledge can be used to assist patients to live optimally within the limitations imposed by an illness and its treatments (King & Hinds, 2003; Rich, 2000; Watson, 2008). By obtaining a subjective description of the experience of living with IV prostaglandin treatment for PAH and determining the structure of the description with study participants, nurses will better understand the patients' experiences and will develop interventions that both anticipate and support their needs.



## Available Literature

A literature search of the Cumulative Index of Nursing and Allied Health Literature (CINAHL) database using the keywords pulmonary hypertension, drug therapy, and nursing care, returned 47 results. A second search of the same database using the keywords pulmonary hypertension, prostaglandins, and nursing care reduced returns to six results. A third search adding the keywords quality of life returned two more documents. Several studies were concerned with developing, using, and verifying quantitative instruments to assess health-related quality of life (HrQOL) in patients with PAH (Cenedese et al., 2006; Chen, Darren, Taichman & Doyle, 2008; McKenna, Doughty, Meads, Doward & Pepke-Zaba, 2006; Shafazand, Goldstein, Doyle, Hlatky & Gould, 2004; Taichman, et al., 2005). Traiger (2007) wrote an article that focused on managing IV and inhaled therapies for PAH, and addressed nursing strategies for helping patients manage the side effects of their prescribed medications.

Within the search results was one qualitative study (Flattery et al., 2005) investigating the lived experiences of patients with PAH arising from varied etiologies and receiving diverse types of approved therapies. Emerging from this study was a theme about managing uncertainty in illness--common to patients with chronic health conditions (Hummel, 2009; Mishel, 1988). The second theme, related to the first, was about coping with uncertainty in order to be able to move ahead with living.

## Significance of the Study

The scarcity of literature regarding the phenomenon of interest spoke to the need for further research to enhance what is known about the issues and coping strategies experienced by patients living with IV prostaglandin treatments. This qualitative study

sample of patients would be small, but the research was designed to be specific to the population. This research proposed to add to what is now known about the lived experiences of adult Group I patients with PAH who are receiving continuous IV prostaglandin treatment. It was anticipated that the stories these patients told could help to determine how nurses can assist them to live optimally within the confines of a palliative treatment for this incurable illness.

### Study Objectives and the Research Question

The objective of this study was to listen to the stories the participants would tell and to take in what comprises their experience. From the individual stories, common elements were to be dissected to determine what the general, essential structure of the phenomenon looks like. Developing this aggregate structure would allow nurses to generalize the experience of the study participants to similar, future situations.

To explore the participants' subjective experiences while receiving IV prostaglandin treatment for PAH in their private home setting, a single open-ended research question was developed to encourage their reflection:

Can you tell me about what it is like for you to live with IV prostaglandin treatment for your pulmonary hypertension? Please share as many of your thoughts, experiences and feelings as you can recall.

My anticipated work as a researcher was to present the collective experience of the selected participants "in...enough detail and... depth [so] that those who read the study can connect to that experience, learn how it is constituted, and deepen their understanding of the issues it reflects" (Seidman, 2006, p. 51).

## CHAPTER 2

### THE RESEARCH TRADITION OF PHENOMENOLOGY

The manner in which a phenomenon presents itself to the consciousness of the researcher is important for determining the strategies needed for studying it (Giorgi, 2009). As a nurse, I ask how should I learn about the suffering of another, and what can be done about such suffering? Because the purpose of this study was to determine the patients' experiences during IV treatment for PAH, an approach influenced by phenomenology was thought to be a useful philosophy and methodology to use for this research.

#### Philosophical Background

Phenomenology is both a philosophy and a method (Giorgi, 2009). The word *phenomenon* comes from the Greek language and means to “appear” or to “show itself.” The philosophy of phenomenology appeared in Germany before the First World War, challenging the dominant viewpoints about the origin and nature of truth at that time (Dowling, 2007). Edmund Husserl is considered to be the father of this philosophical movement. In a rudimentary way, phenomenology can be depicted as “the sustained attempt to describe experiences... without metaphysical and theoretical speculations” (Sawicki, 2006, Introduction, ¶ 1). Husserl regarded experience as the fundamental source of knowledge, and is associated with developing the principle of *intentionality*. Dowling (2007) states that “Intentionality is the principle that every mental act is related to some object and implies that all perceptions have meaning.... [it]... refers to the

internal experience of being conscious of something” (p. 132). The goal of phenomenology for Husserl was to study things *as they appear* to consciousness in order to arrive at an *essential understanding* of human consciousness (Dowling, 2007).

Husserl believed human consciousness exists in a separate sphere from the natural sphere of the physical existence of man. So, in order to study *the things as they appear* to human consciousness and understand such consciousness, he thought it necessary to come to a third sphere of absolute or *transcendental* consciousness. Husserl posited that this absolute consciousness exists outside of the spheres of natural human existence and human consciousness (Sawicki, 2006). Husserl called the roadmap needed for arriving at this essential understanding of consciousness via the transcendental consciousness, *phenomenological reduction*. Phenomenological reduction is a methodological attempt by the phenomenologist

to meet the phenomenon as free and as unprejudiced as possible [from within the third sphere] in order that the phenomenon present itself [in] as free and as unprejudiced [a] way as possible so that it can be precisely described and understood (Dowling, 2007, p. 132).

Husserl’s contribution to phenomenological reduction was later modified by his student, Martin Heidegger, who defined phenomenology not as philosophy, but rather as method (Heidegger, 1962/1927). Unlike his mentor, Heidegger did not separate man’s natural existence from his consciousness. He brought them together as inseparable in his work, *Being and Time*. His aim for phenomenology was not to provide a philosophically detached, descriptive analysis of consciousness from the sphere of transcendental consciousness. Instead, he redefined phenomenology to be a method of analysis using

phenomenological reduction to bring to light understanding of the human being whose “behavior occurs in the context of relationships to things, people, events and situations” (Morse & Richards, 2002, p. 45). For Heidegger, Husserl’s phenomenological reduction became a means for exploring human *being*.

Later, Merleau-Ponty (1962) in the *Phenomenology of Perception* would deepen the concept that natural human existence (body) is inseparable from consciousness (mind). From Husserl’s principle of intentionality, Merleau-Ponty developed the concept “that a person’s description [of an experience] is a *perception* [which is] a form of interpretation” (Morse & Richards, 2002, p. 46). Along with Heidegger, he held open the door for psychology and the human sciences to analyze being from a phenomenological perspective. Amedeo Giorgi (1970, 1985, 1997, and 2009) would soon after develop a scientific phenomenological method in order to help inform the experience of being from the perspective of scientific psychology (Giorgi & Giorgi, 2003) specifically, and more generally, for the human sciences which include nursing.

### The Role of Phenomenology

For a great part of my own nursing career, I have worked at the bedsides of chronically and critically ill patients undergoing various medical treatments for acute exacerbations of underlying illnesses. These periods of illness have been life-threatening to the individual involved. Confronted with these situations, I often would wonder if I were doing enough to affect the present and future well-being of patients in my care. How are my patients experiencing the care I am providing? How can I provide care that matters to them in terms of living a good quality of life? Limited by the demands of

bedside nursing in a critical care ward, I was unable to explore more than the immediate generalities of each patient's experiences.

As a result of my graduate studies, I became aware that phenomenological research methods could be used to search for answers to my questions. This is because phenomenology offers to us that "perceptions present us with evidence of the world—not as it is thought to be, but as it is lived... and that human existence is meaningful and of interest in the sense that we are always conscious of something" (Morse & Richards, 2002, p. 45). In addition, phenomenological researchers have shown nurses that:

... it is possible to explicate [a] person's experience to enhance an understanding. The responses... can provide the health practitioner with an added insight, a greater understanding of the everyday world of a person experiencing such an event... [That] can enamor the health professional's empathy and substantiate and direct their style of care (Robertson-Malt, 1999; p. 292)

As a method, phenomenology is respectful of a person's capacity for self-knowledge and his or her ability to communicate this (Robertson-Malt, 1999). It also recognizes that the human experience occurs within a context--what Heidegger (1962/1927) termed *situated-ness*. As an analytical method, phenomenology gives nurses a rigorous way to dissect the lived experience and its meaning from everyday language into the more explicit language of the human science of nursing. This happens without spoiling the way that these experiences present themselves to everyday life. The phenomenological method encourages the researcher to reflect on and identify factors that influence the everyday lives of the participants as well (Giorgi, 1985, 2009).

By using a phenomenological approach to the research question, it is possible for the participants to talk about the experience of living with IV treatment for PAH in a non-structured, open way during an interview. This approach asks that the researcher pay attention to the everyday language used to describe the experience just as it is given. The subsequent descriptive phenomenological analysis guides the researcher to determine the *structure* of the phenomenological description given to the experience by the participants. The task of the nurse researcher is to maintain the context of this lived experience for the participants and to share the findings with nurses and other health care providers so that future care for participants and for future patients in similar situations can be modified accordingly (Robertson-Malt, 1999).

## CHAPTER 3

### METHODS

In phenomenology, many scholars have developed a variety of inductive methods that have guided examinations into the underlying being of human experience. Common to the methods is a philosophical premise that asks the researcher to ‘return to the things themselves’ which in turn directs and brings together the different methods of phenomenological analysis (Robertson-Malt, 1999). One such scholar, Amedeo Giorgi (2009), provides a method of phenomenological description that would be useful for this study. Giorgi’s (1985, 2009; Giorgi & Giorgi, 2003) method of descriptive phenomenological inquiry provides a framework upon which to expose and explore the key structure of a phenomenon.

Giorgi (1985, 2009; Giorgi & Giorgi, 2003) developed, described and published the steps of phenomenological analysis to meet the rigor of scientific research in the human sciences. His writings identify five basic steps that he believes all qualitative methods share. The methodological steps are outlined below:

- 1) Collecting verbal data which is transcribed verbatim
- 2) Reading the data
  - a) Read the entire text of the experience to get a sense of the whole
  - b) Reread the description
- 3) Breaking the data into some kind of parts



- a) Identify the transition units of the experience
  - b) Clarify and elaborate the meaning by relating constituents to each other and the whole
- 4) Organizing, expressing the data from a disciplinary perspective
- a) Reflection on the constituents in the concrete language of the participant
  - b) Transform concrete language into the language or concepts of science
- 5) Synthesizing or summarizing the data for the purpose of communicating it to the scholarly community

The application of this method to this study will be discussed further in the data analysis section below.

### Sampling

Effective research begins with choosing an appropriate population sample for the investigation. In order to gather the best description of the phenomenon of interest in a phenomenological study, “it is essential that all participants experience the phenomenon being studied” (Creswell, 1998, p. 118). In this study, it was planned that all participants chosen would be people who are living with IV prostaglandin treatment for PAH. This kind of sampling is called *criterion sampling*.

To participate in this study, participants would meet the criteria listed below:

1. Age of 18 years or older, fluent in the English language, capable of reflection and articulation, and with the time needed for an interview, and willing to participate in a private interview.
2. Participants must be classified with Class III or Class IV New York Heart Association/World Health Organization Functional Criteria for PAH. These

stages represent disease that has progressed to the point where the prostaglandin treatment will be needed.

3. Are medically stable--not currently hospitalized.
4. Must be receiving IV prostaglandin therapy for treatment of PAH.

#### *Participant Recruitment and Consents*

Participants in this study were to be selected from clients who are patients in a local PAH clinic operated by a regional health care system in the Midwestern section of the United States. Access to the clinic staff was given by the Senior Nurse Researcher at the health care system (K. J. VanderLaan, personal communication, July 30, 2009). Permission to utilize resources at the clinic was given by the nurse manager at the clinic pending approval of the study by the Human Research Review Committee (HRRC) at Grand Valley State University and by the Institutional Review Board (IRB) of Spectrum Health (A. Byrne-Meyer, personal communication, September 18, 2009).

This study was conducted according to Department of Health and Human Services Title 45 Part 46 Protection of Human Subjects regulations and Institutional research policies and procedures. Subject to HRRC approval at Grand Valley State University and the IRB at Spectrum Health Hospitals, patient contact was to be made in accordance with the above regulatory statements. A letter granting permission to move forward with this research project utilizing resources at the Heart Failure, Transplant and Pulmonary Hypertension Clinic was obtained (Appendix C).

Clients receiving IV prostaglandin treatment were given an introductory letter identifying the study and its objectives (Appendix D), and a stamped, self-addressed envelope by the clinic staff. The number of letters distributed was determined by the

number of patients in the practice meeting criteria. The PAH census for patients receiving prostaglandin treatment at the clinic averages 3 to 5 in any given month (A. Byrne-Meyer, personal communication, November 19, 2009).

To maintain confidentiality but yet help stimulate an adequate response from clients recruited for the study, two strategies were used. One strategy was to send a postcard reminder (Appendix E) to each of the patients who received a recruitment letter from the clinic staff. The reminder card was sent one to two weeks after the recruits received the introductory letter without regard to the actual individual responses to recruitment.

Second, to take advantage of the interest that a potential participant may have had in the study, without inadvertent disclosure of patient identities or diagnoses (protected health information), as the researcher I made myself available at the site of the clinic on several clinic days. I was to be in an area of the building secluded from the reception, waiting and examination areas where patients are seen (so the medical diagnosis of patients will not be possible to guess because of the equipment that must accompany them everywhere they travel). This placement would allow me to readily access the clinic in a timely manner to meet the patients who gave consent to have me discuss the study with them. I had no access to the identities of eligible participants until candidates interested in the study approached me at the clinic or provided written consent to release their names and contact information to me. Similarly, upon explaining the study and determining the interest of the patient in participating, I would not reveal to the clinic staff members whether consent to participate in the study was given. It was in light of the

small patient census and time available for the completion of the research, that I was anticipating recruiting three to five participants for this study.

Following the receipt of returned letters from respondents confirming their desire to participate in this study, each participant was to be contacted by telephone or by e-mail using the information given in the response letter. After allowing an opportunity for the participant to ask pertinent questions, the participant would then be asked for the address of his or her home or place of residence, and an appointment would be made for the research interview. Upon their agreement to interview, each respondent was to be assigned a participant number which would be the only identifier used in the recording, the transcription and the final study report. Next, a second letter was to be sent to each participant. This letter (Appendix F) contained information regarding expectations during the interview as well as a copy of the informed consent and HIPAA Authorization for Release of Health Information for Research Purposes (Appendix G). In this letter the participant was asked to review this information before the interview appointment.

At the interview appointment the participant was to be provided an opportunity to have any questions or concerns about the study clarified (Appendix H). Then, he or she would be asked to sign the consent form and the HIPAA authorization form for release of health information for research purposes. The protected health information (PHI) requested for release included demographic data consisting of the participants' name, date of birth, and insurance status. Social history was requested to determine marital status, living arrangements and religious practices. Health data requested incorporated the participants' previous health history, the age at which PAH was diagnosed, and the etiology of the PAH. The name of the drug currently being used for treatment and the

reason for choosing IV treatment were to be requested. Functional health status results as assessed using the NYHA/WHO modification (Appendix B) at the beginning of IV prostaglandin treatment and at the time of the interview was to be requested. The results of available tests used to diagnose PAH, including echocardiograms, right heart catheterization, histopathology results, electrocardiograms (EKGs), pulmonary function tests (PFTs), 6 minute walk tests (6MWT), results of pulse oximetry (SpO<sub>2</sub>) monitoring and arterial blood gasses (ABGs) were to be asked for as part of the consent. The results of tests used to monitor the progression of PAH including EKGs, 6 MWTs, SpO<sub>2</sub> or ABG determinations were to be requested as well.

Once the consent for the release of the above information was obtained, the interview was to take place. As the researcher, I would seek permission for access to each participant's medical records from the health care system. This would occur following approval to conduct this study from the health care system IRB. Only after consent had been given would the medical record have been accessed to obtain and record the permitted data.

#### The Phenomenological Reduction as Preparation for Collecting and Analyzing Data

In qualitative research, the *phenomenological reduction* "is the scientific process in which a researcher suspends or holds in abeyance... presuppositions, biases, assumptions, theories, or previous experiences [in order] to see and describe the phenomenon" (Gearing, 2004, p. 1430). Recognizing and acknowledging the existence of these elements is an important step to accomplish "before beginning the study and repeatedly throughout data collection and analysis" (Streubert-Speziale & Carpenter, 2007, p.27). The purpose of the phenomenological reduction is to clarify beliefs about the

phenomenon, to withhold judgments about what is being observed or heard as the data is disclosed, and to remain open to data as they are revealed. As such, the reduction preserves objectivity (Streubert-Speziale & Carpenter).

According to Giorgi (2008), achieving and maintaining phenomenological reduction during a study requires two activities:

- (1) The researcher has to *bracket* [italics added] personal and past knowledge... not based on direct intuition, regardless of its source, so that full attention can be given to the instance of the phenomenon that is currently appearing to his or her consciousness; and (2) the researcher... does not make the claim that the object or event really exists in the way that it is appearing. It is seen to be a phenomenon (The interpretation of the phenomenological reduction, ¶ 2).

Addressing the second element first, Moran (cited in Dowling, 2007) states that “this means that explanations about a phenomenon are not to be imposed before the phenomena have [first] been understood from within” (p. 132).

*Bracketing* is an attitudinal perspective invented by Husserl to make the descriptions required by phenomenology more rigorous. First a mathematician, Husserl conceptualized bracketing as in a mathematical equation. In such an equation bracketing is used to “[suspend] certain components by placing them outside the brackets... which then facilitates a focusing in on the phenomenon within the brackets” (Gearing, 2004, pp. 1430-1431).

LeVasseur (2003) clarified the concept of bracketing by defining what requires suspension. She identified two kinds of conscious attitudes articulated by Husserl. One attitude is the *philosophical attitude* which is “a reflective and questioning perspective”

(p. 417). The second is our everyday attitude toward the world which Husserl called the *natural attitude*. The natural attitude encompasses “the ordinary lack of curiosity with which most of life is lived” (p. 417). The natural attitude prevents us from experiencing repeated daily encounters as completely new at each occurrence, allowing us to routinely go about our daily lives. LeVasseur posited that phenomenological researchers should “regard bracketing as extending only to our natural attitude” (p. 417). Thus, bracketing becomes an interval,

... where momentarily we are dispossessed of our assumptions by an upstart curiosity, that new perception of the thing might occur... [Where] the project of bracketing attempts to get beyond the ordinary assumptions of understanding and stay persistently curious about new phenomena... [Providing an] opportunity for fresh experience and the possibility of new horizons of meaning (LeVasseur, pp. 418-419).

However, the process of bracketing data about the phenomenon of interest from the influence of the researcher’s previous suppositions has proven problematic (Gearing, 2004; Giorgi, 2008, 2009; LeVasseur, 2003). How does a researcher enter into this interval of persistent curiosity described by LeVasseur? Gearing offers some helpful guidance while navigating the process of bracketing for this study.

Gearing (2004) traces the development of the process of bracketing which parallels the evolution of phenomenological thought. Her typology reveals six kinds of processes. They range from Husserl’s ideal type and the Dutch (Utrecht) school’s descriptive bracketing, through the existential bracketing of Merleau-Ponty, to the more recent analytical, reflexive and pragmatic bracketing processes. The kind of bracketing

process chosen by a researcher is dependent on the orientation standpoint of the researcher and the theoretical framework chosen for the research project.

The underlying structure of each bracketing process is the same regardless of the type of bracketing used by the researcher. The bracketing process has three distinct phases and each phase is comprised of specific elements (Gearing, 2004). The procedural phases and elements are shown as they occur within the context of descriptive bracketing (See Table 3).

*Table 3: The Phases of Bracketing: The Elements of Each Phase and the Specific Components of Descriptive Bracketing*

Phase	Element	Component of Descriptive Bracketing
Abstract formulation		Post positivism, interpretative
	Orientation Standpoint	Critical realism, relativism
	Theoretical Framework	Descriptive or Utrecht phenomenology qualitative theories
Research Praxis		
	Foundational Focus	Researcher sets aside suppositions; focuses in on immediate
	Internal (Researcher) Supposition	Most held in abeyance



	External (Phenomenon) Supposition	Most held in abeyance
	Temporal Structure	Begins and ends around specific phenomenon
	Parenthesis	Natural
	(Boundaries) composition	
Reintegration/unbracketing and investment		Occurs after investigation of phenomenon; interpretation of data occurs after investigation.

Note. Table adapted from Gearing (2004).

The descriptive form of bracketing is appropriate for the proposed study because to date, little is known about this phenomenon. Descriptive phenomenology focuses on the immediate experience to determine the structure of a phenomenon through intuiting, analyzing, and describing, and is consistent with the descriptive methodology of Giorgi (1985, 2009; Giorgi & Giorgi, 2003).

The process of bracketing would begin before starting data collection. A self-reflective exercise was to be carried out to examine my personal influence in all aspects of this study. This is called *reflexivity*. Primeau (cited in Streubert-Speziale and Carpenter 2007, p. 36) states, “reflexivity enhances the quality of research through its ability to

extend our understanding of how our positions and interests as researchers affect all stages of the research process (p. 9)". Streubert-Speziale and Carpenter add that "as researchers, it is our responsibility to reflect on our influence, critically analyze it, and use it to enhance our work, always being aware of the fact that no research is without its subjective aspects" (p. 36). I was to maintain a journal throughout the data collection and analysis process to document my suppositions and my analysis of any preceding or ongoing influence on the data (Creswell, 1998). Journaling was to be used to support the bracketing process that maintains research objectivity.

#### Collecting Data: The Process of the Interview

The interview is the primary means of collecting data for a phenomenological study. The interviews are in-depth and involve a small number of individuals-- usually as few as one or as many as ten (Creswell, 1998). From the interview, "what is sought is a concrete, detailed description of the subject's experience and actions, as faithful as possible to what happen[s] as experienced by the subject" (Giorgi, 1997, *Philosophical Method*, ¶ 2).

After obtaining an informed, signed consent for research participation and HIPAA authorization for release of medical records from each subject, verbal data about the primary research question was to be collected from the participants. Data would be obtained during a private interview that was to be conducted in the home or current residence of the participant. The single, 45 to 60 minute unstructured, one-on-one interview was devised to allow the participant to express his or her viewpoint about the primary research question at length.

In addition to the primary research question, cue questions were developed within the framework of the primary research question. These cue questions included:

1. What was your life like before you needed this treatment?
2. Can you tell me about your life now—have there been changes?
3. Would you tell me how you feel about being on the IV medicine?
4. What is this experience like for you?
5. Is there anything else about having this treatment that you would like to share?

These cue questions were to be used during the interview as needed to stimulate further reflection about the participant's experience with the phenomenon. Additional questions may have been developed during the interview in accordance with the range of the subject's reflection, an interview guide (Appendix H), and my own clinical knowledge of the subject matter. The interviews were to be digitally recorded for later transcription to text (Seidman, 2006).

#### *Potential Benefits to Participants or to Others*

Participants in this study may or may not have experienced benefits as a result of their participation. Although it was not a goal of this research to enact a therapeutic relationship with the participants, some authors have noted that focused listening or attending is viewed as an element of positive nurse-patient relationships (Godkin, 2001; McCabe, 2004), and there is a body of research that suggests that the act of "telling stories" of stressful experiences may reduce the emotional and physical effects of the stress (Gale, Mitchell, Garand & Wesner, 2003; Pennebaker & Seagal, 1999; Sakalys, 2003). As the planned research would employ a method that involved participants' recounting of stories of their illnesses, it was possible that some might have experienced

a reduction in anxiety or concern about their situation, even if they demonstrated greater emotional upset while describing it. However, the greater benefit would be for future patients in that the information gained by nurses from this study may have helped us to better understand what life is like for patients while on intravenous medicine for PAH. The information may have helped nurses to develop new ways to care for patients who share a similar experience.

*Anticipated Risks of Harm or Discomfort to Participants and Protections against Risks*

During the interview, participants may describe emergent concerns or the student researcher may note issues requiring professional attention. These issues may include, for example, recognition of changes in the individual's ability to cope, distressing symptoms or side effects, or problems with administering the medication. Participants would have been provided with a contact number at the Heart Failure, Transplant and Pulmonary Hypertension Clinic (Appendix I). At that number, the participant would be connected to the appropriate professional able to attend to a specific problem. It is noteworthy that the clinic's licensed social worker was a member of the student researcher's thesis committee, and she could have been explicitly named as a resource for the participant. For equipment problems, contact numbers were provided for medical equipment suppliers in the community, with suggestions of ways the problem could be described to the service representative to evoke a suitable and prompt response.

The physical effort required by the interview might have been tiring for the participant. The pace of the interview was to be directed by the participant, and the participant could stop the interview at any time he or she believed it would have been too hard to finish because of discomforts such as shortness of breath. The interview process

may have brought up areas that caused emotional discomfort. Every effort would have been made to minimize such occasions, but the researcher was to stop the interview if it was determined that continuing would cause increasing discomfort. If necessary, the researcher may have requested that the interview be scheduled at another time. In cases where emotional responses of concern rose to the surface, actions described previously for encouraging consultation with the clinic personnel would have been pursued. As noted previously, however, by relating their stories, participants may have also experienced some relief from stress.

### Data Analysis

Qualitative researchers are concerned with data quality. Does the narrative description obtained during the interview reflect the truth about the state of this particular human experience? Giorgi (2009) has developed a method to enhance the product of credibility, transferability, confirmability and dependability to equal the trustworthiness of data from a phenomenological study. These criteria from Lincoln and Guba (cited in Creswell, 1998; Polit & Beck, 2004) apply to both the assessment of the qualitative data and to the evaluation of interpretations and conclusions drawn from the data. I planned to use Giorgi's (2009) method of descriptive phenomenological data analysis to form a description of the essential structure of living with the experience of taking IV prostaglandin treatment for PAH.

Polit and Beck (2004) state that ..."*Credibility* [italics added] refers to confidence in the truth of the data and interpretations of them....credibility involves carrying out the study in a way that enhances the believability of the findings, and... taking steps to *demonstrate* [italics in original] credibility to consumers" (p. 430). Researcher credibility

begins with careful use of the phenomenological reduction in order to describe and interpret the data cleanly. In addition, my data and findings were to be discussed with members of my thesis committee who are experienced in the methods of phenomenological inquiry and with the phenomenon of interest (Polit & Beck).

When qualitative researchers talk about *dependability*, the researchers are referring to “the stability of the data over time and over conditions” (Polit & Beck, 2004, p. 434). One way to approach verification of dependability is to subject the acquired data and relevant supporting documents to an *inquiry audit* by an external reviewer (Polit & Beck). As stated previously, my data and findings were to be discussed with a member of my thesis committee who is experienced in phenomenological methodology throughout the process of data transcription and analysis.

*Confirmability* of data is defined by Polit and Beck (2004) as ... “refer[ing] to the objectivity or neutrality of the data, that is, the potential for congruence between two or more independent people about the data’s accuracy, relevance, or meaning” (p. 435). Confirmability is enhanced by using phenomenological reduction and by maintaining a reflective journal by the researcher. An *audit trail* consisting of “a systematic collection of materials and documentation that allows an independent auditor to come to conclusions about the data” (Polit & Beck, p. 435) will be available should an audit of my research be made. Interview recordings and transcripts, process notes, reflexive notes and data reconstruction products were to be retained as required by the Grand Valley State University HRRC (2007) procedure.

Finally, “*transferability* [italics added] refers... to the generalizability of the data, that is, the extent to which the findings can be transferred to other settings or groups”

(Polit & Beck, 2004, p. 435). In part, transferability reflects the sampling and study design. It is less a reflection of the soundness of the data. The burden on the researcher is to provide “a... thorough description of the research setting or context and of the... processes observed during the inquiry” (Polit & Beck, p. 436). Transferability requires that enough information about the phenomenon of interest be provided so that consumers may make judgments about contextual similarity (Creswell, 1998; Polit & Beck).

### *Reading the Data*

Achieving transferability requires a well-organized description of the phenomenon of interest—in this case, the experience of having PAH and being treated with IV prostaglandins. Reading the text of each interview seems obvious. It is however, important to define what is involved in reading the text of the interviews during this first step of data analysis in order to lay the foundation for a well-organized description. Once transcribed from the recording, the descriptive text is read initially in the manner of an overview with no particular attitude (Giorgi, 1985, 2009; Giorgi & Giorgi, 2003). Then the text is read again. According to Wertz (1985):

The researcher attempts to put [herself] in the subject’s shoes and to live through the experience from the inside so that [she] is not a mere spectator but achieves a grasp of the meanings the subject has expressed precisely as intended by the subject (p. 164).

Establishing a meticulous baseline description is an important step that is necessary in qualitative research.

### *Breaking the Data into Some Kinds of Parts*

Phenomenology is interested in *meaning*—the particular way in which an object is experienced (Giorgi, 2009). During the process of the re-reading of the data, the researcher begins to establish the *meaning units* in the data. Meaning units are defined initially as ...”a purely descriptive term that signifies that a certain meaning, relevant for the study, and to be clarified further, is contained within the segregated unit” (Giorgi, 1997, *Philosophical Method*, ¶ 20) and then by Wertz (1985) as “a part of the description whose phrases require each other to stand as a distinguishable moment” (p. 165). Meaning units are formed within the attitude of the scientific phenomenological reduction. This early segregation of the interview data into meaning units is preparation for eventual analysis of the data. When done prudently, this step insures that all the data are carefully treated and accounted for (Giorgi, 2009; Giorgi & Giorgi, 2003).

Having established meaning units, the researcher decides what will or will not inform understanding of the phenomenon. Having an *unspecified attitude* is necessary here to maintain the phenomenological reduction. That is...”in order to discover meanings in the data, [the researcher] needs an attitude open enough to let unexpected meanings emerge... [and by maintaining an unspecified attitude] one’s professional sensitivity and spontaneity function[s] so that relevant meanings can be intuited” (Giorgi, 1997, *Philosophical Method*, ¶ 21). In this phase, the challenge to the researcher is to distinguish reflexivity to the phenomenon in each meaning unit in any way possible (Wertz, 1985). If reflexivity to the investigated phenomenon is not found in a meaning unit of the interview text, it is removed. Remaining constituents that are related to each other will be brought together.



The last step of this opening phase of data analysis involves the removal of redundant statements from the data. A re-description of the experience is then constructed from a first-person perspective in the participant's own language. The result is an *individual phenomenal description* from each interview which will serve as a basis for further analysis (Wertz, 1985). Read by the participant, this construction would be "an obvious restatement of their own phenomenal experience with no analysis or interpretation" (Wertz, pp. 168-169). While still in this early phase, the nursing perspective in the individual phenomenal description will not be explicit. However the understanding, judgments about relevance and the organization of the elements of the phenomenal description will be drawn from the perspective of nursing as human caring, or *caritas* (Watson, 2008).

#### *Organizing and Expressing the Data into the Disciplinary Language of Nursing*

From a phenomenological viewpoint, the life-world [of the subject] is pre-theoretical and pre-scientific and not yet theoretical or scientific in itself. [But it] is the foundation... and so its [language] must be taken up, examined and re-described more rigorously from the perspective of a chosen discipline (Giorgi, 1997, *Philosophical Method*, ¶ 24).

During this next step of analysis, the statements of the subjects will be transformed to the language of nursing. This is necessary because the statements of the subjects are in the language of everyday life. The language of nursing that will be used for analysis is not as broadly based as the language of everyday life (Giorgi, 1997) but does serve to narrow the focus of the data to nursing and to make the data more manageable. How then does the phenomenological researcher examine the raw data to

discover, gain insight about and make sense of the data from the professional perspective while not losing contact with the lived situation of the subject?

This is where Giorgi's (1985, 2009) method of *free imaginative variation* is first employed in order to help establish the essential intuitions along disciplinary lines. In Giorgi's (2009) words, the practice of free imaginative variation is demonstrated:

An active imagination is helpful when trying to discover the essence of a phenomenon or attempting to clarify the meaningful structure of an experience. Free imaginative variation requires that one mentally remove an aspect of the phenomenon that is to be clarified in order to see whether the removal transforms what is presented in an essential way. If the given appears radically different because of the removal of a part, it is leaning toward being essential. If the given is still recognizable as the same after the removal of a part, it is most likely a contingent part... each of these decisions has to be critically evaluated by the researcher through further imaginative effort before a final assessment can be made (pp. 69-70).

In this way, the researcher contemplates the details of the description. Using free imaginative variation, the researcher determines what *must* be involved in the phenomenon, thus snaring essential determinations of the phenomena for each individual subject (Wertz, 1985).

The new phenomenal description now will be in the voice of the researcher but originating from contact with the subject. It is the expression of reflection on the text from within the context of the concept of nursing's caring consciousness (Watson, 2008). This is essential for understanding and communicating another person's perspective to

nurses (Cara, n.d.). The accuracy of this description was to be ensured by maintaining constant contact with the original phenomenal description for verification, modification or negation of any reflective understanding brought to the surface through free imaginative variation (Wertz, 1985).

An individual description of the phenomenon as it relates to nursing was to be developed exposing the *structure* of each individual case. To reveal the *structure* of a phenomenon means to identify “the constituents that are essential for the phenomenon to manifest itself in [a] particular way as well as [to] understand... how the constituents relate to each other” (Giorgi, 2009, p. 200). The structure was intended to show how everything essential to the individual in the experience of living with IV prostaglandin treatment comes from the participant’s description. The nursing narrative would bring light to the phenomenon from the nursing perspective as it maintains association with the participant’s own depiction.

*Synthesizing or Summarizing the Data for the Purpose of Communicating to the Scholarly Community*

Wertz (1985) draws our attention to the limitations of the individual structure. The individual structure reflects “only an individual instance of the phenomenon” (p.188). Moving from each individual structure to a more general structure of a phenomenon requires “understanding [the] diverse individual cases as instances of something more general and articulating that generality of which there are particular instances” (p. 189). The process of shifting each individual structure of the phenomenon to a more generalized, aggregate structure that is transferable to other instances of the

phenomenon is dependent on attitudes and operations similar to those already discussed (Wertz).

When looking again at the individual structures, the researcher was to assess those descriptions for meanings, themes and relations that are articulated and true of all cases. The researcher may find that an individual feature can pertain to many individuals, but not necessarily to all of the individuals in the study.” The researcher... determine[s] which features of the individual structure [represent] a general truth [about the phenomenon] and which [features] do not (p. 189). But none of these truths can be assumed (Wertz, 1985). Individual descriptions were to be tested for evidence of the general truth about a phenomenon in all of the descriptions. The descriptions were to be not only cross-checked, but reflection and free imaginative variation was to be employed. Application of the method of imaginative variation (Giorgi, 2009) at this juncture was hoped to give insight into what is *generally essential* to the phenomenon. This questioning act would establish what is necessary and not necessary to the phenomenon, defining what is needed to understand what is true of the phenomenon (Wertz).

Finally, the essential common elements were to be pulled together to describe the general structure of the experience of living while on IV prostaglandin treatment for PAH. Following completion of this very deliberate analysis, the researcher would have presented the essential structure of this phenomenon in language nurses understand and use in practice. Within the discussion section of the results of the study, thoughts about the meanings of the study findings for nursing practice were to be brought to light, and determining what questions remain to be answered for nursing would be discussed.

## CHAPTER 4

### RESULTS

The protocol for conducting this clinical research study was approved by the university's HRRC and by the IRB at the hospital in August of 2010 (Appendix J). Upon approval, contact was made with the PAH clinic staff, a participant recruitment in-service was conducted by the researcher (Appendix K), and several recruitment packages were left with the nursing staff to distribute to clients receiving IV prostaglandin therapy as treatment for their pulmonary hypertension. The recruitment procedure was double-blinded to protect patient privacy.

To maintain clinic staff awareness of the proposed study, the staff was contacted regarding the study at one month and again at the sixth and eighth weeks of the recruitment period. Despite the distribution of recruitment packages to eligible participants by clinic staff members, no responses were returned to the researcher. At eight weeks approval for a modified recruitment protocol was sought from both the HRRC at the university and the IRB at the hospital. The revision allowed the researcher to be on site but secluded from patient reception and examination areas on the days that the pulmonary hypertension clinic would be conducted. The new arrangement would allow direct patient access to the researcher should the patient be curious about the opportunity to participate in this study. It was expected that the number of potential

obstacles caused by the need to return a letter to the researcher would be reduced, facilitating participant recruitment.

This revision was approved by both committees by the last week in November (Appendix J). Unfortunately, despite these additional efforts, by the seventeenth week of the recruitment period no patient had responded to enrollment requests. Given the limited time frame for completion of the study and having exhausted the anticipated pool of recruits, a consultation was held with the thesis committee chairperson. It was determined that this study would be closed in late December 2010, and an examination of the experience of living with IV prostaglandin treatment would be conducted by examining themes found in the current body of literature and defining the related nursing implications.

#### Themes from the Literature

This study proposed to obtain a subjective description of the experience of living with IV prostaglandin treatment for PAH. It was intended to determine what kinds of elements are common to the experiences of study participants and to develop an aggregate structure of the experience from their individual descriptions of it. It was hoped that the research findings would add to what is now known about this phenomenon. It was anticipated that the stories told by the participants could help to determine how nurses can help future patients to live optimally within the confines of a palliative treatment for this incurable illness.

To date, there are still few studies specific to the experiences of patients with PAH. This researcher was able to find only one qualitative study describing the experiences of patients living with PAH (Flattery et al., 2005). Other studies were found

that described physical and emotional symptoms associated with the disease (Löwe, et al., 2004; Rubenfire et al., 2009; Shafazand et al., 2004; Taichman, et al., 2005; White, Hopkins, Glissmeyer, Kitterman & Elliott, 2006; Wryobek, Lippo, McLaughlin, Riba & Rubenfire, 2007) and problems affecting patient's quality of life (Reubenfire et al., 2009; Wryobek et al., 2007).

### *Experiencing Physical and Emotional Symptoms*

From the literature, there is a great deal of evidence supporting an elevated presence of anxiety, panic disorders, panic attacks and depression among patients who have PAH (Löwe, et al., 2004; Reubenfire et al., 2009; Shafazand et al., 2004; Taichman, et al., 2005; White et al., 2006; Wryobek et al., 2007). Löwe, et al. constructed a broadly based study using members from a European, non-profit, pulmonary hypertension organization to investigate whether anxiety disorders, depression or other mental disorders were actually more prevalent in this patient group. The study participants were located in Germany, Switzerland and Austria. The 164 participants were matched with 164 control patients with inflammatory rheumatic disease (IRD) and 164 control primary care (PC) patients. The controls had chronic problems not causing dyspnea. All groups were well matched for age, sex, educational level and nationality. Notably, 6.5% of the PAH patients were on IV prostaglandin therapy, and work disability was 45% higher in the PAH group than in either the IRD or PC groups.

All study participants completed the Patient Health Questionnaire (PHQ), a self-administered instrument used to diagnose mental disorders in non-psychiatric settings (Löwe, et al., 2004). Patients with pulmonary hypertension were assigned to one of the four NYHA functional classes predicated upon their report of dyspnea at various levels of

physical activity (Löwe, et al.). From the questionnaire, it was determined that the prevalence of participants with PAH who experienced panic attacks was 25%; experienced a panic disorder was 10.4%; and had a major depressive disorder was 15.9%. IRD and PC participants who experienced panic attacks was 12.2% and 14.0% respectively; experienced a panic disorder was 6% and 4% respectively; and a major depressive disorder was 18% and 17%, respectively.

The results showed that at least one third of patients with pulmonary hypertension suffer from panic disorder and a major depressive disorder, and there was a very high prevalence of panic attacks among patients with pulmonary hypertension. These findings by Löwe, et al. (2004) were significant when compared to those of the groups not experiencing dyspnea. It appeared from the study findings that panic attacks and panic disorders were less likely a function of prostanoid therapy for PAH and more likely a function of the advancing stages of the disease; and, according to Löwe, et al., as in other patients with medical diagnosis, only 24% identified as having a mental disorder reported being treated for it.

In the study by Löwe, et al. (2004) the data collected was reported on a self-administered questionnaire. While using interviews to establish psychiatric diagnosis is considered the gold standard reference (Löwe, et al.), the use of reliable, sensitive, specific and validated self-report instruments like the PHQ to ascertain the presence of psychiatric symptoms in the study participants should not diminish the quality of the findings from this research. There may have been sampling bias related to the fact that the sample group participants were members of a pulmonary hypertension organization.



Strengths of the study included equivalent representation in the control groups of equally matched participants without respiratory disease.

In addition to emotional disruptions, persons with PAH demonstrated physiological disturbances beyond the effects of the disease on the pulmonary vasculature. Despite reports by patients of problems with memory and attention, White et al. (2006) found little information on the subject. So researchers determined to study the relationship between PAH and cognitive impairment in a well-defined PAH population.

Forty-six subjects, 38 (82.6%) of them female, with a mean age of 48.2 ( $\pm$  11.8 years) were enlisted in the study (White et al., 2006). The participants were evaluated to confirm the diagnosis of familial or idiopathic PAH by a board certified pulmonologist. The mean value of the time from diagnosis of PAH to testing for this study was 2.6 years. Twenty-eight participants were on IV prostacyclins and 30 were receiving supplemental oxygen. Each participant was subjected to extensive neuropsychological testing which was administered in person using a comprehensive battery of validated instruments. Among the tests used were the Beck Depression Inventory, the Beck Anxiety Inventory and the 36-item Medical Outcomes Short Form. Before and after testing, the oxygen saturation level and heart rate of each participant were evaluated to ensure that their oxygen levels were within normal limits during the tests.

White et al. (2006) found that there was a high incidence (58%) of cognitive sequelae associated with PAH. The impairment was found across an array of cognitive domains, including motor abilities, memory, mental processing speed, executive function and attention. Specifically, patients in the study struggled with activities requiring memory, executive function, attention, and rapid mental functioning. Of interest to this

researcher was the report of one patient who wrestled with memory problems that caused her to make mistakes when mixing her medicine. “[She] would forget which steps she had completed [while preparing Flolan®]....To prevent using incorrectly mixed medication, she discarded the medicine and started over. [The result was] wasted medication and increased drug costs” (White et al., 2006, Discussion, ¶ 2).

Within the findings of this study, White et al. (2006) found a 26% prevalence of moderate to severe depression and a 20% prevalence of moderate to severe anxiety among this cohort of study participants. In this study, the relationship between cognitive function, depression or anxiety and the kinds of medication therapy used among the participants was not examined. However, the prevalence of these disorders is no less noteworthy for patients receiving IV prostacyclin therapy, given that patients needing IV medications have severe disease and have endured the illness for a long time.

Shafazand et al. (2004) found that patients who were severely ill but on epoprostenol had better scores for emotional distress. It was postulated that this might have occurred in part because of drug effect, but was more likely a result of having a longer duration of disease at the time of the study. Patients on epoprostenol

... had more time to understand their disease, accept their functional limitations, develop coping strategies and build an adequate support system....they have more interactions with physicians and nurses....and may be... selected because of their ability to cope with the challenges of such therapy ....Nevertheless, compared with population norms, they continued to have substantial functional and emotional limitations...(pp. 1457-1458).

The examined literature demonstrated that functional status for patients with PAH declined with the increasing severity of the disease, symptoms of the disease and with emotional responses (Löwe, et al., 2004; Rubenfire et al., 2009; Shafazand et al., 2004; Taichman, et al., 2005; White et al., 2006; Wryobek et al., 2007). Instruments used to measure the severity of illness among participants included the WHO Functional Classification (Appendix A), the NYHA Functional class (Appendix B), and the 6-minute walk test (6MWT). The Nottingham Health Profile, the Saint George's Respiratory Questionnaire, and the Minnesota Living with Heart Failure Questionnaire were among instruments used to measure disease symptoms. Measures used to assess emotional responses included the Patient Health Questionnaire, the Hospital Anxiety and Depression Scale; and, in the study by Löwe, et al. (2004), the Beck Depression Inventory and the Beck Anxiety Inventory.

#### *Living with Uncertainty*

The research done by Flattery et al. (2005) identified that the over-arching theme of living with PAH is to experience a great deal of uncertainty. In this study, eight women and three men were interviewed using a semi-structured interview design. Six of the eleven participants were on a prostacyclin analog. The experiences of these six participants were not analyzed and segregated from the experiences of the other patients who were receiving other authorized treatments for PAH. The study participants described learning to cope with the uncertainties associated with their illness and moving on with their lives.

Coping, as described by the researcher, was characterized in several ways. It was associated with seeking information, with making memories, using humor, engaging in spirituality and with seeking support. Flattery et al. (2005) summarized the concept of moving on with life with these descriptors: “[Doing] what I have to do... [Making] adjustment[s] to treatment... [And] resuming life’s activities” (p. 102).

During the long period of diagnosis, several participants reported that they sought information using the internet (Flattery et al., 2005). One participant who did this reported that “the hardest thing was not knowing” (p. 101), but sometimes the knowing was difficult: “... it said the life expectancy was 3 to 5 years. It was a shock” (p. 101). Another woman coped by making memories through painting pictures for various family members “for them and for me” (p. 101). Others used humor as a coping strategy, and spirituality played a role as well. “... [If] you got a strong faith, you go with that. If you don’t, I’m not sure what you do” (p. 102). Several reported that they were involved in support groups that helped them to cope with having PAH.

It appeared that the participants on IV prostacyclins had to make many adjustments to life with treatment, as their comments were highlighted during this part of the analysis. On mixing epoprostenol: “It’s just a part of my life, it’s just what I do... like everything else... You can make a huge thing out of anything, and I don’t think mixing Flolan® is a huge thing” (Flattery et al., 2005, p. 105). As they made adjustments, a participant noted that “it’s added years to my life... but it’s bittersweet in a way” (p. 102). Those adjustments were often difficult but eventually resolved to a new definition of what would become normal in their lives. Many reported that they were able to resume activities as a result of the physical improvement their treatment brought. One reported

resuming gardening and fishing but “I can’t do it as long before I have to rest” (p. 102).

One participant summed up the thoughts of many participants when he said, “I tell people, you have a pie every day and you have so many pieces of it and you have to figure out that once you use it up, it is gone” (p. 102).

### *Living with End-of-Life Concerns*

Managing end-of-life issues poses a burden on patients and their care givers. Patients who have PAH die as a result of right heart failure or from sudden cardiac death, and, anecdotally, have not survived cardiopulmonary resuscitation (CPR). Hoepfer, Galié, Murali, Olschewski, Rubenfire and Robbins et al. (2002) investigated the outcome of CPR in a group of PAH patients to validate its effectiveness. The study was retrospective, using multiple centers in both Europe and the United States. Between 1997 and 2000, 513 patients had a circulatory arrest. Of those, 132 received CPR in a hospital environment, and the results were unsuccessful in 104 (79%) of the patients. An additional 13% died within 7 days. Eight survivors of more than 90 days and without neurological deficit had rapidly reversible identifiable causes of their circulatory arrests. The researchers concluded that “CPR for circulatory arrest in this patient population is rarely successful unless the cause of the cardiopulmonary decompensation can be corrected” (Abstract).

Wyrobeck et al. (2007) notes that an additional, unique problem for PAH patients nearing the end of life may be the denial of hospice care because of the expense of their IV prostacyclin treatment. Yet, if discontinued, death would occur within minutes to hours (Barst, et al., 1996; Roncesvalles et al., 2008; Traiger, 2007). Wyrobeck et al. likens “the decision to stop the IV prostacyclin [as] comparable to removing a conscious

patient from a ventilator... so, without hospice care, the patient and family are left with few choices and limited support... [when most needed]" (p. 473).

## CHAPTER 5 DISCUSSION

### Practice Implications of Themes in the Literature

The results of the literature review show that there remains little in the literature that determines what it is like to experience PAH. Moreover, there is a lack of studies that separate human responses to the experience of treatment for PAH with continuous intravenous medicines. It is not known whether the lived experience of patients on IV prostaglandins is by nature different from the experiences of others with PAH receiving oral and inhaled therapies. What is known is that as a group, patients with PAH suffer high levels of major depressive disorders, anxiety disorders, panic disorders and panic attacks. There is disease-related progressive decline in physical function, cognition and memory, which may progressively and concurrently affect individual coping responses (Löwe, et al., 2004; Rubenfire et al., 2009; Shafazand et al., 2004; Taichman, et al., 2005; White et al., 2006; Wryobek et al., 2007). It is known that PAH patients must marshal an arsenal of coping strategies to contend with the uncertainties associated with their diagnosis, the life sustaining medicines and equipment, and the effects of treatment. Patients with PAH are vulnerable, and developing research protocols that will help nurses to identify effective interventions for this patient population needs to be done.

Until such research is completed, some recommendations for nursing care of the patient receiving IV prostaglandin treatment for PAH can be made, based on the findings of the literature review and by understanding Mishel's (1990) reconceptualized theory of

uncertainty in illness. Mishel found that uncertainty can be viewed in two ways: first, within a *mechanistic paradigm* where uncertainty is viewed “as an enemy that must be eliminated” (p. 261); and second, in the *probabilistic paradigm* where uncertainty is viewed as a naturally inherent part of human existence. In the probabilistic paradigm, life experience cannot be determined with certainty. Within this paradigm, however, nurses can partner with chronically ill patients to use uncertainty as a springboard for expanding possibilities and growth. According to Mishel (1990), within this partnership nurses may help patients explore new ways to complete desired activities, consider different ways to adjust to the changing nature of the illness or promote the idea that many factors can influence treatment response in order to “facilitate the patient’s evaluation of uncertainty and promote a probabilistic view of life [with chronic illness]” (p. 261). Through this process, nurses can help and support patients living with PAH to cope with the uncertainties of their disease and its treatment in healthy and creative ways.

The finding by White et al. (2006) that 58% of the patients with PAH in their study experienced cognitive impairments across all of the cognitive domains is significant. Living with PAH requires immense physical, emotional and social adjustments (Traiger, 2007). Cognitive impairments add to the difficulty of coping and adjusting successfully to this burdensome health status. Nurses need to be aware of adverse brain-related outcomes in this patient population, and to ensure that optimal treatment interventions encompassing the physical, emotional (including psychological counseling and treatment) and social domains are in place to prevent or reduce the impact of cognitive dysfunction on patients with PAH.



Access to this timely and optimal treatment can be facilitated by nursing case managers. Hesselgrave (2003) notes that there are challenges coming from within the health care system

... that focus on cost-containment [and] perpetuate the gap between patients and the care they need....Patients report difficulty in getting referrals to [specialists], a matter they believe stems from the lack of understanding [about PAH] by plan administrators, payors and primary clinicians (p. 65).

The role of the case manager is to monitor the use of resources by patients who may require excessive support. Hesselgrave (2003) posits that in that role, case managers become “the liaison to ensure access to the thorough and attentive clinical experts that are necessary.... [And] get payor clients to realize that the right medical care at the right time is essential [for patients with PAH]” (p. 69). These advocacy efforts can improve patient outcomes and reduce the cost of treatment. Through these efforts, the nursing case manager can help to alleviate the anxiety felt by patients throughout the period of diagnosis and treatment of PAH.

Nurses must support patients in the use of healthy coping strategies to manage the uncertainties encountered by having PAH. In the study by Flattery et al. (2005), coping methods that patients use were identified. Seeking information about their disease from internet web sites is common. Because nurses are instrumental in providing information and education to patients, nurses must direct patients and their families to internet sites that provide accurate and up-to-date information about PAH, especially during the period when diagnostic testing is taking place or when changes are being made in treatment. A popular and reliable website for patients and their health care providers is maintained by

the Pulmonary Hypertension Association (PHA) at <http://www.phassociation.org>. Nurses must be prepared for ensuing questions and concerns that patients may have as a result of their investigations, and be able to provide direction to address those matters in light of what is known about each patient's health status and treatment plan.

The PHA (2010) webpage is comprehensive. On it, the PHA hosts a wealth of information and resources for patients, their caregivers, and health care professionals in the United States. Written materials are also available. The webpage has a listing of national, regional and local support groups for patients. Sister organizations exist internationally, and can be accessed at the provided PHA website address. Becoming familiar with this organization and its website may prove beneficial for professional development and research, and for assisting nurses to help patients seeking information about PAH.

Traiger (2007) notes that nurses are instrumental for giving patients and families the information they need to understand the disease process and "all the available and appropriate treatment options" (p. 33), including medications, research protocols, surgical options and lung transplantation. Patients and their families need to have any misinformation clarified. When a treatment plan is made, nurses will teach the patient and caregiver about therapy management, the expected effect of treatment and any side effects. They need information about symptom management. Patients receiving IV prostaglandin therapy require education about pump use and implanted catheter care, as well as what to do in any emergency. Patients getting IV therapy require regular contact from nurses who specialize in the assessment and education of patients on IV

prostaglandins (Traiger, 2007). These specialized nurse educators have a crucial role in helping patients comply with the demands of IV treatment for PAH.

Spirituality has a role among the coping strategies found by Flattery et al. (2005). While making significant life changes in order to maintain a quality of life with PAH, patients may increasingly rely on psychological and spiritual resources for support during those times of adjustment. According to Schirm (2009), spirituality is defined broadly in the nursing literature “as embracing ‘love, compassion, caring, transcendence, relationship with God, and connection of body, mind and spirit’” (p. 145). Spirituality as a belief-system affects all aspects of a person’s well being. Thoughtful evaluation by nurses of the extent and type of belief system that a patient has, along with assuring the ongoing provision of needed resources for spiritual support will help patients effectively cope with their changing status.

There is no cure yet for PAH. Presently, the aim of treatment is palliative--to lengthen survival time, relieve symptoms and improve quality of life (McKenna et al., 2006). However, the cost of IV prostaglandin therapy has impacted not only the ability of patients to pay for the drugs (Löwe, et al., 2004; Rich, 2000; Traiger, 2007), but also the ability of these vulnerable patients to access hospice care when it is most needed (Traiger, 2007; Wryobeck et al., 2007). Survival rates for patients with PAH and circulatory collapse given CPR is poor (Hoepfer, et al., 2002). Recognizing this, nurses and other health care providers need to begin discussions about issues related to end-of-life care with patients early in the course of treatment so there is time for decision-making. Nurses are committed patient advocates, and creative solutions must be designed

and tested so that patients on this form of treatment continue to receive compassionate, holistic care during their final days.

Researching the lived experience of patients receiving IV prostaglandin therapy for PAH remains a viable nursing endeavor, especially given that nursing is focused on caring science (Watson, 2008) and has developed expertise using qualitative methodology to explore questions in patient care (Streubert-Speziale & Carpenter, 2007). Such studies will contribute to nursing knowledge a sharpened understanding of the issues facing patients and enable nurses to closely match nursing interventions to support what matters most to this patient population.

#### Limitations of the Current Study

As a researcher, I was disappointed that I was unable to carry my proposed research forward. However, my experience prompted me to think about why I experienced recruitment failure. Chin Feman, et al. (2007) report that “recruitment challenges are reported to be the cause of 45% of study delays with delays often exceeding 6 months” (Introduction, ¶ 1). What strategies are being used by other investigators to recruit study participants? How do the HIPAA Privacy Rule and the federal rule for Protection of Human Subjects (Common Rule)—the two federal laws that mandate how personal health information can be used and mandate the required consent process (Rothstein, 2005)—affect the recruitment process? What future strategies may be useful to recruit participants from populations with a rare disease and/or treatment?

#### *Regulatory Constraints on Research Recruitment*

Prior to the implementation of the HIPAA Privacy Rule in 2003, the regulation of privacy issues in research involving human subjects was the domain of the Common

Rule. This rule was developed in response to the Belmont Report of 1978, which became the basis for the Common Rule. The report “articulated the ethical principles upon which standards of ethical conduct in research are based: beneficence, respect for human dignity, and justice” (Polit & Beck, 2004, p. 143). The Common Rule identified the means by which ethical conduct in research would be assessed and applied.

On April 14, 2003, the HIPAA Privacy Rule became effective. The new Privacy Rule and the older Common Rule were intended to be complementary in regulating research privacy. Both rules define research “as a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge” (45 C.F.R. § 164.501 [2004] {Privacy Rule}; 45 C.F.R. § 102(d) [2004] {Common Rule} as cited in Rothstein, 2005). But there are areas where the rules diverge, which has caused some confusion, frustration and misunderstandings by researchers, research subjects and institutional review boards (Gostin & Nass, 2009; Marsh, McMaster, Parvizi, Katz & Spindler, 2008; Ness, 2007; Rothstein, 2005) since the Privacy Rule has been implemented.

To sort through this confusion, it is helpful to understand that the general provisions of the Privacy Rule and the Common Rule are different in important respects. According to Rothstein (2005), they differ in coverage, what is protected, and in oversight. The Privacy Rule applies to:

Certain health providers, health plans and health clearinghouses and their business associates. The Common Rule applies to researchers receiving federal financial support... [that are performing] research conducted in contemplation of submission to the Food and Drug Administration... [that are performing] research

[representing] an institution that has signed a ‘multiple project assurance’ with Health and Human Services (HHS), [meaning that the institution promises] to comply with the Common Rule in all research, regardless of the funding source (p. 155).

The Privacy Rule is designed to maintain the privacy of protected health information in its use and disclosure by the covered entities listed above. The Common Rule is designed to protect the welfare of human research subjects, which includes the privacy of the participants and the confidentiality of the data they provide. If the Privacy Rule is violated, the complaint is directed to the Office for Civil Rights of HHS, which is responsible for its oversight. The primary responsibility for ensuring compliance with the Common Rule lies with the IRB of the institution performing the research. The IRBs, in turn, are overseen by the Office for Human Research Protections that is within HHS (Rothstein, 2005).

There are also notable discrepancies between the Common Rule and the Privacy Rule which have led to inconsistencies in research oversight. A problem consistently identified by researchers is about the discrepancy between the rules regarding preparation for research (Gostin & Nass, 2009; Marsh et al., 2008; Ness, 2007; Rothstein, 2005). Under the Privacy Rule within the preparatory to research provision, a covered entity may permit a researcher who works for that covered entity to review protected health information (PHI) in preparation for research—perhaps to aid study recruitment—without prior permission given by the individual for access to his or her personal PHI. The preparatory research provision allows such “a researcher to identify prospective research participants for purposes of seeking their Authorization to use or disclose [PHI]

for a research study” (National Institutes of Health, 2007, Activities Preparatory to Research, ¶ 2). Under the Common Rule however, all recruitment activities are considered an element of research. Therefore, the research protocol must first be approved by the IRB before recruitment activities of any kind may take place. In this instance, the Privacy Rule permits conduct that is not allowed under the Common Rule, creates an artificial distinction between researchers who are internal or external to a covered entity, and offers fewer protections than the Common Rule provides (Gostin & Nass, 2009; Rothstein, 2005).

According to findings by Ness (2007) and Wolf and Bennett (2005), the primary focus by the Privacy Rule on consent has diminished the ability of investigators to recruit participants, increased the time required to complete a study, and has added to the cost. Gostin and Nass (2009) points out that the “universal requirement for consent... creates selection bias, which limits the generalizability of results and leads to invalid conclusions” (p. 1374). Among several recommendations made in the article by Gostin and Nass to address rule discrepancies, was a proposal that there be made by HHS “consistent rules for activities conducted in preparation for research, such as identifying and recruiting potential research participants” (p. 1374). Clarification of the rules will make a level field for researchers not employed by a covered entity, may help to reduce study delays, and facilitate resource utilization.

#### *Interventions to Address Recruitment Constraints Suggested by the Literature*

Since implementation of the HIPAA Privacy Rule, investigators are finding ways to stimulate recruitment into research studies that meet the requirements of the Privacy Rule and improve the recruitment of participants into studies from all segments of the

population, including those that have historically been poorly represented (Fouad, et al., 2004). Because many issues influence whether a person chooses to participate in research or not, investigators have used several approaches to help stimulate participant recruitment. Sometimes the strategies have been used alone, and at other times, synergistically (Chin Feman, et al., 2008; Fouad, et al., 2004; Richesson et al., 2009). Fouad, et al. described study-wide recruitment efforts and site-specific recruitment strategies that were effective based on their experience with the Women's Health Initiative (WHI).

The WHI was a large, national, multicenter study that investigated the major causes of death and disability among postmenopausal women. The investigators were challenged to recruit a sufficient number of women from diverse populations, including older women and women from ethnic minorities who are typically underrepresented in clinical studies. The investigators evaluated the scientific literature to determine why this problem exists, and used their findings to formulate specific recruitment strategies to stimulate recruitment to the study at the national and local levels.

The WHI study involved 40 clinical centers across the United States including Hawaii but not Alaska. Of the 40 centers, 10 were classified as minority centers and were in areas where minority populations live. The WHI used the national media for publicity about the study as well as a mass mailing package about the study with contact information for locally funded centers. Each individual center devised materials to appeal to its own population such as culturally specific materials or materials aimed at women with specific demographics, like age. Recruitment coordinators targeted public databases such as insurance companies and large corporations to find possible participants. Mass



media strategies included the use of paid newspaper advertisements, newspaper and periodical articles about the study, and radio and television public service announcements at both national and local levels.

Investigators also used direct physician and other health-care provider contact to request referral of potential participants, worksite recruitment, and a program that asked enrolled participants to, with the permission of the participants' friend, to provide that friend's name to the investigators as a possible recruit. Participants were given a gift certificate to a retail store for each friend recruited. Community outreach activities included health fairs and church presentations. In some instances, transportation was provided to a clinical site, and Saturday hours were instituted. Responses were generous because individual clinics tailored their recruitment strategies to targeted populations. Once recruited, respondents underwent a series of face-to-face screening events to introduce the study, determine interest levels, establish trust and ascertain eligibility.

Overall, recruitment to the WHI was successful. Fouad, et al. (2004) found that the key to recruitment "is in getting the information out to the target audience: making the first contact and providing information" (p. 350). The investigators also noted that, for minority recruitment, "the [reported] distrust [of the medical community by minority groups] can be overcome by interpersonal contact through community outreach, referral, and other culturally appropriate recruitment strategies" (p. 351).

Chin Feman, et al. (2008) conducted an NIH funded study "testing the effect of the patient-physician relationship and acupuncture on irritable bowel syndrome patients at a large tertiary care hospital in a major metropolitan area" (p. 242). Following "four months of recruitment and one enrollment" (p. 243), the investigators re-evaluated their

recruitment plan. To recruit the number of participants needed for the study successfully, adjustments were made.

The researchers used several recruitment strategies. Strategies included the use of mass media, including paid newspaper and television advertisements, free classified advertisements in university newspapers, and the strategic placement of fliers. Not only were fliers placed in areas that might be noticed, but at different, scheduled times as well. A similar strategy was used for placing advertisements on mass transit. The internet was used. Short text advertisements were placed for free on craigslist.com, clinicaltrials.gov, and on a disease-specific website. The researchers also maintained a small website for the study. Informational materials were delivered to local, private gastroenterology practices. Several local private psychology and general medicine practices were notified of the study as well.

Chin Feman, et al. (2008) used a novel equation to determine the efficacy of each recruitment strategy, based on the ratio between fractional cost to fractional enrollment, called the Efficacy Index (EI). From the calculations, Chin Feman, et al. found that physician referrals and posting fliers were efficient methods for recruitment to this study. Internet advertisements were also efficient, but website recruitment was not. Using mass transit advertisements and newspaper advertisements was the least effective methods, but some respondents did report that they had seen information about the study in more than one place.

Richesson et al. (2009) evaluated the impact of an automated, administrative registry on enrollment and participation in advertised clinical research studies. The registry consists of individuals who have self-identified one or more rare disease entities,

and who have acknowledged a willingness to be contacted for possible enrollment in clinical research studies. This registry, the Rare Diseases Clinical Research Network (RDCRN), actively began accepting enrollment via the internet in 2004 and sending automated messages by e-mail about clinical trials to its enrollees since 2007. Automated methods like this registry "... offer an inexpensive approach to communicating with potential study participants, and are scalable to communicate with ever-growing numbers of individuals without a corresponding increase in resources" (p. 60). The online patient registry can be an important tool for clinical research by increasing the efficiency of research recruitment.

The RDCRN is diverse by disease process but the majority of enrollees are Caucasian, which, according to Richesson et al. (2009), may "reflect the demographics of those having these diseases, [may reflect] the likelihood... [of] better access to rare disease specialists for disease diagnosis and care... or access to the internet" (p. 60). The authors believe that further evaluation of the registry enrollment is needed to determine whether the composition is generalizable to the greater population affected by rare diseases or if there is access or other barriers to enrollment.

#### Conclusions Regarding Recruitment Literature and Application to Current Study

An ideal approach to research recruitment produces a number of calls and rapid enrollments with little effort by the recruitment staff and with the least cost (Chin Feman, et al., 2008). No one method works to stimulate recruitment in every situation and recruitment difficulties increase when researchers want to investigate the problems associated with rare illnesses and treatments (Richesson et al., 2009; Steinke, 2004). Among the ways that potential participants have learned about clinical trials is by

physician referral, through registries, fliers and brochures, the media; including television, newspapers and the radio, community advertising, the internet, from a friend, or by a cold call (Chin Feman et al, 2007; Fouad, et al., 2004; Richesson et al., 2009; Steinke, 2004). Fouad, et al. (2004) noted recruitment success in some populations when socioeconomic issues were addressed and strategies were individualized to communities. While the literature reviewed involved two large studies that sought participants from the general public and one that involved the recruitment of participants with rare diseases, elements of their recruitment strategies could be used to stimulate recruitment into many kinds of investigations.

The current study was to involve a limited population defined by the relatively rare condition of PAH. Additionally, the defined population was to be receiving a specific and difficult treatment for their disease. Related to working as a staff nurse at a local, tertiary care hospital system, this researcher was aware that within the system there was an outpatient clinic that enrolled members of the population of interest. After contacting the clinic's nurse manager to learn about the number of patients seen with this diagnosis and treatment, my thesis committee chairperson and I believed the study would be feasible despite the small number of potential participants in the clinic patient population for this qualitative investigation.

To comply with the HIPAA Privacy Rule for research, an opt-in approach to recruitment was devised. Potential participants were to be given a recruitment package by clinic staff, and as the researcher, I would follow-up only with those who returned the letter. After developing the study proposal, I sought the approval of the IRBs for my proposed study from both my university and from the hospital system. Ultimately, despite

regular contact with clinic staff to remind them of the study, their diligent effort, and a revision of the protocol that allowed this researcher to meet with interested recruits on site, recruitment failed. I believe that I underestimated the resources that I would need for recruitment.

In addition to the local clinic from which I sought participants, there is an important resource that may have been helpful for recruiting participants—the PHA internet website at <http://www.phassociation.org>. Not only does this virtual community provide patient information and support as described previously, there is support for the practice of health care professionals in regards to the diagnosis and treatment of PAH, too. Researchers may post information to the online lay community about opportunities to participate in research (Pulmonary Hypertension Association, 2010). Using this resource to cast a wider recruitment net might have helped to prevent recruitment failure for this study.

Disease registries have been used to assist the clinical research process for many years. According to Richesson et al., (2008), such registries have been used since the 1940s in cancer research. Because of the recruitment challenge of identifying potential participants for a given study, the idea of maintaining lists of affected persons who have an interest in participating in clinical research is an appealing method for researchers to use. These managed lists of potential research subjects are seen to potentially ease recruitment and increase the likelihood of acquiring an adequate representative sample from which to generalize study results.

There are two types of registries. The first type is called an administrative registry. Individuals with particular diagnoses may join this kind of registry to receive

personal notification of research projects they may be eligible to participate in.

Researchers can approach the registry for assistance recruiting people to participate in their studies (Richesson et al., 2008). The second type is population based.

Population based registries collect disease-related data, either from self-report or, with individual consent, from medical records. This information is used for data mining, generating research hypotheses, and secondary research questions (Richesson et al., 2008). The Registry to Evaluate Early and Long-term PAH Disease Management (REVEAL) is a population based registry for patients with WHO group I PAH (McGoan, et al., 2008). It is a multicenter, observational, US-based registry designed to study the disease course and disease management over time of patients with PAH. Among its objectives is “to identify clinical predictors of short-term and long-term outcomes” (Table 1, p. 924), and, in anticipation of unseen research goals not anticipated at the study’s inception, is the objective “to collect timely and relevant data that will assist in the evolving research needs of the PAH community” (Table 1, p. 924). Investigating access to this registry may have also helped to provide a pool of participants for my proposed research. I noted that, in the list of principal investigators were local individuals from whom this researcher might have been able to request information about registry access for the proposed research. While examining the literature on a topic of interest for research, it may help recruitment efforts to collaborate with other investigators sharing interest in a study topic.

Given the impact of recruitment delays and failure can have on worthwhile projects (Chin Feman, et al., 2008), novice researchers should become familiar with currently effective recruitment methods and strategies for their research projects. While

nurses may possess a general awareness of sample recruitment strategies (Polit & Beck, 2004), nurses are not educated about the kinds of marketing strategies that can increase the efficacy of recruitment. Consideration should be given to expanding the topic of recruitment methods in nursing research texts and directing students to research articles addressing recruitment methods appropriate to their research.

There is a burden placed on nurse educators and experienced researchers mentoring novices to ensure that the student is familiar with federal rules affecting research and participant privacy, including the Common Rule and HIPAA Privacy Rule. A useful approach to ensuring such familiarity is to take a course such as the ones offered by the Collaborative Institutional Training Initiative (CITI) at [www.citiprogram.org](http://www.citiprogram.org). The CITI courses offer a menu of research ethics education to investigators. Courses are generally required for researchers in institutions where human or animal research takes place, and certification is issued to those satisfactorily completing the educational modules.

### Summary

Despite encountering a failure of recruitment into the present research study, from the synthesis of current literature about PAH, conclusions about nursing care and interventions have been made that are based on the present state of science regarding the experience of enduring the symptoms of PAH and its treatment. Additionally, the usefulness of a phenomenological approach for increasing our understanding of patients' experiences in order to better provide nursing care to them as they undergo new treatments or use technology for their chronic illness has been discussed. A descriptive phenomenological approach helps nurses gain needed insight into the human experience

of these phenomena, enabling us to more fully focus on and support what matters most to our patients.

Completing a research project can be a difficult but rewarding endeavor. There can also be disappointments, including research delays and recruitment failures. Obstacles to recruitment and strategies for overcoming these obstacles were discussed. It is hoped that by sharing this experience, others investigators will have awareness not only of the challenges of participant recruitment but of some workable strategies to help ensure success in research efforts.



## APPENDICES

## APPENDIX A

Table 1: Classification of Pulmonary Hypertension: Third World Conference on  
Pulmonary Hypertension; 2003; Venice

APPENDIX A

Table 1

*Classification of Pulmonary Hypertension: Third World Conference on Pulmonary Hypertension; 2003; Venice*

Group I—Pulmonary arterial hypertension (PAH)
Idiopathic PAH
Familial PAH
PAH associated with:
Collagen vascular disease
Congenital systemic to pulmonary shunts (large, small, repaired, or unrepaired)
Portal hypertension
HIV infection
Drugs and toxins
Other (glycogen storage disease, Gaucher disease, hereditary hemorrhagic Telangiectasia, hemoglobinopathies, myeloproliferative disorders, splenectomy)
PAH associated with significant venous or capillary involvement:
Pulmonary veno-occlusive disease
Pulmonary capillary hemangiomatosis

<p>Group II—Pulmonary venous hypertension</p> <p>Left-sided atrial or ventricular disease</p> <p>Left-sided valvular heart disease</p>
<p>Group III—Pulmonary hypertension associated with lung diseases and/or hypoxemia</p> <p>Chronic obstructive pulmonary disease</p> <p>Interstitial lung disease</p> <p>Sleep-disordered breathing</p> <p>Alveolar hypoventilation disorders</p> <p>Chronic exposure to high altitude</p>
<p>Group IV—Pulmonary hypertension due to chronic thrombotic and/or embolic disease</p> <p>Thromboembolic obstruction of proximal pulmonary arteries</p> <p>Thromboembolic obstruction of distal pulmonary arteries</p> <p>Nonthrombotic pulmonary embolism (tumor, parasites, foreign material)</p>
<p>Group V—Miscellaneous</p> <p>Sarcoidosis, histiocytosis X, lymphangiomatosis, compression of pulmonary vessels (adenopathy, tumor, fibrosing mediastinitis)</p>

Note. From “Clinical classification of pulmonary hypertension” by Simmoneau, Galie,

Rubin et al., 2004, *The Journal of the American College of Cardiology*, 43, p. S10.

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## APPENDIX B

### NYHA/WHO Functional Classification for Pulmonary Arterial Hypertension

APPENDIX B

Table 2

*NYHA/WHO Functional Classification for Pulmonary Arterial Hypertension*

Class I	No limitation of usual physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain or near-syncope.  Asymptomatic
Class II	Slight limitation of physical activity; no discomfort at rest, ordinary activity causes undue dyspnea, fatigue, chest pain, or near syncope.
Class III	Marked limitation of physical activity; no discomfort at rest, but less than ordinary physical activity causes undue dyspnea, fatigue, chest pain, or near syncope.

Class IV	Inability to perform any physical activity without symptoms. Signs of right ventricular failure or syncope.  Dyspnea and/or fatigue may be present at rest, discomfort increased by any physical activity.
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Note: The NYHA/WHO modification (Rich, 1998, cited in Traiger, 2007).

APPENDIX C

Permission Letter, PAH Clinic



APPENDIX C

Permission Letter, PAH Clinic

Permission to Conduct Research, Spectrum Health Heart Failure and PAH Clinic

Phyllis Boone  
1000 Grand Valley Ave  
Grand Rapids, MI 49503  
616-486-6577  
616-486-6577  
616-486-6577

December 23, 2009

To Whom It May Concern,

I have been contacted by Phyllis Boone, student from Grand Valley State University, to have the Spectrum Health Heart Failure, Transplant and Pulmonary Hypertension Clinic assist in her education requirements by participating in a research project. I have reviewed the information/clinic requirements with her and agree to allow Phyllis to move forward with this research project.  
Please do not hesitate to call me if you have any questions.

Respectfully,



Andrea Byrne-Meyer, RN, MS - Manager  
Preventive Cardiology & Rehabilitation and  
Heart Failure/Transplant & Pulmonary Hypertension Clinics  
Spectrum Health Grand Rapids  
2902 Bradford St NE  
Grand Rapids, MI 49525  
616-486-6577 or 486-6920  
fax 616-486-0105

**APPENDIX D**  
**Recruitment Letter**

APPENDIX D  
Recruitment Letter

301 Michigan St. NE  
Grand Rapids, MI 49503-3314

Dear Patient:

The purpose of this letter is to invite you to participate in a clinical study about what it is like for you to take IV medicine to treat your Pulmonary Arterial Hypertension. Talking about your experience can help nurses understand what this is like for you in order to better meet special needs you may have. Other patients taking the medicine might have the same kinds of experiences, and your story may help nurses to help them as well. The newness of this treatment makes the need for this kind of research greater.

This study asks for your participation in a single interview, which will take place in your home or place of residence. There will be one researcher, who is a graduate student at Kirkhof College of Nursing at Grand Valley State University. The interview will take 45 to 60 minutes. It will be electronically recorded and notes will be taken. You will be able to stop the interview at any time if you do not feel well or become tired. Your identification will remain confidential. Unique situations that may reveal who you are will be removed, and specific statements will not be linked to you. When the study is finished, the research findings will be shared with the clinic staff, students at Grand Valley State University, and with nurses working in hospitals, clinics and in education. The findings may be shared at a nursing conference.

If you want to learn more, or if you are interested in participating in this study, mark the “Yes blank below. Then return this letter with your contact information below

in the stamped, self-addressed envelope provided. After I receive your letter, I will contact you within 3 business days to answer questions and set up a time for the interview. You are welcome to contact me by e-mail. Thank you for thinking about taking part in this study.

Sincerely,

Phyllis Boone, BSN, RN, MSN student

Kirkhof College of Nursing at Grand Valley State University

[boonep@mail.gvsu.edu](mailto:boonep@mail.gvsu.edu)

Yes, I am interested \_\_\_\_\_

Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

Phone Number: (\_\_\_\_) \_\_\_\_\_ E-mail: \_\_\_\_\_

**APPENDIX E**

**Text Message of the Reminder Postcard**

## APPENDIX E

### **Text Message of the Reminder Postcard**

This is a reminder to you about the study of what it is like for you to take intravenous medicine for your PAH. If you have not done so already and would like to be part of this study by sharing your story, please fill out and return the letter in the envelope that you were given at the PAH clinic. If you have any questions about the study, you can contact the primary researcher at the e-mail address or the phone number that is given in the letter you received at the clinic. She will be happy to help you. Whether you have already returned the letter or decided that you cannot participate, we'd like to thank you for considering being a participant in this study.

**APPENDIX F**

**Confirmation Letter**

APPENDIX F  
Confirmation Letter

301 Michigan St. NE  
Grand Rapids, MI 49503-3314

Dear Participant,

Thank you again for being willing to take part in this research study. We are meeting together on Date: \_\_\_\_\_, Time: \_\_\_\_\_ at your home or place of residence for a 45 to 60 minute interview. There are some things that will help to make our time together productive. This letter will give you some helpful hints to meet that goal.

A copy of the research consent form and HIPAA authorization for the release of personal health information for research has been sent to you with this letter. Before we meet, please take some time to read the forms. It is very important for you to understand the messages there before the interview starts. You may write down any questions you have for me about the forms. You may call me or e-mail your questions or concerns to me using the contact information below. We will sign the forms together just before the interview will start.

Then I will set up some equipment so that the interview can be digitally recorded. When the interview begins, please speak as clearly as you can. It will help if we can work together in a quiet room that is comfortable for you. It will also be helpful to reduce interruptions during the interview. Switching off electronic devices like cell phones will be important during our time together.

The physical effort required by the interview may be tiring for you. You may stop the interview at any time you believe that it is too hard to finish. For example, you might have too much physical discomfort like shortness of breath. I may stop the interview if I



see that you are having trouble. You may be asked if you would be willing to re-schedule an interview at another time.

The process of in-depth interviewing may bring up areas that cause emotional discomfort for you. I will make every effort to minimize such occasions. The interview may expose some new areas of difficulty for you-such as difficulty managing symptoms, the medication and equipment, financial issues or support problems. You will be given a contact number for the Heart Failure, Transplant and Pulmonary Hypertension Clinic, and you will be directed to the appropriate person that can help you address your problem.

The information we nurses learn in this study may help us to better understand what life experience while on IV medicine for treatment of pulmonary arterial hypertension is like for you and for our future patients. It may help us develop new ways to care for patients who share your situation. Thank you for your time and energy that will help to meet these goals.

Sincerely,

Phyllis Boone BSN, RN, MSN Student

Kirkhof College of Nursing at Grand Valley State University

boonep@mail.gvsu.edu

**APPENDIX G**

**Research Informed Consent & HIPAA Authorization for Release of Health Information for  
Research Purposes**

## APPENDIX G

### **Research Informed Consent & HIPAA Authorization for Release of Health Information for Research Purposes**

#### **Research Consent For:**

The lived experience: Pulmonary arterial hypertension and intravenous prostaglandin therapy

#### **Protocol number:**

**Principal Investigator:** Phyllis D. Boone, BSN, Graduate Nursing Student

**Affiliation:** Kirkhof College of Nursing at Grand Valley State University

“You” refers to the patient.

#### **Introduction:**

You are being asked to be a part of a clinical research study. Clinical research is the study of human diseases and associated problems, of possible treatments, or ways to diagnose disease. It is up to you to decide whether to be a part of a research study, or not. To help you make this decision, you need information about the study’s possible risks and benefits and alternatives. This process is called informed consent.

This consent form gives detailed information about the research study. The researcher will discuss this information with you. You can also ask any questions you have. After you have received this information, if you decide to participate in this study, you will be asked to sign this form. You will be given a copy of the signed form.

### **Nature and Purpose of this Study:**

The purpose of this research study is to learn what it is like for you to live with IV treatment for pulmonary arterial hypertension (PAH). During an interview in your home or place of residence, you will be asked to tell the student researcher about your experience. The study is being done to help nurses understand what it is like for you and others like you to have this treatment. Your story can help nurses provide care that supports the unique needs that you and others being treated with these medicines may have.

To be a part of this study, you must:

1. Be age 18 years or older, able to speak and understand the English language, be able to think about a question and discuss your answer, and have the time needed for an interview.
2. Be willing to participate in a private interview.
3. Be medically stable. This means you are not in the hospital.
4. Have a Class III or Class IV Functional Health status. This is based on a diagnosis from your health-care provider.
5. You must be receiving IV epoprostanil (Flolan®) or IV treprostinil (Remodulin®) treatment for pulmonary arterial hypertension (PAH).

You are being asked to participate in this study because you are receiving IV treatment with epoprostanil or treprostinil for your pulmonary arterial hypertension (PAH).

It is expected that 3 to 5 people will join this study.

### **Study Procedures:**

You are being asked to participate in one interview. The topic will be about your experience living with IV treatment for your pulmonary arterial hypertension (PAH). The private interview will last 45 to 60 minutes. The interview will take place in your home or place of residence.

The interviews will be audio-taped and written out later. You will be given a participant number which will be the only identifier used in the recording, the written information and in the final study report.

Any information that identifies you specifically will be used only for contacting you to arrange for the interview. It will be used to access your medical record after you give the researcher your permission to see your medical records.

### **What Information is Needed from my Medical Record?**

Your medical record will be used to obtain your health history. This means that your past health history, the age at which you were diagnosed with PAH, and what caused you to have PAH, will be obtained.

The results from tests that were used to make sure of your diagnosis of PAH will be obtained. Those tests might include ultrasounds, heart catheterizations, biopsies, EKGs, lung function tests, 6 minute walking tests, and pulse oximetry, blood gas tests or other lab tests.

Information about your health since you started taking IV medicine will be obtained. This information includes the name of the drug you are taking and why the drug was prescribed for you. Information about your health status at the time you started the medicine and what it is like now will be gathered. The results of recent EKGs, 6 minute

walk tests, pulse oximetry readings, blood gas readings and other lab tests will be gathered as well.

**Risks, Discomforts and Vulnerabilities:**

The in-depth interviews may bring up areas that are hard for you to think about. They may cause emotional uneasiness. Every effort will be made on the part of the nurse researcher to minimize such occasions. You will be given a list of people that you can contact at the PAH clinic if you need help managing this uneasiness.

The physical effort needed to do the interview should be about the same as other discussions, but it might be tiring for you. You may stop the interview at any time if you think it is too hard to finish because of physical concerns such as being out of breath. You may be asked to finish the interview at another time.

If many words typical of your discussions are used in the research report, it is possible that you would be recognized. Every effort will be made to disguise situations or words that might show your identity.

**Potential Benefits:**

You may not benefit from your participation in this study. The information that nurses learn in this study may help us to better understand what life is like for you and for our future patients who are on IV medicine for treatment of pulmonary arterial hypertension. The information you share may help us develop new ways to care for patients who share your situation.

**Costs/Payment for Study Participation:**

There are no costs to you or to your insurance company for participating in this study. To thank you for your time and for sharing your experiences, a gift card valued at \$15.00 from Meijer will be provided to you at the end of the interview.

**Voluntary Participation:**

Joining this study is voluntary and solely your decision. You may refuse to be a part of this study. You may also stop being a part of this study at any time. Refusing to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled. The nurse researcher may also stop your study involvement at any time without your permission if she believes it to be in your best interest, or if the study is ended.

**Confidentiality (Privacy):**

Your privacy is respected. It is important for you to understand that we cannot promise complete confidentiality of your medical information if you decide to be a part of this study. People who might look at your medical information are:

1. The student nurse researcher and her study advisor,
2. Representatives from Grand Valley State University,
3. Representatives from Spectrum Health,
4. The Human Research Review Committee at Grand Valley State University,
5. The Spectrum Health Research and Human Rights Committee, and/or
6. Representatives from governmental regulatory agencies.

Those listed above may see parts of your medical records related to this study and, therefore, will see your name and other personally identifiable information about you.

They must also preserve confidentiality (privacy).

The information collected for this study will be sent to and stored at Grand Valley State University. It is the property of the University and you will not be able to get it back.

Your information is protected by (1) using only your participant number on the information we are storing; (2) separating papers with your contact information and name from the information that is labeled with your participant number; (3) storing the information and papers in a locked file and locked room; (4) limiting the people who have access to it; and (5) limiting how the information may be used. Details about permitted uses and disclosures of your information are described under the ***HIPAA Authorization*** section of this document. Your name will not be shown in any reports or publications from this study, unless you first give the nurse researcher your consent to use your name. It is expected that the study will be published as the nurse researcher's thesis, and that she will present the findings in presentations and professional meetings. She may also publish a shortened version of the study in a journal for nurses or other health care professionals. If you would like a summary of the study, please initial the line after you sign this consent.

Your privacy and confidentiality will be kept as required by law.

Your access to your medical records on file at Spectrum Health will not be changed by this study.

A copy of the information collected for this study will be kept by the student nurse researcher at her home. Only your participant number will be written on this information. Your name and all other identifying information will not be allowed and will be removed from the documents.

Electronic copies of audio recordings will be kept at her residence for the time needed to analyze the information you give during the interview. After this is completed, the audio recordings will be given to Grand Valley State University. They will be stored at the University.



The audio recordings in electronic format will be kept in locked files in offices at Grand Valley State University for a period of three years, after which they will be destroyed.

**HIPAA Authorization for Release of Health Information for Research Purposes**

As part of this research study, you are being asked to release your health information.

The Health Insurance Portability and Accountability Act (HIPAA) allows a hospital or doctor's office to use or release protected health information (PHI) for the purposes of treatment, payment or health care operations. Health care operations activities include such things as audits, quality assurance initiatives, audits from insurance companies, treating physicians, legal advisors, insurers and data storage companies.

A HIPAA authorization gives permission from you to use or release your PHI for research purposes.

A HIPAA authorization is in addition to your consent to participate in this research study.

**1. What will you do with this information and why am I being asked to allow you to release this information?**

This information will be collected and entered in a database along with the information from other people taking part in this study. This information will be used to confirm identifying information, to confirm your diagnosis and treatment.

**2. What are you asking to release?**

To complete this research study, information about you needs to be collected.

This information may include:

- a. Your date of birth, name, contact information and medical record number.
- b. Existing medical records and medical history.

**3. Who may use or share your protected health information for this research study?**

- a. Grand Valley State University Kirkhof College of Nursing staff and members of the Human Research Review Committee of Grand Valley State University,
- b. Spectrum Health staff, employees or other agents,
- c. The Spectrum Health Research and Human Rights Committee,
- d. Agencies that accredit the university, the hospital or the research programs.

Once your protected health information has been disclosed it is possible that anyone who receives that information may re-disclose it. Because some of these individuals who receive your protected health information may not be required by law to keep your information confidential, we cannot guarantee that your information will not be released or made available to another party once it leaves Grand Valley State University or Spectrum Health. Therefore, we share your information only if necessary and we use all reasonable efforts to request that those individuals who receive your information take steps to protect your privacy.

**4. How long will this authorization last?**

This authorization has no expiration date.

**5. Can I stop my information from being used?**

You can cancel this authorization at any time. Your cancellation must be in writing. Once you cancel your authorization, we will stop collecting your medical

information. Any information that was collected before you stopped your authorization will still be used as described above.

If you decide to stop the collection of your protected health information for this study, you must send a written, signed and dated notice to the principal researcher at the address provided below:

Phyllis Boone, BSN, RN, MSN student  
Kirkhof College of Nursing at Grand Valley State University  
301 Michigan St. NE  
Grand Rapids, MI 49503

**6. What if I do not authorize you to collect and release my health information?**

If you decide not to authorize release of your health information as part of this study, your decision will in no way affect your medical care or cause you to lose any benefits to which you are entitled.

You cannot participate in this research study if you do not authorize the use or release of your PHI.

**7. When will my PHI collected for this study be destroyed?**

Your PHI will be destroyed when the research project is completed.

**Contact Persons:**

The nurse researcher involved with the study is available to answer any questions you may have about this study. The study advisor may also be able to answer your questions. If you have questions, concerns or complaints, you may contact Phyllis Boone at the address above or the study advisor, Dr. Cynthia Coviak at the same address. The contact information below may be used if you have any questions, concerns or complaints about

the research, or think the research has hurt you. You may use this contact information if you want to get information or provide input about this research. You may use this contact information if you have questions about your rights as a research volunteer.

- The Spectrum Health Office of the IRB at (616) 486-2031
- The Grand Valley State University Human Rights and Research Committee Representative at 616-331-3197

**Consent:**

By signing this consent form and HIPAA authorization, you certify you have read this form, you have had the opportunity to ask questions about this study and this form, and you have received answers that fully satisfy those questions. You are voluntarily signing this consent form and HIPAA authorization because you have decided to participate in this study. You are also giving authorization for release of all of your protected health information relative to this research. You understand that you may withdraw your consent and HIPAA authorization at any time and your care will not suffer.

You will receive a signed copy of this Research Informed Consent Form and HIPAA Authorization.

By signing this consent form, you will not give up any of your legal rights or release the parties involved in this study from liability for negligence.

Printed Name of Patient: \_\_\_\_\_

Signature of Patient: \_\_\_\_\_ Date: \_\_\_\_\_

I would like a summary of the study results. (Initial) Yes \_\_\_\_\_ No \_\_\_\_\_

Signature of Person Obtaining Consent:

\_\_\_\_\_

Date: \_\_\_\_\_

APPENDIX H  
Interview Guide

APPENDIX H  
Interview Guide

Interview Guide

Participant # \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

The participant understands the purpose of the study, his or her role, has had an opportunity to clarify concerns, and has signed the consent for participation and HIPAA release: Yes \_\_\_\_\_ No \_\_\_\_\_

Can you tell me about what it is like for you to live with IV prostaglandin treatment for your pulmonary hypertension? Please share as many of your thoughts, experiences and feelings as you can recall.

Can you tell me what your life like before you needed this treatment?

Can you tell me about your life now—have there been changes?

Can you tell me how you feel about being on the IV medicine?

What is this experience like for you?

Is there anything else about being on this treatment that you would like to share?

Notes:

Does participant have concluding questions or concerns? Yes \_\_\_\_\_ No \_\_\_\_\_

The participant has a PAH Clinic Contact sheet. Yes \_\_\_\_\_ No \_\_\_\_\_

The participant is to be thanked for time and participation. Token gift for participation given: Yes \_\_\_\_\_

Time concluded: \_\_\_\_\_

## APPENDIX I

### Contact Information for the Heart Failure Clinic

## APPENDIX I

### Contact Information for the Heart Failure Clinic

(616) 486-6550

By dialing the number above, you will be directed by a telephone tree or by the administrative assistant to the appropriate agency or person that will be able to help you with problems that may arise during or as a result of your participation in the research interview.

**For life-threatening, emergent conditions you will be directed to call the emergency response system at 9-1-1.**

Clinic Physicians are: Dr. Wilt and Dr. Berjaoui. They are available on PAH clinic days.

There are 3 Nurse Practitioners as well as Registered Nurses that may help you.

A Pharmacist is available on Pulmonary Hypertension clinic days.

A Social Worker is available.

#### Additional Resources

Airway Oxygen Inc. (616) 247-3900 or toll free (800) 632-0730

Carelinc Medical Equipment and Supply (616) 776-3602

Wright & Filippis Medical Equipment and Supply (616) 531-1340



**APPENDIX J**

**IRB and HRRC Research Approval Letters**

APPENDIX J

IRB and HRRC Research Approval Letters

IRB Approval of Research at Spectrum Health July 26, 2010

**Institutional Review Board**

100 Michigan NE, MC 038

Grand Rapids, MI 49503

616.391.3050

[irb@spectrum-health.org](mailto:irb@spectrum-health.org)

[www.spectrum-health.org/research](http://www.spectrum-health.org/research)

APPROVAL OF RESEARCH

July 26, 2010

Phyllis Boone RN BSN

Kirkhof College of Nursing at GVSU

807 Cooks Crossing Dr. SE

Byron Center, MI 49315

TYPE OF REVIEW: Initial, Non-Committee Review

IRB#: **2010-109** *(please reference this number in all correspondence with the IRB)*

PROTOCOL NAME: **The lived experience: Pulmonary arterial hypertension and intravenous prostaglandin therapy**

Dear Ms. Boone:

The above referenced protocol and associated materials were reviewed and approved by the IRB via

expedited review on July 21, 2010 under Categories 5, 6, and 7 as described in 45 CFR 46.110.

The approval period for this research is from **July 21, 2010** to **July 20, 2011**.

The IRB reviewed the following documents related to the approval of the research proposal:

- Study protocol dated 7/12/2010
- Informed Consent Form dated 7/12/2010
- Data collection form dated 7/12/2010
- Recruitment postcard dated 7/12/2010
- Recruitment letters dated 7/12/2010
- Study Application dated 07/14/2010
- PAH clinic contact sheet dated 7/12/2010
- Interview guide dated 7/12/2010

Any changes made to the study following this approval, including informed consent changes, require

submission in writing to the IRB and approval by the committee. Changes may not be implemented until

approved by the IRB except when necessary to eliminate apparent immediate hazards to the subject.

Approval of your research means you are responsible for complying with all applicable policies and

procedures of the FDA, OHRP, HIPAA, Spectrum Health, and the Spectrum Health IRB.

Also, please be

advised that unanticipated problems involving risk to subjects or others must be *promptly* reported to the

IRB. You may reference the Investigator Manual for guidance on expectations of the IRB after approval.

The IRB requires submission of the “FORM: Continuing Review Progress Report or Study Completion

Report” to the committee prior to the study expiration date. It is recommended you submit this form 4-6

weeks prior to the expiration date to allow time for processing. Your study approval expires on **July 20,**

**2011 at 11:59pm** and cannot continue until re-approved by the Spectrum Health IRB. If your study has

been completed, terminated, or if you do not wish to continue, please submit the study completion portion

of the aforementioned form before the expiration date.

If you have any questions please contact the Spectrum Health IRB office at 616-486-2031, email

[irbassist@spectrum-health.org](mailto:irbassist@spectrum-health.org), or visit us on the web at [www.spectrum-health.org/research](http://www.spectrum-health.org/research).

Sincerely,

Jeffrey Jones MD

Chair, Spectrum Health IRB

cc: Dr. Cynthia Coviak, PhD, RN

IRB Approval of Research at Spectrum Health November 8, 2010

**Institutional Review Board**

100 Michigan NE, MC 038

Grand Rapids, MI 49503

616.391.3050

[irb@spectrum-health.org](mailto:irb@spectrum-health.org)

[www.spectrum-health.org/research](http://www.spectrum-health.org/research)

APPROVAL OF RESEARCH

November 8, 2010

Phyllis Boone RN BSN

Kirkhof College of Nursing at GVSU

807 Cooks Crossing Dr. SE

Byron Center, MI 49315

TYPE OF REVIEW: **Modifications, Non-Committee Review**

IRB#: **2010-109** *(please reference this number in all correspondence with the IRB)*

PROTOCOL NAME: **The lived experience: Pulmonary arterial hypertension and**

**intravenous**

**prostaglandin therapy**

Dear Ms. Boone:

The request for modification of approved human research and associated materials were reviewed and

approved on November 8, 2010.

As a reminder, IRB approval for this research expires on **July 20, 2011**.

The IRB reviewed the following documents related to the approval of the modification:

- Modification of Approved Research form signed 11/03/10
- Study protocol dated 10/30/2010

If you have any questions please contact the Spectrum Health IRB office at 616-486-2031, email

[irbassist@spectrum-health.org](mailto:irbassist@spectrum-health.org), or visit us on the web at [www.spectrum-health.org/research](http://www.spectrum-health.org/research).

Sincerely,

Jeffrey Jones MD

Chair, Spectrum Health IRB

IRB Study Completion at Spectrum Health, January 31, 2011

Page 1 of 1 HRP-516

**Institutional Review Board**

100 Michigan NE, MC 038

Grand Rapids, MI 49503

616.391.3050

irb@spectrum-health.org

[www.spectrum-health.org/research](http://www.spectrum-health.org/research)

**STUDY COMPLETION**

January 31, 2011

Phyllis Boone RN BSN

Kirkhof College of Nursing at GVSU

807 Cooks Crossing Dr. SE

Byron Center, MI 49315

IRB#: **2010-109**

PROTOCOL TITLE: **The lived experience: Pulmonary arterial hypertension and intravenous**

**prostaglandin therapy**

Dear Phyllis,

On January 31, 2011 the IRB reviewed and has acknowledged your request for closure of the human

subject research for the above referenced protocol.

As part of this action:

- The research is permanently closed to enrollment.
- All subjects have completed all research-related interventions.
- Collection of private identifiable information is completed.
- Analysis of private identifiable information is completed.

Should you have any questions please contact the Spectrum Health IRB office at 616-486-2031.

Sincerely,

Jeffrey Jones MD

Chair, Spectrum Health IRB



HRRC Approval of Research, GVSU August 11, 2010

Please note that Grand Valley State University Human Research Review Committee has taken the following action on IRBNet:

Project Title: [142412-2] The lived experience: Pulmonary arterial hypertension and intravenous prostaglandin therapy

Principal Investigator: Phyllis Boone, MSN Student

Submission Type: Amendment/Modification

Date Submitted: July 29, 2010

Action: APPROVED

Effective Date: August 11, 2010

Review Type: Expedited Review

Should you have any questions you may contact Christina Moord at [moordc@gvsu.edu](mailto:moordc@gvsu.edu).

Thank you,

The IRBNet Support Team

[www.irbnet.org](http://www.irbnet.org)

HRRRC Change in Protocol Approval, GVSU November 10, 2010

Please note that Grand Valley State University Human Research Review Committee has published the following Board Document on IRBNet:

Project Title: [142412-3] The lived experience: Pulmonary arterial hypertension and intravenous prostaglandin therapy

Principal Investigator: Phyllis Boone, MSN Student

Submission Type: Amendment/Modification

Date Submitted: November 10, 2010

Document Type: Change in Protocol Approval Letter

Document Description: Change in Protocol Approval Letter

Publish Date: November 16, 2010

Should you have any questions you may contact Paul Reitemeier at [reitemep@gvsu.edu](mailto:reitemep@gvsu.edu).

Thank you,

The IRBNet Support Team

**APPENDIX K**

**The Inservice Protocol for the Nursing Staff, Spectrum Health Heart Failure, Transplant and  
Pulmonary Hypertension Clinic**

## APPENDIX K

### The Inservice Protocol for the Nursing Staff, Spectrum Health Heart Failure, Transplant and Pulmonary Hypertension Clinic

#### **The Lived Experience: Pulmonary Arterial Hypertension and Intravenous Prostaglandin Therapy**

- 1) Objectives
  - a) A descriptive phenomenological study that will
    - i) Obtain a subjective description of the experience of living with intravenous prostaglandin therapy for Pulmonary Arterial Hypertension (PAH)
    - ii) Determine what kinds of elements are common to the experience with study participants
    - iii) Develop an aggregate structure of the experience from the individual descriptions of it
    - iv) Add to what is now known about the phenomenon
  - b) To determine how nurses can help future patients to live optimally within the confines of a palliative treatment for this incurable illness.
- 2) Study Related Functions for the Nursing Staff
  - a) A possible research opportunity for your patient
    - i) Double blinded to protect the identity and participation of clinic patients to meet HIPAA requirements
    - ii) Identify patients among the clinic population that are receiving intravenous prostaglandin therapy for PAH.
    - iii) Distribute the study introductory letter to clients identified as receiving intravenous prostaglandin therapy for the study.

- (1) The clients will respond by returning the letter to the primary investigator in a stamped envelope self-addressed to the primary investigator.
  - (2) The identity of clients receiving the introductory letter is to remain confidential
    - (a) The researcher will only know about clients who choose to respond to the recruitment letter.
    - (b) Clinic staff will only know the identities of clients to whom they have distributed the recruitment letter.
  - (3) Maintain a list of clients receiving the introductory letter using the log form provided. The log will be used solely for the purpose of sending reminder cards.
- iv) Postcard reminder to clinic patients for the purpose of stimulating recruitment.
- The stamped postcards will provided by the primary researcher.
- (a) All clinic clients that were given a recruitment letter will be sent a postcard reminder by clinic staff one week after the letters are distributed.
  - (b) The card will have the following message:
    - (i) This is a reminder to you about the study of what it is like for you to take intravenous medicine for your PAH.
    - (ii) If you have not done so already and would like to be part of this study by sharing your story, please fill out and return the letter in the envelope that you were given at the PAH clinic.

(iii) If you have any questions about the study, you can contact the primary researcher at the e-mail address or the phone number that is given in the letter you received at the clinic. She will be happy to help you.

(iv) Whether you have already returned the letter or decided that you cannot participate, we'd like to thank you for considering being a participant in this study.

b) Direct any questions or concerns you may have about your role to the primary researcher.

i) Contact information for the primary researcher:

Phyllis D. Boone BSN, RN, MSN student

Kirkhof College of Nursing at Grand Valley State University

[boonep@mail.gvsu.edu](mailto:boonep@mail.gvsu.edu)

ii) Contact information for the faculty advisor:

Dr. Cynthia Coviack, PhD, RN, CNE

Kirkhof College of Nursing at Grand Valley State University

[coviack@gvsu.edu](mailto:coviack@gvsu.edu)

iii) Contact information for the on-site coordinator:

Kristina Simmons, LMSW

Spectrum Health Heart Failure, Transplant and PAH Clinic

[kristina.simmons@spectrum-health.org](mailto:kristina.simmons@spectrum-health.org)

APPENDIX L

Research Certifications for Phyllis D. Boone

APPENDIX L

Research Certifications for Phyllis D. Boone

National Institutes of Health Certificate for completion of Human Research Course

**Certificate of Completion**

The National Institutes of Health (NIH) Office of Extramural Research certifies that **Phyllis Boone** successfully completed the NIH Web-based training course “Protecting Human Research Participants”.

Date of completion: 10/26/2009

Certification Number: 327845



CITI Human Research Course Record of Completions for GVSU

**CITI Collaborative Institutional Training Initiative**

**Human Research Curriculum Completion Report**

**Printed on 1/8/2011**

**Learner:** Phyllis Boone (username: boonep)

**Institution:** Grand Valley State University

**Contact Information** 807 Cooks Crossing Drive SE

Byron Center, MI 49315 USA

Department: Nursing

Phone: 616-204-2481

Email: boonepd\_1@comcast.net

**Group 1 Biomedical Research Investigators and Key Personnel:** Biomedical Research Investigators and Key Personnel. To meet the basic GVSU requirements, complete all 9 "required" modules plus any 3 "optional" Modules. Be sure to complete all associated quizzes.

**Stage 2. Refresher Course Passed on 10/15/09 (Ref # 3645859)**

<b>Required Modules</b>	<b>Date Completed</b>	
Refresher Course 200 Introduction	10/15/09	no quiz
History and Ethical Principles.	10/15/09	no quiz
Regulations and Process, Part 1	10/15/09	1/1 (100%)
Regulations and Process, Part 2	10/15/09	1/1 (100%)
Informed Consent.	10/15/09	1/1 (100%)
Social & Behavioral Research (SBR)	10/15/09	2/2 (100%)
Genetics Research, Part 1	10/15/09	1/1 (100%)
Genetics Research, Part 2	10/15/09	1/1 (100%)
Records-Based Research, Part 1	10/15/09	1/1 (100%)
Records-Based Research, Part 2	10/15/09	1/1 (100%)

Records-Based Research, Part 3	10/15/09	1/1 (100%)
Research with Protected Populations - Vulnerable Subjects: A Definition.	10/15/09	1/1 (100%)
Vulnerable Subjects - Prisoners, Part 1	10/15/09	1/1 (100%)
Vulnerable Subjects - Prisoners, Part 2	10/15/09	1/1 (100%)
Studies With Minors, Part 1	10/15/09	1/1 (100%)
Studies With Minors, Part 2	10/15/09	1/1 (100%)
Studies With Minors, Part 3	10/15/09	1/1 (100%)
Studies with Pregnant Women and Fetuses, Part 1	10/15/09	1/1 (100%)
Studies with Pregnant Women and Fetuses, Part 2	10/15/09	1/1 (100%)
Group Harms: Research with Culturally or Medically Vulnerable Groups.	10/15/09	3/3 (100%)
HIPAA and Human Subjects Research.	10/15/09	2/2 (100%)
Conflicts of Interest in Research Involving Human Subjects.	10/15/09	2/2 (100%)
How to Complete the CITI Refresher Course and Receive a Completion Report	10/15/09	no quiz

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Paul Braunschweiger Ph.D.  
Professor, University of Miami  
Director Office of Research Education  
CITI Course Coordinator

## CITI Collaborative Institutional Training Initiative

### Human Research Curriculum Completion Report

Printed on 1/8/2011

**Learner:** Phyllis Boone (username: boonep)

**Institution:** Spectrum Health

**Contact Information** 100 Michigan NE  
 Grand Rapids, MI 49501 USA  
 Phone: 616-391-3050  
 Email: boonepd\_1@comcast.net

**Biomedical Research:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in biomedical research with human subjects.

**Stage 1. Basic Course Passed on 10/15/09 (Ref # 3645947)**

Required Modules	Date Completed	Score
Belmont Report and CITI Course Introduction	10/15/09	3/3 (100%)
History and Ethical Principles	11/02/06	5/5 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process-	11/02/06	5/5 (100%)
Informed Consent	11/02/06	4/4 (100%)
Social and Behavioral Research for Biomedical Researchers	11/02/06	4/4 (100%)
Records-Based Research	11/02/06	2/2 (100%)
Genetic Research in Human Populations	11/03/06	2/2 (100%)
Research With Protected Populations – Vulnerable Subjects: An Overview	11/03/06	4/4 (100%)
Vulnerable Subjects – Research Involving Minors	10/15/09	3/3 (100%)
FDA-Regulated Research	10/15/09	5/5 (100%)
Research and HIPAA Privacy Protections	11/03/06	2/2 (100%)
Hot Topics	10/15/09	no quiz

Conflicts of Interest in Research Involving Human Subjects	11/03/06	2/2 (100%)
Spectrum Health	10/15/09	no quiz

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 CITI Course Coordinator

CITI Health Information Privacy and Security Curriculum Completion Report for  
Spectrum Health

**CITI Collaborative Institutional Training Initiative**

**CITI Health Information Privacy and Security (HIPS) Curriculum Completion  
Report**

Printed on 1/8/2011

**Learner:** Phyllis Boone (username: boonep)

**Institution:** Spectrum Health

**Contact Information**

100 Michigan NE  
Grand Rapids, MI 49501 USA  
Phone: 616-391-3050  
Email: boonepd\_1@comcast.net

**Health Information Privacy and Security (HIPS):**

**Stage 1. Basic Course Passed on 10/19/09 (Ref # 3645950)**

<b>Elective Modules</b>	<b>Date Completed</b>	<b>Score</b>
About the Course	10/19/09	1/1 (100%)
Privacy Rules: Introduction to Federal and State Requirements*	10/19/09	9/10 (90%)
Privacy Rules: Clinicians*	10/19/09	8/8 (100%)
Privacy Rules and Research*	10/19/09	10/10 (100%)
Privacy Rules: Students and Instructors*	10/19/09	4/4 (100%)
Privacy Rules: Fundraisers*	10/19/09	5/5 (100%)
Privacy Rules: Marketers*	10/19/09	5/5 (100%)
Security Rules: Basics of Being Secure, Part 1*	10/19/09	no quiz
Security Rules: Basics of Being Secure, Part 2*	10/19/09	10/10 (100%)
Security Rules: Protecting your Computer*	10/19/09	7/8 (88%)

Security Rules: Picking and Protecting Passwords**	10/19/09	8/8 (100%)
Security Rules: Protecting your Portables*	10/19/09	6/7 (86%)
Security Rules: Protecting your identity*	10/19/09	7/7 (100%)
Security Rules: Safer Email-ing and IM-ing, Part 1*	10/19/09	no quiz
Security Rules: Safer Email-ing and IM-ing, Part 2*	10/19/09	15/16 (94%)
Security Rules: Safer Web Surfing*	10/19/09	8/8 (100%)
Security Rules: Introduction to HIPPA Security Requirements*	10/19/09	4/6 (67%)
Security Rules: Issues for Work/Workers Off-Site*	10/19/09	4/4 (100%)
Completing the Privacy and Security Course	10/19/09	no quiz

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Re

CITI Responsible Conduct of Research Curriculum Report for Spectrum Health

**CITI Collaborative Institutional Training Initiative (CITI)**

**Responsible Conduct of Research Curriculum Completion Report**

**Printed on 1/8/2011**

**Learner:** Phyllis Boone (username: boonep)

**Institution:** Spectrum Health

**Contact Information**      100 Michigan NE  
 Grand Rapids, MI 49501 USA  
 Phone: 616-391-3050  
 Email: boonepd\_1@comcast.net

**Social and Behavioral Responsible Conduct of Research Course 1.:**

**Stage 1. Basic Course Passed on 10/20/09 (Ref # 3645949)**

<b>Required Modules</b>	<b>Date Completed</b>	<b>Score</b>
The CITI Course in the Responsible Conduct of Research	10/15/09	no quiz
Introduction to the Responsible Conduct of Research	10/15/09	no quiz
Introduction to Research Misconduct	10/16/09	no quiz
Research Misconduct 2-1495	10/20/09	5/6 (83%)
Case Study - In the Field, No One Will Know 2-1218	10/20/09	3/3 (100%)
Introduction to Data Acquisition and Management	10/20/09	no quiz
Data Acquisition, Management, Sharing and Ownership 2-1523	10/20/09	5/5 (100%)
Case Study - Data Management "The New Clinical Data Manager" BioMed 12-1201	10/20/09	no quiz
Introduction to Responsible Authorship	10/16/09	no quiz
Publication Practices and Responsible Authorship 2-1518	10/20/09	5/5 (100%)
Responsible Authorship -Taking Shortcuts (All Science)	10/20/09	5/5 (100%)

Responsible Authorship -The Deceased Author (All Science)	10/20/09	4/4 (100%)
Case Study in Irresponsible Authorship Sherry's Secret (All Science)	10/20/09	1/1 (100%)
Introduction to Peer Review	10/18/09	no quiz
Peer Review <a href="#">20521</a>	10/20/09	5/5 (100%)
Peer Review and Controversial Research <a href="#">20529</a>	10/20/09	2/2 (100%)
Introduction to Mentoring	10/18/09	no quiz
Mentoring Case Study: O, What a Tangled Web We Weave.	10/18/09	3/4 (75%)
Mentoring Case Study: The Graduate Student Laborer.	10/18/09	4/4 (100%)
Mentoring Case Study: Sherry's Secret.	10/18/09	4/4 (100%)
Mentoring Case Study: Lisa Bach's Case	10/18/09	3/3 (100%)
Mentoring Case Study: The Business of Mentoring.	10/18/09	4/4 (100%)
Mentoring Case Study: Too Much Help is Just Too Much!	10/18/09	3/3 (100%)
Introduction to Conflicts of Interest and Commitment	10/18/09	no quiz
Conflicts of Interest and Commitment <a href="#">20521</a>	10/20/09	5/6 (83%)
CoI Case Study -The Case of the Entrepreneurial Psychologist <a href="#">20521</a>	10/20/09	3/3 (100%)
Introduction to Collaborative Relationships	10/18/09	no quiz
Collaborative Research <a href="#">20521</a>	10/20/09	6/6 (100%)
Marriage Has it's Advantages <a href="#">20521</a>	10/20/09	2/2 (100%)
The Price of Collaboration	10/18/09	no quiz
A Possible Co-Author	10/18/09	no quiz
Supporting Documentation	10/18/09	no quiz
Facilitating Sharing Between Collaborators	10/18/09	no quiz
The CITI RCR Course Completion Page.	10/18/09	no quiz
Spectrum Health	10/15/09	no quiz



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APPENDIX M

Research Certifications for Cynthia Coviak PhD, RN, CNE

APPENDIX M

Research Certifications for Dr. Cynthia Coviak

**CITI Collaborative Institutional Training Initiative .**

**Human Research Curriculum Completion Report**

**Printed on 5/14/2010**

**Learner:** Cynthia Coviak (username: ccoviak)

**Institution:** Grand Valley State University

**Contact Information** 301 Michigan Street, NE  
Cook-DeVos Center for Health Sciences  
Suite 330  
Grand Rapids, Michigan 49305 USA  
Department: Nursing  
Phone: 616-331-7170  
Email: coviakc@gvsu.edu

**Group 1 Biomedical Research Investigators and Key Personnel:** Biomedical Research Investigators and Key Personnel. To meet the basic GVSU requirements, complete all 9 "required" modules plus any 3 "optional" Modules. Be sure to complete all associated quizzes.

**Stage 1. Basic Course Passed on 01/03/10 (Ref # 695893)**

<b>Required Modules</b>	<b>Date Completed</b>	
History and Ethical Principles	12/31/09	6/7 (86%)
Introduction	12/31/09	no quiz
Basic Institutional Review Board (IRB) Regulations and Review Process	12/31/09	5/5 (100%)
Informed Consent	12/31/09	4/4 (100%)
Social and Behavioral Research for Biomedical Researchers	01/01/10	3/4 (75%)
Records-Based Research	01/03/10	2/2 (100%)

Genetic Research in Human Populations	01/03/10	2/2 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview	01/03/10	4/4 (100%)
Group Harms: Research With Culturally or Medically Vulnerable Groups	01/03/10	3/3 (100%)
Conflicts of Interest in Research Involving Human Subjects	01/03/10	2/2 (100%)
Grand Valley State University	01/03/10	no quiz

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# CITI Collaborative Institutional Training Initiative

## Human Research Curriculum Completion Report

Printed on 5/14/2010

**Learner:** Cynthia Coviak (username: ccoviak)

**Institution:** Spectrum Health

**Contact Information** Phone: 616-331-7170  
Email: coviakc@gvsu.edu

**Social/Behavioral Research Course:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in biomedical research with human subjects.

**Stage 1. Basic Course Passed on 05/14/10 (Ref # 3952529)**

<b>Required Modules</b>	<b>Date Completed</b>	<b>Score</b>
Belmont Report and CITI Course Introduction	05/09/10	3/3 (100%)
Students in Research - SBR	05/09/10	8/10 (80%)
History and Ethical Principles - SBR	05/09/10	4/4 (100%)
Defining Research with Human Subjects - SBR	05/09/10	5/5 (100%)
The Regulations and The Social and Behavioral Sciences - SBR	05/09/10	5/5 (100%)
Assessing Risk in Social and Behavioral Sciences - SBR	05/09/10	5/5 (100%)
Informed Consent - SBR	05/09/10	5/5 (100%)
Privacy and Confidentiality - SBR	05/09/10	3/3 (100%)
Research with Children - SBR	05/09/10	2/4 (50%)
Research in Public Elementary and Secondary Schools - SBR	05/14/10	4/4 (100%)
Internet Research - SBR	05/14/10	4/4 (100%)
HIPAA and Human Subjects Research	05/14/10	2/2 (100%)

Conflicts of Interest in Research Involving Human Subjects	01/03/10	2/2 (100%)
Spectrum Health	05/14/10	no quiz

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APPENDIX N

Research Certifications for Kristina Simmons, LMSW

APPENDIX N

CITI Human Research Curriculum Completion Report, Spectrum Health for Kristina

Simmons, LMSW

Completion Report

Page 1 of 1

**CITI Collaborative Institutional Training Initiative**

**Human Research Curriculum Completion Report  
Printed on 1/19/2010**

**Learner:** Kristina Simmons (username: simmkj)  
**Institution:** Spectrum Health  
**Contact Information:** 2902 Bradford St NE  
 Grand Rapids, Mi 49505 USA  
 Department: Care Management  
 Phone: 616-486-6990  
 Email: kristina.simmons@spectrum-health.org

**Biomedical Research:**

**Stage 1. Basic Course Passed on 01/17/10 (Ref # 3864714)**

Required Modules	Date Completed	Score
Belmont Report and CITI Course Introduction	12/26/09	3/3 (100%)
History and Ethical Principles	12/26/09	6/7 (86%)
Basic Institutional Review Board (IRB) Regulations and Review Process	01/16/10	5/5 (100%)
Informed Consent	01/16/10	4/4 (100%)
Social and Behavioral Research for Biomedical Researchers	01/16/10	3/4 (75%)
Records-Based Research	01/16/10	2/2 (100%)
Genetic Research in Human Populations	01/16/10	2/2 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview	01/17/10	4/4 (100%)
Vulnerable Subjects - Research Involving Minors	01/17/10	3/3 (100%)
FDA-Regulated Research	01/17/10	4/5 (80%)
HIPAA and Human Subjects Research	01/17/10	2/2 (100%)
Hot Topics	01/17/10	no quiz
Conflicts of Interest in Research Involving Human Subjects	01/17/10	2/2 (100%)
Spectrum Health	01/17/10	no quiz

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Clinical classification of  
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Gerald Simonneau,  
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Rubin, David Langreben,  
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Domenighetti, Simon Gibbs,  
Didier Lebrec, Rudolf Speich,  
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8

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## LIST OF REFERENCES

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