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Date _____

HUMAN SUBJECT RESEARCH REVIEW FORM
NEW JERSEY INSTITUTE OF TECHNOLOGY
INSTITUTIONAL REVIEW BOARD APPLICATION

Name of Principal Investigator(s) _____

Faculty members and/or staff must be principal investigators. Students can serve as co-principal investigators under faculty/staff supervision for expedited projects.

NJIT Address: _____

Department: _____

E-mail Address: _____

NJIT Affiliation of Principal Investigators (Check all that apply):

☐ Faculty ☐ Student ☐ Other - Describe: _____

*Note students and doctoral candidates applying for IRB approval must submit written documentation from their faculty advisors (via e-mail) stating that research is being conducted under their supervision.

Project Title: _____

This project will be conducted:

☐ On Campus ☐ Off Campus: Location: _____ ☐ Both

Is this research funded by outside source(s)? ☐ Yes ☐ No

If yes, indicate name(s) and type of funding source(s):

Name of Funding Source(s): _____

Type:

☐ Government (County, State or Federal)
☐ Foundation
☐ Corporation
☐ Other _____

Anticipated Starting Date of Project _____

Anticipated Closing Date of Project: _____

Number of Subjects: _____

NOTE: All principal investigators, faculty, and students who will be interfacing with human subjects in this study must complete an online training course in the protection of human subjects. This course can be accessed by going to the US Department of Health and Human Services' Office for Human Research Protection website (http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp). There are three modules you must complete. All certificates indicating course completion must be submitted with this application. . For NIH investigator training, please see the following URL: http://phrp.nihtraining.com/users/login.php.

To Principal Investigator: In addition to the questions below, please furnish copies of any questionnaires interview formats, testing instruments or other documents necessary to carry out the research. Any advertising materials used to recruit subjects must also be submitted.

The completed forms should be sent electronically to: irb@njit.edu

1. Project Title:

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2. List the names and status (faculty, student, etc.) of the persons conducting the research:

   a. Principal Investigator(s):

   b. Other Members of Research Team:

   c. NJIT Faculty Advisor(s) if Student Project:

3. Describe the objectives, methods and procedures of the research project. This summary will used to describe your project to the IRB. Use up to 2 pages, if necessary. You may also attach a copy of an abstract or full research proposal describing this work.

4. List name and institutional affiliation of any research assistants, workers student that will be working on this project.

5. If research assistants, workers, students will be working on the project describe their qualifications, special training and how they will be supervised.

6. What is the age of the subjects and how will they be recruited?

7. Attendant risks: Indicate any physical, psychological, social or privacy risk or pain, which may be incurred by human subjects, or any drugs medical procedures that will be used. (This includes any request for the subjects to reveal any embarrassing, sensitive, or confidential information about themselves or others.) Also, indicate if any deception will be used, and if so, describe it in detail. Include your plans for debriefing.

8. Evaluate the risks presented in 7.
   a. Is it more that would normally be encountered in daily life? _____

   b. Do your procedures follow established and accepted methods in your field? _____

9. How will the risk be kept at a minimum? (e.g. describe how the procedures reflect respect for privacy, feeling, and dignity of subject and avoid unwarranted invasion of privacy or disregard anonymity in any way.) Also, if subjects will be asked to reveal any embarrassing, sensitive, or confidential information, how will confidentiality of the data be insured? Also include your pans for debriefing. If subjects will be placed under any physical risk, describe the appropriate medical support procedures.

10. Describe the benefits to be derived from this research, both by the subject and by the scientific community (this is especially important if research involves children).

11. Describe the means through which human subjects will be informed of their right to participate, not to participate, or withdraw at any time. Indicate whether subjects will be adequately informed about the procedures of the experiment so that they can make an informed decision on whether or not to participate.

12. Complete the attached copy of the Consent Form and the Institutional Review Board will make a determination if your subjects will be at risk. This Consent Form must include the following five pieces of information: (1) The purpose of the research, (2) the procedures involved in the work, (3) the potential risk of participating, (4) the benefits of the research, (5) that the subjects are free to withdraw from the research at any time with no adverse consequences.

13. Furnish copies of questionnaires, interview formats, testing instruments or other documents to carry out the research. If questionnaires are not complete pleas submit an outline of the questions to be used. You will have to submit the completed questionnaire to the Committee before the research can begin.

14. If the subjects will be minor children, complete Consent Form as prescribed in paragraph 12 for signature by parent or guardian. If the project is approved (regardless of the Board's determination concerning risk), it will be necessary that a Consent Form be secured for every minor child.

15. Attach copy of permission of facility to conduct the proposed research (if other that NJIT).

Complete a Consent Form Using the Model Below:

NEW JERSEY INSTITUTE OF TECHNOLOGY
323 MARTIN LUTHER KING BLVD.
NEWARK, NJ 07102

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF STUDY:

RESEARCH STUDY:
I,_____, have been asked to participate in a research study under the direction of Dr(s). (Insert name(s) of faculty or staff)

_____
. Other professional persons who work with them as study staff may assist to act for them.

PURPOSE (INSERT DESCRIPTION OF THE PURPOSE OF YOUR STUDY HERE):

_____
_____
_____

DURATION:
My participation in this study will last for _____.

PROCEDURES:
I have been told that, during the course of this study, the following will occur (INSERT EXPECTATIONS WITH REGARD TO PARTICIPATION HERE):

_____
_____
_____

PARTICIPANTS:
I will be one of about _____ participants in this study.

EXCLUSIONS:
I will inform the researcher if any of the following apply to me (INSERT EXCLUSIONS HERE):

_____
_____
_____

RISKS/DISCOMFORTS:
I have been told that the study described above may involve the following risks and/or discomforts (INSERT ANY RISKS HERE):

_____
_____
_____

There also may be risks and discomforts that are not yet known.

I fully recognize that there are risks that I may be exposed to by volunteering in this study which are inherent in participating in any study; I understand that I am not covered by NJIT's insurance policy for any injury or loss I might sustain in the course of participating in the study.

CONFIDENTIALITY:

I understand confidential is not the same as anonymous. Confidential means that my name will not be disclosed if there exists a documented linkage between my identity and my responses as recorded in the research records. Every effort will be made to maintain the confidentiality of my study records. If the findings from the study are published, I will not be identified by name. My identity will remain confidential unless disclosure is required by law.

VIDEOTAPING/AUDIOTAPNG: (NEED TO INCLUDE ONLY IF APPLICABLE)

I understand that I will be video and audio taped during the course of this study. Video and audio tapes will be stored for (insert time frame) after the end of this project (enter date in parentheses). After that time, the tapes will be erased by recording over my recorded sessions.

The tapes will be stored in a locked office at NJIT and will not be made available to anyone except (insert names) who are involved in this research.

PAYMENT FOR PARTICIPATION:

I have been told that I will receive $_____ compensation for my participation in this study.

RIGHT TO REFUSE OR WITHDRAW:

I understand that my participation is voluntary and I may refuse to participate, or may discontinue my participation at any time with no adverse consequence. I also understand that the investigator has the right to withdraw me from the study at any time.

INDIVIDUAL TO CONTACT:

If I have any questions about my treatment or research procedures, I understand that I should contact the principal investigator at (INSERT CONTACT INFORMATION (I.E., MAILING ADDRESS, TELEPHONE NUMBER, AND E-MAIL OF) FACULTY OR STAFF HERE):

_____

_____

_____

If I have any addition questions about my rights as a research subject, I may contact:

Farzan Nadim, IRB Chair
New Jersey Institute of Technology
323 Martin Luther King Boulevard
Newark, NJ 07102
(973) 596-5825
irb@njit.edu/ farzan@njit.edu

SIGNATURE OF PARTICIPANT

I have read this entire form, or it has been read to me, and I understand it completely. All of my questions regarding this form or this study have been answered to my complete satisfaction. I agree to participate in this research study.

Participant Name _____

Signature _____

Date _____

SIGNATURE OF READER/TRANSLATOR IF THE PARTICIPANT DOES NOT READ ENGLISH WELL (Only needed if English fluency is not an exclusion criteria)

The person who has signed above, _____, does not read English well, I read English well and am fluent in (name of the language) _____, a language the subject understands well. I have translated for the subject the entire content of this form. To the best of my knowledge, the participant understands the content of this form and has had an opportunity to ask questions regarding the consent form and the study, and these questions have been answered to the complete satisfaction of the participant (his/her parent/legal guardian).

Reader/Translator Name _____

Signature _____

Date _____

SIGNATURE OF INVESTIGATOR OR RESPONSIBLE INDIVIDUAL (Only required for consent forms of projects requiring full IRB approval)

To the best of my knowledge, the participant, has _____ understood the entire content of the above consent form, and comprehends the study. The participants and those of his/her parent/legal guardian have been accurately answered to his/her/their complete satisfaction.

Investigator's Name _____

Signature _____

Date _____

NJIT New Jersey's Science & Technology University

DISCLOSURE OF FINANCIAL RELATIONSHIP FOR SPONSORED PROJECTS

The following form must be completed by all Principal Investigators and members of the research team, including faculty advisors if student projects. Please use a separate form for each person.

Date: _____

Name (Print and SIGN):
(ORIGINAL SCANNED, FAXED, OR HARDCOPY SIGNATURE REQUIRED) _____

This form shall be completed by all members of the research team.

1. **Funding Source.** Does the research involve financial relationships that could create potential or actual conflicts of interest?

☐ Yes ☐ No

How is the research supported or financed?

_____

_____

2. **Payment for Services.** Are you receiving any salary and other payment for services (e.g., compensation in the form of equipment, consulting fees; honoraria, study design; management position, independent contractor, service on advisory committees or review panels for for-profit entities, board membership of for-profit entities; seminars, lectures or teaching engagements for for-profit entities) for this research?

☐ Yes ☐ No

If Yes, note amounts with explanation of source and activities:

_____

_____

If Yes, is this payment affected by the study outcome?

☐ Yes ☐ No

If Yes, explain:

_____

_____

Do you receive payment per participant or incentive payments?

☐ Yes ☐ No

If Yes, note amounts with explanation of terms.

3. **Equity (Ownership) Interests**. Do you have any and all equity interests or ownership interests (e.g. stock, stock options, and partner) in entities related to the research activity?

☐ Yes ☐ No

If Yes, note amount with explanation of source:

4. **Other Financial Interests or Relationships**. Do you have any financial interests in the product, including patents, trademarks, copyrights, or licensing agreements?

☐ Yes ☐ No

If Yes, note amount with explanation of source:

5. **Incentives**. If involved in any research activity will you receive any money, gift or anything of monetary value above and beyond the actual costs of enrollment, conduct of the research, and reporting on the results, including, but not limited to, finders fees, referral fees, recruitment bonuses, an enrollment bonus for reaching an accrual goal or similar types of payments?

☐ Yes ☐ No

If Yes, note amount with explanation of source:

6. **Other**. Are there any other interests or relationships (including volunteer services) that might constitute a conflict of interest or an appearance of conflict of interest in connection with the research project?

☐ Yes ☐ No

If Yes, note amount with explanation of source:

Questions or concerns can be addressed to the IRB Chairperson, Farzan Nadim