

Pittsburg State University
Application for Approval of Investigations
Involving the Use of Human Subjects

This application must be completed by the Investigator and sent to the Office of Graduate and Continuing Studies by the first Tuesday of the month during the fall and spring academic semesters to be considered for full review on the second Tuesday of the month.

Expedited and exempt reviews can be turned in any time. For questions about the review process contact Brian Peery in Russ Hall, #112, Ext. 4175.

1. Investigator(s) Name(s): Katelyn Triplett

2. Department: Irene Ransom Bradley School of Nursing

3. Local Address: 1701 South Broadway Street, Pittsburg, KS 66762

4. Phone: 620-235-4431

5. E-mail Address: katelyntriplett@gmail.com

6. Project Title:
Autism Spectrum Disorders and How Increased Knowledge of Disorders Reduces Stress Levels in Staff Caring Directly for Autism Spectrum Disorder Patients.

7. Expected Completion Date: March 2020

8. Expected Starting Date January 2020

9. Is this project (check all that apply): Use review criteria in Form CR-1 to determine which category of review applies.

- Application for Full Review Protocol Change Thesis/Special Investigation
 Being submitted for external support Continued Review Application for Expedited Review
 Being conducted in a foreign country Faculty Research Application for Exempt Review
 Publishable research A Class Project

10. If notification of human subject approval is required give date required: _____

Name of agency: _____

11. If you are a student, complete the following:

Faculty Sponsor: Barbara McClaskey

Department: Nursing

Phone: 235-4443

**** If submitted externally, a complete copy of the proposal must be submitted to the IRB. ****

CERTIFICATION AND APPROVAL

Certification by Investigator: I certify that (a) the information presented in this application is accurate, (b) only the procedures approved by the IRB will be used in this project, (c) modifications to this project will be submitted for approval prior to use, and that all guidelines outlined in the PSU Policy and Assurance Handbook for the Protection of Human Research Subjects will be followed as well as all applicable federal, state and local laws regarding the protection of human subjects in research as outlined in Form VA-1.

Katelyn Elaine Triplett

12/05/2019

Signature of Investigator

Date

Faculty Sponsor: If the Investigator is a student, his/her Faculty Sponsor must approve this application. I certify that this project is under my direct supervision and that I accept the responsibility for ensuring that all provisions of approval are met by the investigator.

Barbara McCaskey

12/6/19

Signature of Faculty Sponsor

Date

Department Review Committee Chair: I acknowledge that this research is in keeping with the standards set by our department, university, state and federal agencies and I assure that the student principal investigator has met all departmental requirements for review and approval of this research.

Sheryl Hefner

12/6/19

Signature of Department Review committee Chairperson

Date

Carol K. Kessler

12/13/19

CPHRS Chairperson

Date

I. Description of the Subjects (If advertising for subjects, include a copy of the proposed advertisement.)

A. How many subjects will be involved? Approximately 60

B. Subject Population (check all that apply) Adults

Adults Prisoners Minors Mentally Retarded

Mentally Ill Physically Ill Disabled Special Education Other

C. For projects conducted in schools or school settings:
(Written approval from the Building Administrator must be obtained)

What grade are the students in? _____

Approximate Age of Students _____

How many classes involved? _____
What subject: (secondary)? _____

Location: _____

Name of School: _____

D. What criteria will be used to select subjects AND/OR what criteria will be used to exclude individuals? (e.g., age, sex, race, ethnic origin, religion, or any social or economic qualifications)? State why the selection will be made on the basis or bases given.

Inclusion criteria includes individuals working at Heartland Behavioral Health Services and they must regularly attend monthly in-service trainings as required by their CEO.

Exclusion criteria includes those employees who are knowingly ending job employment status at Heartland Behavioral Health Services prior to March 2020 as they will be unable to complete the follow-up survey and that data will be unable to be collected after the pre-test and post-test survey are completed.

II. Abstract: Describe the purpose of the research and summarize the strategies used to collect data and protect participants.

The purpose of the research is to determine the amount of baseline knowledge that direct care staff have on Autism Spectrum Disorders (ASD) and the level of comfort that they experience when caring for these patients. Surveys without any identifying information will be the basis of the data collection. The surveys are identical and therefore, will not be able to identify the nurses from other staff members participating in the survey.

III. Procedure: Activities Involving Human Subjects (Attach additional sheet if needed)

A. Give a brief description or outline of your research procedures as they relate to the use of human subjects.

1. Who will be the subjects? How will you enlist their participation?

The subjects are adults, greater than 18 years of age, who are currently employed at HBHS. Their participation in the study will be determined on their attendance at their required, routine monthly in-service.

2. What precisely will be done to the subjects? State instructions given to the subjects, activities in which they will engage, tests and questionnaires (if you are using questionnaires or handouts, please include a copy with this application.)

The participants will engage in an educational presentation over ASD and asked to complete a total of 3 surveys and questionnaires over the course of the study (total of 8 weeks). The educational presentation consists of background information and characteristics of ASD and then suggestions on implementations to use in practice when caring for these patients.

Attached is the copy of questionnaires.

3. If any of the subjects are minors or "vulnerable" (children, prisoners, mentally or physically disabled, pregnant women), discuss how their special condition will be handled. 4. How will subjects be informed of research findings?

There are no vulnerable populations used in this study.

IV. Confidentiality and Anonymity

How will the data be collected? (Check all that apply)

- Questionnaires (Submit a copy) Observations (describe how they will be conducted)
 Interviews (Submit sample questions) Standardized tests (attach a copy if possible; list names)
 Test (Submit a copy if possible) Task(s) (briefly explain)
 Video or Audio Tapes Computer Entries (explain)
 Other in description of above:

A. Explain the procedures for collecting, recording and storing that data during the study.

questionnaires will be obtained for collecting data. Recording and storing of data will be completed through an Excel spreadsheet that will only be accessible to this investigator and the board members that are requiring it to help statistically analyze the data.

B. Who will have access to the data during the study? (Access should be limited to protect anonymity of subjects and confidentiality of subject responses)

Access to the data during the study will be this investigator and the committee members that sit on the board of this scholarly project.

C. Explain what will happen to the data once the study is completed. Is there a need to keep the data or will it be destroyed? If kept, how long and where will it be stored, how will confidentiality be ensured, who will have access to it?

Once the study is completed and once the data has been statistically analyzed, the data will be destroyed.

D. Explain the level of confidentiality you are guaranteeing the participants.

Complete confidentiality will be guaranteed to the participants. There will be no names or identifying factors linked to the data collected in the data collection portion of this study.

V. Benefits, Risks, and Costs of this Study

A. What are the potential benefits to the subjects, to the field or discipline, or to the University?

Potential benefits to the subjects include increased knowledge about the patients in which they care for, Autism Spectrum Disorder (ASD) patients, and their ability to care for them with less stress.

Potential benefits to the field is a better understanding of guidelines that can be implemented to better care for ASD patients in the inpatient setting and to encourage further research on guidelines that can be set in place to care for ASD patients in a multitude of settings.

B. Will compensation (money, extra credit, etc.) be offered to the subjects? If so, how will it be dispersed?

Compensation will not be offered to the subjects, aside from the pay that they receive in terms of attending their routine monthly in-service meeting as required by Heartland Behavioral Health Services.

C. What risks or discomforts are most likely to be encountered by the subjects? Please consider carefully.

- | | |
|---|--|
| <input type="checkbox"/> Employability | <input type="checkbox"/> deception (benevolent misdirection) |
| <input type="checkbox"/> financial or personal reputation | <input type="checkbox"/> embarrassment |
| <input type="checkbox"/> emotional stress or discomfort | <input type="checkbox"/> psychological stress or discomfort |
| <input type="checkbox"/> loss of confidentiality | <input type="checkbox"/> criminal or civil liability |
| <input type="checkbox"/> physical stress or discomfort | <input type="checkbox"/> other (explain below) |

D. What safeguards will you use to eliminate or minimize these risks? If there is the possibility of adverse reactions by the subjects, explain where the subjects can receive help.

Survey responses will be confidential; therefore, the participants will be unable to be identified. There will not be any adverse reactions experienced by the participants as they are simply given education regarding ASD characteristics and potential behavior triggers and ways in which to reduce those triggers in the inpatient setting.

E. In your opinion, does the research involve **more than minimal risk** to subjects? ("Minimal risk" means "the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine or psychological examinations or tests.")

This research does not involve more than minimal risk to the subjects.

VI. Additional Information or Completion of a Previous Section:

Not applicable.

VII. Informed Consent: (Not needed for exempt review)

Unless authorized by the IRB, no investigator may involve a human being as a subject in research under the auspices of the University unless the investigator has obtained the informed consent of the subject or the subject's legally authorized representative.

Attach a copy of all consent documents that will be used to this application.

For further information about informed consent processes review the information on Continuing and Graduate Studies web page in the Forms for Research Involving Human subjects.

A. Explain the procedures that will be used to obtain consent:

Participants will be informed of the purpose of the study and their involvement is strictly on volunteer basis.

B. Federal regulations state that the following elements of information should be provided to each subject. (Place a check mark before each component included in your consent document.)

- An explanation of the purpose of the project and the expected duration of the subject's participation.
- An explanation of the activities or procedures to be followed.
- A description of any risks or discomforts to the subject.
- A description of any benefits of the project to the subject or to others.
- A statement that participation in this project is voluntary and the subject may withdraw at any time.
- A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
- An explanation of whom to contact with questions regarding the study.

1. Explain request for waiver of any component listed above or other special conditions related to informed consent.

Explanation of the purpose of the project and timeline in which the participants will be engaging will be discussed prior to the start of the study. An explanation of the procedures involved throughout the study will be addressed with the participants prior to start the of the study. The survey answers will not be linked with any names during the course of the study and the refore, complete confidentiality will be obtained.

PITTSBURG STATE UNIVERSITY
COMMITTEE FOR THE PROTECTION OF HUMAN RESEARCH
SUBJECTS
(CPHRS)

Verification of Assurance Form

PRINCIPAL INVESTIGATOR ASSURANCE

I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human subjects and the ethical conduct of this research application.

I agree to comply with all PSU policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

- Title 45, Part 46 of the Code of Federal Regulations
- The Belmont Report, *Ethical Principles and Guidelines for the Protection of Human Subjects and Research*
- The project will be performed by qualified personnel according to the research protocol
- Maintaining a copy of all questionnaires, survey instruments, interview questions, data collection instruments, and information sheets for human subjects in the respective department
- Necessary review by the PSU IRB (The Committee for the Protection of Human Research Subjects –CPHRS) will be sought if changes made in the research protocol may result in the research no longer meeting the original approved criteria.
- The Principal Investigator has completed the NIH Protection of Human Research Subjects On-Line Training Program.
- The Principal Investigator has read and understands the PSU Assurance Handbook concerning human subjects research protocols.

Exemption for Research Involving Human Subjects Criteria Form Project

Title: Autism Spectrum Disorders and How Increased Knowledge of Disorders Reduces Stress Levels in Staff Caring Directly for Autism Spectrum Disorder Patients

Principal Investigator: Katelyn Triplett

Unless otherwise required by Department or Agency heads, research activities in which the involvement of human subjects will be in one or more of the following categories are exempt from review by the entire Committee for the Protection of Human Research Subjects (CPHRS). All of the project activity must qualify as exempt according to one of the criteria below for the project to be ruled exempt from CPHRS review.

Note: listed exemption categories do not apply when the research activities include:

- a. **prisoners, fetuses, pregnant women or human in vitro fertilization**
- b. **survey or interview techniques which include minors (under 18 years of age) as subjects**
- c. **research involving the observation of the public behavior of minors (under 18 years of age)** d. **the deception of the subjects**
- e. **techniques which expose the subject to discomfort or harassment beyond levels encountered in daily life (the research activity presents more than minimal risk to human subjects)**

Instructions: check the applicable category(s) which make this research applicable for exempt review.

EX1: Is this research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: research on regular and special education instructional strategies, **OR** research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

EX2: Does this research involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **WITHOUT** : information being obtained and recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, **OR** any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

EX3: Does this research involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior **EXCLUDING**: human subjects who are elected or appointed public officials or candidates for public office, **OR** federal statute(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research thereafter.

EX4: Does this research, involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens where the subjects cannot be identified, directly or through identifiers linked to the subjects?

EX5: Is this research or demonstration project(s) subject to the approval of department or agency heads designed to study, evaluate, or examine (**ONLY ONE CRITERIA NEEDS TO APPLY**): Public benefit or service programs? Procedures for obtaining benefits or services under programs? Possible changes in or alternatives to those programs or procedures? Possible changes in methods or levels of payment for benefits or services under those programs?

EX6: Do these taste and food quality evaluations and/or consumer acceptance studies **INCLUDE (ONLY ONE MUST APPLY)**: wholesome foods without additives being consumed? a food that is consumed containing a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below

Pre-Educational Survey

1. **What is your job title?**

BHS

LPN

RN

Therapist

2. **How many years have you been in this job title?** _____

3. **How many total years have you worked at HBHS?** _____

4. **Autism Spectrum Disorder is caused by receiving vaccinations as an infant.**

Strongly Disagree

Disagree

No Opinion

Agree

Strongly Agree

5. **Three previously separate diagnoses are now included in the Autism Spectrum Disorders**

Strongly Disagree

Disagree

No Opinion

Agree

Strongly Agree

6. **How plausible is that the ticking of a clock can evoke a reaction in a patient diagnosed with ASD**

Very Unlikely

Unlikely

No Opinion

Likely

Very Likely

7. **How plausible is it that a tactile stimulation, such as touching a piece of paper, can evoke a reaction in a patient diagnosed with ASD.**

Very Unlikely

Unlikely

No Opinion

Likely

Very Likely

8. **How plausible is it that an odor, good or bad, can evoke a reaction in a patient diagnosed with ASD.**

Very Unlikely

Unlikely

No Opinion

Likely

Very Likely

For the following questions, please choose the answer that you feel most appropriately describes you currently. Please answer honestly.

9. I have the ability to address restrictive and repetitive behaviors when caring for a patient with Autism Spectrum Disorder.

Strongly Disagree Disagree No Opinion Agree Strongly Agree

10. When a patient is having behaviors on the unit, I am comfortable and confident in my ability to de-escalate that patient without using any restrictive means (restraint, PRN medication, etc.)

Strongly Disagree Disagree No Opinion Agree Strongly Agree

11. My stress level increases when I am caring for a child that consistently exhibits behaviors on the unit I am working.

Strongly Disagree Disagree No Opinion Agree Strongly Agree

Post-educational Survey

1. Autism Spectrum Disorder is caused by receiving vaccinations as an infant.

Strongly Disagree Disagree No Opinion Agree Strongly Agree

2. Three previously separate diagnoses are now included in the Autism Spectrum Disorders

Strongly Disagree Disagree No Opinion Agree Strongly Agree

3. How plausible is it that the ticking of a clock can evoke a reaction in a patient diagnosed with ASD

Very Unlikely Unlikely No Opinion Likely Very Likely

4. How plausible is it that a tactile stimulation, such as touching a piece of paper, can evoke a reaction in a patient diagnosed with ASD.

Very Unlikely Unlikely No Opinion Likely Very Likely

5. How plausible is it that an odor, good or bad, can evoke a reaction in a patient diagnosed with ASD.

Very Unlikely Unlikely No Opinion Likely Very Likely

For the following questions, please choose the answer that you feel most appropriately describes you currently. Please answer honestly.

6. I have the ability to address restrictive and repetitive behaviors when caring for a patient with Autism Spectrum Disorder.

Strongly Disagree Disagree No Opinion Agree Strongly Agree

7. When a patient is having behaviors on the unit, I am comfortable and confident in my ability to de-escalate that patient without using any restrictive means (restraint, PRN medication, etc.)

Strongly Disagree Disagree No Opinion Agree Strongly Agree

8. My stress level increases when I am caring for a child that consistently exhibits behaviors on the unit I am working.

Strongly Disagree Disagree No Opinion Agree Strongly Agree

9. I am pleased with the amount of education and training I have received over Autism Spectrum Disorder prior to the educational presentation received today.

Strongly Disagree Disagree No Opinion Agree Strongly Agree

10. I learned something new during the educational presentation today that I wasn't aware of before.

Strongly Disagree Disagree No Opinion Agree Strongly Agree

11. If given the opportunity to attend an educational service on autism, I would like to participate.

Strongly Disagree Disagree No Opinion Agree Strongly Agree

Follow up Survey

1. **I have utilized the interventions that were discussed in the presentation over Autism**

0 times 1-5 times 6-10times 11-15 times More than 15 times

2. **I have found that the interventions that were suggested were helpful in de-escalating behaviors or decreasing the amount of behaviors that I saw on my unit.**

Strongly Disagree Disagree No Opinion Agree Strongly Agree

3. **Following the educational presentation over autism, I found myself more able to care for patients with autism.**

Strongly Disagree Disagree No Opinion Agree Strongly Agree

4. **Following the educations presentation over autism, I found myself feeling less stress when patients began to exhibit undesirable or restrictive and repetitive behaviors.**

Strongly Disagree Disagree No Opinion Agree Strongly Agree

5. **Following the educational presentation over autism, I found myself searching for and eliminating potential triggers for autism spectrum disorder patients when they presented themselves.**

Strongly Disagree Disagree No Opinion Agree Strongly Agree

6. **I have a better understanding of autism spectrum disorder and potential intervention strategies that can be applied when caring for patients with autism spectrum disorder.**

Strongly Disagree Disagree No Opinion Agree Strongly Agree

7. I am interested in continuing to learn more about autism spectrum disorders in order to improve the care that is given to patients diagnosed with ASD.

Strongly Disagree Disagree No Opinion Agree Strongly Agree

8. I have a better understanding of how my behavior, body language, voice volume, and voice intonation can escalate or de-escalate a patient's behavior.

Strongly Disagree Disagree No Opinion Agree Strongly Agree