



FORT HAYS STATE
UNIVERSITY

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**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: www.irbnet.org

Student and Adjunct Faculty researchers: Please note that Faculty Research Supervisor approval is required prior 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 <https://www.citiprogram.org/> 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 | Undergraduate | Independent Study |
| Thesis | Specialist Field 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: The IRB will not review submissions 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 recruitment methods. (Please provide copies of materials).

- | | |
|---|--|
| Flyers | Internet |
| Purchased Sample List | Letter |
| Email | Personal or Professional Contacts |
| Telephone | Amazon MTurk |
| Newspaper | Social Media |
| Poster | SONA |
| Class Announcement | Snowball method (if used, must describe process in detail) |
| Departmental Communication | Other (describe) |
| Third Party (Professional or Charitable Organization) | |

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

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

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 | |
| 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 [IRBNet](#) study workspace. Instructions for using IRBNet are located at [the FHSU IRB website](#). 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 Parent-Guardian Informed Consent Statement
(To be used when participants are under age 18)**

Name of the Study: Influence of Friendship on Motivation and Academic Achievement

INTRODUCTION

The Department of Psychology at Fort Hays State University supports the practice of protection for human subjects participating in research. The following information is provided for you to decide whether you wish your child to participate in the present study. You may refuse to sign this form and not allow your child to participate in this study. You should be aware that even if you agree to allow your child to participate, you are free to withdraw at any time. If you do withdraw your child 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 and better understand how different factors (e.g., age, grade level, and friendship quality) and the various aspects of friendship, such as conflict and companionship, length of friendship, time spent with friends, and motivation impact students' academic achievement. If you allow your child to participate, they will be asked about their friendships in the classroom.

PROCEDURES

If your child is to participate, he/she will complete a survey via computer. Students will complete the measures on the computer during their designated computer class time so that the surveys can in no way be associated with the consent forms or with any reportable results to ensure confidentiality and participant anonymity. For students in the class who are not participating, they will be given an alternative activity on the computer for them to engage in so that it is unknown who is or is not participating in the survey. During the survey, your student will be asked to identify a peer who they consider to be their best friend based on a definition of friendship given to them, and then asked to complete the questionnaires. The surveys are expected to last 15-20 minutes, although some survey questions may take a little longer. Your student may choose to stop answering questions at any time with no penalty, and they will be reminded of this throughout the study.

RISKS

We do not anticipate any risk with this study. However, the primary researcher, the faculty sponsor, and the teacher of the class will all be present and available in the case that a student feels uncomfortable.

BENEFITS

The results of this research may impact how teachers and parents understand the influence of friendships. Your child may benefit from any changes incorporated in the classroom as a result. Your student may benefit both socially and academically from any changes incorporated in the classroom as a result of this study.

PAYMENT TO PARTICIPANTS

Students will not receive compensation for completing this study.

PARTICIPANT CONFIDENTIALITY

Your child's name will not be associated in any publication or presentation with the information collected about your child or with the research findings from this study. Instead, the researcher(s) will use a study number or a pseudonym rather than your child's name. Your child's 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, at which time data will be destroyed. By signing this form you give permission for the use and disclosure of your child's information, excluding your child's name, for purposes of this study at any time in the next five years.

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. However, if you refuse to sign, your child cannot participate in this study.

CANCELLING THIS CONSENT AND AUTHORIZATION

You may withdraw your consent to allow your child 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 your child, in writing, at any time, by sending your written request to: Dr. Monica Gellar, Department of Psychology, 600 Park St., Hays, KS 67601.

If you cancel permission to use your child's information, the researchers will stop collecting additional information about your child. 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 child's rights as a research participant, I may call (785) 864-7429, write to 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 allow my child 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

Parent/Guardian Signature

[If signed by a personal representative, a description of such representative's authority to act for the individual must also be provided, e.g. parent/guardian.]

Researcher Contact Information:

Rachel Green	Monica Gellar Ph.D.
Principal Investigator	Faculty Supervisor
Department of Psychology	Department of Psychology
600 Park St.	600 Park St.
Fort Hays State University	Fort Hays State University
Hays, KS 67601	Hays, KS 67601
(785) 628-5555	(785) 628-5555

Assent Procedures: Assent is an active affirmation of a desire to participate and differs from consent which is recognized as being granted from an individual with the legal authority to do so. When children/minors under eighteen are involved in research, informed consent must be obtained from the parent/guardian *and* assent must be obtained from the child/minor. Similarly, participants for whom the ability to give informed consent may be otherwise compromised, such as individuals with developmental disabilities, must be afforded the same process.

Assent should be obtained in a manner that is easily understood by the potential participant (either written or verbal) and should be limited to a one-page format. The individual should be given an explanation of the proposed research procedures, the purpose of the research, and any discomforts, in language that is appropriate to the individual's age, experience, maturity, and condition. Illustrations might be helpful and larger type makes it easier for some individuals to read.

If an assent procedure is to be used, a prototype of the 'script' of this procedure should be included with the application. Whereas an assent 'script' may not be appropriate considering the age range or cognitive capacity of some subjects, researchers should nonetheless provide a description of the measures they will take to assess whether the individual assents or is comfortable participating, such as explaining how they will interpret non-verbal cues like crying or fatigue.

A particular subject's capacity to assent must be evaluated on an individual basis. Keep in mind that your tone, facial expressions and body language may influence a child's assent!

We have provided some Assent Script templates for your assistance. While you are not required to use these templates, you may find them helpful in constructing your assent procedures. The first template represents an assent script that might be used for adolescents and which provides room for more detail regarding the study purpose and procedures. The second template represents an assent script that might be used for younger children. The third template represents assent procedures that describe how a researcher might interpret non-verbal cues.

You may use the templates on the following page as guidance →

Sample Assent Script (used for adolescents)

My name is Rachel. I am interested in learning about friendships between classmates, because friendship is an important part of social and school life. If you would like, you can be in my study. I would like you to take part in answering some questions about your friendships. If you choose to be in this study, it will take about 15 to 20 minutes to complete.

If you decide you want to be in my study, you will be given a survey on the computer that asks you about your thoughts on school and on your friends. Please remember that it is your choice to be in this study, and you do not have to participate if you do not want to.

If you decide you want to be in my study, your school might benefit in knowing how friendship plays a role in social and school success, and you may benefit from the changes your school decides to make.

Other people will not know if you are in my study. I will put things I learn about you together with things I learn about other students, so no one can tell what things came from you. When I tell other people about my research, I will not use your name, so no one will be able to tell who I am talking about.

Your parents or guardian have to say it's OK for you to be in the study. After they decide, you get to choose if you want to do it too. If you don't want to be in the study, no one will be mad at you. If you want to be in the study now and change your mind later, that's OK. You can stop doing the study at any time.

If you don't feel like answering any questions, you don't have to, and you can stop speaking with me at any time. I will be happy to answer any questions you may have now or when we are talking together. Do you have any questions? Do you want to take part in this project?

Sample Assent Script (used for young children)

My name is Rachel, and I am learning about friendships. I would like you to answer some questions. Answering these questions will take 15 to 20 minutes. I would like you to answer questions about friendship and for you tell me how you feel about the friends you have here at school. If you don't feel like answering my questions, you don't have to. If you would like to answer my questions, but we get to one that you do not want to answer, then you do not have to. Also, you can stop answering my questions any time and that will be all right. Do you want to answer some questions about friendship?

Debriefing Form: “Influence of Friendship on Motivation and Academic Achievement”

You have just completed a study titled “Influence of Friendship on Motivation and Academic Achievement.” The purpose of this study was to examine how friendships impact motivation and success in the classroom. You were asked to questions about your thoughts and opinions about your friendships in class. The information provided will help us understand how important friends are.

We are so thankful for your help with this project! If you feel sad are uncomfortable after you’re done with this project, you can tell your teacher and they will help schedule an appointment to talk with someone about how the project made you feel. If your parents have questions about the project, they can contact the Office of Scholarship and Sponsored Projects at 785-625-4349 at fort Hays State University. They also can contact me (Rachel Green) or Dr. Gellar.

Thank you for answering our questions!

Rachel Green
rgreen5@mail.fhsu.edu

Dr. Monica Gellar
mgellar@fhsu.edu
(Faculty Supervisor)