

FOR IRB USE ONLY:

Protocol Number: IRB-_____

Received:_____

Approved :_____

Rowan University
INSTITUTIONAL REVIEW BOARD
HUMAN RESEARCH REVIEW APPLICATION

INSTRUCTIONS: Check all appropriate boxes, answer all questions completely, include attachments, and obtain appropriate signatures. Submit an **original and two copies** of the completed application to the Office of the Associate Provost for Research.

NOTE: **Applications must be typed. Incomplete and handwritten applications will be returned.**
Be sure to make a copy for your files.

Step 1: Determine if the proposed research subject to IRB review

All research involving human participants conducted by Rowan University faculty and staff is subject to IRB review. Some, but not all, student-conducted studies that involve human participants are considered research and are subject to IRB review. See Appendix A for more information.

Step 2: If you have determined that the proposed research is subject to IRB review, complete the identifying information below.

Project Title: _____

Researcher: _____	Date: _____
Department: _____	Location _____
Mailing Address: _____ (Street)	
_____ (Town/State/Zip)	
E-Mail: _____	Telephone: _____
Co-Investigator/s: _____	
Faculty Sponsor (if student)* _____	
Department _____	Location: _____
E-Mail: _____	Telephone: _____

Step 3: Determine if your research study requires a full IRB review

The Rowan University IRB handles reviews on an expedited basis (meaning that the protocol is examined by one IRB reviewer and the chair) with the exception of those that put the participant at greater than “minimal risk” (see below).

(Note: "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests. The concept of risk goes beyond physical risk and includes risks to the participant's dignity and self-respect as well as psychological, emotional, or behavioral risk.)

Please indicate the level of risk participants will face in your research study:

_____ Greater than minimal risk _____ Not greater than minimal risk

Step 4: Complete the following information:

PROTOCOL DESCRIPTION:

1. THE HUMAN SUBJECTS INVOLVED IN THIS RESEARCH:

- a) Who are the subjects?**

- b) How many subjects will be involved in the project?**

- c) Specify your plans for including women and minorities, if appropriate.**

- d) List all inclusion and exclusion criteria.**

- e) Do your subjects include any of the following:**
 - ___ Yes ___ No Pregnant Women or Human Fetuses or Neonates?
 - ___ Yes ___ No Children and Minors ages seven through seventeen?
 - ___ Yes ___ No Infants or Children younger than seven years of age?
 - ___ Yes ___ No Cognitively Impaired Persons?
 - ___ Yes ___ No Inmates/Prisoners?
 - ___ Yes ___ No Elderly/Aged Persons?
 - ___ Yes ___ No Non-English Speaking Persons?

NOTE: These subjects, by virtue of their age or status, may not be competent or free to give their own consent and may be particularly vulnerable to coercion and undue influence. Investigators must incorporate additional safeguards into the research plan and document fully the informed consent of these individuals and/or that of their legal representatives.

- f) Are your subjects students?**
 - ___ Yes ___ No If YES, name the institution(s) in which they are enrolled:

g) Are there prospective subjects who, if selected for this project, would be especially vulnerable to risk because of the procedures you will be using?

Yes No If YES, describe the process you will use to screen such subjects:

2. RECRUITMENT:

a) Specify how you will gain access to, recruit, and select your subjects.

b) Are you advertising or posting a notice for subjects/volunteers?

Yes No If YES, submit a copy of the advertisement or notice.

c) Will the subjects be recruited from your place of employment?

Yes No If YES, explain how this research relates to your job role and provide any other information pertinent to your relationship with the subjects (e.g., how will you ensure against the possibility of coercion?):

3. COST/PAYMENT:

a) Are you paying your subjects?

Yes No If YES, indicate the amount of payment and describe if (and how) you will prorate the payments to subjects who withdraw before they complete their participation:

b) Will participation in the study involve any cost to the subject?

Yes No If YES, indicate the anticipated costs to the subject.

4. INFORMED CONSENT:

a) Does your protocol involve the use of an informed consent form?

Yes No If YES, enclose a copy of the form. Informed consent must be obtained from the subjects and/or, in the case of minors under the age of 18, the parent or legal guardian. See Appendix B for instructions on informed consent. All requirements **must** be met. If NO, explain how consent will be obtained.

NOTE: If the only record linking the subject and the research would be the consent document and the research presents no more than minimal risk of harm to subjects, you may use an alternative procedure for consent. (See **Appendix B** for more information)

b) Will the research be conducted at a site other than Rowan institution?

Yes No If YES, list the institutions and provide letters from appropriate institutional official(s) with the authority to approve research at their institution (e.g. school principal, school superintendent, director of institution, IRB)

5. **THE RESEARCH PROCEDURES:**

- a) **Describe in non-scientific language exactly what you will be doing to, or with, your subjects. Include in your description:**
- The goal/s of the research
 - The procedures to be followed

- b) **Will you be carrying out procedures or asking questions that might disturb your subjects emotionally or produce stress or anxiety?**

Yes No If YES, describe your plans and criteria for counseling such subjects:

- c) **Are you using a questionnaire, survey, and/or an interview as part of your procedure?**

Yes No If YES, submit a copy of the questionnaire(s) and/or interview questions.

- d) **Are you using focus group discussions as a part of your procedure?**

Yes No If YES, submit a copy of the focus group guide.

- e) **Does your study involve deception of your subjects?**

Yes No If YES, describe the deception, justify its need, and describe the procedure you will use to debrief your subjects. Submit a copy of the debriefing statement, which should include a statement of your willingness to allow subjects to withdraw from your study after debriefing and to remove from your files all records of their involvement.

- f) **Will this study involve the use of existing data, documents, records, pathological specimens, or diagnostic specimens?**

Yes No If YES, include authorization to access the data if not publicly available from an official with authority to provide such permission.

6. **DATA STORAGE/DISPOSITION:**

- a) **Will participants names be kept:**

confidential anonymous neither

(See Appendix B (Informed Consent) for definitions of these terms)

b) If participants names are to remain confidential how will confidentiality be maintained?

c) Describe how you will keep your data secure:

a) Describe how you will **ultimately dispose of your data** (notes, drafts, lists of subjects, photographic records, tapes, computer disks, etc.) **after you have completed your research** (e.g. shredding, burning) (please note that all research records must be maintained for **at least three years after the completion of the research**, including consent forms, flyers, etc.). **If you do not plan to destroy research data, please provide a justification for maintaining the data for an indefinite period of time and how you will ensure confidentiality:**

7. **RISK/BENEFIT:**

In three or four sentences, summarize the risk/benefit ratio of the proposed research, with regard to the human subjects, the risks to them, and the potential benefits to knowledge or society:

8. **COLLABORATION:**

Does this research project involve the IRB approval of one or more participating institutions or organizations other than that of Rowan?

Yes No If YES, list the institutions and submit copies of the related IRB approval notices.

9. **ADDITIONAL INFORMATION (OPTIONAL) (Attach a separate sheet if needed)**

CERTIFICATIONS:

Rowan University maintains a Federal-wide Assurance (FWA) with the Office of Human Research Protection (OHRP), U.S. Department of Health & Human Services. This Assurance includes a requirement for all research staff working with human participants to receive training in ethical guidelines and regulations. "Research staff" is defined as persons who have direct and substantive involvement in proposing, performing, reviewing, or reporting research and includes students fulfilling these roles as well as their faculty advisors.

Please attach a copy of your "Completion Certificate for Human Participant Protections Education for Research Teams" from the National Institutes of Health.

If you need to complete that training, go to the Web Tutorial at <http://cme.nci.nih.gov/>

Researcher: I certify that I am familiar with the ethical guidelines and regulations regarding the protection of human participants from research risks and will adhere to the policies and procedures of the Rowan University Institutional Review Board. I will ensure that all research staff working on the proposed project who will have direct and substantive involvement in proposing, performing, reviewing, or reporting this research (including students fulfilling these roles) will complete IRB approved training. I will not initiate this research project until I receive written approval from the IRB. I agree to obtain informed consent of participants in this project if required by the IRB; to report to the IRB any unanticipated effects on participants which become apparent during the course or as a result of experimentation and the actions taken as a result; to cooperate with the IRB in the continuing review of this project; to obtain prior approval from the IRB before amending or altering the scope of the project or implementing changes in the approved consent form; and to maintain documentation of consent forms and progress reports for a minimum of three years after completion of the final report or longer if required by the sponsor or the institution. I further certify that I have completed training regarding human participant research ethics within the last three years as indicated below my signature.

Signature of Researcher: _____ Date: _____

Faculty Advisor (if Researcher is a student): I certify that I am familiar with the ethical guidelines and regulations regarding the protection of human participants from research risks. I further certify that I have completed training regarding human participant research ethics within the last three years as indicated below my signature (attach copy of your "Completion Certificate for Human Participant Protections Education for Research Teams" from the National Institutes of Health).

Signature of Faculty Advisor: _____ Date: _____

Step 5: Complete the checklist below.

INVESTIGATOR CHECKLIST

DIRECTIONS: *(use X if "yes" and NA if "not applicable")*

- Application typed or computer-generated, not hand written
- Identifying information complete
- Principal Investigator's signature on application
- Names of all investigators specified
- Summary in non-technical terms
- Risks and benefits specified
- Informed Consent form appended
- All instruments appended (e.g. questionnaires, standardized tests, interview schedules)
- Advertisement for recruitment of participants appended, if relevant
- Approval letter(s) from ALL relevant off-campus site(s) (e.g. school principal, other IRB's) appended
- If applicant is a STUDENT, advisor signature included
- "Certifications" form completed and signed

Step 6: **Submit an original and two copies to the Office of the Associate Provost for Research, Memorial Hall. If you have questions about your IRB application, you may send an e-mail to kuder@rowan.edu or call 856-256-4167.**

**DO NOT INCLUDE THE APPENDICES IN YOUR SUBMISSION.
THEY ARE FOR YOUR INFORMATION ONLY.**

Appendix A

How is “Research” Defined?

The Rowan University IRB defines "research" as a *systematic* investigation designed to develop or contribute to *generalizable knowledge*. All **research** involving human participants conducted by Rowan University faculty and staff is subject to IRB review.

Some, but not all, student-conducted studies that involve human participants are considered research and are subject to IRB review. Student research that is subject to IRB review includes research:

- Intended to satisfy the academic requirements for the Master’s Thesis/Project or Doctoral Dissertation;
- Intended or expected to result in publication, presentation outside the classroom, or public dissemination in some other form;
- Conducted outside the classroom and/or departmental research participant pool if they involve
 - minors (*i.e.*, persons under the age of 18),
 - a targeted population of adults whose ability to freely give informed consent may be compromised (*i.e.*, persons who are socioeconomically, educationally, or linguistically disadvantaged, cognitively impaired, elderly, terminally ill, or Incarcerated),
 - pregnant women and/or fetuses who may be put at risk of physical harm,
 - a topic of a sensitive or personal nature, the examination or reporting of which may place the research participant at more than minimal risk, or
 - any type of activity that places research participants at more than minimal risk.

Student-conducted research that is conducted solely within the confines of the classroom or within a departmental research participant pool and:

- is a general requirement of a course,
- has the sole purpose of developing the student's research skills, and
- will be overseen by a faculty member;

may not be subject to IRB review. Check with your class instructor for guidance as to whether you must submit your research protocol for IRB review. If you or your instructor have any doubts, apply for an IRB review.

Oral history projects are not generally subject to IRB review. It is up to the individual faculty member, in consultation with their department chair and/or dean, to determine whether a project must be submitted to the IRB. If the project meets the guideline for research established by the U.S. Office for Human Research Protection, it must be submitted to the IRB for approval. That definition states that research is a, “systematic investigation designed to develop or contribute to generalizable knowledge.” Projects that involve participation by protected groups under US Code 45 CFR part 46 (e.g. children, prisoners) must be reviewed by the IRB

For more information, go to:

http://www.rowan.edu/open/provost/research/Integrity_and_compliance/Irb/Irb.htm

Appendix B
Consent Procedures

The following information is to be provided to each subject in the informed consent form:

1. A statement that the study involves research, an explanation (in non-technical language) of the purposes of the research, a description of the procedures to be followed, and identification of any procedures that are experimental.
2. A description of any reasonably foreseeable *risks* or discomforts to the subject.
3. A description of any *benefits* to the subjects or other persons, that may reasonably be expected to result from the research.
4. A disclosure of appropriate alternative procedures or treatments that might be beneficial to the subject.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. Your proposal must specify *precisely* whether the identity of your subjects will be: a) Anonymous; b) Confidential; or c) Neither.

Note: Your subjects' responses may be recorded and maintained as confidential or anonymous, but not both.

Definition of Anonymous: *Data are recorded such that no identifier whatsoever exists to link a subject's identity to that subject's response.* Examples: (1) subject fills out and mails back to the investigator a questionnaire that does not provide subject's name, social security number, phone number, or any other identifier; (2) investigator interviews subject by phone and notes responses, but does not have any record connecting any response to any phone number.

Definition of Confidential: *There exists a documented linkage between a subject's identity and his/her response in the research, and the investigator provides assurance in the protocol and in the informed consent form that the identity of any individual subject will not be revealed in any report of the study.* Example: a subject's data record is assigned a code, and a "master list" that links the code to the subject's identity is maintained in a secure location.

6. A statement specifying the amount of time required for participation in the study (e.g. a *realistic* estimate of the number of minutes required to complete a questionnaire, the number of separate sessions, the overall duration [days, weeks, months] that the subject will be involved in the study).
7. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation *at any time* without penalty or loss of benefits to which the subject is otherwise entitled. Specify the consequences, if any, to the subject of his/her decision to withdraw from the research before completing the protocol (e.g. loss of pro-rated compensation for participation in the study) and procedures for orderly termination of participation by the subject (e.g. exit interview).
8. Statement regarding financial or other compensation, if any, to the subjects, giving precise amounts and providing for prorating of payment if a subject withdraws before completing the study. Also, specify

any uncompensated costs to the subject that may result from participation in the research (e.g. travel costs, absence from the workplace).

9. A statement regarding accessibility of the investigator to the subjects for questions related to the research (e.g. phone number, email address, institutional address).

10. The following statement regarding subjects' rights:

If you have any questions about your rights as a research subject, you may contact the Associate Provost for Research at:

*Rowan University Institutional Review Board for the Protection of Human Subjects
Office of the Associate Provost for Research
201 Mullica Hill Rd.
Glassboro, NJ 08028-1701
Tel: 856-256-4053*

Format of the Informed Consent Form:

Text should be written in non-technical terms, at a sixth-grade reading level, with non-technical explanation of any specialized terms. If the consent form is more than one page, include a notation, "Subject's Initials _____", at the bottom of each page except the signature page.

If non-English speaking subjects will be involved, a consent form that has been translated into the relevant language is required.

Signature lines for the Principal Investigator and the subject, with corresponding lines for the date of each signature, are required. Signature lines for a legally authorized representative or minor subject may also be necessary, depending upon the categories of subjects that are involved. A witness signature is not required in most cases; exceptions are oral consent verification (below) and situations in which a legally authorized representative signs for the subject.

If the protocol involves videotaping, audiotaping, or photographing of subjects, the consent form must include either a separate statement of agreement for these procedures within the consent document, with signature line, or an addendum to the consent form describing the recording procedure with a statement of agreement and signature line. The purpose of the distinct signature for these procedures is to ensure that the subject is aware of their inclusion, and if the study design permits, to allow the subject to participate in the study without being recorded.

Alternate Consent Procedure

If the only identifying link between the subject and your research procedure would be the consent form, you may obtain consent simply by informing the participant about your research project.

Example: You are conducting a survey and are not asking for any identifying information from participants. In this case, using a consent form would require that the participants reveal their identity by signing the form. As long as the survey did not put the participants at more than minimal risk, a consent form may not be required.

If the IRB grants permission to use an alternative method to obtain consent, you must state the following at the top of the instrument you are using to collect data or on an accompanying cover letter on department stationery:

1. A statement that all participation is voluntary
2. A statement that you are conducting research and the reason for it (e.g., master's thesis, publication, etc.)
3. Purpose of the research - what you are investigating
4. A statement that all responses will be kept anonymous and confidential
5. A statement that participants need not respond to all questions
6. If participants are students, a statement that class standing will not be affected in any way based on participation.
7. The name and telephone number of the Principal Investigator (PI) and faculty sponsor (if applicable)

Sample Informed Consent Forms

(These should be used as a guide only--each PI should tailor the form to fit the research)

Sample 1. Participants over the age of 18

I agree to participate in a study entitled "Problem Solving in Groups Versus Individuals", which is being conducted by Dr. Jane Doe of the Psychology Department, Rowan University.

The purpose of this study is to evaluate the methods used by individuals and groups to solve difficult problems. The data collected in this study will be combined with data from previous studies and will be submitted for publication in a research journal.

I understand that I will be required to attempt to solve a logic problem, and I will be assigned to work either individually or as part of a group. My participation in the study should not exceed one hour.

I understand that my responses will be anonymous and that all the data gathered will be confidential. I agree that any information obtained from this study may be used in any way thought best for publication or education provided that I am in no way identified and my name is not used.

I understand that there are no physical or psychological risks involved in this study, and that I am free to withdraw my participation at any time without penalty.

I understand that my participation does not imply employment with the state of New Jersey, Rowan University, the principal investigator, or any other project facilitator.

If I have any questions or problems concerning my participation in this study I may contact Dr. Jane Doe at (609) 256- _____ ext. _____.

(Signature of Participant) (Date)

(Signature of Investigator) (Date)

Sample 2. Participants are minors

Dear Parent/Guardian:

I am a graduate student in the Education Leadership Department at Rowan University. I will be conducting a research project under the supervision of Dr. John Doe as part of my master's /doctoral thesis concerning how children make decisions and develop strategies when playing games. I am requesting permission for your child to participate in this research. The goal of the study is to determine how strategy development changes as the children mature.

Each child will be invited to play a game during the recess period and will be led to a quiet corner of the recess yard. Any child who expresses a desire not to play will be escorted back to the main area of yard immediately. While playing the game, each child will be asked a series of questions and will be videotaped. I will retain the videotapes at the conclusion of the study. To preserve each child's confidentiality only first names will be used to identify individuals. The videotapes may be viewed by other researchers when the data are presented at a professional conference. All data will be reported in terms of group results; individual results will not be reported.

Your decision whether or not to allow your child to participate in this study will have absolutely no effect on your child's standing in his/her class. At the conclusion of the study a summary of the group results will be made available to all interested parents. If you have any questions or concerns please contact me at 55-1845 or you may contact Dr. John Doe at (609) 256-____ext.____. Thank you.

Sincerely,
Mary Fawn

Please indicate whether or not you wish to have your child participate in this study by checking the appropriate statement below and returning this letter to your child's teacher by Feb. 1.

I grant permission for my child _____ to participate in this study.

I do not grant permission for my child _____ to participate in this study.

(Parent/Guardian signature (Date))