University at Albany
Office of Research Compliance

For ORC Office Use Only
Protocol #

MSC 312 – 437-4569
Research Involving Human Subjects

IRB Annual Approval Continuation/Status Change Request Form

Version 11.16.06

Principal Investigator(s): Bob Edward Vasquez
Protocol Number: 05349
Protocol Title: A test of interactional theory and the interactive effects of close peers on delinquency
Protocol Expiration Date: 10/21/2008

DO NOT LEAVE ANY QUESTIONS BLANK, INDICATE N/A WHEN NECESSARY

1. Protocol Status (Check One):

☐	Research Not Started	No participants have been enrolled.
☐	Protocol is Active – Work in Progress	Participant recruitment, enrollment and interventions are on-going.
☐	Protocol in Follow-Up Only	Participant enrollment is closed, all interventions completed; participants are being followed for outcomes.
☒	Data Analysis	No further participant contact will take place.
☐	Work Completed	Project completed and no further analysis is planned. This is the final report protocol can be closed.
☐	Work on Protocol Will Not Be Done	This is the final report; protocol can be closed.

2. If protocol is to continue, identify which type of continuation is needed:

☒ **Protocol to continue as approved.**

☐ **Protocol requires modification to continue.** (Includes items such as changes in key personnel, number of participants, study procedures, collaborators, funding agency requests, etc.) ***If your protocol requires modifications, attach a completed "Modification Request Form" available at http://www.albany.edu/research/compliance/Forms.htm#IRB with this continuation request.***

☐ **Protocol to continue for data analysis only**

3. For all active protocols in which participant enrollment is on going, ***you must include one copy of your current consent form (CLEAN ORIGINAL)***. ***NOTE*: Before submitting your consent forms,** please replace the human rights statement with this updated language: ***"If you have any questions concerning your rights as a research participant that have not been answered by the investigator or if you wish to report any concerns about the study, you may contact the Office of Research Compliance at 518-437-4569 or orc@uamail.albany.edu."*** ***ADDITIONAL NOTE*:** If any of the participants in your study will be outside the 518 calling area, please substitute the toll-free number: 1-800-365-9139.

☐ **Updated Consent Form attached** ☒ **Not Applicable**

4. For all research that is funded, you are to report all changes that have been made or will be made to the sponsor's application concerning human subjects in the upcoming year. Submit **2 copies** of the *revision(s)* with the relevant human subject sections highlighted.

☐ **Grant has NOT been revised** ☐ **Grant revision is attached** ☒ **Not Applicable**

5. **You and your study personnel are required to meet the University's on-going educational requirements. Please refer to http://www.albany.edu/research/compliance/IRB/IRB-Train.htm for current training requirements.**

- **Provide a list of the current study personnel for this research in the table below.**

Study Personnel

Study personnel include the ***faculty advisor, principal investigator and all individual(s) who will interact*** with the study participants, collaborate on study design, analyze or record data or view any personal identifying information about the participants.

Study Personnel Name(s)	Role in Research	CITI Training Completion Date*	Study Personnel Name(s)	Role in Research	CITI Training Completion Date*
Bob Edward Vasquez	Principal Investigator	9-8-2006			
Marvin Krohn	Faculty Advisor	4-23-2006			

*You do not need to submit training certification. If ORC is not able to verify the date that is listed, the PI will be contacted for proof of training.

Attach additional page if necessary

- **All personnel associated with this project are required to complete human subjects training as a condition of IRB approval.** (Refer to the IRB human subjects training section for the current requirements available on the office of research compliance website at: HTTP://WWW.ALBANY.EDU/RESEARCH/COMPLIANCE/TRAINING.HTM

- **Please note:** If training for any key personnel will expire within this protocol's next renewal period, it will be necessary for him/her to complete the appropriate refresher training course, as noted on the above website, on or before the training certification's expiration date.

6. **Provide the following information for research involving human subjects for the current approval period. Information can be provided on this form or submitted as a separate memo.**

- *The number of participants approved for this research study:* N/A
- *The number of participants enrolled to date (completed informed consent process):* N/A
- *The number of participants who withdrew or discontinued participation in the research to date:* N/A
- *The number of participants who completed the study:* N/A
- *Have any participants become incarcerated?* ☐*Yes* ☐*No If yes, include number* N/A

- *A brief summary of any amendments or modifications to the research since your last IRB approval:*

  No amendments are being made.

- *A summary of any adverse events and unanticipated problems involving risks to participants or others: (Criteria for reporting of adverse events can be found at http://www.albany.edu/research/compliance/Forms/NEW%20Adverse%20Event%20Form%20.doc.)*

  N/A

- *A summary of the reasons for participant withdrawal and any complaints about the research since the last IRB review:*

  N/A (Existing Data and secondary analysis)

- *A summary of any relevant literature, interim findings or other relevant information affecting the risk/benefit ratio of this study:*

  The data do not contain personally identifable information.

- *Are you aware of any new findings that may relate to the participant's willingness to continue in this research project? If so, describe:*

  N/A (Existing Data)

- *A summary of any relevant multi-center trial reports:*

  N/A

- *Were any unexpected benefits to the subjects discovered during this review period?*

  N?A

7. **For Data Analysis (Please answer ALL questions):**

- **Does the data set contain personal identifiers?** ☐ **Yes** ☒ **No**
  (Personal identifiers include items such as birthdates, address, SS#, etc)

- **Is an individual's identity maintained in the dataset?** ☐**Yes** ☒ **No**

- **Can an individual's identity be ascertained by one or a combination of variables in your data set?**
  ☐ **Yes** ☒ **No**

- **Does your dataset contain a code that is linked to an individual?** ☐ **Yes** ☒ **No**

- **Is your dataset de-identified?** ☐ **Yes** ☒ **No**
  (e.g. no code or personal identifiers can exist)

- ***Provide a summary of the work completed.***

Multiple waves of data have been merged in order to examine relationships between variables over time. Analyses have been conducted but due to various statistical issues, findings are only preliminary. However, more appropriate statistical methods will be used soon.

- ***A brief summary of any amendments or modifications to the research since your last IRB approval:***

  None

- ***A summary of any adverse events and unanticipated problems involving risks to participants or others: (Criteria for reporting of adverse events can be found at http://www.albany.edu/research/compliance/Forms/NEW%20Adverse%20Event%20Form%20.doc)***

  None

8. **If your research has not yet started, please provide an explanation for the delay.**

9. **PRINCIPAL INVESTIGATOR ASSURANCE: By signing this form you are acknowledging the following:**
   - You certify that all submitted statements about this research study are true and accurate.
   - You will conduct this study in strict accordance with all submitted statements except where a change is necessary to eliminate an immediate hazard to a research participant.
   - You will report all intended changes in previously approved research prior to implementation.
   - You will maintain accurate and complete records of research data.
   - You will conduct the research in compliance with University at Albany Policies, federal, state and local laws, Declaration of Helsinki and the Belmont Report.
   - You will report all adverse events within 10 calendar days of the occurrence to the Office of Research Compliance.
   - **If you have obtained funding for this research, you will submit all changes in research that have been made to the sponsor's funding application which relate to human subjects within 30 calendar day to the Office of Research Compliance.**
   - If you are a student principal investigator, you are responsible for obtaining review and approval for this continuing review from your faculty advisor.

Bob Edward Vasquez		9-15-2008
Print Principal Investigator Name	**Principal Investigator Signature**	**Date**

FACULTY ADVISOR ASSURANCE (if applicable; required when PI is a student) - By signing this form you are acknowledging the following:
- You have reviewed and approved the information reported on this form.
- You will oversee the conduct of the research for compliance with University at Albany Policies, federal, state and local laws, Declaration of Helsinki and the Belmont Report and will promptly report any deviations to the Office of Research Compliance.

Marvin D. Krohn		9-15-2008
Print Faculty Advisor Name	**Faculty Advisor Signature**	**Date**