

INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH

NEW IRB SUBMISSION

I. Project Title and Research Team Members

Project Title:

Principal Investigator Name:

Faculty Research Supervisor (If student is the PI):

Additional Team Members:

This form must be used to submit an application through the IRBNet system. No other methods of submission will be accepted.

Access the system here: <u>www.irbnet.org</u>

Student and Adjunct Faculty researchers: Please note that Faculty Research Supervisor approval is required <u>prior</u> to submission to IRB. The Faculty Research Supervisor signature in IRBNet indicates approval and agreement with section XII. For faster processing, ensure all research team members have completed all required CITI training through <u>https://www.citiprogram.org/</u> prior to submitting this application.

II. Type of investigator and nature of the activity: (Check all appropriate categories.)

A. Faculty/Staff at FHSU:

Submitted for extramural funding to: Submitted for intramural funding to: Project unfunded Quality improvement/program evaluation Quality assurance Other (Please explain)

B. Student at FHSU: Graduate Thesis Specialist Field Study Undergraduate Independent Study Graduate Research Paper C. Class Project (Course Number and Course Title), explain activity:

D. Other than faculty, staff, or student at FHSU (Unaffiliated with FHSU) Please explain:

III. Human Subjects Research Ethics Training: <u>The IRB will not review submissions</u> without verification of appropriate CITI training. The Principal Investigator and all members of the research team must complete the appropriate CITI training modules. Faculty Research Advisors, when listed above, must also complete CITI training. If the PI is not affiliated with FHSU, documentation of CITI or other comparable training must be provided.

Date completed CITI training:

IV. Project Information

A. Expected study period from:

To:

B. Describe the purpose of the research. Explain what is intended to be discovered, including goals, aims, and objectives and/or state the hypothesis to be tested. Background: provide a brief scientific or scholarly rationale for the research activities, and address gaps in current knowledge. Investigators NOT currently affiliated with FHSU will collaborate on this project.

C. (If checked above) Identify any cooperating institutions by name.

D. This study is being/has been reviewed by another IRB. Yes No If yes, please attach relevant documentation.

V. Subject Information

- A. Number of subjects:
- B. Subject Age (Check all that apply):

1-7 8-17 18-65 65+

- C. Special Populations (Check all that apply):
 - Minors Non-English speaking Prisoners Individuals with impaired decision-making capacity Individuals who are economically or educationally disadvantaged Individuals with Legally Authorized Representatives Individuals who are vulnerable to coercion or undue influence

D. Describe target demographic of proposed subjects; explain how you will ensure that selection is equitable and that all relevant ethnic groups, genders, and populations have access to the study.

E. Describe any specific populations targeted for inclusion or exclusion: Justify criteria based on age, gender, race, ethnicity, sexual orientation, or origin.

VI. Recruitment

A. Describe the recruitment process for the study. Explain in detail how you will gain access to and recruit participants for participation in this project. Upload scripts, emails, letters, advertising, and all marketing materials with your application. Provide a step-by-step description of how potential participants will be recruited.

 B. Identify all applicable in Flyers Purchased Sample Liss Email Telephone Newspaper Poster Class Announcement Departmental Commu Third Party (Profession Charitable Organization) 	nication nal or	(Please provide copies of materials). Internet Letter Personal or Professional Contacts Amazon MTurk Social Media SONA Snowball method (if used, must describe process in detail) Other (describe)		
C. Are you recruiting students from a class you teach or for which you have responsibility?				
	Yes	No		
D. Are you recruiting employees who directly or indirectly report to you?				
	Yes	No		
F If yes to either VI C or D please explain why this population is necessary and				

E. If yes to either VI C or D, please explain why this population is necessary and describe what precautions have been taken to minimize potential undue influence or coercion.

VII. Compensation

Participants will not receive compensation Students will receive extra credit or course credit Participants will receive monetary compensation Participants' names will be entered into a drawing for a prize

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Describe the compensation or credit, including amount, scheduling and method. Explain what will happen if participants withdraw from the study.

VIII. Risks and Benefits

A. Describe the anticipated benefits of the research for individual subjects.

B. Describe the anticipated benefits of the research for society or the discipline. Explain how the benefits outweigh the risks.

C. Does this study involve any of the following	? (Check all that apply.)
Deception	Information relating to sexual attitudes,
	orientation or practice
Omission	Private identifiable information
Misleading Information/false feedback	Personal or sensitive information
Physical or mental stress	Private records (academic or medical)
Collection of fluids or tissue	Social or economic burden to participants
Substances taken internally or applied externally	Mechanical or electrical device applied to subjects
Information pertaining to illegal activity	Information pertaining to substance use
DXA Scan, X-RAY, MRI	
Collection of fluids or tissue Substances taken internally or applied externally Information pertaining to illegal activity	Social or economic burden to participants Mechanical or electrical device appl to subjects Information pertaining to substance

Information that, if released, could damage an individual's financial standing, reputation, employability, or cause social stigmatization, discrimination, or embarrassment Other

None of these

D. Describe the nature and degree of the risk or harm checked above. If using deception, include a justification for the deception.

E. What steps will be taken to minimize risks or harm and to protect the subject's welfare (when risk is greater than minimal)?

IX. Emergencies

How will emergencies or unanticipated events related to the research be handled if they arise? (Please note that this refers to an emergency situation associated with the research activity not an emergency such as a fire alarm.)

X. Data Collection and Security

A. Procedures: Describe the setting and tasks subjects will be asked to perform. Describe the frequency and duration of procedures, tests, and experiments. Include a timeline or a step-by-step description. B. Describe the steps that will be taken to secure the data during storage, use, and transmission. How and where will the data be stored, for how long will it be kept, when will it be destroyed, what safeguards are in place for data with identifying information? Include a description of physical and electronic security.

C. Identify any direct identifiers like name, unique identifier, address, email, etc. that will be kept with the records. Explain why it is necessary to record the identifiers and describe the coding system to be used.

D. If retaining a link between study code numbers and direct identifiers after data collection is complete, please explain why this is necessary, how long the link will be kept, how it will be stored, and when it will be destroyed.

E. Data collection methods (check all that apply)

Observation	Blood draw, saliva swab, or other biological sampling
Interviews	Audio recording (see section X. F)
Focus groups	Video Recording (see section X. F)
Surveys/Questionnaires	Previously collected data
	(no individual identifiers)
Psychological tests	Previously collected data
	(with individual identifiers)
Educational tests	Internet-based methods
	Other (describe)

F. If using audio or video recording, describe how the recordings will be used, how confidentiality will be maintained, who will have access, and how and when the recordings will be destroyed or completely deidentified.

 G. Protected data to be collected (check all that apply) Protected health Information (see Section X, Part H) Unique ID number (e.g. employee ID, driver's license number, student ID number, etc.) Academic records Social security number Other personally identifiable information

H. If the research involves protected health information, it must comply with the HIPAA Privacy Rule.

Select one:

The research does not involve protected health information

Do you plan to use or disclose identifiable health information outside FHSU? Yes No

If yes, the consent form must include a release of protected health information.

The IRB may make a waiver of authorization for disclosure if criteria are met under the HIPAA Privacy Rule. *If a waiver of authorization is being requested, the researcher must contact the IRB administrator prior to submitting this application.*

Will the protected health information to be used or disclosed be deidentified, or will a limited data set be used or disclosed? *Please describe*:

I. Sharing results with subjects (Indicate if results, like tests or incidental findings, will be shared with the subject or others, and if so, indicate how it will be shared.)

J. Withdrawal of subjects (Describe the procedures to be followed when subjects withdraw from research or under what circumstances subjects may be withdrawn without their consent.)

XI. Informed Consent

A. Specify the type of informed consent you will use with this research project. **Signed Consent**

Consent forms included with this submission:

Adult	Assent Script/Procedures	Parent/Guardian
Foreign Language Version		Agency Consent

Oral Consent (Waiver of documentation of consent, include script with application) Signed consent form would be the only record linking the subject to the research, and the principal risk of signing a consent form would be the potential harm resulting from a breach of confidentiality.

The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

Information Statement (include with application)

Debriefing Statement (include with application)

B. Describe any potential concerns with obtaining informed consent (Foreign language, minimizing possibility of coercion, etc.)

C. Describe the process you will follow to obtain consent and/or assent. Include names of individuals on the research team who will obtain consent, where and when the process will take place, and how you will ensure the subject's understanding.

All materials related to this study must be uploaded into your <u>IRBNet</u> study workspace. Instructions for using IRBNet are located at <u>the FHSU IRB website</u>. Required materials may include, but are not limited to:

- Completed application
- Copies of all recruiting materials, including scripts, emails, letters, posters, advertising, etc.
- Copies of all measurements, instruments, surveys, interview questions being used, etc.
- All consent forms and assent forms or scripts (for children).
- Debriefing materials, if used.

Please note that all materials and scripts to be used for this study need to be reviewed and approved by the IRB.

XII Certifications:

I am familiar with the policies and procedures of Fort Hays State University regarding human subjects in research. I subscribe to the university standards and applicable state and federal standards and will adhere to the policies and procedures of the Institutional Review Board for the Protection of Human Subjects. I will comply with all instructions from the IRB at the beginning and during the project or will stop the project.

AND

I am familiar with the published guidelines for the ethical treatment of human subjects associated with my particular field of study.

Statement of Agreement:

By electronically signing and submitting this application package, I certify that I am willing to conduct and /or supervise these activities in accordance with the guidelines for human subjects in research. Further, I certify that any changes in procedures from those outlined above or in the attached proposal will be cleared through the IRB.

If the Principal Investigator is a student, the electronic signature of the Faculty Advisor certifies:

1) Agreement to supervise the student research; and, 2) This application is ready for IRB review. The Student is the "Principal Investigator". The Faculty Research Advisor is the "Advisor". Designees may not sign the package. It is the student's responsibility to contact their Faculty Research Advisor when the study is ready for the Advisor's signature.

I certify the information provided in this application is complete and correct. I understand that I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects and strict adherence to any stipulations imposed by the IRB. I agree to comply with all FHSU policies, as well as all federal, state and local laws on the protection of human subjects in research, including:

- Ensuring all study personnel satisfactorily complete human subjects research training.
- Performing the study according to the approved protocol.
- Implementing no changes in the approved study without IRB approval.
- Obtaining informed consent from subjects using only the currently approved process and form.
- Protecting identifiable health information in accordance with HIPAA Privacy rule.
- Promptly reporting significant or untoward adverse effects or unanticipated problems to the IRB.

Example of Adult Informed Consent Statement

Name of the Study: Delinquency and Maturity

INTRODUCTION

The Department of Sociology at Fort Hays State University supports the practice of protection for human subjects participating in research. **You are being asked to participate in a research study. It is your choice whether or not to participate.** The following information is provided for you to decide whether you wish to participate in the present study. You may refuse to sign this form and not participate in this study. You should be aware that even if you agree to participate, you are free to withdraw at any time. If you do withdraw from this study, it will not affect your relationship with this unit, the services it may provide to you, or Fort Hays State University.

PURPOSE OF THE STUDY

The purpose of this study is to examine the presence of minor crimes that plague college campuses, such as underage alcohol use and vandalism. We also will be looking at individual's perceptions of the parenting style they encountered growing up. By examining parenting styles and some types of misconduct an individual may engage in, we may be able to better understand how parenting styles and individual differences impact decision-making processes for young adults.

PROCEDURES

After you finish reading the consent and your questions are answered, you may click the "next" button to move on to the next section of the survey. Clicking "next" is giving consent to participate. You will be asked whether or not you currently live with your parents. Based on your response, you will be routed to one of two follow-up pages. Next, you will be asked to fill out a series of brief questionnaires related to behaviors, opinions, and a basic demographics. Once you have completed all sections of the survey you will be routed to the debriefing statement. The last page of the online survey is the debriefing document. You may print out the debriefing page or just read the form and exit the survey. The debriefing form also provides you with contact information for the principal investigator, my thesis advisor, and the Kelly Center. The debriefing form may also be used by course instructors to award research or extra credit for participation.

If you decide to participate in this research study, you will be asked to sign this consent form after you have had all of your questions answered and understand what will happen to you. The length of time of your participation in this study is 20 minutes. Approximately 200 participants will be in this study.

RISKS

We do not anticipate more than minimal risk with this study. As this study is in an online survey format, all responses will be anonymous. There are items that could cause embarrassment if you were identified and your answers were exposed. You may experience psychological distress due to thinking about the items on the survey; however, this should be no more than you would

experience in everyday life. To protect confidentiality, your name will not be linked to your responses.

As this study is anonymous there is no opportunity to directly follow up with you or ascertain your stress level following completion of the survey. If you are an FHSU student, you will be referred to the Kelly Center if you feel distressed both at the bottom of this informed consent form and in the debriefing form on the final screen of the survey. The phone number and address of the Kelly Center is provided as well as the contact information for the principal researcher. If you are participating through an institution other than FHSU, you will be referred to your respective counseling center. If you become distressed during the survey, you may close the window and stop participating at any time. All questions are voluntary; therefore, if you feel that a question is too distressing, you may skip that question.

BENEFITS

You may be offered course credit or extra credit as determined by your instructor, which may enhance your overall course grade. You may also benefit from participation by seeing how a research study operates and may even spark interest in conducting research. Finally, you may gain personal insight to your own experiences and factors that influence behavior. The field of sociology could also benefit from your participation in this research by gaining an understanding of how experiences during development may influence behaviors as a young adult.

PAYMENT TO PARTICIPANTS

You will not receive any compensation for participation in this experiment. However, you may receive extra credit or research credit, but this is at your instructor's discretion.

PARTICIPANT CONFIDENTIALITY (HOW WILL PRIVACY BE PROTECTED)

Your name will not be associated in any publication or presentation with the information collected about you or with the research findings from this study. Instead, the researcher(s) will use a study number or a pseudonym rather than your name. Your identifiable information will not be shared unless (a) it is required by law or university policy, or (b) you give written permission.

Permission granted on this date to use and disclose your information remains in effect for five years. By signing this form, you give permission for the use and disclosure of your information for purposes of this study at any time in the five years the data is stored on the principal researcher's password-protected laptop.

OTHER IMPORTANT ITEMS YOU SHOULD KNOW

- Withdrawal from the study: You may choose to stop your participation in this study at any time. Your decision to stop your participation will have no effect on your academic standing in the class or at Fort Hays State University.
- **Funding:** There is no outside funding for this research project.
- Alternative options: If your instructor is providing extra credit or research credit for your participation, he/she should also provide you with alternative ways to earn this credit that do not include participating in this research study if you do not want to. Please speak directly with your instructor about alternative options.

REFUSAL TO SIGN CONSENT AND AUTHORIZATION

You are not required to sign this Consent and Authorization form and you may refuse to do so without affecting your right to any services you are receiving or may receive from Fort Hays State University or to participate in any programs or events of Fort Hays State University. However, if you refuse to sign, you cannot participate in this study.

CANCELLING THIS CONSENT AND AUTHORIZATION

You may withdraw your consent to participate in this study at any time. You also have the right to cancel your permission to use and disclose further information collected about you, in writing, at any time, by sending your written request to: James Dean, Department of Sociology, 600 Park St. Hays, KS 67601.

If you cancel permission to use your information, the researchers will stop collecting additional information about you. However, the research team may use and disclose information that was gathered before they received your cancellation, as described above.

QUESTIONS ABOUT PARTICIPATION

Questions about procedures should be directed to the researcher(s) listed at the end of this consent form.

PARTICIPANT CERTIFICATION:

I have read this Consent and Authorization form. I have had the opportunity to ask, and I have received answers to, any questions I had regarding the study. I understand that if I have any additional questions about my rights as a research participant, I may call (785) 628-4349, write the Office of Scholarship and Sponsored Projects (OSSP), Fort Hays State University, 600 Park St., Hays, Kansas 67601, or email irb@fhsu.edu.

I agree to take part in this study as a research participant. By my signature I affirm that I am at least 18 years old and that I have received a copy of this Consent and Authorization form.

Type/Print Participant's Name

Date

Participant's Signature

RESEARCHER CONTACT INFORMATION:

James Dean Principal Investigator Department of Sociology 600 Park St. Fort Hays State University Hays, KS 67601 (785) 628-5555 Paul Newman, Ph.D. Faculty Supervisor Department of Sociology 600 Park St. Fort Hays State University Hays, KS 67601 (785) 628-5555

Recruitment Message: "Delinquency and Maturity"

Hello. My name is James Dean, and I am a graduate student in the Sociology Department. I would like to invite you to participate in a research experiment. The purpose of my experiment is to gain a better understanding of the effects of parenting styles on conduct behaviors as a young adult.

If you choose to participate, you will be given a survey to fill out asking questions about your behaviors and perceptions of your caregivers' parenting style(s). Your professor may be offering research or extra credit for participating. I would appreciate your help with this research project.

If you would like to participate you will be asked to fill out a consent form related to the study after your questions are answered. You will then be asked to complete a survey. If you choose to participate, the study will take approximately 20 minutes. If you have any questions about the study and/or would like more information about the study before making a decision to participate, please contact me (James Dean) or my faculty adviser (Dr. Paul Newman).

Thank you!

James Dean jbdean2@mail.fhsu.edu

Dr. Paul Newman pnewman@fhsu.edu (Faculty Supervisor)

Debriefing Form: "Delinquency and Maturity"

You have just completed a study titled "Delinquency and Maturity." The purpose of this study was to examine the effect of parenting on an outcome of social misconduct in relation to psychosocial maturation. You were asked to fill out a survey asking questions about your behaviors and perceptions. The information provided will help researchers understand how parenting styles affect both psychosocial maturity and delinquent behaviors. This information could also aid in development of prevention programs and assist clinical practitioners in identifying which facets of psychosocial maturity to focus on in order to effect a change in antisocial or delinquent behaviors.

The research team greatly appreciates your help with this project! If you feel distressed after your participation in this project, you can contact the Kelly Center (free to students) at 785-628-4401 to schedule an appointment to talk with someone about how the project impacted you, or the Office of Scholarship and Sponsored Projects at 785-625-4349 if you have questions about the process of this research project. For more information about the research project, you can contact the principal researcher, James Dean. You may also contact the faculty adviser, Dr. Paul Newman.

Sincerely,

James Dean jbdean2@mail.fhsu.edu

Dr. Paul Newman pnewman@fhsu.edu (Faculty Supervisor)