

# INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH

# **NEW IRB SUBMISSION**

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 <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 <a href="https://www.citiprogram.org/">https://www.citiprogram.org/</a> 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: based on age, gender, race, ethnicity, sexual orientation, or origin.	Justify criteria

# 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 Departmental Communication describe process in detail)

Third Party (Professional or Other (describe)

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?

′es N

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. Explanation benefits outweigh the risks.	ain

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 Mechanical or electrical device applied

to subjects

Information pertaining to illegal activity Information pertaining to substance

use

DXA Scan, X-RAY, MRI

applied externally

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)?
<b>IX. Emergencies</b> 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)

Psychological tests

**Educational tests** 

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)
Previously collected data

(with individual identifiers)

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)

<ol> <li>Describe any potential concerns with obtaining informed consent (Foreign language ninimizing possibility of coercion, etc.)</li> </ol>	∋,
Describe the process you will follow to obtain consent and/or assent. Include name 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.	?S

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**

**Study name**: The Examination of Film Preferences and Attitudinal Outlook

# INTRODUCTION

The Department of Psychology 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 optimism/pessimism levels and movie preferences. We hypothesize that people who identify their movie preference as comedy will be more inclined to score higher on the optimism scale. Also, those people who identify their movie preference as drama will be more inclined to score lower on the optimism scale.

# **PROCEDURES**

You will be given a survey asking questions about your thoughts/opinions, please answer all questions honestly. Your participation is voluntary and anonymous; you may withdraw at any time if you do not wish to continue. When you finish with the surveys, you will place them in a box at the front of the room. When you have finished the study, you will be read a debriefing statement and asked if you have any additional questions. We will also have the contact information for who you could contact should you have questions after completing the study.

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 15 minutes. Approximately 100 participants will be in this study.

#### RISKS

There are no foreseeable risks involved with participation in this study. However, if you feel uncomfortable at any time while completing the study, you may skip questions that make you feel uncomfortable and/or stop participation at any time. In addition, no identifiable information will be collected linking the survey responses to your name in order to minimize any risks.

#### **BENEFITS**

You may benefit from receiving course credit or extra credit points offered by the instructor as compensation for participation. You may also learn more about your attitudes and preferences through completing this research project. Another benefit to your participation in this study is that it may help to expand current research knowledge on the influence of culture/movies/media on students' attitudinal outlook.

#### PAYMENT TO PARTICIPANTS

Participating in this study does not include monetary payment. However, you may receive extra credit or research credit for participating as outlined by your professor.

# PARTICIPANT CONFIDENTIALITY (HOW WILL PRIVACY BE PROTECTED)

Your name will not be linked to your responses to the survey items nor will it be associated in any publication or presentation with the information collected about you or with the research findings from this study. Instead, the researchers 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 indefinitely. 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 future.

# OTHER IMPORTANT ITEMS YOU SHOULD KNOW

- Withdrawal from the study: You may choose to withdraw at any point in the study and your materials will not be used in the study if you decide to stop participation. You will not receive any penalty for withdrawing and your academic standing will not be affected if you choose to withdraw from the study.
- **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 choose not 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: M. J. Jones, Department of Psychology, 600 Park St. Fort Hays State University, 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 researchers 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:**

Mary Smith Principal Investigator Department of Psychology 600 Park St. Fort Hays State University Hays, KS 67601 (785) 628-5555 John Brown Principal Investigator Department of Psychology 600 Park St. Fort Hays State University Hays, KS 67601 (785) 628-5555

Vic Tiger Principal Investigator Department of Psychology 600 Park St. Fort Hays State University Hays, KS 67601 (785) 628-5555

M. J. Jones, Ph.D.
Faculty Supervisor
Department of Psychology
600 Park St.
Fort Hays State University
Hays, KS 67601
(785) 628-5555

# Recruitment Message: "The Examination of Film Preferences and Attitudinal Outlook"

Hello,

We are Mary Smith, John Brown, and Vic Tiger, and we are undergraduate students in the Psychology department here at Fort Hays. We would like to invite you to participate in a psychology experiment. The purpose of our experiment is to see how optimism/pessimism levels impact movie preferences. If you choose to participate, you will be given a survey to fill out asking questions about your thoughts and opinions related to optimism, pessimism, and movie preferences. Participating might help you to learn something new about yourself. Your professor also may be offering extra credit for participating. We would appreciate your help with this research project. If you would like to participate you will be given an informed consent that includes more information about the study. You will have time to read the consent and ask any questions you might have before signing the consent form. After your questions are answered, you will then be asked to complete a short survey. Please do not hesitate to email us and/or our faculty supervisor if you have any questions about participating in this study.

Thank you!

Mary Smith msmith@mail.fhsu.edu

John Brown jbrown@mail.fhsu.edu

Vic Tiger vtiger@mail.fhsu.edu

Dr. M. J. Jones mjjones@fhsu.edu (Faculty Supervisor)

# "The Examination of Film Preferences and Attitudinal Outlook"

# **Debriefing Form**

You have just completed a study titled "The Examination of Film Preferences and Attitudinal Outlook." The purpose of this study was to examine how an individual's optimism/pessimism levels impact their film preferences. You were asked to fill out a survey asking questions about your thoughts and opinions related to different topics. The information provided will help researchers understand how impactful a person's attitudinal outlook is on deciding what type of film they will want to watch. This research might help us to better understand why people make certain entertainment decisions.

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 general questions about the research process. For more information about this research project, you can contact the principal researchers, Mary Smith, John Brown, and/or Vic Tiger. You also may contact the faculty advisor on this project, Dr. Jones.

Sincerely,

Mary Smith, msmith@mail.fhsu.edu

John Brown, jbrown@mail.fhsu.edu

Vic Tiger, vtiger@mail.fhsu.edu

Dr. M. J. Jones, mjjones@fhsu.edu (Faculty Supervisor)