Care Coordination Home Telehealth: Reducing Hospital Bed Days in Veterans with Newly Diagnosed Heart Failure

By

Diana M. Sage

A project submitted in partial fulfillment of the requirements for the degree of

MASTERS IN SCIENCE OF NURSING

WASHINGTON STATE UNIVERSITY

College of Nursing

May 2009
To the Faculty of Washington State University:

The members of the Committee appointed to examine the project of Diana M. Sage find it satisfactory and recommend that it be accepted.

Committee Chair: Janet Katz

Committee Member: Alice Dupler

Committee Member: Janet Purath
The Veterans Affairs Medical Center (VMAC) introduced a home telehealth program, Care Coordination Home Telehealth (CCHT) in August of 2005. Its purpose was to coordinate the care of veteran patients with chronic conditions and avoid unnecessary bed days of care related to these conditions. This study examined the effectiveness of two nursing approaches to improve self management skills of veterans with newly diagnosed heart failure in reducing bed days of care within 30 days and 3, 6, 9 and 12 months of discharge. A quasi-experimental, longitudinal, repeated-measures design was used with a sample of 88 participants. The CCHT group (N=61) showed a significantly reduced rate of hospital bed days at the specified intervals as compared to veterans who received standard discharge teaching of self care by a staff nurse (N=27). Many veterans admitted to the hospital are at high risk for unplanned readmissions and subsequent hospital bed days within 30 days of discharge, especially those with newly diagnosed heart failure (AHA, 2009). CCHT home telehealth, and disease management technology may help veterans live independently at home while reducing readmissions and hospital bed days.
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CARE COORDINATION HOME TELEHEALTH: REDUCING HOSPITAL BED DAYS IN VETERANS WITH NEWLY DIAGNOSED HEART FAILURE

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This work is original, has not been published previously and is not under consideration for publication elsewhere.
Dedication

I wish to acknowledge the undying love, support, patience and continued encouragement of my best friend and husband Jeff, and children Katelyn, John and Sarah, who have made me so very proud to be a parent. I would like to sincerely thank my dear mother-in-law Judy, for her years of support, encouragement and understanding throughout this endeavor.

I dedicate the accomplishment of this work to Janet Katz, Alice E. Dupler, and Janet Purath, who understand my professional commitments and provided unfailing support and encouragement in advancing the nursing profession forward during my educational journey. Without the mentorship, collaboration and respectful manner in which they supported me, this work would not have materialized.
CARE COORDINATION HOME TELEHEALTH: REDUCING HOSPITAL BED DAYS IN VETERANS WITH NEWLY DIAGNOSED HEART FAILURE

Introduction

Many people admitted to the hospital are at high risk for unplanned bed days of care within 30 days of discharge, especially those with a new diagnosis of heart failure (Yu, Ravelo, Wagner, 2003). Heart failure puts very significant health and financial burdens on patients, their families and society as a whole. According to the American Heart Association (AHA) in 2008, about 5 million people had heart failure and its prevalence was growing. The AHA estimated the total costs of heart failure in the United States will be more than $35 billion dollars (2008). A major factor that determines the cost of treating heart failure is the high incidence of hospitalization as (defined by the National Center for Health Statistics 2009).

Decreasing hospitalization can save money and lead to better health outcomes (Yu, Ravelo, and Wagner, 2003). This study examined how effectively two nursing approaches increased the self management skills of veterans with newly diagnosed heart failure in reducing unplanned bed days of care at 30 days, and 3, 6, 9 and 12 months of discharge. The research question was: In veterans with heart failure, is there a decrease in unplanned bed days of care if they are enrolled in the Care Coordination Home Telehealth (CCHT) Program compared to veterans receiving usual self care teaching by a registered nurse at the time of discharge?

Background Information

The American Heart Association (AHA) estimates that approximately 5 million people nationwide have heart failure; and its prevalence is growing (2008). According to the National Institute of Health, 550,000 new cases of heart failure are diagnosed and 300,000 deaths are caused by heart failure each year (2009). Concurrently, the prevalence of heart failure is 1 – 2 %
of the general population; and treating heart failure consumes 1 – 2% of all health care resources (AHA, 2008). The estimated total cost of heart failure in the United States was over 35 million dollars in 2008 according to the AHA.

The incidence of heart failure increases with age. The Center for Disease Control (2008) stated that among United States residents who have heart failure, 70% are 60 years of age or older. In 2000, approximately 12.7% of the American population was 65 years of age or older. It is estimated that in 2020, 16.5% will be in this age group. Since the AHA estimated that about 1% of all people over the age of 65 have heart failure, a significant increase in the prevalence of heart failure is expected in the coming years. The major factor that exponentially contributes to the cost of treating heart failure is the high incidence of hospitalization (as defined by the National Center for Health Statistics 2008).

A large percent of health care costs associated with heart failure are due to hospitalization of patients. Patients with heart failure are at high risk to require acute care, due to the high incidence of hospitalization and lack of successful avenues of self care to date. Results of a National Hospital Discharge Survey (2008) showed that the number of hospitalizations for heart failure increased substantially, from more than 400,000 in 1979 to more than 1.1 million in 2004. This accounts for almost 2% of all hospital admissions in the United States.

Among people receiving Medicare Part A, heart failure is the most common reason for hospitalization, accounting for approximately 800,000 hospitalizations yearly (CDC, 2008). In 2005 the average hospital stay was about six days (CDC, 2008). Re-hospitalization rates in the six months following discharge were as high as 50%. Repeated hospitalizations bode poorly for a patient’s prognosis and quality of life and also cause increase health care costs.
Many patients admitted to the hospital are at high risk for unplanned readmission within 30 days of discharge, especially those with a new diagnosis of heart failure (Yu, Ravelo, Wagner, 2003). Within nursing literature, there is sparse research examining the cost prevention associated with readmissions related to heart failure. Moser and Riegel (2001) identified multiple models for improving outcomes of patients with heart failure. These models include disease management, community case management, clinical management specific for heart failure care, and the use of multidisciplinary disease management models. Nordgren, Asp, and Fagerberg examined the effects of education and counseling by nurses on adherence to nonpharmacological treatments since they are so important to the patients' survival. Data collected from 17 hospitals and 1,023 heart failure patients (mean age 71), illustrated that nurses made a positive impact on nonpharmacologic adherence, resulting in patients reporting as sense of security, control and the ability to handle their chronic illness. (2004). Research by Lorig, Stewart, Ritter, Gonzales, Laurent, and Lynch (1996) and by Madigan, Schott, and Matthews (2001) illustrated that specific nursing approaches used during the provision of care have positively influenced outcomes, particularly in home care.

Studies investigating ways to improve self-management for persons with chronic illnesses include Jaarsma and Stewart (2004) who described growing knowledge about the care of patients with heart failure, especially relating to home care. A summary of the findings identified nursing roles as assisting, coordinating, directing, and managing the care. Whereas these studies give directions for nurses in home care, they do not include telephonic case management or the use of technologies in the home for patient self-management. Other home care strategies for heart failure management include nursing phone assessment with follow-up recommendations and collaboration with the physician (Stewart & Horowitz, 2002).
The literature on heart failure management indicated that a major deficiency in post hospital care was inadequate for patients to manage their illnesses (Wagner, 2001). This framework focused on the idea that if taught self care patients will change their behavior and have improved outcomes in the form of decreased hospitalizations. Yet that proved to be untrue, according to Lorig and Gonzales (2002). Health professionals within hospital settings have traditionally been the main providers of heart failure education; yet, completion of the education did not equate to an avoidance of a future hospitalization. Additionally, many patients are elderly and may be unable to access the education classes provided at outpatient settings, causing them to be a vulnerable group for readmission (Yu et al. 2003). Also identified in that research was the inability of the elderly patient to retain the standard heart failure education completed by the staff nurse at the time of discharge, as evidenced by re-admission rates as high as 50% (CDC, 2008).

Fewer studies have been conducted with the veteran population diagnosed with heart failure and, how the Veterans Health Administration (VHA) cares for this aging population (Centers for Disease Control [CDC], 2005. Garrison (1997) studied the benefit of telephone case management and home care in the management of chronic illnesses such as diabetes self-management. The focus of this study was to achieve positive health related outcomes through behavior changes. Garrison (1997) identified that self-management education is a process that involves assisting individuals to manage their disease through goal setting, self-monitoring, support and direction that is reinforced by a facilitator. There have been studies with telephone case management in treating heart failure, but there is no research discussing the benefit of combining telehealth, technology and self-management.
This study addresses this critical research issue; it describes the findings of veterans with newly diagnosed heart failure being monitored using the Care Coordination Home Telehealth (CCHT) Program. CCHT is a new program combining telehealth, technology and self-management to improve veteran outcomes. It uses technology in the home to provide the health care team with individualized current data and trends that facilitates intervention prior to exacerbation and possible re-hospitalization. The objective of the program is to promote self-management and provide the right care, at the right time, in the right place.

Methods

This study compared the effectiveness of two nursing approaches to decrease hospital bed days for veterans with newly diagnosed heart failure. The research question was: In veterans with heart failure, is there a decrease in unplanned hospital bed days of care if they are enrolled in the Care Coordination Home Telehealth (CCHT) Program compared to veterans receiving usual self care teaching by a staff RN at the time of discharge?

A quasi-experimental, longitudinal, repeated measures design was used to evaluate the effectiveness of two nursing approaches to decrease hospital bed days of veterans with newly diagnosed heart failure. The target population was veterans, 18 years of age or older, assigned to a primary care provider at a Veterans Affairs Medical Center (VAMC) in the Pacific Northwest, with a primary diagnosis of heart failure, and discharged from the hospital with either enrollment into CCHT or discharged with usual patient teaching by a staff nurse. Using convenience sampling, patients were selected from the Intensive Care Unit (ICU) or the Acute Care Unit (ACU) at the VAMC with an admitting diagnosis of heart failure. The CCHT lead nurse screened daily admissions for newly diagnosed heart failure patients. Eligible patients were offered enrollment into CCHT. The nurse enrolling them was asked to seek approval from these
patients for participation in the comparison study to be explained to them. If the participants agreed to hear an explanation, they became potential participants. The data collection nurse them approached the potential participants and provide a scripted explanation of the comparison. If potential participants agreed to participate, informed consent was obtained and enrollment into the comparison study was completed. If potential participants opted not to participate, informed consent was obtained to simply monitor any hospital bed days of care in the next 12 months.

Baseline data were collected within two days of admission to the ICU or ACU. When participants were discharged they either agreed to CCHT enrollment or received usual patient teaching by a staff nurse at the time of discharge.

Participants were placed in the intervention group if they volunteered to participate. Consenting participants who declined the interventions, and who agreed to readmission monitoring were placed in the comparison group. All the subjects received the usual care provided by the inpatient staff at discharge. In addition, the CCHT group received ongoing self monitoring, mutual goal setting, and self care education via the telephone equipment and CCHT nurse.

The comparison group received education based on Orem’s (2001) conceptual model of nursing practice; this approach was a one-time self care management teaching strategy done just prior to discharge. Since the discharge instructions were already in use, the fact that they were based on Orem’s conceptual model was not intentional, rather it was by coincidence. This approach taught self-care management strategies. Examples of this approach include learning about living with heart failure, low sodium significance in managing heart failure, and the importance of daily weights. Each subject in this group was given a copy of heart failure instructions taught at discharge.
The CCHT group received education based on King’s conceptual model of mutuality and theory of goal attainment (King, 1981). King’s model was used due to the mutuality and theory of goal attainment, the process through which the CCHT RN and the veteran collaboratively identified patient goals and the means to attain them. The CCHT program emphasis is on goals mutually identified by the patient and RN, rather than by the nurse alone. Each participant in this group was given a copy of the heart failure instructions taught at discharge, along with specific CCHT equipment including a scale, a Viterion 100, and goal attainment information. Additionally, they were questioned about any weight gain or loss greater than 3 lbs. and instructed to call the CCHT nurse if this occurred. This is the standard of care for heart failure (AHA, 2009); and indicates if fluid is building up due to a weakening heart. Standard interventions of the CCHT nurse for a 3 lbs. weight gain include medication reconciliation, review of sodium intake, review and ordering of current serum values if the electrolyte panel is more than 30 days old, and, assessment of symptomology related to exacerbated heart failure. Usual treatment is medication titration until ideal weight is achieved and/or symptomology resolves.

Data were collected over a 12-month period, beginning with the baseline data collection. Demographic information was obtained at the first data collection visit only. Subsequently, data were collected again at the specific intervals of 30 days and 3, 6, 9 and 12 months. The same research assistant completed the data collection at all time periods to ensure consistency.

The measurement of hospital bed days was obtained at specific intervals, 30 days and at 3, 6, 9 and 12 months for all participants. This was a retrospective chart review, the veterans were not contacted or questioned about the incidence of readmission with resulting bed days. Since the VAMC utilized a computerized charting system, only those given access to the patient
sensitive information could view it, therefore there was no need for further patient information safety measures. The participants had already been given a study number and that information was locked in a filing cabinet after base line data was collected. All reference to participants was done by study number, not any other personal identifying information. This measurement was significant because it equated to costs associated with managing heart failure in veterans who were newly diagnosed with heart failure.

Results

Data were analyzed using the Statistical Package for Social Sciences, with .05 as the significance levels for all procedures. The original intent was to use repeated measures analysis of variance (ANOVA) for comparison. However, because of the relatively small sample size, analysis was restricted to a one-way ANOVA for between group comparisons and paired t tests for within-group comparison across time.

At the of the 12 month data collection period, 56 participants remained in the study. Of the 96 potential participants, 88 agreed to participate. Of the 88 enrolled participants 71% (n=40) were men and 29% (n=16) were women. Of active, enrolled participants, 32 did not complete the study, leaving 56 participants in the comparison who completed the data collection series.

The 64% retention rate during the 1 year follow-up period for patients with heart failure is noteworthy. Of the 32 who did not complete the study, 10 withdrew, 8 died, 2 moved away, 2 entered long-term care facilities, 1 was too ill to continue and 9 could not be located. Those who withdrew included 7 from the intervention group and 3 from the comparison group. Their ages ranged from 53 to 91 years of age. The mean age of the comparison group was 64.07 (s.d. = 9.06) years. The intervention group’s mean age was 71.0 (s.d. = 11.0) years. Additional
characteristics analyzed were marital status, income and education level, this is illustrated in Table 1.

Characteristics of Comparison and Intervention Groups at Baseline (N=88)

<table>
<thead>
<tr>
<th>Participant Characteristics at Baseline</th>
<th>Comparison (N=27)</th>
<th>Intervention (N=61)</th>
<th>p</th>
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<tbody>
<tr>
<td>Average Age (years)</td>
<td>64.07 SD = 9.06</td>
<td>71.0 SD = 11.0</td>
<td>.049 *</td>
</tr>
<tr>
<td>% Married</td>
<td>29%</td>
<td>47%</td>
<td>.090 *</td>
</tr>
<tr>
<td>Average Income</td>
<td>22,925</td>
<td>31,760</td>
<td>.001 *</td>
</tr>
<tr>
<td>Average Years of Education</td>
<td>12.44 SD =.80</td>
<td>13.31 (1.6)</td>
<td>.000 *</td>
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In this study, participants in the comparison group were younger, less likely to be married, reported less income and education. This is significant since it weakens the study by raising the following question: Is it the CCHT program or the increase education/income and spousal support that contributed to the decreased bed days of care in the intervention group? The correlation between demographic characteristics and bed days of care are illustrated in Table 2.

Correlation between demographic characteristics, with Bed Days of Care

<table>
<thead>
<tr>
<th>Characteristics of Participants</th>
<th>Total Group Bed Days (N=54)</th>
<th>Total Intervention Group Bed Days (N=39)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>-.344 *</td>
<td>.032</td>
</tr>
<tr>
<td>Income</td>
<td>-.175</td>
<td>.106</td>
</tr>
<tr>
<td>Education</td>
<td>-.170</td>
<td>.128</td>
</tr>
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p = 0.05  **p = 0.01
This illustrates a negative correlation between age, income, education and bed days of care in the total group. The intervention group had an average 1.1 (1.6) bed days of care in the 12 month period while the comparison group had an average 7.9 (2.9) bed days of care in the same 12 month period a between group variability of 5.363 (F=5.363, df=52 and p=.025) bed days of care, illustrated in Table 3.

Comparison of Total Bed Days by Group

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean Bed Days (sd)</th>
</tr>
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<tbody>
<tr>
<td>Intervention (n=39)</td>
<td>1.1 (1.6)</td>
</tr>
<tr>
<td>Comparison (n=15)</td>
<td>7.9 (2.9)</td>
</tr>
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</table>

Discussion

The results indicated that when comparing hospital bed days of care, the intervention group had mean bed days of 1.1 (1.6); while the comparison group had mean bed days of 7.9 (2.9). Indicating that CCHT is very effective in reducing unplanned hospital bed days in veterans with newly diagnosed heart failure. Other findings include a negative correlation between age, income, education and bed days of care in the total group. This research is vital to the nursing profession in several ways. By adding to the overall knowledge base, this type of nursing intervention program may be applied to more than just heart failure patients; other chronic diseases may be managed. Also, it demonstrated evidence-based research and the application of that research to nursing practice. These findings are paramount as they apply to veterans. The basis for the reduced bed days of care for the veterans in the CCHT program is likely due to its underpinnings in patient self-management, disease management, and the use of
nurses as case managers by utilizing technology in the home. Future studies should investigate the correlation between depression and PTSD scores as they relate to increased bed days of care in this population. Additionally, the cost of increased bed days should be investigated as it compares to the cost of running the CCHT program.

Conclusion

Heart failure affects approximately 5 million people nationwide (AHA, 2008). Rehospitalization rates in the six months following discharge were as high as 50% (CDC, 2008). Repeated hospitalizations bode poorly for a patient’s prognosis and quality of life. The purpose of this paper was to determine the effectiveness of CCHT in reducing unplanned hospital bed days in veterans with newly diagnosed heart failure. This study illustrates that unplanned bed days of care are significantly reduced in CCHT patients when compared to standard discharge teaching of self care by a staff nurse; the program reduced bed days by 6.8 in this study.
References


Institutional Review Board
Certification of Exemption

This form must be submitted with the Proposed Project Questionnaire (PPQ), abstract, and protocol. The Institutional Review Board Chair or a qualified designee will review and make a recommendation regarding exemption from IRB oversight. The R&D Committee will review and make the final determination. If you have questions regarding whether or not your research may qualify for Exemption, please call the Research Assurance & Compliance Coordinator at ext. 54989, prior to submission of this form.

If the project involves any human subject participation or procedures not listed below or is FDA-regulated (except for category 6), this project does NOT qualify for exemption. When deciding if a protocol is FDA-regulated, a determination must be made whether or not research results will be submitted to or held for inspection by the FDA. If so, then the research must be considered FDA-regulated. See the PVAMC IRB SOP (http://www.visn20.med.va.gov/portland/research/pdf-documents/irb/irb-sop.pdf), page 11 for the FDA definition of research.

Research involving children, or focused primarily on pregnant women, human in vitro fertilization or fetuses is not allowed by the PVAMC and will not be considered for IRB approval or exemption.

Principal Investigator (PI): (First Name, Middle Initial, Last Name, Degree(s))
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Service: Pcs Position Extension Mail Code Beeper E-mail
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Study Coordinator/Contact Person: (All Correspondence will be sent to this person)
Rebecca Sevores

Extension Mail Code Beeper E-mail
7781 111

Project Title: CCHT effectiveness in reducing ED visits and readmissions in veterans with newly diagnosed CHF compared to standard discharge teaching completed by a staff nurse at discharge.

Funding Source or Sponsor: NA Start Date End Date
1/2006 1/2009

Protocol Details
Please explain in detail the following information. If necessary, please attach your answers on additional sheet(s) of paper.
1. Purpose of the research: To study the effectiveness of the CCHT program.
2. Subject(s)' role (if applicable) in the research: NA
3. The nature of the data to be obtained: Historical
4. How the privacy and confidentiality of research data and subject information will be maintained: PKI, locked coded and limited to CCHT personnel.
Determining Whether Human Research is Exempt from the Regulations

Key:
- Solid box: All items in the box must be true.
- Dotted box: One item in the box must be true.

The only involvement of human participants will be in one or more of the following categories: (Check all of the following that are true.)

**Category 1 (All of the following are true):**
- Research conducted in established or commonly accepted educational settings;
- The research involves normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods;
- The research is NOT subject to FDA regulation;¹
- The research does NOT involve prisoners as participants;
- The research meets the organization’s ethical standards governing the conduct of research (see below).

**Category 2 (All of the following are true):**
- The research involves the use of one or more of the following:
  - Educational tests (cognitive, diagnostic, aptitude, achievement)
  - Survey procedures
  - Interview procedures
  - Observation of public behavior
- The research does NOT involve children as participants:
  - NOTE: The Portland VAMC does not participate in research conducted with children.
- Information obtained is recorded in such a manner that either:
  - Participants CANNOT be identified, directly or through identifiers linked to the participants.
  - Both of the following are true:
    - Participants CAN be identified, directly or through identifiers linked to the participants.
    - Any disclosure of the participants’ responses outside the research could NOT reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, reputation or loss of insurability.
- The research is NOT subject to FDA regulation.¹
- The research does NOT involve prisoners as participants.
- The research meets the organization’s ethical standards governing the conduct of research (see below).

**Category 3 (All of the following are true):**
- The research is NOT exempt under Category 2 above.
- The research involves the use of one or more of the following:
  - Educational tests (cognitive, diagnostic, aptitude, achievement)
  - Survey procedures
  - Interview procedures
  - Observation of public behavior
- Either of the following is true:
  - The participants are elected or appointed public officials or candidates for public office.
  - Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- The research is NOT subject to FDA regulation.¹
- The research does NOT involve prisoners as participants.
- The research meets the organization’s ethical standards governing the conduct of research (see below).

¹ Information obtained is recorded in such a manner that either:
- Participants CANNOT be identified, directly or through identifiers linked to the participants.
- Both of the following are true:
  - Participants CAN be identified, directly or through identifiers linked to the participants.
  - Any disclosure of the participants’ responses outside the research could NOT reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, reputation or loss of insurability.
- The research meets the organization’s ethical standards governing the conduct of research (see below).
Category 4 (All of the following are true):

- The research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens (the reviewed materials currently exist and are NOT prospectively collected).
- At least one of the following is true:
  - These sources are publicly available.
  - Information is recorded by the investigator in such a manner that both of the following are true:
    - Participants cannot be directly identified.
    - Participants cannot be identified through identifiers linked to them.
    - The investigator should describe what information will be recorded and how it will be recorded.
- The research is NOT subject to FDA regulation.
- The research does NOT involve prisoners as participants.
- The research meets the organization's ethical standards governing the conduct of research (see below).

Category 5 (All of the following are true):

- The project is a research or demonstration project.
- The project is conducted by or subject to the approval of Department or Agency heads.
- The project is designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- The program under study delivers a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).
- The project is conducted pursuant to specific federal statutory authority.
- There is no statutory requirement that an IRB review the project.
- The project does not involve significant physical invasions or intrusions upon the privacy of participants.
- The research is NOT subject to FDA regulation.
- The research does NOT involve prisoners as participants.
- The research meets the organization's ethical standards governing the conduct of research (see below).

Category 6 (All of the following are true):

- The research involves a taste and food quality evaluation and consumer acceptance studies.
- One of the following is true:
  - Wholesome foods without additives will be consumed.
  - A food will be consumed that contains a food ingredient and both of the following are true:
    - The food ingredient is at or below the level to be safe.
    - The food ingredient is for a use found to be safe.
  - A food will be consumed that contains an agricultural chemical or environmental contaminant and one of the following is true:
    - The agricultural chemical or environmental contaminant is at or below the level found to be safe by the Food and Drug Administration.
    - The agricultural chemical or environmental contaminant is at or below the level approved by the Environmental Protection Agency.
    - The agricultural chemical or environmental contaminant is at or below the level approved by the Food Safety and Inspection Service of the U.S. Department of Agriculture.
- The research meets the organization's ethical standards governing the conduct of research (see below).
The research meets the organizations ethical standards for exempt research: (All of the following must be true.)

- The research presents no more than minimal risk to participants.
- The research does NOT involve pregnant women, fetuses, children or prisoners.
- The research does NOT involve vulnerable populations (frail, elderly, demenited or mentally challenged persons, blind populations, medically incapacitated, terminally ill, etc.).
- Selection of participants is equitable.
- Either of the following are true:
  - The research involves no interventions or interactions on participants.
  - All of the following are true:
    - There are adequate provisions for informed consent of participants.
    - Provisions for protecting the privacy interests of participants are adequate.
- Either of the following are true:
  - No private identifying data are collected.
  - Provisions for maintaining the confidentiality of data are adequate.


According to OHRP, this exemption is most appropriately invoked with authorization or concurrence by the funding agency.

These requirements are not regulatory, but give criteria to meet ethical standards.

Investigator Assurances

1. I certify that the information provided, regarding the proposed research project is complete and accurate.
2. I certify to the best of my ability that this research project qualifies for exemption from IRB oversight and review.
3. The research project will be conducted in accordance with institution policies and state and federal regulations.
4. Any proposed modification(s) to this research project that might disqualify the research project for exemption from human subjects regulations and IRB oversight will be immediately reported to the PVAMC Institutional Review Board and the appropriate IRB and R&D Committee approvals will be sought prior to implementation.

Principal Investigator

1/15/09

REVIEWER USE ONLY

By completing this section of this form, and by signing below, I certify that I do not have a conflict of interest, real or apparent, with this request for exemption from additional IRB oversight or review.

This research project qualifies for an exemption from IRB oversight and review.

Institutional Review Board Reviewer

Date

Research & Development Committee Chair

Date