

HUMAN SUBJECTS RESEARCH APPLICATION

Brenau University
Institutional Review Board
School of Health and Science

Check One

New Application:

Resubmission: Revision (All changes must be highlighted)

One Centennial Circle
Gainesville, Georgia 30501
(770) 718-5304

Applying for Exempt review (see guidelines)

Applying for Expedited review (see guidelines)

NOTE: Application must have a Brenau e-mail address.
All communication will occur via e-mail.

MAIL 7 COPIES (2 copies for expedited review) OF APPLICATION TO ABOVE ADDRESS 4-6 weeks prior to start date

Dr. Mr. Ms.

Dr. Mr. Ms.

Faculty Undergraduate Graduate

Faculty Undergraduate Graduate

Jennifer C.

Name of Principal Investigator

Soc. Sec. No.

(if project is grant affiliated)

Name of Co-investigator(s)

Soc. Sec. No.

(if project is grant affiliated)

Psychology/ jc@lib.brenau.edu

Brenau Department AND Brenau e-mail address

Brenau Department AND Brenau e-mail address

Mailing Address (if you prefer not to receive mail in dept.)

8:00 a.m. - 5:00 p.m. Phone Number (s)

Phone Number (s)

E-Mail (REQUIRED)

Phone Number (s)

E-Mail

**Signature of Principal Investigator

Signature of Co-investigator (s)

Brenau Faculty

Advisor:

Dr. Battle
Name

Psychology
Dept.

CCPS
Building

Phone No.

Soc. Sec. No.:

(if grant affiliated)

Date:

**Signature:

**Your Signature indicates that you accept responsibility for the research described in this application.

If funded:

***Sponsored Programs Proposal#

Name of Funding Agency

***By listing a proposal number, you agree that this application matches the grant application and that you have disclosed all financial conflicts of interest (see Q6a)

TITLE OF RESEARCH:

Psychological and abuse-related differences between child sexual abuse victims and victims who become sexually abusive youth.

Start Date:

1/30/04

(Must be 4-6 weeks after date of submission to IRB)

End Date:

05/30/04

(Approval is granted only for a year at a time)

Check all that apply:

Deception Illegal Activities Minors Pregnant Women/Prisoners

Data Sets Bio Medical (describe) _____

HUMAN SUBJECTS RESEARCH APPLICATION

1. **PROBLEM ABSTRACT:** *State rationale and research question or hypothesis (why is this study important and what do you expect to learn?).*

The purpose of this study is to determine differences in child sexual abuse victims and child sexual abuse victims who become sexually abusive towards others. The differences determined can be used to better preventative interventions for sexually abused victims in order to prevent them from becoming sexually abusive towards others. The Hypotheses are as follows: Victims who wait a longer period of time before disclosure after initial victimization are more likely to become sexually abusive youth. Victims who have a close relationship to the perpetrator are more likely to become sexually abusive youth. Victims who are at a younger age at initial victimization are more likely to become sexually abusive youth. Victims who have a same-sex perpetrator are more likely to become sexually abusive youth. Victims who have lower levels of social support at time of disclosure are more likely to become sexually abusive youth. Victims who have low self-concept are more likely to become sexually abusive youth. Victims who have post traumatic stress symptoms related to the abuse are more likely to become sexually abusive youth.

2. **RESEARCH DESIGN:** *Identify specific factors or variables, conditions or groups and any control conditions in your study. Indicate the number of research participants assigned to each condition or group, and describe plans for data analysis.*

The study will consist of two groups: a child sexual abuse victim group and a child sexual abuse victim-perpetrator group. . The victim group will include children have been the victim of sexual abuse but who have never acted out sexually on other children. The victim-perpetrator group will include children who have been the victim of sexual abuse and have also acted out sexually on other children. There will be 20 participants in each group. Predictors include: age at time of initial victimization, identity and gender of perpetrator, length of time for disclosure after initial victimization, amount of social support after initial disclosure of abuse, post-traumatic stress symptoms, and level of self-concept. Data will be analyzed statistically using chi-square and logistic regression on SPSS version 11.0.

3. **RESEARCH SUBJECTS:**

- a. *List maximum number of subjects 40 , targeted age group/ range 8-17 (specified in years); targeted gender selection not based on gender, but an attempt will be made to have fairly equal groups; targeted ethnicity/ race selection not based on ethnicity*

- b. *Method of selection and recruitment - list inclusion and exclusion criteria. Describe the recruitment procedures (including all follow-ups).*

Forty children/adolescents will be recruited from Family Relations Program/Project Pathfinder in which both victims and victim-perpetrators are provided with clinical treatment, social support, and education regarding sexual abuse. The participants will be divided into two groups on the basis of whether they are child sexual abuse victims or child sexual abuse victims who are or have been sexually abusive towards others. Twenty children/adolescents will make up the victims group and twenty children/adolescents will make up the victim-perpetrators group. Participants in the victims group will be selected based on having been a victim of sexual abuse in the past and participants in the victim-perpetrator group will be selected based on having been a victim of sexual abuse in the past and then in turn having sexually perpetrated against an other(s). Also, participants will be selected based on their legal guardian's willingness to sign informed consent for participation in the research study, as well as the participant's willingness to sign informed assent.

- c. *The activity described in this application involves another institution (e.g. school,*

university, hospital etc.) and/or another country. Yes No

If yes, provide the following details:

1) Name of institution: Family Relations Program/Project Pathfinder

2) County and state: Hall, Georgia

3) Country: USA

4) *Written letter of authorization (on official letterhead only)/ IRB approval:*

Attached:

Pending:

d. *Is there any working relationship between the researcher and the subjects?*

Yes No , If yes, explain.

Yes, the researcher, research assistants, or therapists will be administering the Children's Impact of Traumatic Events Scale –Revised to participants in an interview format and Piers-Harris Self-Concept Scale-2 to participants.

e. *Describe any incentives (payment, gifts, extra credit).*

Extra credit cannot be offered unless there are equal non-research options available for research using students

The participants will not be paid to participate in the study in order to ensure that the study will be non-coercive; however, while participants are administered the assessments, they will be provided with refreshments to compensate for their time and effort.

4. **PROCEDURES:** *State in chronological order what a subject is expected to do and what the researcher will do during the interaction. Indicate time commitment for each research activity. And detail any follow-up.*

Participants and their legal guardians will be individually informed of the procedure of the study and confidentiality in an understandable manner and will be asked to repeat details in order to ensure understanding. Participants and their legal guardians will be notified of the limitations to confidentiality, in which information obtained from the participants will not be kept confidential such as if there is a subpoena from court or if there were threats of or instances of harm to self, others, or current or past child abuse which has not been previously disclosed. All participants and their legal guardians will be made aware that this study is voluntary and will be told that they may discontinue participation at any point during the study.

Once informed consent and informed assent are received, the examiner then will complete a chart review in which information related to the sexual abuse, such as gender and identity of the perpetrator, time of disclosure after sexual abuse occurred, and age in which the participant was initially victimized, is gathered. Next the participants will be asked to complete a form that is used to gather demographic information. Once demographic information is obtained, the assessments, the Piers-Harris Self-Concept Scale (used to measure self-concept) and the Children's Impact of Events Scale-Revised (used to measure post-traumatic stress symptoms and social support at time of victimization) will be administered by the primary researcher, a research assistant or the therapist. It will take approximately 1 hour to complete the assessments. The participants will be given the opportunity for a 5 minute break in between the administrations of each assessment. After administration of assessments, there will be time allotted for debriefing. Scores on the Piers-Harris 2 and Children's Impact of Events Scale-Revised will be compared between the two groups, as well as demographic information and information related to the abuse of the participants, in order

to determine differences between sexual abuse victims and victims who become sexually abusive.

Duration of participation in the study: _____ Months

No. of testing/training sessions: 1 Length of each session: 1 hr

5. **Check all other materials that apply and are attached:**

Interview protocol Debriefing Statement Recruitment flyers or advertisements

Consent/Assent forms Photo/Video release on consent form

If no consent documents are attached, justify this omission under Q. 8

6. **RISK:** *Detail risks to a subject as a result of data collection and as a direct result of the research and your plans to minimize them and the availability and limits of treatment for sustained physical or emotional injuries.*

NOTE: REPORT INCIDENTS CAUSING DISCOMFORT, STRESS OR HARM TO THE IRB IMMEDIATELY!

- a. **CURRENT RISK:** *Describe any psychological, social, legal, economic or physical discomfort, stress or harm that might occur as a result of participation in research. How will these be held to the absolute minimum?*

The questions presented may involve sensitive issues and could cause feelings of discomfort. If the questions should cause feelings of discomfort, the therapists who administer the assessments will be available when the participants complete the assessments for any aftercare/counseling that the participants may need in order to address the participants' concerns/feelings of discomfort.

- b. **FUTURE RISK:** *How are research participants to be protected from potentially harmful future use of the data collected in this project? Describe your plans to maintain confidentiality, including removing identifiers, and state who will have access to the data and in what role. Justify retention of identifying information on any data or forms.*

DO NOT ANSWER THIS QUESTION WITH "NOT APPLICABLE"!

Anonymous Confidential *Check one only and explain below.*

To ensure that all of the participants' names will be kept confidential all forms and assessments will be kept in a locked filing cabinet during the study, with only the researcher and the participants' therapists having access to the data. The researcher will use data in order to run comparison analyses and the therapists will have access to the data in order to incorporate information obtained into treatment. No identifiable information will be included in the study, such as the location of the study or the program in which the study will take place. All forms and assessments will be destroyed after the completion of the study.

Audio-taping Video-taping Pictures

If taping, how will tapes be securely stored, who will have access to the tapes, will they be publicly disseminated and when will they be erased or destroyed? Justify retention.

7. **BENEFIT:** *State the benefits to individuals and humankind. Potential benefits of the research should outweigh risks associated with research participation.*

- a. *Identify benefits of the research for participants, e.g. course credit, educational benefits:*

Information obtained from assessments of the participants will be shared with participants' therapists in written format after the completion of the scoring of the assessments. This will enable therapists to integrate the results into the treatment of the participants.

- b. *Identify any potential benefits of this research for humankind in general, e.g. advance*

our knowledge of some phenomenon or help solve a practical problem.

This research will serve to increase knowledge about what circumstances increase the likelihood that a child sexual abuse victim will sexually perpetrate against others. Also, it will be used to identify variables that can be focused on in treatment to prevent of child sexual abuse victims from becoming sexually abusive towards others.

8. CONSENT PROCESS:

a. *Detail how informed consent will be obtained from all research participants and, when applicable, from parent(s) or guardian(s).*

Participants and their legal guardians will be individually informed of the procedure and purpose of the study and confidentiality in an understandable manner and will be asked to repeat details in order to ensure understanding. They will also be informed of the risks and benefits of participation. Participants and their legal guardians will be notified of the limitations to confidentiality, in which information obtained from the participants will not be kept confidential such as if there is a subpoena from court or if there were threats of or instances of harm to self, others, or current or past child abuse which has not been previously disclosed. Also, participants and their legal guardians will be made aware that the assessment results will be given to their therapist in order to integrate results into treatment and that their participation in the study will not affect their ability to continue in treatment. All participants and their legal guardians will be made aware that this study is voluntary and will be told that they may discontinue participation at any point during the study.

Request for waiver of signed consent using data sets Yes No

If yes, a full explanation must be submitted for approval, including assurance that risk to the participant will be minimal. Also submit a consent script that will be used in lieu of a form.

b. **Deception** Yes No

If yes, describe the deception, why it is necessary, and how you will debrief them. The consent form should include the following statement: "In order to make this study a valid one, some information about my participation will be withheld until completion of the study."

9. VULNERABLE PARTICIPANTS: Yes No

Minors Prisoners Pregnant women/fetuses Elderly

Immigrants/non-English speakers Mentally/Physically incapacitated Others *List below.*

Outline procedures to obtain their consent/assent to participate. Describe the procedures to be used to minimize risk to these vulnerable subjects.

Participants will be explained the procedure and purpose of the study, as well as the risks and benefits of participation. They will also be informed that the study is completely voluntary and that they are able to discontinue participation at any time throughout the study. Also, they will be made aware that participation in the study does not affect their ability to continue in therapy. They will be informed of limitations to confidentiality. Participants will be asked to repeat details of the study in order to ensure understanding before having participants sign informed assent. In addition, informed consent will be obtained from the parents of potential participants.

10 ILLEGAL ACTIVITIES: (illegal drug use, prostitution, undocumented immigrants, etc)

- . NOTE: Some ILLEGAL ACTIVITIES must be reported, e.g. child abuse.
Does the data collection relate to illegal activities? Yes No
If yes, explain how subjects will be protected.

11 **STUDENTS** (check all that apply to this application)

. This application is being submitted for :

Class assignment Pilot study

Applied Project, Thesis or Exit Exam Research