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Stress Relief Habits and Perceived Stress among College Nursing Students

Thesis submitted in partial fulfillment of Honors

By:

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Stress Relief Habits, 3

Introduction

The challenges of nursing school can be very stressful for students. With busy schedules, critical thinking examinations, and clinical experiences at hospitals, students often feel overwhelmed by the many requirements of nursing curricula. All of these elements combined with outside responsibilities such as family, children, and jobs have the potential to create intense stress in students' lives. Students handle stress in a variety of ways. This study explores how students in East Tennessee State University's College of Nursing perceive stress, and what they do specifically to relieve their stress. The researcher surveyed nursing students to discover specific strategies students use for stress relief and the activities they would most like to participate in to relieve their stress if given the time and resources. The results of the study provide suggestions for further research and implications for both nursing education and nursing practice.

#### Review of the Literature

According to the World Health Organization, "health" can be defined as, "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (WHO, 1948). This state of health and well-being is not achieved overnight. Health is a continual process through which individuals develop every aspect of the mind, body and spirit. Health is not only a process; it is a lifestyle (Berman & Snyder, 2012). In today's busy society, health and well-being are threatened on a daily basis. Environmental hazards, diseases, and stress, defined as "any physical, physiological, or psychological force that disturbs equilibrium" have the potential to disrupt the sense of well-being ("Stress," 2009).

Regardless of the source, stress can cause a variety of physical symptoms. The American Psychological Association's 2010 "Stress in America" report gathered data about the emotional and physical tolls of stress. Symptoms reported by Americans included anger, irritability, fatigue, lack of interest, motivation or energy, headaches, upset stomachs, changes in appetite, and changes in sex drive (APA, 2010). The survey also reported that as many as nine in ten adults believe that long term stress can lead to major illnesses including hypertension, heart disease, obesity, and depression, and as many as 92% of surveyed adults believe that some types of stress can trigger fatal arrhythmias and heart attacks in individuals with existing cardiovascular conditions (APA, 2010).

Despite the knowledge of these long-term health consequences, only 29% of Americans say they are doing an excellent or very good job at reducing their stress when it occurs, and only 31% think that stress has only a slight or no impact on their own physical and mental health (APA, 2010). Along with affecting the health of the general population, high levels of stress are believed to affect students' health (Sheu, Lin & Hwang, 2002). More specifically, nursing students experience higher levels of stress than other students in similar health related fields (Beck et al, 1997). Hsieh's (2011) review of multiple studies found that nursing students experience stress from many sources including academic workload, lack of clinical experience, new roles and responsibilities, and poor relationships with clinical staff.

Because the stress experienced during school could negatively impact patients in the future, the need for effective stress management among undergraduate nursing students is apparent. It is well known that nurses who care for themselves are in better positions to adequately care for their patients than nurses who do not (Chow & Kalischuk, 2008). Therefore, students' ability to recognize oncoming stress, assess the effects of stress on their overall well-

being, and understand effective coping mechanisms can help them handle stress more effectively (Sheu, Lin & Hwang, 2002). Students can even improve their stress tolerance by discovering effective lifestyle habits and coping strategies (Welle & Graf, 2011).

However, certain coping strategies can actually worsen stress. Using drugs, drinking alcohol, smoking, and excessive non-nutritious eating are counterproductive and may not provide adequate stress relief (Shaikh et. al., 2004). According to a study done on the lifestyle needs of medical students, stress is best managed by regular exercise, relaxation techniques, structured time outs, and effective coping strategies that create a sense of structure and predictability in one's life (Shaikh et al., 2004; Carter et al., 2003).

With the health of both nursing students and their future patients at risk, actions must be taken to ensure students are caring for themselves by effectively managing their stress and accessing information that can help them do so. Nursing school is an ideal time for students to become aware of the importance of self-care and its impact on their lives as future health care providers (Horneffer, 2006). This study examines both the perceived stress and the specific coping strategies among nursing students at a regional public university.

#### Methodology

This descriptive correlational study was designed to determine if a correlation exists between the perceived stress levels and coping mechanisms of nursing students. Data for this survey were collected using two surveys: The Perceived Stress Scale (PSS) (see Appendix A) and a researcher-developed "Coping with Stress" Questionnaire (see Appendix B). Developed by Dr. Sheldon Cohen, the "Perceived Stress Scale" is a ten item questionnaire that asks participants how often during the past month they felt they were able to handle both positive and negative aspects of stress. The tool uses a likert scale, asking participants to circle "0" for "Never," "1" for "Almost Never," "2" for "Sometimes," "3" for "Fairly Often," and "4" for "Very Often" for each item on the survey. Possible scores range from 0, indicating no perceived stress, to 40, indicating maximum perceived stress. The tool itself is not meant to be diagnostic; however, the higher the PSS score, the more likely individuals perceive environmental demands exceeding their ability to cope with stress (Cohen, Kamarck & Mermelstein, 1983). The survey is scored by reversing responses (e.g., 0 = 4, 1 = 3, 2 = 2, 3 = 1 & 4 = 0) to the four positively stated items (items 4, 5, 7, & 8) and then summing the answers to all ten questions (Cohen & Williamson, 1998).

The second survey, a researcher-developed "Coping with Stress Questionnaire," asks students about the specific activities they engage in, if any, to help relieve stress. The survey directs participants to write down their "Top 3 activities/behaviors," rank them by effectiveness, and rank them by frequency. The last question asks, "Given the time, resources, and ability, what stress relieving activities/behaviors would you most like to participate in?" The surveys were anonymous, asking only for the semester of nursing school in which the participant was currently enrolled. The surveys were voluntary, completed by 444 baccalaureate nursing students at a regional public university during a Sigma Theta Tau, local chapter Research Day.

Three hypotheses were posed prior to data collection: 1) At least half of the nursing students will score 20 or higher on the Perceived Stress Scale, indicating that their reported stress level is midway between no perceived stress and maximum perceived stress, 2) Less than half of the nursing students will report engaging in some kind of physical activity or meditation practice as a way to relieve stress, and 3) Students who "sometimes" or "frequently" engage in some kind of physical activity or meditation practice to relieve stress will have lower scores on the Perceived Stress Scale than those students who do not engage in physical activity.

To analyze the data, the surveys were divided into two groups: students who participated in physical activity or meditation and students who did not participate in physical activity or meditation. If students wrote in more than one answer on a single blank, the first answer listed was counted as their response for that particular question. Physical activity was defined as recreational activities such as running, biking, swimming, lifting weights, and organized sports. Meditation included activities such as yoga, praying, deep breathing, massage therapy, and aromatherapy (See Appendix C). Using Excel spreadsheets, SPSS software and the assistance of a statistician, the researcher compared the average Perceived Stress Scale scores for the two groups to determine if those who engaged in physical activity or meditation reported lower stress scores.

#### Results

After close examination of the completed surveys, the researcher discovered that many participants did not correctly fill in the questions regarding effectiveness and frequency of stress relieving activities thus prohibiting accurate analysis of the third hypothesis. A new, simpler hypothesis was constructed and states that those students who engage in physical activity and/or meditation to relieve stress will also report lower perceived stress.

Of the 439 usable surveys, 356 (approximately 81%) respondents reported engaging in some kind of physical activity or meditation to relieve stress. The researcher's hypothesis that less than half of responding nursing students would report engaging in physical activity or meditation was not supported. The remaining 83 (approximately 19%) survey respondents reported stress relieving activities other than physical activity and meditation. The PSS scores for the group who reported physical activity/meditation ranged from 1 to 36, with an average of 19.8. The PSS scores for the group who reported activities other than physical

activity/meditation also ranged from 1 to 36, and had an average of 21.2. To determine if the difference in the average scores were statistically significant, a t-test for unequal variances was performed using an  $\alpha$  value of 0.05. The test yielded a p-value of 0.049, demonstrating *statistical* significance between the average stress scores, thus confirming the researcher's hypothesis that those nursing students who reported engaging in physical activity or meditation would also report less perceived stress.

The results of the PSS scale are as follows:

# In the last month, how often have you been upset because of something that happened unexpectedly?

Response	Frequency	Percent
Never	12	2.7
Almost Never	69	15.5
Sometimes	160	36.0
Fairly Often	123	27.7
Very Often	75	16.9

## In the last month, how often have you felt you were unable to control the important things in your life?

Response	Frequency	Percent
Never	34	7.7
Almost Never	97	21.8
Sometimes	132	29.7
Fairly Often	118	26.6
Very Often	57	12.8

## In the last month, how often have you felt nervous and "stressed"?

Response	Frequency	Percent
Never	2	0.5
Almost Never	20	4.5
Sometimes	75	16.9
Fairly Often	118	26.6
Very Often	224	50.5

Response	Frequency	Percent
Never	7	1.6
Almost Never	22	5.0
Sometimes	124	27.9
Fairly Often	197	44.4
Very Often	87	19.6

## In the last month, how often have you felt confident about your ability to handle your personal problems?

## In the last month, how often have you felt that things were going your way?

Response	Frequency	Percent
Never	12	2.7
Almost Never	48	10.8
Sometimes	196	44.1
Fairly Often	143	32.2
Very Often	39	8.8

# In the last month, how often have you found that you could not cope with all the things you had to do?

Response	Frequency	Percent
Never	47	10.6
Almost Never	122	27.5
Sometimes	149	33.6
Fairly Often	71	16.0
Very Often	49	11.0

## In the last month, how often have you been able to control irritations in your life?

Response	Frequency	Percent
Never	8	1.8
Almost Never	41	9.2
Sometimes	189	42.6
Fairly Often	150	33.8
Very Often	50	11.3

Response	Frequency	Percent
Never	14	3.2
Almost Never	64	14.4
Sometimes	200	45.0
Fairly Often	128	28.8
Very Often	30	6.8

## In the last month, how often have you felt that you were on top of things?

## In the last month, how often have you been angered because of things that were outside your control?

Response	Frequency	Percent
Never	19	4.3
Almost Never	85	19.1
Sometimes	161	36.3
Fairly Often	109	24.5
Very Often	65	14.6

# In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?

Response	Frequency	Percent
Never	50	11.3
Almost Never	114	25.7
Sometimes	141	31.8
Fairly Often	72	16.2
Very Often	62	14.0

The most frequently reported stress relieving activities included various forms of physical activity, meditation, and miscellaneous hobbies. Only two students (less than 1%) reported that they did not engage in any kind of stress relieving activities, and only fourteen students (approximately 3.2%) reported using alcohol or drugs as a way to cope with their stress. In response to the question, "Given the time, resources, and ability, what stress relieving activities/behaviors would you most like to participate in?," many of the answers were similar, and most students gave multiple answers.

The most commonly given answers are as follows:

Activity	Number of students who listed the activity
Exercise/group fitness classes	129
Yoga	56
Running	43
Traveling	37
Time with friends/family	37
Massage therapy	28
Hiking	27
Sleeping	24
Playing musical	21
instruments	
Reading	19
Watching TV/movies	19
Shopping	18
Play organized sports	18
Cooking/baking	17
Walking	14
Swimming	13
Biking	12
Praying	10
Listening to music	10
Lifting weights	10

The students surveyed listed 725 total activities in which they would like to participate given the time, resources, and ability. Sixty-eight students did not provide an answer regarding desired activities. Approximately 14.9% of all students who listed activities on the last question of the survey expressed the desire for *more time* to engage in stress relieving activities in general. Many students attributed their lack of time to factors such as busy schedules, employment, family responsibilities, and a heavy academic work load. These answers from the students demonstrate a desire to engage in stress relieving activities.

Desired Physical Activity	313
Desired Meditation	163
Desired Miscellaneous Hobbies	249
TOTAL ACTIVITIES LISTED	725

#### Discussion

Two of the three original hypotheses were tested and neither was supported by the research results. The third original hypothesis was discarded following data collection due to many surveys being inaccurately completed. The implementation of a new hypothesis guided the researcher to examine the data in a broader sense and focus on the stress scores of the two groups.

Even though a majority of students are engaging in some kind of stress relieving activities, the student body as a whole still reports substantial stress. With half of the students saying that in the last month they felt nervous and stressed "VERY OFTEN" and almost 15% wishing for "more time" to relieve stress, it seems that nursing students are not finding adequate time to engage in stress-relieving activities. These students report significant stress as they attempt to balance a challenging curriculum, employment and family responsibilities. Many

students acknowledge that they do not have adequate time to relieve stress. As part of their survey response, two students even suggested making exercise classes part of nursing school or holding fitness classes specifically for nursing students to allow easier access to stress relief.

The stress students experience during school may follow them into the workplace, creating a new generation of professional nurses who experience both work and personal stress. When nurses are unable to cope effectively, their patients may be adversely affected. Studies have shown that stressful work environments can have negative consequences for patients (Berland, Natvig & Gundersen, 2008). To guarantee quality care for all patients, nurses must learn to constructively and efficiently relieve stress during nursing school. The strategies nursing students learn can be used during nursing education and continued into nursing practice.

The Patient Protection and Affordable Care Act will soon add 32 million new patients to the healthcare system, creating an unprecedented demand for nurses (American Nurses Association, 2012). With this advent of substantial health care reform and the ever increasing population of retiring "baby boomers", nurses are and will continue to be in high demand. With an impending nursing shortage, significant numbers of students will continue to pursue nursing careers. The complexity of health care, the needs of patients and their families, and the frequent shortage of health care personnel, including professional nurses, will create stressful work environments. These stressful environments will be more manageable for nurses if they have learned how to efficiently cope with stress during nursing school.

#### Implications

Nursing education programs and nurse employers can promote effective coping by establishing policies that create positive learning and work environments that support nurses and reduce stress. Healthy coping can be promoted by creating opportunities and resources for students and nurses to engage in stress relieving activities. Such opportunities may include recreational facilities, quiet rooms for private meditation, and information regarding support groups and counseling services. University-based nursing programs may consider offering incentives to students who take time to relieve stress, i.e., a schedule that intentionally leaves open time slots between classes to give students time to attend a fitness class or relax in a student lounge with classmates.

Based on the levels of reported stress from students in a college nursing program, steps could be taken to incorporate stress management content and even practice into the undergraduate nursing curriculum. Nursing professors could include lectures that address the benefits of coping with stress and how students can apply such measures to their own lives and eventually relay this information to their patients. Information could also be provided to students regarding the benefits of healthy stress relief habits such as physical activity and meditation, versus the negative consequences of unhealthy stress relief habits such as smoking and excessive alcohol use.

Teaching students to effectively cope with occupational stress while in their educational programs may improve their performance as they begin their professional nursing careers. The current trends in healthcare reform clearly demonstrate not only the need for nurses, but also the reality that their work environments will be stressful. New nurses will be able to cope with the stresses of their jobs using the knowledge of healthy stress relief methods they learned during their undergraduate careers. These coping mechanisms will allow nurses to manage their responsibilities while maintaining a sense of professionalism. According to the American Nurses Association, registered nurses now have "greater opportunities to lead and contribute to a healthcare delivery that increasingly can focus on wellness and prevention, rather than simply

'sick care'" (2012). The emphasis on health promotion and maintenance will be easily implemented by nurses who are already well educated about healthy stress management.

#### Recommendations for Future Research

Further research is needed to explore possible revisions to BSN curricula that will include information about healthy stress management. Studies could be conducted that ask students in what activities they would most likely participate if they were provided. If exercise classes are made available but many students cannot participate due to injuries or other special circumstances, alternatives such as deep breathing classes or group counseling sessions should be explored. To encourage maximum participation, student recommendations for specific activities should also be considered when deciding what resources to provide.

Surveys could be conducted that ask current registered nurses about the coping strategies they find to be most effective in their jobs. Their answers could guide undergraduate nursing professors as they instruct students on healthy, effective coping. Revisions to baccalaureate curricula could include registered nurses sharing some of the struggles and stresses they faced as new nurses. Suggestions from registered nurses about coping with occupational stress could help students as they transition from the stress of nursing school to the stress of a professional nursing position.

Studies could also be conducted that use several different universities in different areas of the state or country to get input from students in other colleges of nursing. Additionally, using students from different types of programs could help identify which nursing students are at highest risk, thus allowing development of stress-reducing activities tailored to those at highest risk.

#### Limitations

Due to the nature of the Perceived Stress Scale and the collection of the data all on a single day, the results of the surveys display only a cross-sectional view of nursing students' perceived stress. The data represents a snapshot of the students' stress on the day of data collection, and their answers regarding specific stress relieving behaviors may change based on extenuating circumstances. Generalizations about all nursing students cannot be made because not every student in the nursing program was present on the day of data collection. Additionally, since only one college of nursing at one university was used, a generalization cannot be made about all nursing students in nursing programs.

Of the 444 surveys completed, five surveys had to be discarded due to either incomplete information or unusable data. Even though confidentiality was assured, it is possible that students did not respond truthfully to every question on the surveys due to their apprehension that someone might identify their answers. The cultural stigma in the Southeast associated with the consumption of alcohol, particularly in the Northeast Tennessee region of Appalachia, may have kept students from providing information about that particular stress relieving activity

#### Summary

Overall, this study found that nursing students are under substantial stress as they balance school with multiple outside responsibilities. Responses to the Perceived Stress Scale and Coping with Stress Questionnaire reveal that most students are stressed, many students do not have time to adequately relieve their stress, and almost all students would like to engage in some sort of stress relieving behavior. Nursing school is an ideal time to teach students about the benefits of effectively coping with stress. Undergraduate nursing curricula would benefit from including coping strategies for students and stress management content. The strategies learned during nursing school could help students cope with the stresses they will encounter upon entering the nursing profession, thus equipping them to meet the growing demands of today's healthcare industry.

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## Appendix A

## **Perceived Stress Scale**

The questions in this scale ask you about your feelings and thoughts **during the last month.** In each case, you will be asked to indicate by circling *how often* you felt or thought a certain way.

0 = Never 1 = Almost Never 2 = Sometimes 3= Fairly Often	4	4= Very Often			
<ol> <li>In the last month, how often have you been upset because of something that happened unexpectedly?</li> </ol>	1	2	3	4	
<ol> <li>In the last month, how often have you felt that you were unable to control the important things in your life?</li> </ol>	1	2	3	4	
<ol> <li>In the last month, how often have you felt nervous and "stressed"?</li> </ol>	1	2	3	4	
<ol> <li>In the last month, how often have you felt confident about your ability to handle your personal problems?</li> </ol>	1	2	3	4	
5. In the last month, how often have you felt that things were going your way? <b>0</b>	1	2	3	4	
<ol> <li>In the last month, how often have you found that you could not cope with all the things you had to do?</li> </ol>	1	2	3	4	
<ol> <li>In the last month, how often have you been able to control irritations in your life?0</li> </ol>	1	2	3	4	
8. In the last month, how often have you felt that you were on top of things? <b>0</b>	1	2	3	4	
<ol> <li>In the last month, how often have you been angered</li> <li>because of things that were outside of your control?</li> </ol>	1	2	3	4	
10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	1	2	3	4	

### Appendix B

## Coping with Stress Questionnaire

**Instructions**: Below, you will find four categories of stress relievers. As you read them, think about the things you do personally to relieve your stress. Once you have read them, **follow the prompts**. \*\*\*If you do not engage in any type of stress relieving activity, mark the appropriate space.

### HOBBIES

-shopping, reading, traveling, gardening, sewing, scrapbooking, cooking, crafting, playing an instrument, puzzles, etc.

## MEDITATION

-yoga, tai chi, deep breathing, praying, reflecting, journaling, listening to music, spending time alone, take bath/shower, massage therapy, aromatherapy, etc.

## • MISCELLANEOUS

-sleeping, eating, watching television/movies, talking to friends/family, cleaning, crying, drinking alcohol, drugs (prescription or illicit), smoking, etc.

## PHYSICAL ACTIVITY

-running, biking, walking, hiking, swimming, climbing, wrestling, ballet, martial arts, lifting weights, club teams, organized sports, group exercise classes, etc.

<u>Step One:</u> In the blanks provided, **list the top 3 activities/behaviors you use** to cope with stress. **There are no right or wrong answers.** 

<u>Step Two:</u> **Rank your answers in order of effectiveness**, with "**1**" meaning "Least Effective," "**2**" meaning "Somewhat Effective," and "**3**" meaning "Most Effective." **Use each ranking only once**.

<u>Step Three</u>: **Rank your answers in order of frequency**, with "**1**" meaning, "I do this the least," "**2**," meaning, "I do this sometimes," and "**3**" meaning, "I do this the most." **Use each ranking only once.** 

Top 3 activities/behaviors: (including, but not limited to, list above) Effectiveness Frequency

\_\_\_\_\_ I do not engage in any type of stress relieving activity/behavior.

Lastly, please respond to the following question:

Given the time, resources, and ability, what stress relieving activities/behaviors would you most like to participate in? (Please be specific)

## Appendix C

## Columns (based on every option provided under "top 3 activities/behaviors")

<mark>Physical Activity</mark> Meditation

- 1. Miscellaneous
- 2. Hobbies
- 3. Praying
- 4. Sleeping
- 5. taking naps
- 6. Running
- 7. Smoking cigarettes
- 8. Working out/exercising
- 9. Sports
- 10. Fishing
- 11. Whitewater rafting
- 12. kayaking
- 13. Yoga
- 14. Taking bath/shower
- 15. Reading
- 16. Shopping
- 17. Lifting weights
- 18. Talking/hanging out with friends/family
- 19. Listening to music
- 20. Meditation
- 21. reflecting
- 22. Watching TV
- 23. Watching movies
- 24. Crafting
- 25. Physical activity
- 26. group exercise
- 27. Being outdoors in nature
- 28. Crying
- 29. Driving
- 30. Fly fishing
- 31. Deep breathing
- 32. Dancing
- 33. competition dance team
- 34. Cleaning
- 35. Playing an instrument (guitar, mandolin, fiddle, piano)
- 36. Puzzles

- <mark>37. Biking</mark>
- 38. mountain biking
- <mark>39. Swimming</mark>
- 40. Play games
- <mark>41. Hiking</mark>
- 42. Climbing
- 43. Cooking
- 44. Writing
- 45. Walking
- <mark>46. Zumba</mark>
- 47. Playing with pets

48. Rest

## 49. Massage therapy

- 50. Watching Netflix
- 51. Playing with my kid(s)
- 52. Biting finger nails
- 53. Juggling

## 54. Relax

- 55. Talk to people that make me happy
- 56. Traveling
- 57. Play soccer
- 58. Play racquetball
- 59. Intramural sports
- 60. Crocheting
- 61. Riding horses
- 62. Eating
- 63. eat chocolate
- 64. Drinking alcohol
- 65. Photography
- 66. Playing Minecraft
- 67. video games
- 68. Laughing
- 69. Kill small animals
- 70. Set things on fire
- 71. Wet the bed

## <mark>72. P90X</mark>

- 73. Church/church events
- 74. Gardening
- 75. Artwork/drawing
- 76. Vacation
- 77. Watching sports
- 78. Making lists
- 79. Sex

- 80. Staying organized
- 81. Work
- 82. Sexy time
- 83. Dirt bike racing

## 84. Spending time alone

- 85. Playing golf
- 86. Pace
- 87. Remodel house
- 88. Martial arts

## 89. Tai chi

- 90. Musical instrument construction
- 91. Animal caretaking
- 92. Singing
- 93. Disc golf
- 94. Medication (anxiety pills)
- 95. Medication (prescription drugs)

## 96. Create a relaxing study area with candles

- 97. Work on assignments early
- 98. Watch a fun activity
- 99. Wrestling
- 100. Playing basketball
- 101. Riding motorcycle
- 102. Making fun of life
- 103. Scrapbooking
- 104. Cuss
- 105. Ballet
- 106. Stretching
- 107. Hunting
- 108. Tanning
- 109. Disassociation
- 110. Yell at people
- 111. Boating
- 112. Illicit drugs
- 113. Violence/domestic
- 114. Fighting
- 115. Harming small animals
- 116. Study daily to stay ahead
- 117. aromatherapy
- 118. journaling
- 119. camping



East Tennessee State University

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## **IRB APPROVAL – Initial Exempt**

August 20, 2012 Geneva Record

RE: Stress relief habits and perceived stress among college nursing students: A Descriptive Correlational Study IRB#: 0812.6 ORSPA#:

On **August 20, 2012**, an exempt approval was granted in accordance with 45 CFR 46. 101(b)(2). It is understood this project will be conducted in full accordance with all applicable sections of the IRB Policies. No continuing review is required. The exempt approval will be reported to the convened board on the next agenda.

 X Form, Cited works abstract, CV, ICD 9/18/2012, Perceived Stress Scale, Coping with Stress Questionnaire

## Projects involving Mountain States Health Alliance must also be approved by MSHA following IRB approval prior to initiating the study.

Unanticipated Problems Involving Risks to Subjects or Others must be reported to the IRB (and VA R&D if applicable) within 10 working days.

Proposed changes in approved research cannot be initiated without IRB review and approval. The only exception to this rule is that a change can be made prior to IRB approval when necessary to eliminate apparent immediate hazards to the research subjects [21 CFR 56.108 (a)(4)]. In such a case, the IRB must be promptly informed of the change following its implementation (within 10 working days) on Form 109 (www.etsu.edu/irb). The IRB will review the change to determine that it is consistent with ensuring the subject's continued welfare.

Sincerely, George Youngberg, M.D., Chair ETSU/VA Medical IRB



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