NEW JERSEY CITY UNIVERSITY
INSTITUTIONAL REVIEW BOARD

Procedures and Guidelines for Researchers for the Protection of Human Participants

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Upon completion of IRB Application, please submit to The Office of Grants and Sponsored Programs, Professional Studies 402 or email to rmebuin@njcu.edu. For questions, please call 200-3312.

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Institutional Review Board

Introduction

The Institutional Review Board (IRB) at New Jersey City University is an administrative body established to protect the rights and welfare of human research subjects. The Board was created in accordance with rules maintained by the U.S Department of Health and Human Services (DHHS, specifically the Code of Federal Regulations, 45 CFR 46.101b). The actions of the NJCU IRB further conform to all applicable federal, state and local laws and regulations, as well as University policy governing the protection of human research participants.

The purpose of the IRB is to assure, both in advance and on a continuum, that research pursued with the cooperation of human participants is conducted ethically and in full compliance with mandatory directives. As required by federal policy, the University's IRB is directed by a Chair and is comprised of members with multidisciplinary expertise and backgrounds. The IRB employs a group deliberation process to assess proposed research protocols and related materials (i.e., informed consent documents, investigator brochures, intake and measurement).

The IRB at New Jersey City University has license to review, approve, refuse, monitor, challenge, and terminate all research activities human subjects research that fall under its authority. Studies that qualify as human subjects research include those in which data, samples, or specimens are collected from human participants in the course of investigation, and those which utilize data, samples, or specimens gathered from human participants at some prior time, either by the active researchers or by another party. Such research must be evaluated and approved prior to such studies being undertaken. The policy applies to:

- Any research whether new, ongoing, or proposed, regardless of funding status and source, whether conducted at New Jersey City University or elsewhere, by anyone affiliated with NJCU (including faculty, staff, administrators or students).
- Any person performing research under the auspices of another organization at NJCU.
- Any investigator(s) from outside of the NJCU community that wishes to perform research on members of the community or on its campus, with the additional requirement that he/she must designate an NJCU faculty or staff member serve as principal or co-principal investigator.

All IRB applications should be sent to the Office of the Grants and Sponsored Programs, Attn: Mr. Reuel Mebuin Administrative Assistant, NJCU Institutional Review Board, New Jersey City University, 2039 Kennedy Boulevard, Pro Studies 402, Jersey City, NJ 07305 or email to **rmebuin@njcu.edu.**

NEW JERSEY CITY UNIVERSITY
INSTITUTIONAL REVIEW BOARD
Revised April 2014

PROCEDURES AND GUIDELINES FOR RESEARCHERS FOR THE PROTECTION OF HUMAN PARTICIPANTS

I. Policy for Human Research Participants

New Jersey City University is obliged to safeguard the rights and welfare of persons participating in any research project initiated by or involving New Jersey City University personnel. **All research involving human participants, regardless of funding source or status of researcher (i.e., faculty, staff, or student), must be reviewed and approved by the New Jersey City University Institutional Review Board (hereinafter "IRB") before such research is initiated**. The policies and procedures of the IRB are guided by the *Federal Policy for the Protection of Human Subjects; Notices and Rules*, Federal Register, Vol. 56, No. 117, June 18, 1991, and are explained in detail in the New Jersey City University Institutional Review Board policy statement. Copies of this document are available in the Office of Grants and Sponsored Programs, Professional Studies 402.

II. Purpose

The purpose of the New Jersey City University IRB is to provide an independent determination concerning:

A. How the rights and welfare of individual research participants are safeguarded; and

B. Whether these participants are placed at risk; and, if risk is involved, the risks for participants are minimized:

1. The risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept such risks;

2. The rights and welfare of all participants are protected;

3. Legally effective informed consent will be obtained by adequate and appropriate means;

4. The conduct of the activity will be reviewed at timely intervals.

III. IRB Membership and Responsibilities

Federal regulations state that IRBs must have at least five members with various backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB must possess the professional competence necessary to review specific research activities and must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Any IRB regularly reviewing research involving a vulnerable category of participants must include at least one person primarily concerned with the welfare of these participants.

Further, the IRB must include at least one scientist and at least one non-scientist, as well as at least one member who is not otherwise affiliated with the institution. This individual should be knowledgeable about the local community and willing to discuss issues and research from that perspective.

A. IRB Membership at New Jersey City University *(See Appendix A for List of IRB Members)*

1. The IRB will consist of ten (10) members. The Provost will appoint the members of the IRB according to Code of Federal Regulations (CFR) guidelines. One member of the IRB will be an individual not employed by the University or dependent on the University for facilities who will also be appointed by the Provost. In addition to the ten members, the Provost will appoint two alternates who will serve on the board in cases where regular members must excuse themselves from voting.

2. Members will be identified by name, position and earned degrees as evidence of their qualification to serve on the IRB. This information will be made available to the University community at the start of the academic year.

3. No member of the IRB shall participate in the review of an activity in which he/she has a professional responsibility or a conflicting interest except to provide information requested by the IRB.

4. The University's President or her designee will appoint the IRB Chairperson.

5. A majority of the IRB membership must be present for IRB deliberations to commence. A majority of those present shall be necessary for approval of an application.

6. Each member of the committee will be appointed to a term of three years. Initial appointments will be staggered to prevent complete turnover every three years.

7. Individuals with competence in special areas may be invited to assist in reviewing proposed projects requiring expertise beyond that available on the IRB. These individuals may not vote with the IRB and will not be counted in determining the existence of a quorum.

B. Meetings/Record Keeping

1. The IRB will meet monthly, as needed, and will consider applications that have been submitted at least 10 days prior the meeting. Meeting dates will be announced well in advance. The Chair will convene meetings as necessary. In exceptional cases, the IRB may conduct business via telephone, mail, or e-mail.

2. The University is responsible for seeing that adequate documentation of IRB activities is maintained. This will include, at minimum, copies of all research proposals reviewed, minutes of IRB meetings, actions taken, and the basis for requiring changes in or disapproving research. IRB records must be maintained for at least three years after completion of the research. Student IRB records are to be kept by their faculty sponsor for three years as long as they are a member of the NJCU faculty. Such records must be reasonably accessible by authorized representatives of the department or sponsoring agency.

IV. Research Studies Requiring Review

Research proposals and activities that include data collection procedures and testing that involve human participants require IRB review. The scope of this policy includes, but is not limited to, surveys, case studies, experimentation, testing and other sources of data collection that engage human participants.

All research activity involving students of the University as participants and/or for investigators are covered by this policy as is research conducted or supervised by faculty in their professional capacity as members of the faculty.

Any research activity involving human participants, whether conducted at the University or under the sponsorship of the University at another location, must be reviewed and approved by the IRB before project approval will be granted.

If an investigator plans to collect data from or about participants outside of NJCU, he/she must receive approval from NJCU's IRB and, if applicable, the other institutions' IRBs.

A. Principal Investigators (PI) and their responsibilities - The New Jersey City University IRB will accept, review, and consider for approval research activities for studies by members of the faculty, staff or administration of the University, or co-sponsored outside investigators. All student applications (e.g. students preparing a master's thesis) must be sponsored by a faculty or staff member familiar with the student and the proposed activity. Principal Investigators shall:

1. Be responsible for complying with all IRB decisions, conditions, and requirements. PI's are responsible for reporting the progress of their research to the IRB and/or appropriate institutional officials as often as, and in the manner prescribed by, the IRB but no less than, once per year.

2. Immediately notify the IRB and the department chairperson of any injury (physical, psychological, or social) suffered by a subject because of his or her participation in a research activity.

3. Make provisions to keep records, documents, and informed consent forms for at least three years following the completion of the project or activity, or for a longer period as judged necessary. PI's, participants and/or investigators must retain adequate records relating to IRB approved research for a period of at least three years following completion of the research. No records related to the project or activity may be destroyed without approval of the IRB which shall consult with the State Division of Archives and Records Management concerning record retention schedules.

4. Take proper measures to ensure confidentiality and security of all information obtained from the participants. A written explanation of these measures must be included with the application for review.

B. Student Research - All undergraduate and graduate students intending to perform research using human participants must follow the procedures set forth by the IRB **except when the research is a classroom demonstration guided by a faculty member in which the goal is to teach research techniques by acquiring anonymous data**. In this instance the faculty member will have the responsibility of overseeing the collection of the data and ensuring that the students comply with all ethical guidelines established by the University. All other research (e.g., master's theses, honors projects, independent projects) must be reviewed by the IRB. Research that is part of an NJCU course, guided by a NJCU faculty member must, be terminated at the end of the faculty members' employment period. Research guided by adjuncts must be terminated by the fulfillment of the adjunct contact. All student applications must be sponsored by a faculty member who has expertise in the area of research and is willing to serve as an advisor.

C. Course-Related Research - Research that is conducted solely as an instructional technique in a course does not require IRB approval. It is assumed that all instructors who use this instructional technique are well versed in the ethical treatment of human participants and are knowledgeable of all IRB policies concerning the ethical treatment of human participants. If the purpose of course-related research is to advance knowledge in a particular field or discipline and the possibility exists that the knowledge will be disseminated beyond the classroom, then the faculty member is required to seek the approval IRB.

V. Definitions of Human Participants and Human Research; Minimum Risk; Informed Consent; IRB Approval

A. Human Participants - Human participants include fetuses, children, adults, and the deceased.

B. Research – Any systematic investigation, including method development, testing, and evaluation, designed to develop or contribute to a given knowledge base. Activities of which the sole purpose is related to a course or program development are not considered research.

C. Minimal Risk - The probability and magnitude of harm or discomfort anticipated in the research is not greater than those ordinarily encountered in daily life or during the performance of a routine physical or psychological examination.

D. Informed Consent - Voluntary approval given by human participants to take part in research based on investigator-provided information as to the nature and parameters of a given study.

Requests for informed consent must be free of coercion and undue influence (e.g. no sanctions against individuals who choose not to participate). To this end, faculty serving in the role of researchers and student-teachers conducting research with their own classes/students must exercise care to ensure that there is no pressure exerted in securing student consent to participate in research activity.

No exculpatory language should be used anywhere in the consent form. All potential participants must be told the following:

1. that they will be participating in research;
2. the purpose of the research;
3. the expected duration of the participant's participation;
4. the procedures to be followed;
5. any foreseeable risks or discomforts the participant may suffer;
6. the benefits to the participant and others that may occur as a result of the research;
7. appropriate alternative procedures or courses of treatment that are open to the participant;
8. the extent to which confidentiality and anonymity will be maintained;
9. the amount of compensation or medical treatment that is available for research that involves more than minimal risk;
10. whom to contact (principal investigator) with any questions they may have;
11. the name and contact information for the IRB Chairperson;
12. that participation is voluntary, and that the participant may withdraw at any time without suffering a penalty; and
13. that participation does not imply that an employer-employee relationship exists between the participant and the state of New Jersey, New Jersey City University, the principal investigator or any other project facilitator.

Consent is given by signing a written statement that includes the above elements. Consent must be obtained from parent or a legal guardian if the participants are minors or unable to give consent (i.e., developmental disability).

There may be instances where the integrity of the research could be compromised by adhering to the above informed consent requirements. In such a case, modifications to the informed consent may be requested by the investigator but all modifications must be approved by the IRB.

A copy of the informed consent form must be included with each application submitted to the IRB. Copies of sample informed consent forms can be found in (Appendix B).

E. IRB Approval - Approval is given to research that complies with the institutional and federal requirements concerning the ethical treatment of human participants. Approval by the IRB does not indicate the quality of research, only that it is in compliance with the established policies.

VI. Procedures for Submitting an Application for Full Review (See Appendix C for Application Forms)

A. Preparing an Application for Review - PIs shall prepare protocols giving complete descriptions of the proposed research. The research plan must include provisions for the adequate protection of the rights and welfare of prospective participants and ensure that pertinent laws and regulations are observed. Examples of informed consent forms must be included with the protocols and applications.

Any individual intending to conduct research involving human participants, whether or not the research is supported by a grant, contract or fellowship from any public or private agency, has, as a minimum, the responsibility to file an IRB application (see below) in order to determine whether the activities proposed require formal IRB review.

If a grant or contract application is involved, this application should be sent directly to the IRB (c/o Office of Grants and Sponsored Programs, Professional Studies 402) sufficiently in advance of the due date of the application in order to allow time for the review process, should it be deemed necessary. All research involving more than minimal risk or those involving
extramural funding must be reviewed by the IRB.

B. Application Preparation - All applications for IRB review must be filled out completely and accurately before they will be considered. All research protocols (i.e., the purpose of the research, the recruitment of the procedures the participants will follow the analysis to be performed) must be explained in sufficient detail such that the IRB can make an informed decision. A copy of all surveys, questionnaires, and standardized tests must accompany the application.

C. Consent Form Preparation - A copy of the Informed Consent Form must be submitted with all applications. Applications that do not contain an Informed Consent Form will be returned to the applicant without consideration by the IRB.

VII. Research Exempt From Full Review

Per the Federal Policy for the Protection of Human Participants: Notices and Rules, certain types of research are exempted from a full IRB review. Responsibility for granting an exemption rests solely with the IRB. If the PI believes that the research falls into an exemption category, he/she must submit the IRB application, indicating under which category the research should be considered for an exemption (item #11-Application). Those PIs seeking an exemption must file an application for expedited review. Under an expedited review procedure, the review may be carried out by the IRB chairperson and by one or more experienced reviewers designated by the chairperson from among the members of the IRB. The IRB will adopt a method to keep all members advised of research proposals which have been approved under the expedited procedure. No research proposal may be disapproved under the expedited review process; those research proposals which are not approved under the expedited process must be forwarded to the IRB for consideration under the non-expedited procedure. The IRB will inform the principal investigator if the research is exempt, in writing.

Exemption Categories (45 CFR 46.101b)

Unless otherwise required by department or agency heads, research activities in which the only involvement of human participants will be in one or more of the following categories are exempt from this policy:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior unless: (i) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of human participant's responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

All research involving survey and interview procedures is exempt when the participants are elected or appointed public officials or candidates for public office. Confidentiality must be maintained when required by federal statute.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statue(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment of benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed, or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

VIII. Expedited Review

The IRB may use an expedited procedure to review:

1. Research proposed by the reviewers(s) to involve no more than minimal risk, or

2. Minor changes in previously approved research.

Under an expedited review procedure, the review may be carried out by the IRB Chairperson and by one or more experienced reviewers designated by the Chairperson from among the members of the IRB. The IRB will adopt a method to keep all members advised of research proposals that have been approved under the expedited procedure. No research proposal may be disapproved under the expedited review process; those research proposals not approved under the expedited process must be forwarded to the IRB for consideration under the non-expedited procedure. The IRB will inform the principal investigator if the research is exempt in writing.

IX. Action by the IRB

Applications submitted no later than 10 days prior to the monthly meeting will be discussed by IRB members in order to determine if the proposed research complies with the ethical guidelines established by the IRB. The committee may take one of the following actions:

A. Approve as Submitted - The PI will be sent an approval notice including a statement of his/her responsibility to report any kind of adverse reactions to the research protocol and/or changes to the research protocol to the IRB.

B. Approve Contingent on Specific Revisions - The PI will be sent a memo describing the revisions requested. The revised application will be forwarded to the IRB Chair. If the revisions are satisfactory, the PI will receive written notification of approval. If the PI disagrees with the requested revisions, he/she will present in writing the reasons for non-compliance. The Chair will review the response and, if necessary, will request the PI to appear at the next IRB meeting to answer specific questions and explain in further detail the reasons for non-compliance. The PI will be notified in writing of the decision of the IRB.

C. Disapprove - The PI will be sent a disapproval notice describing the reasons for disapproving the application. Disapproval usually occurs when the IRB determines that the risks of the protocol outweigh the benefits to be gained. The PI may respond to the disapproval notice in writing and may submit a revised application for review at a subsequent meeting.

X. Institutional Endorsement

Many funding agencies require certification that research involving human participants is conducted according to the ethical guidelines outlined in this document and has been approved by an authorized IRB. The IRB Chair will be responsible for submitting such certification to funding agencies.

XI. Re-approval Process/Continuing Review

Federal regulations require that all research involving human participants be reviewed at least every 12 months as long as the project is continued. PIs will be responsible for submitting re-approval applications every 12 months.

XII. Protocol Changes

If the PI plans to make changes to the research protocol, the changes must be communicated to the IRB. If the changes necessitate changes in the Informed Consent Form a revised Informed Consent Form should be forwarded to the IRB. The PI will be notified in writing as to whether the changes have been approved by the IRB.

XII. Adverse Reactions

If any participants have suffered harm as a result of participation in the research, the PI must notify the IRB immediately. The IRB will review the matter and may decide to terminate approval if it appears that participants are at risk of psychological and/or physical harm.

APPENDIX A

INSTITUTIONAL REVIEW BOARD MEMBERS

NEW JERSEY CITY UNIVERSITY

Institutional Review Board Members

Provost and Senior Vice President
Daniel J. Julius
Provost and Senior Vice President
Hepburn Hall 309
(201) 200-3003

IRB Chair
Dr. Beimnet Teclezghi
Professor, Mathematics
Karnoutsos 506
(201) 200-3139
bteclezghi@njcu.edu

Members

Dr. Robert Aslanian
Associate Professor, Chemistry
Grossnickle 342
(201) 200-3069
raslanian@njcu.edu

Dr. Nurdan Aydin
Professor, Geoscience
Rossey 609
(201) 200-3108
naydin@njcu.edu

Dr. Barbara Blozen
Associate Professor, Nursing
Rossey 405
(201) 200-3157
bblozen@njcu.edu

Dr. William Calathes
Professor, Criminal Justice
Professional Studies 223
(201) 200-3492
wcalathes@njcu.edu

Dr. Christopher Carnahan
Assistant Professor, Educational Technology
Professional Studies 203A
(201) 200-3078
ccarnahan@njcu.edu

Dr. Max Herman
Assistant Professor, Sociology/Anthropology
Rossey 451
(201) 200-2280
mherman2@ncju.edu

Dr. Jayadhurganandh Jayaraman
Associate Professor, Finance
School of Business, Harborside
(201) 200-2297
jjayaraman@njcu.edu

Dr. James Lennon
Professor, Psychology
Science Building 431
(201) 200-3309
jlennon@njcu.edu

Mr. Erie Lugo
Dean/Principal
University Academy Charter High School
275 West Side Avenue
Jersey City, NJ 07305
(201) 200-3224
elugo@njcu.edu

Dr. Maria Lynn
Professor, Psychology
Professional Studies 430
(201) 200-2071
mlynn@njcu.edu

Dr. Yumiko Ogawa
Professor, Ed. Leadership and Counseling
Rossey 536
(201) 200-2474
yogawa@njcu.edu

Dr. Deborah Woo
Associate Provost
Hepburn Hall 309
(201) 200-3003
dwoo@njcu.edu

Alternates
Dr. Sai Jambunathan
Professor, Early Childhood Education
Professional Studies 329
(201) 200-2114
sjambunathan@njcu.edu

IRB Administrative Assistant
Mr. Reuel Mebuin
Office of Grants and Sponsored Programs
Professional Studies 402
(201) 200-2466
rmebuin@njcu.edu

APPENDIX B

SAMPLE INFORMED CONSENT FORMS

Appendix B

Sample Informed Consent Forms

These should be used as a guide only - each PI should tailor the form to fit their 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 (*Faculty Mentor)* of the (*Department Here)*, New Jersey City 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, New Jersey City 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 *(Faculty Mentor)* at *(phone number here)* or Dr. Beimnet Teclezghi, Chair of NJCU Institutional Review Board, at 201-200-3139 or email bteclezghi@njcu.edu.

_____ _____

Signature of Participant Date

_____ _____

Signature of Principal Investigator Date

Sample 2. Participants are Minors/Graduate Student as Researcher

Dear Parent/Guardian:

I am a graduate student in the *(Name)* Department at New Jersey City University. I will be conducting a research project under the supervision of (*Faculty Mentor here)* as part of my master's 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 201-555-5555 or you may contact (*Faculty Mentor*) at *(Phone)* or Dr. Beimnet Teclezghi, Chair of NJCU Institutional Review Board, at 201-200-3139 or email bteclezghi@njcu.edu.

Sincerely,

(Name Here)

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 February 1, 20XX.

☐ 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

_____ _____
Signature of Principal Investigator Date

Sample 3. Participants are Minors/Faculty Member as Researcher

Dear Parent/Guardian:

I am a faculty member of the *(Name)* Department at New Jersey City University. I will be conducting a research project 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 (Phone). Thank you.

Sincerely,

Name Here

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 February 1, 20XX.

☐ 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

_____ _____
Signature of Principal Investigator Date

APPENDIX C

SAMPLE FORMS

DISPOSITION FORM
IRB NOTICE OF EXEMPTION FROM REVIEW
NOTICE OF IRB REVIEW AND APPROVAL FORM
(Initial, Revised or Continuation)

File No. _____

JERSEY CITY UNIVERSITY
INSTITUTIONAL REVIEW BOARD

DISPOSITION FORM

Principal Investigator	Co-Principal Investigator (if applicable)
Address of Principal Investigator	Address of Co-Principal Investigator
City, State, and Zip Code	City, State, and Zip Code
Telephone # - Fax # - E-mail address	Telephone # - Fax # - E-mail address

Title of Research: _____

_____

ADMINISTRATIVE DISPOSITION

PART 1: Your Claim for Exemption for the research study identified above has been reviewed. The Action taken is indicated below:

☐ **APPROVED FOR EXEMPTION AS CLAIMED:** **CATEGORY#** ☐

Note: Anything that conceivably changes the exempt status of this study must be presented to the IRB for approval before the changes are implemented. Such modifications should be sent to the IRB Office at the address above.

1. That the materials you submitted to the New Jersey City University IRB provide a complete and accurate account of how human subjects are involved in your project.
2. That you will carry on your research according to the procedures described in those materials.
3. That you will report to IRB any changes in your procedures that would remove the project from the exempt category and make it subject to IRB review.
4. That if such changes are made, you will submit the project for IRB review.
5. That you will immediately report to the IRB any problems that you encounter while using human subjects.

☐ **NOT APPROVED:**

FULL REVIEW: _____ APPROVED

FULL REVIEW: _____ APPROVED WITH MODIFICATIONS

FULL REVIEW: _____ DENIED

DENIED: _____

See the attached Committee Action Letter for additional comments.

_____ _____

Chair, IRB Date

NEW JERSEY CITY UNIVERSITY

Last Name: _____

File No.: _____

Project: _____

NOTICE OF EXEMPTION FROM IRB REVIEW

The project identified below has been declared exempt from review by the IRB under the provision of Federal Regulations 45 CFR 46.101(b).

Your Research is exempt under category ☐

This exemption is based on the following assumptions:

1. That the materials you submitted to the New Jersey City University IRB provide a complete and accurate account of how human subjects are involved in your project.
2. That you will carry on your research according to the procedures described in those materials.
3. That you will report to IRB any changes in your procedures that would remove the project from the exempt category and make it subject to IRB review.
4. That if such changes are made, you will submit the project for IRB review.
5. That you will immediately report to the IRB any problems that you encounter while using human participants.

Name of Chief Investigator: _____

Name of Co-Investigators: _____

Title of Project: _____

Conditions: _____

Note: For Categories 2 & 3, a consent form is not needed for subjects asked to complete an anonymous questionnaire.

Signed _____ _____

Chair of IRB at New Jersey City University Date

NEW JERSEY CITY UNIVERSITY

Last Name: _____

File No.: _____

Project: _____

INITIAL, REVISED OR CONTINUATION

PART II: NOTICE OF IRB REVIEW AND APPROVAL

The project identified below, for which you requested review and approval by the NJCU Institutional Review Board for the Protection of Human Participants in Research, has now been reviewed and approved. This approval is based on the assumption that the materials you submitted to the NJCU IRB c/o Grants and Sponsored Programs contain a complete and accurate description of all the ways in which human subjects are involved in your research.

This approval is given with the following conditions:

1. That you will conduct the research according to the plans and protocol you submitted.
2. That you will immediately inform the IRB of any injuries to subjects that occur in the course of your research.
3. That you immediately inform the IRB of any problems that arise in the course of your research.
4. That you will immediately inform the IRB of any changes that you make in the protocol of the research.
5. That you will give each person who signs the consent document a copy of that document, if you are using such documents in your research.
6. That you will retain all signed consent documents for at least three years after the termination of the research.

Failure to comply with these conditions will result in the withdrawal of this approval.

☐ Approved ☐ Not Approved

Note: _____

_____

Name of Principal Investigator: _____

Title of Project: _____

Period of Approval: _____

Additional Conditions: _____

One month before the end of the period of approval, you must file with the IRB a new application for revised or continuation of your research project.

_____ _____

NJCU Institutional Review Board Chair Date

APPENDIX D

APPLICATION FOR REVIEW OF RESEARCH

NEW JERSEY CITY UNIVERSITY
INSTITUTIONAL REVIEW BOARD

File # _____

APPLICATION FOR REVIEW OF RESEARCH

1. TYPE OF APPROVAL REVIEW REQUESTED (CHECK ONE):

   ☐ FULL REVIEW ☐ EXPEDITED ☐ EXEMPT REVIEW

2. PRINCIPAL INVESTIGATOR: _____

   DEPARTMENT: _____

   PHONE: _____

   TITLE OF RESEARCH: _____

   _____

   _____

   CO-INVESTIGATORS: _____

3. PURPOSE OF RESEARCH (INDEPENDENT PROJECT, MASTER'S THESIS, AND COURSE WHICH INCLUDES COURSE TITLE, SEMESTER AND INSTRUCTOR'S NAME.) ETC.

   _____

   _____

4. IF YOU ARE A STUDENT RESEARCHER PLEASE PROVIDE THE FOLLOWING:

   MAILING ADDRESS: _____

   CITY/STATE/ZIP: _____

   TELEPHONE: _____ EMAIL: _____

   FACULTY SPONSOR NAME: _____

   DEPARTMENT OF SPONSORING FACULTY: _____

   EXT. FAX : EMAIL: _____

   FACULTY SPONSOR SIGNATURE: _____

   DATE: _____

5. HAS THIS RESEARCH PROJECT BEEN CONSIDERED PREVIOUSLY BY THE IRB? YES ☐ NO ☐

   IF YES, GIVE LAST APPROVAL DATE: _____

6. SOURCE OF FUNDING (IF APPLICABLE):

☐ UNIVERSITY GRANTS: PLEASE INDICATE WHICH GRANT PROGRAM: (FOUNDATION, SBR)

_____

☐ EXTRAMURAL FUNDS: PLEASE INDICATE AGENCY NAME: _____

TITLE: _____

AWARD NUMBER: _____ DATE : _____

7. ARE YOU WORKING WITH A RESEARCHER FROM ANOTHER INSTITUTION? IF SO, BE AWARE THAT YOUR CO-INVESTIGATOR MUST ALSO SUBMIT YOUR JOINT PROPOSAL TO THE IRB AT THE INSTITUTION THAT EMPLOYEES HIM/HER.
☐ YES ☐ NO

8. WHAT IS THE OBJECTIVE OF THE RESEARCH?

_____

_____

_____

9. DOES YOUR RESEARCH INVOLVE ANY OF THE FOLLOWING (CHECK ALL THAT APPLY)?

- ☐ MINORS
- ☐ PRISONERS
- ☐ PREGNANT WOMEN
- ☐ USE OF THE INVESTIGATORS' CURRENT STUDENTS AS SUBJECTS
- ☐ DRUGS OR OTHER CONTROLLED SUBSTANCES
- ☐ PSYCHOLOGICAL OR PHYSIOLOGICAL STRESS ABOVE THE LEVEL OF NORMAL EVERYDAY ACTIVITIES
- ☐ MISLEADING OR DECEIVING SUBJECTS ABOUT ANY ASPECT OR PURPOSE OF THE RESEARCH
- ☐ COLLECTION OF INFORMATION WHICH DEALS WITH SENSITIVE ASPECTS OF THE PARTICIPANTS' BEHAVIOR (ILLEGAL ACTIVITY, DRUG OR ALCOHOL USE, SEXUAL BEHAVIOR, ETC.)
- ☐ COLLECTION OF INFORMATION WHICH WOULD PLACE SUBJECTS AT RISK OF CRIMINAL OR CIVIL LIABILITY IF IT BECAME KNOWN
- ☐ COLLECTION OF INFORMATION WHICH COULD AFFECT SUBJECTS' FINANCIAL STANDING, EMPLOYABILITY, OR REPUTATION
- ☐ EXAMINATION OF EXISTING DATA, RECORDS, DOCUMENTS, OR SPECIMENS THAT ARE NOT PART OF THE PUBLIC RECORD
- ☐ CHILDREN INVOLVED IN YOUR RESEARCH WITHOUT SENSITIVE INFORMATION ABOUT THEMSELVES OR THEIR FAMILIES.
- ☐ COLLECTING OR STUDYING EXISTING DATA, DOCUMENTS, RECORDS, PATHOLOGICAL SPECIMENS OR DIAGNOSTIC SPECIMENS WHICH ARE PUBLICLY AVAILABLE AND FROM WHICH PARTICIPANTS CANNOT BE IDENTIFIED BY ANYONE OTHER THAN THE INVESTIGATOR(S).

IF ANY OF THE ABOVE ITEMS ARE CHECKED
YOUR PROPOSAL DOES NOT QUALIFY FOR AN EXEMPT REVIEW

10. DESCRIBE THE DESIGN OF THE RESEARCH INCLUDING WHAT WILL BE REQUIRED OF SUBJECTS (ATTACH ADDITIONAL SHEET IF NECESSARY):

_____

_____

_____

11. UNDER WHICH OF THE FOLLOWING CATEGORIES ARE YOU APPLYING FOR EXEMPTION?

☐ 1. RESEARCH CONDUCTED IN ESTABLISHED OR COMMONLY ACCEPTED EDUCATIONAL SETTINGS, INVOLVING NORMAL EDUCATIONAL PRACTICES, SUCH AS (I) RESEARCH ON REGULAR AND SPECIAL EDUCATION INSTRUCTIONAL STRATEGIES, OR (II) RESEARCH ON THE EFFECTIVENESS OF THE COMPARISON AMONG INSTRUCTIONAL TECHNIQUES, CURRICULA, OR CLASSROOM MANAGEMENT METHODS.

☐ 2. RESEARCH INVOLVING THE USE OF SOCIAL SCIENCE OR EDUCATIONAL TESTS (COGNITIVE, DIAGNOSTIC, APTITUDE, ACHIEVEMENT),SURVEY PROCEDURES, INTERVIEW PROCEDURES, OR OBSERVATION OF PUBLIC BEHAVIOR UNLESS (I) INFORMATION IS OBTAINED IN SUCH AWAY AS THAT THE PARTICIPANTS CAN BE IDENTIFIED DIRECTLY OR INDIRECTLY OR (II) THE PARTICIPANTS' RESPONSES, IF THEY BECAME KNOWN, COULD PLACE THE PARTICIPANT AT RISK OF CRIMINAL OR CIVIL LIABILITY OR BE DAMAGING TO THE PARTICIPANTS' FINANCIAL STANDING, REPUTATION, OR EMPLOYABILITY. (ALL RESEARCH INVOLVING SURVEY AND INTERVIEW PROCEDURES IS EXEMPT WHEN THE PARTICIPANTS ARE ELECTED OR APPOINTED PUBLIC OFFICIALS OR CANDIDATES FOR PUBLIC OFFICE. HOWEVER, CONFIDENTIALITY MUST BE MAINTAINED WHEN REQUIRED BY FEDERAL STATUTE.)

☐ 3. RESEARCH INVOLVING THE COLLECTION OR STUDY OF EXISTING DATA, DOCUMENTS, RECORDS, PATHOLOGICAL SPECIMENS, OR DIAGNOSTIC SPECIMENS, IF THESE SOURCES ARE PUBLICLY AVAILABLE OR IF THE INFORMATION IS RECORDED BY THE INVESTIGATOR IN SUCH A MANNER THAT PARTICIPANTS CANNOT BE IDENTIFIED.

☐ 4. RESEARCH AND DEMONSTRATION PROJECTS WHICH ARE FUNDED BY A FEDERAL AGENCY AND DETERMINED TO BE EXEMPT BY THE AGENCY HEAD AND WHICH ARE DESIGNED TO STUDY, EVALUATE, OR OTHERWISE EXAMINE: (I) PUBLIC BENEFIT OR SERVICE PROGRAMS; (II) PROCEDURES FOR OBTAINING BENEFITS OR SERVICES UNDER THOSE PROGRAMS; (III) POSSIBLE CHANGES IN OR ALTERNATIVES TO THOSE PROGRAMS OR PROCEDURES; OR (IV) POSSIBLE CHANGES IN METHODS OR LEVELS OF PAYMENT FOR BENEFITS OR SERVICES UNDER THOSE PROGRAMS.

☐ 5. EXEMPTION FOR COLLECTION OR STUDY OF EXISTING DATA: RESEARCH INVOLVING COLLECTION OR STUDY OF EXISTING DATA, DOCUMENTS, RECORDS, IF THESE DATA ARE NON-IDENTIFIABLE AND PUBLICLY AVAILABLE OR INFORMATION IS RECORDED BY THE INVESTIGATOR IN SUCH A MANNER THAT SUBJECTS CANNOT BE IDENTIFIED DIRECTLY THROUGH IDENTIFIERS LINKED TO THE SUBJECT (CODES LINKING NAMES TO DATA ARE CONSIDERED INDIRECT IDENTIFIERS).

☐ 6. EXEMPTION FOR STUDY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES: UNLESS SPECIFICALLY REQUIRED BY THE STATUTE, RESEARCH AND DEMONSTRATION PROJECTS WHICH ARE CONDUCTED BY OR SUBJECT TO THE APPROVAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, AND WHICH ARE DESIGNED TO STUDY, EVALUATE, OR OTHERWISE EXAMINE:

(A) _____PROGRAMS UNDER THE SOCIAL SECURITY ACT OR OTHER PUBLIC BENEFIT OR SERVICE PROGRAMS
(B) _____PROCEDURES FOR OBTAINING BENEFITS OR SERVICES UNDER THOSE PROGRAMS
(C) _____POSSIBLE CHANGES IN OR ALTERNATIVES TO THOSE PROGRAMS OR PROCEDURES
(D) _____POSSIBLE CHANGES IN METHODS OR LEVELS OF PAYMENT FOR BENEFITS OR SERVICES UNDER THOSE PROGRAMS.

IF YOUR RESEARCH IS GIVEN EXEMPTION STATUS, THE FOLLOWING MUST BE STATED ON A COVER LETTER ACCOMPANYING ANY SURVEY OR QUESTIONNAIRES.

1. A STATEMENT THAT ALL PARTICIPATION IS VOLUNTARY
2. A STATEMENT THAT YOU ARE CONDUCTING RESEARCH AND THE REASON FOR IT (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 YOUR OWN STUDENTS, A STATEMENT THAT CLASS STANDING WILL NOT BE AFFECTED IN ANY WAY BASED ON PARTICIPATION
7. AHE NAME AND TELEPHONE NUMBER OF THE PRINCIPAL INVESTIGATOR (PI) AND FACULTY SPONSOR (IF APPLICABLE)

CLAIMS FOR EXEMPTION MAY NOT BE MADE FOR (A) RESEARCH INVOLVING CHILDREN, (B) AIDS-RELATED RESEARCH, (C) RESEARCH INVOLVING SUBSTANCE OR CHILD ABUSE OR (D) RESEARCH TO BE CONDUCTED AT THE V.A. (RESEARCH UNDER THESE CATEGORIES IS SUBJECT TO SPECIAL FEDERAL GUIDELINES.)

ALL IRB APPLICANTS MUST COMPLETE QUESTIONS 12 – 18

12. DESCRIBE THE SUBJECTS WHO WILL BE PARTICIPATING (NUMBER, AGE, GENDER, ETC.)

13. HOW WILL SUBJECTS BE RECRUITED? IF STUDENTS, WILL THEY BE SOLICITED FROM CLASS?

14. WHAT RISKS TO SUBJECTS (PHYSIOLOGICAL AND/OR PSYCHOLOGICAL) ARE INVOLVED IN THE RESEARCH?

15. IS DECEPTION INVOLVED IN THE RESEARCH? IF SO, WHAT IS IT AND WHY WILL IT BE USED?

16. WHAT INFORMATION WILL BE GIVEN TO THE SUBJECTS AFTER THEIR PARTICIPATION? IF DECEPTION IS USED, IT MUST BE DISCLOSED AFTER PARTICIPATION.

17. HOW WILL CONFIDENTIALITY BE MAINTAINED? WHO WILL KNOW THE IDENITY OF THE SUBJECTS? IF A PRE AND POST TEST DESIGN IS USED HOW WILL THE SUBJECTS BE IDENTIFIED?

18. HOW WILL THE DATA BE RECORDED AND STORED? WHO WILL HAVE ACCESS TO THE DATA? WHERE WILL IT BE STORED? ALL DATA MUST BE KEPT FOR A MINIMUM OF THREE YEARS.

APPENDIX E

INSTITUTIONAL REVIEW CHECK LIST

Attach with your IRB Application

Institutional Review Board

Check List for Submitting a Complete IRB Application

1.	That they will be participating in research;	□ Yes	□ No
2.	The purpose of the research;	□ Yes	□ No
3.	The expected duration of the participant's participation;	□ Yes	□ No
4.	The procedures to be followed;	□ Yes	□ No
5.	Any foreseeable risks or discomforts the participant may suffer;	□ Yes	□ No
6.	The benefits to the participant and others that may occur as a result of the research;	□ Yes	□ No
7.	Appropriate alternative procedures or courses of treatment that are open to the participant;	□ Yes	□ No
8.	The extent to which confidentiality and anonymity will be maintained;	□ Yes	□ No
9.	The amount of compensation or medical treatment that is available for research that involves more than minimal risk;	□ Yes	□ No
10.	Whom to contact (principal investigator) with any questions they may have;	□ Yes	□ No
11.	All questions on the application have been completed.	□ Yes	□ No
12.	All supporting documents have been attached. This includes protocol, survey instruments, interview schedules and letters.	□ Yes	□ No
13.	If this study requires approval of another Committee or cooperating agency, documentation of approval or notice of application has been attached.	□ Yes	□ No
14.	Signatures of advisor for student research been secured.	□ Yes	□ No
15.	A copy of this application has been made for the investigator's records. *If this Application is approved, this copy must be maintained for 3 years after the completion of the study by the PI or faculty sponsor.*	□ Yes	□ No
16.	That participation is voluntary, and that the participant may withdraw at any time without suffering a penalty; and	□ Yes	□ No
17.	That participation does not imply that an employer-employee relationship exists between the participant and the State of New Jersey, New Jersey City University, the principal investigator or any other project facilitator.	□ Yes	□ No

Consent is given by signing a written statement that includes the above elements. If participants are minors or unable to give consent (due to a mental disability, etc.) consent must be obtained from the legal guardian. A copy of the informed consent form must be included with each application and submitted to the IRB.