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Family Caregivers of Recurrent Breast Cancer Patients:  
Factors Affecting Perceived Burden

A: Specific Aims

Among women, breast cancer is the most frequently diagnosed cancer and the second most common cause of cancer related death in the United States (American Cancer Society [ACS], 2006). As many as 44% of women with a past diagnosis of breast cancer will have a recurrence of the disease within 5 to 10 years of initial diagnosis (Kaufmann & Rody, 2005). A recurrent diagnosis and the subsequent treatment of the breast cancer is a traumatic and stressful event for the women but also for their family caregivers (Bull, Meyerowitz, Hart, Mosconi, Apolonge & Libarati, 1999; Northouse, Dorris, & Charron-Moore, 1995; Thomas, Morris & Harman, 2002; Vanderwerker, Laff, Kadan-Lottick, McColl & Prigerson, 2005). Caregiving is often described as burdensome and related to a decreased quality of life; however, existing quality of life research primarily focuses on the cancer patient and to a much lesser degree the patients' caregivers (Aranda & Hayman-White, 2001; Ben-Zur, Gilbar & Lev, 2001; Gaston-Johansson, Lachica, Fall-Dickson & Kennedy, 2004). The quality of life of the caregiver is important because her/his psychological and emotional well-being can have both a direct and indirect impact on the quality of life of the cancer patient (Aranda & Hayman-White, 2001; Schulz, Newsom, Mittelmark, Hirsch & Jackson, 1997).

Certain factors, such as social support, age, gender, income and the relation of patient and caregiver, have been shown to be associated with caregivers' perception of burden (Nijboer et al., 2000; Oberst et al., 1989). However, existing literature primarily focuses on the caregivers of individuals with dementia and caregivers of patients receiving palliative care. A gap is apparent in the literature. It is not known how these same factors (social support, age, gender, income and relation of patient and caregiver) are related to, or how they influence the perception of burden which caregivers of women with recurrent breast cancer may experience. A deeper understanding of these factors will facilitate the identification of caregivers at risk for negative outcomes and guide the formulation of interventions that will contribute to the

psychological and emotional well-being of family caregivers of women with recurrent breast cancer.

Thus, there are two specific aims for this study:

Specific Aim 1: To explore the relationship between social support and caregiver's perceived burden on family caregivers of patients with recurrent breast cancer.

H1.1: Caregivers with higher level of social support will report lower levels of perceived burden as compared to caregivers reporting low levels of social support.

Specific Aim 2: To explore the relationship between specific person factors (age, gender, income and relation of caregiver to cancer patient) and caregiver's perceived burden in family caregivers of women with recurrent breast cancer.

H2.1: Younger caregivers will report higher levels of perceived burden than older caregivers.

H2.2: Male caregivers of women with recurrent breast cancer will report higher levels of perceived burden than female caregivers of women with recurrent breast cancer.

H2.3: Caregivers with a lower income will report higher levels of perceived burden when compared to caregivers with higher income.

H2.4: Spousal caregivers of women with recurrent breast cancer will experience higher levels of perceived burden than non-spousal caregivers of women with recurrent breast cancer.

#### B: Background and Significance

An estimated 1,399,790 new cases of cancer will be diagnosed in the United States in 2006 (ACS, 2006). Secondary to changes in the healthcare system, specifically, the shift from inpatient to outpatient care, the majority of these cancer patients will be cared for at home by family caregivers. The phrase "family caregiver" for the purpose of this study is defined as the individual whom the patient identifies as her/his primary source of physical and emotional support (National Alliance for Caregiving [NAC] and the American Association of Retired Persons [AARP], 2004; Northouse et al., 2002). Caregivers provide physical, emotional and financial support to the cancer patient. The toll of being a caregiver to a cancer patient can be physically, mentally, emotionally and financially staggering. Research indicates that caregivers often delay, neglect or forego their own healthcare needs secondary to caring for the person with cancer. Delaying, neglecting or forgoing their own health needs can result in increased burden on the stability of the family in addition to increased use of healthcare resources for the caregiver and the patient (Aranda & Hayman-White, 2001; Schulz et al., 1997). The National Cancer Institute (NCI, 2006) and the National Institute of Nursing Research (NINR, 2006) recognize the significant role of the cancer caregiver and have made the reduction of the burden of cancer on patients and their caregivers a priority area of research. This study will advance current nursing knowledge related to the concept of burden, and factors that may influence it, in family caregivers of women with recurrent breast cancer.

#### Theoretical Framework

The conceptual model for this study is based on two theoretical frameworks, the Stress-Coping Theoretical Model and the Resiliency Model of Family Stress, Adjustment, and Adaptation. The Stress-Coping

Theoretical Model was adapted by Northouse, Templin, Mood and Oberst (1998) from the Transactional Model of Stress and Coping (TMSC) to explain individual coping and adaptation to a stressor or stressful situation. For the purpose of this study, recurrent breast cancer is the stressor. The Stress-Coping Theoretical Model is comprised of three major components, antecedents, proximal outcomes and distal outcomes. According to the model, antecedents influence the individual's appraisal of and coping with a stressor which directly impacts the individuals' quality of life (distal outcomes). The quality of life of the caregiver is directly related to the quality of life of the patient and visa versa. Specific antecedents and proximal outcome will be the focus of this study (see Figure 1). Personal factors and social resources are the two categories of antecedents that will be considered. Four personal factors and one social resource will comprise the study's independent variables. Personal factors under consideration will include: age, gender, income and caregivers' relation to the cancer patient. Social support represents the social resource under consideration in this study. Proximal outcomes are the individual's appraisal of the stressor and specific coping resources. The dependent variable or the proximal outcome in this study will be the caregiver's perceived burden.

The Resiliency Model of Family Stress, Adjustment, and Adaptation provides further context for this study. The Resiliency Model is a stress and coping framework based on a family systems approach (Bomar, 2004; McCubbin, Cauble & Patterson, 1982). The major underlying premise of the model is that a serious crisis (recurrent breast cancer) has an impact on the whole family. A crisis, such as cancer, can derail the functioning of the family unit, endangering all members, and their relationships and roles. According to the model, there are a number of factors that affect how a family responds to a stressor. One such factor is family resources. Family resources are characteristics and traits of the individuals and the family that can be utilized during stressful times (Lustig, 1999; McCubbin, Thompson & McCubbin, 1996). Social support represents a specific family resource. The source of social support can be relatives, friends, neighbors and healthcare services. Researchers McCubbin and McCubbin (as cited in Bomar, 1993) suggest that the amount of social support a family has access to is inversely related to the family's ability to adjust to a crisis.

Figure 1. Conceptual model of specific factors affecting caregiver's perceived burden.

#### Disease Incidence

The American Cancer Society estimates that during the year 2006, approximately 212,920 women will be diagnosed with breast cancer and 41,430 will die because of the disease (2006). Women with a past diagnosis of breast cancer have an increased risk of recurrent disease. Recurrence rates range from 10% to 44% depending on factors such as initial tumor size, stage of disease at diagnosis, number of involved lymph nodes, length of cancer-free interval and estrogen receptor status (Giordano et al., 2003; Hess, Pusztai, Buzdar, & Hortobagyi, 2003; Kaufmann, & Rody, 2005). Both an initial diagnosis of breast cancer and a recurrent diagnosis can be a very traumatic and life altering event for a woman. However, a diagnosis of breast cancer affects more than just the woman; it can have a very significant impact collectively on the family unit and individually on each family member.

#### Burden

Quality of life is conceptualized as four domains: health, socioeconomic, psychological, and family (Ferrans & Powers, 1985). Burden can be associated with a change in one or more of the four domains. In the context of caregiving, burden is defined as the demands of providing care and the difficulties associated with meeting those demands (Given et al., 1993; NAC & AARP, 2004; Nujboer et al., 1998). The specific demands, according to Loveys and Klaich (1991), can be related to any of the following areas of caregiving: treatment, healthcare interaction, role changes, social interaction and support, physical changes, uncertainty, loss, mortality, financial and occupational. Furthermore, demands in the literature are often viewed as objective while the difficulty of meeting those demands is seen as subjective (Oberst, 1991; Oberst, Thomas, Gass & Ward, 1989).

The majority of research related to personal factors and caregiver burden center on the elderly and individuals with dementia (Barusch & Spaid, 1989; George, & Gwyther, 1986; Horowitz, 1985; Miller, & Cafasso, 1992). A gap exists in the literature related to specific person factors (age, gender, income and relation to patient) and perceived burden in the family caregivers of women with recurrent breast cancer.

#### Caregivers

A survey conducted by the National Alliance for Caregiving and the American Association of Retired Persons is the source of the most current data related to caregivers in the United States (2004). According to the NAC and AARP, a caregiver is defined as the person the patient identifies as her/his primary source of unpaid physical and/or emotional care. Current estimates of the number of caregivers in the United States are over 44.4 million, which represents approximately 21% of all households. Eighty-three percent of caregivers are relatives of the patient, though not necessarily spouses, and 17% are friends or neighbors. The per week assistance provided by caregivers ranges from 3.5 to 87.2 hours (NAC & AARP, 2004). Caregivers often ignore their own health and healthcare needs secondary to the demands of caregiving. A longitudinal, randomized

trial of 161 caregivers of cancer patients found that caregivers with their own health issues were at higher risk for psychosocial morbidity (Jepson, McCorkle, Adler, Nuamah, & Edward, 1999). Schultz and Beach (1999) conducted a study of 392 caregivers and 427 non-caregivers and found that the four-year mortality rate of the caregivers experiencing strain was 63% higher than non-caregivers. Christakis and Allison (2006) studied 518,240 couples prospectively and found a significant relationship between the hospitalization and subsequent death of the hospitalized patient's spouse. Within one year of hospitalization, the mortality rate ranged from 2.8% to 8.6%. The highest level of mortality was seen in spouses of patients with psychiatric disorders. However, mortality rates among spouses of cancer patients were nearly as high, ranging from 5.1% to 7.5%. Clearly, caregiving can be detrimental to the well-being of the caregiver.

To date, much of the caregiver research available has focused on caregivers of individuals with dementia and caregivers of patients receiving palliative care. Far less research has been conducted on caregivers of cancer patients and even less on caregivers of women with recurrent breast cancer.

In general, studies have shown that caregivers experience increased levels of burden, stress, depression, and isolation (Given, Stommel, Given, Osuch, Kurtz, & Kurtz, 1993; Kim, Duberstein, Sorensen, & Larson, 2005; Kurtz, Kurtz, Given & Given, 1995; Oberst et al., 1989; Blanchard, Albrecht, & Ruckdeschel, 1997). According to the survey conducted by the NAC and AARP, between 20 and 30 percent of caregivers consider caregiving a burden and approximately the same number of caregivers report experiencing depression (2004).

#### Caregivers' of Cancer Patients

Looking specifically at the family caregivers of cancer patients, research indicates that the role of caregiving for the cancer patient can be highly stressful and lead to increased feelings of burden (Gaugler et al., 2005; Kozachik, Given et al., 2001; Hagedoorn, Buunk, Kuijer, Wobbes & Sanderman, 2000; Northouse et al., 2002). Kurtz and colleagues (1995) surveyed 150 cancer patients and their caregivers. Their findings suggest that between 18% and 58% of the caregivers experience clinical levels of depression. Spouse caregivers of men with prostate cancer reported significantly more distress than their partners (Kornblith, Herr, Ofman, Scher, & Holland, 1994). Grunfeld et al. (2004) examined caregivers' depression and perceived burden in breast cancer patients and their caregivers. Results of this study indicated that the caregivers had significantly higher levels of depression and perceived burden. Similar results were seen by Ben-Zur, et al. (2001) in a study comparing 73 breast cancer patients and their spouses. Results indicated that the spouses had higher levels of distress than their wives. Kim and colleagues (2005) studied 120 spouses of cancer patients and, utilizing structural equation modeling, found a significant association between depressive symptomatology and caregiver burden. Literature clearly shows that, in general, family caregivers of persons with cancer can experience dramatic negative physical and emotional outcomes related to their role as caregiver.

#### Caregivers of Recurrent Breast Cancer

Caregivers of recurrent breast cancer have not been studied as extensively as caregivers of women with a first time diagnosis of breast cancer. One might ask is there a difference between the initial diagnosis

and a recurrent diagnosis? The literature indicates that there is a substantial difference. A diagnosis of recurrent cancer has been found by many researchers to be more traumatic than the initial cancer diagnosis (Frost et al., 2000; Gotay, 1984; Weitzner, McMillian, & Jacobsen, 1999). A recurrence of breast cancer can cause feelings of hopelessness and uncertainty in both the patient and her caregiver. The prognosis associated with recurrent breast cancer is not as optimistic as a first-time diagnosis of breast cancer (Jemal et al., 2006). The woman is often sicker and requires more physical and emotional care which can result in an increase burden on their caregiver (Northouse et al., 2002). The question begs itself: should nurses and the healthcare system be more aggressive with women and their families that present with recurrent breast cancer? Are the caregivers of these women at greater risk for adverse physical and emotional outcomes related to their role of caregiving? These questions can only be addressed when we have a more thorough understanding of factors that contribute to the burden associated with caring for a woman with recurrent breast cancer.

Potential Contributing Factors Related to Caregiver Burden

Social Support. Literature has shown that positive social support can have a protective effect on physical and emotional well-being (Northouse, 1988; Fuhrer, & Stansfeld, 2002). A study by Kornblith and colleagues (2001) examined social support as a buffer to the stress in women receiving chemotherapy for breast cancer. The results did not support the buffering effect of social support but rather supported a direct effect. Northouse (1988) assessed the relationship between social support and adjustment in the husbands of women newly diagnosis with breast cancer. Results indicated that husbands with more social support had fewer adjustment problems when compared to husbands with less support. However, multiple studies have shown that caregivers perceive that they receive low levels of social support (Davis-Ali, Chesler, & Chesney, 1993; Northouse, 1988; Northouse et al., 1998; Sharpe, Butow, Smith, McConnell, & Clarke, 2005). Additionally, some studies have shown that as cancer progresses and the demands of managing the disease increase the level of social support drops off even further (Weitzner et al., 1999). Only one study was located that addressed the relationship between social support and caregiver burden. Sharpe and colleagues (2005) examined social support and caregiver burden in patients with advanced cancer and their caregivers. They found that the relationship between social support and caregiver burden was highly significant. However, it is unclear whether the study included incidences of recurrent cancer in general or specifically recurrent breast cancer. It is apparent that social support plays an integral role for both the cancer patient and their caregiver, yet there remains a gap in the literature related to social support and burden in the caregivers of women with recurrent breast cancer.

Age, gender, income and relation to patient. Among general female caregivers, younger age and lower socioeconomic status (SES) have been associated with higher levels of burden; however, the findings are not so consistent among cancer caregivers (Blood, Simpson, Dineen, Kauffman, & Raimondi, 1994; Kurtz et al., 1995; Oberst et al., 1989). In a longitudinal study of caregivers of newly diagnosed colorectal cancer patients it was found that low SES predicted a negative caregiving experience (Nijboer, Triemstra, Tempelaar, Sanderman & Van den Bos, 1999). Results of a study by Nijboer et al., (2000) found that younger



caregivers, females and caregivers with higher SES reported their experience as a caregiver of a cancer patient more negatively. Carey and colleagues (1991) assessed the relationship between age and burden among 49 caregivers of patients receiving chemotherapy. They found no significant relationship. Northouse and colleagues (2005) found no significant effect when they compared spouse caregiver and non-spouse caregiver with level of uncertainty and hopelessness. No studies were found that examined the relationship of specific person factors (age, gender, income and relationship to patient) and perceived burden in caregivers of women with recurrent breast cancer.

#### Summary

The body of literature related to family caregivers of cancer patients has grown substantially in the last 20 years; however, many gaps still remain. Even though the potential burden associated with caregiving has been shown to have a direct and indirect impact on both the caregiver and the cancer patient, few studies have addressed burden specific to the women with recurrent breast cancer. No studies were located that examined the relationship between caregiver burden and social support, nor between specific person factors and caregiver burden. More information is needed to ascertain factors that affect caregiver burden. The purpose of the proposed study is to gain a more thorough understanding of the relationship between burden and specific variables that may potentiate, dissipate or negate the level of burden experienced by caregivers of women with recurrent breast cancer. Ultimately, the goal is to provide a foundation for future research to decrease caregiver burden, prevent negative psychosocial and physical outcomes and maximize the caregiver's overall well-being.

#### C: Preliminary Study

No preliminary studies have been completed.

#### D: Design and Methods

##### Design

The proposed study uses a descriptive correlational design. The specific aims of this study will be accomplished by conducting a secondary analysis using data from an intervention study of women with recurrent breast cancer and their primary informal caregivers (Principle Investigator, Northouse, # PBR 102 American Cancer Society). Northouse's study was a randomized clinical trial to evaluate the effect of a family-focused intervention on the quality of life of the cancer patient and her/his family caregivers. Data collection for the Northouse study was collected at baseline (within one month of a diagnosis of recurrent breast cancer), at three-months and at six-months following baseline collection.

For the purpose of the proposed study, a subset of the original dataset will be utilized. The subset is comprised of the family caregivers of women with recurrent breast cancer. The study will focus on data obtained at the three-month period. This time point was chosen because the investigators clinical experience and the literature suggests that the patient and family have had an opportunity to adjust to the initial shock of recurrent cancer and are now dealing with the cancer treatment, side effects and overall uncertainty of the disease and their future (Pearlin, Mullan, Semple, & Skaff, 1990). This time point is reinforced with the results of a study of 69 women with recurrent breast cancer by Bull and colleagues (1999). They found that as the months passed the women experienced a significant decrease in their overall

quality of life. Givens and Givens (1992) advanced this area of research by comparing family caregivers of women with recurrent breast cancer to the women cancer patient. They found that the caregivers experienced higher levels of depression which increased with time as compared to the women cancer patient.

#### Sample

To achieve a power of 80% at a 0.05 level of significance to determine a medium effect for multiple regression, a sample size of 91 is required (Lenth, 2006). Participants in the primary study were obtained from four large comprehensive cancer centers in the Midwest. Caregivers were eligible for the study if they met the following inclusion criteria: age 21 or older, mentally and physically able to participate in the study, spoke and understood English, and were identified by the patient (a women diagnosed with recurrent breast cancer within the last month) as her primary source of physical and emotional support.

#### Variables and Instruments

The concepts to be measured in this study include social resources (social support), personal factors (age, gender, income and relation of caregiver to cancer patient) and caregiver perceived burden.

**Social resources.** The concept of social support will be assessed in this study from data obtained using the Personal Resource Questionnaire (PRQ). The PRQ was developed by Brandt and Weinert (1981) to measure situational and perceived social support. The instrument is composed of two parts; however only data obtained from Part 2 of the PSQ will be used for this study.

Part 2 consists of 25, self-report items that measure the subject's perceived level of social support. The concept of social support is based on five dimensions of: intimacy, social integration, assistance, affirmation of worth and opportunity for nurturance. Each dimension is addressed with 5 items. Subjects respond to each item using a seven-point Likert scale. Items are scored from "strongly agree (7) to "strongly disagree" (1). Total scores range from 25 to 175, higher scores indicating higher levels of perceived social support.

The PSQ has been widely used in psychosocial research, including the caregivers of the chronically ill and cancer patients (Brandt & Weinert, 1981; Rose, 1997; Snelling, 1994; Tilden & Weinert, 1987; Weinert, 1991; Weinert & Long, 1993). In these studies the reliability of the PSQ was demonstrated with Cronbach's alpha coefficients ranging from 0.89 to 0.92, indicating high internal consistency. Evidence of construct validity was substantiated with convergence validity utilizing two further measures of social support: the Cost and Reciprocity Index and the Interpersonal Support Evaluation List (Cohen, S., Mermeistein, Kamarck, & Hoberman, 1985; Weinert & Tilden, 1990).

**Personal factors.** Age, gender, income and caregiver's relationship to the patient will be assessed in this study from data obtained using the Omega Screening Questionnaire (OSQ). The OSQ is a self-report instrument developed by Weisman and Worden and adapted by Mood and Bickes (1989). The instrument is comprised of 4 sections, (a) demographic and background information, (b) medical history, (c) symptom scale, and (d) inventory of current concerns scale. Basic demographic information (age, gender and income) will be assessed from data obtained from the demographic section of the OSQ.

**Perceived burden.** Perceived caregiver burden was measured using the Caregiving Burden Scale (CBS), a self-report measure which is a



modification of the Caregiver Load Scale (Carey, Oberst, McCubbin & Hughes, 1991; Oberst et al., 1989). The CBS measures the demands and difficulties associated with family caregiving. The measure is composed of 14 items. Using principle components analysis with varimax rotation, three factors were extracted. The cumulative variance explained by the three factors was 57%. The three factors are labeled: Instrumental, Direct and Interpersonal. The instrument has two subscales and requires two responses to each of the 14 items. The participants are asked (1) how demanding is the task and (2) the difficulty associated with the task. Each response has 5 options ranging from "A great deal" to "None". Items are scored from 1 (none) to 5 (a great deal). Total burden scored is calculated by determining the square root of the product of demand multiplied by difficulty, item by item; then the 14 resultants are summed. Total CBS scores range from 14 to 70, with the higher scores indicating greater caregiver perceived burden. The CBS has been used extensively with caregiver populations, specifically caregivers of cancer patients receiving outpatient chemotherapy (Oberst, 1991). Reliability of the instrument is dependent on the reliability of each of the two subscales. Alpha coefficients for the subscale of demand ranges from 0.83 to 0.88 and for the subscale of difficulty the range is 0.89 to 0.91, suggesting high internal consistency (Carey et al., 1991).

#### Data Analysis

Prior to conducting data analysis approval will be sought from the Institutional Review Board for Human Subject Research at the University of Michigan. Data analysis will be completed using the Statistical Package for the Social Sciences (SPSS), student version 13.0. Initial descriptive statistics will be run to explore the data and to become more familiar with specific characteristics of the sample population. Data will be examined for missing values and outliers. Correlations will be conducted between the independent variables and the dependent variable. Finally, if intercorrelation is established between the independent variables multiple regression analysis will be done to measure the effects of the independent variables on the dependent variable.

Analysis for Specific Aim 1: The purpose of Specific Aim 1 is to explore the relationship between social support and caregiver's perceived burden on family caregivers of patients with recurrent breast cancer. It is hypothesized that caregivers with higher level of social support will report lower levels of perceived burden as compared to caregivers reporting low levels of social support. Pearson correlation coefficient will be performed between social support and caregiver's perceived burden to determine if there is a relationship. If a significant relationship is present, correlation analysis will indicate the direction and the magnitude of the relationship. Underlying assumptions for correlation analysis are: (1) that the variables are measured on an interval or a ratio level, (2) variables are normally distributed, (3) the relationship between variables is linear, and (4) the scores for each variable are homoscedastic (Polit, 1996). Specific to the sample to be studied, the first assumption has been met; and the second, third and fourth assumptions will be evaluated with descriptive statistical analysis (frequency distributions and scatter plots). If the descriptive statistical analysis indicates that the data are nonparametric, either Spearman's rank-order correlation or Kendall's tau will be utilized to facilitate further data analysis. Finally, the hypothesis will be tested using analysis of variance (ANOVA).

Analysis for Specific Aim 2: The purpose of Specific Aim 2 is to explore the relationship between specific person factors (age, gender, income and relation of caregiver to cancer patient) and caregiver's perceived burden in family caregivers of women with recurrent breast cancer. To this end, bivariate correlations will be done on each independent variable and the dependent variable to determine if there is a significant relationship. If there is a significant relationship, as is suggested by the literature, the independent variables will be entered into the multiple regression model. Regression analysis will then be used to determine the magnitude of the relationship between the dependent variable and the independent variables, when all are considered simultaneously. Literature suggests that specific personal factors have a greater influence on caregiver perceived burden than do others, therefore, hierarchical multiple regression analysis will be run to ascertain the effect of specific independent variables while holding all other variables constant. Finally, stepwise multiple regression analysis will be run. Utilizing stepwise regression, the computer program (SPSS) will determine the order in which the independent variables are added to the regression equation based on how much of the variable accounts for the variance in the dependent variable.

Four hypotheses are proposed for the second specific aim: 1) younger caregivers will report higher levels of perceived burden than older caregivers; 2) male caregivers of women with recurrent breast cancer will report higher levels of perceived burden than female caregivers of women with recurrent breast cancer; 3) caregivers with a lower income will report higher levels of perceived burden when compared to caregivers with higher income; and 4) spousal caregivers of women with recurrent breast cancer will experience higher levels of perceived burden than non-spousal caregivers of women with recurrent breast cancer. To test these hypotheses ANOVA will be conducted.

#### Limitations

A potential limitation of secondary analysis is that the instruments were not designed to specifically address the theoretical framework of the proposed study or the proposed population. However, the specific instruments to be used have been used in very similar models and tested with similar populations resulting in good reliability and validity. The instruments reflect the conceptual definitions of the variables, therefore, it is anticipated that the instruments will prove to be appropriate for this study.

Internal validity of the study is potentially threatened by the presence of confounding variables such as caregiver and patient co-morbidities. Not controlling for co-morbidities may result in variance in the dependent variable of caregiver burden. Confounding variables cannot be controlled for in this study due to the limited sample size, however, future studies are planned that will expand on the present study.

#### E: Human Subjects

The proposed study is a secondary data analysis using an existing dataset. The sample is comprised of Caucasian and African American men and women age 21 and older. Sensitive information was collected in the primary dataset, however, the applicant does not have access to the linkage between specific subjects and their data; therefore risks related to identifying subjects are minimal.

Data and Safety Monitoring Plan:

Not applicable because the proposal is a secondary data analysis using an existing dataset.

Inclusion of Women and Minorities:

Women and minorities will be included in the proposed study.

Inclusion of Children:

Children (under the age of 21) will not be included in this study as the existing dataset had an inclusion criteria of 21 years of age or older.

F: Vertebrate Animals

Not applicable

#### G: Literature Cited

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