New York University • University Committee on Activities Involving Human Subjects
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(212) 998-4808 • fax: (212) 995-4304 • ask.humansubjects@nyu.edu

For UCAIHS internal use
HS# _____
Meeting date: _____

APPLICATION FOR REVIEW BY THE UNIVERSITY COMMITTEE ON ACTIVITIES INVOLVING HUMAN SUBJECTS (UCAIHS)

Instructions

Applicants must take the Humans Subjects Tutorial and pass the Certification Exam before submitting their application: www.nyu.edu/ucaihs/tutorial/

All Applications must be typed or word-processed (single spaced). Do not type on back.

Applicants should refer to the UCAIHS online tutorial for guidance available on the UCAIHS website at www.nyu.edu/ucaihs/.

Principal Investigator (PI)

First name: **James** Last name: **Jaccard**

School: **School of Social Work** Department: _____

Work phone: **212-998-5892** Home phone: **305-299-6760**

PI mailing address: **1 Washington Square North, Room 303, NY, NY 10003**

Email address: **jjaccard@gmail.com** PI NYU net ID: **jj76**

Status *(check one):*

☒ NYU Faculty ☐ NYU Student ☐ Other NYU ☐ Non-NYU

Student mailing address *(if not a faculty project):*

Street: _____

City: _____ State: _____ Zip Code: _____

Faculty sponsor *(required for all students or non-NYU investigators):*

First name: _____ Last name: _____

School: _____ Department: _____

Faculty sponsor email: _____ Faculty Sponsor NetID: _____

Co-investigator

First name: _____ Last name: _____

School: _____ Department: _____

Additional investigators

First name: _____ Last name: _____

First name: _____ Last name: _____

Project Title

Modified Linear Probability Models: An alternative to more traditional logistic modeling

Are you requesting **Exempt Status**? *(See page 3 for definition.)*

☒ Yes ☐ No *If yes, fill out Request for Exempt Status on page 3.*

Are you requesting **Expedited Status**? ☐ Yes ☒ No *If yes, complete expedited checklist*

Investigator's Agreement

I agree to use procedures with respect to safeguarding human subjects in this activity that conform to federal, state, local and University policy. If significant change in investigative procedure involving human subjects is called for during the activity covered by this Application, I shall seek prior approval for such change from the UCAIHS and agree to follow the advice of the UCAIHS. If this activity is a continuation or renewal of an ongoing program, I affirm that the procedures followed during the current period conform to this policy.

Principal Investigator signature: _____ Date: 4/10/2012

Faculty sponsor signature: _____ Date: _____

UCAIHS Internal Use
HS Exam Passed:
☐ PI
☐ Faculty Sponsor
☐ Inv2
☐ Inv3
☐ Inv4

Has this study been **previously approved** by the UCAIHS?

☐ Yes ☒ No *If yes, what was the most recent approval date?* _____

If yes, what was the name of project as approved?

_____

_____

Have procedures changed since the most recent UCAIHS review?

☐ Yes ☒ No *If yes, provide details as part of this Application as appropriate.*

Will data be collected from or about any of the following protected populations? *(Check all that apply.)* **Note:** There are additional protections and procedures required for the use of protected populations as subjects in research. Please consult Chapter 13 of the UCAIHS tutorial at http://www.nyu.edu/ucaihs/tutorial/ to review these protections. Additional questions should be directed to the UCAIHS staff at 212/998-4808 or ask.humansubjects@nyu.edu .

☐ Minors (under 18 years of age) *If checked, specify age range:* _____

☐ Prisoners

☐ Pregnant women

☐ Fetuses

☐ Institutionalized mentally disabled (individuals residing as patients in an institution who are mentally ill or retarded; emotionally disturbed; psychotic; or senile)

Will the project involve any of the following? *(Check all that apply.)*

☐ Deception (research in which subjects are purposely led to have false beliefs or assumptions)

☐ More than minimal risk to subjects (i.e., risk greater than that of everyday life)

☐ Investigational new drug or device exemption *If checked, include IND/DE/510(k) information.*

If the Investigator is a student, indicate if the project is a:

☐ Thesis ☐ Dissertation ☐ Class project ☐ Other *(please specify):* _____

Is the application for a Pilot Study?

☐ Yes ☒ No

Is the proposed project being supported by any **external (non-NYU) funding or from an NYU competitive research program** or has such funding been applied for?

☐ Yes ☒ No

If yes, what is the name of the funding agency, organization or NYU program?

_____

What is the status of the request for funding?

☐ Submission planned in near future ☐ Submitted & Pending

☐ Initial award ☐ Continuation award ☐ Renewal award

If already awarded, what is the award or grant number? _____

What is the title of the project as it appears in the submission for funding or award?

_____

_____

REQUEST FOR EXEMPT STATUS FROM FULL HUMAN SUBJECTS COMMITTEE REVIEW

Certain categories of research deemed very low risk under Federal regulations may be granted Exempt Status once the appropriate review has been conducted by the UCAIHS. If Exempt Status is granted, the study will not require continuing or other review unless procedures are revised which deviate from those originally approved by the UCAIHS.

Note that only the UCAIHS may grant Exempt Status. Therefore, applications for Exempt Status must include the completed remainder of the application in addition to the information requested below.

Part 1
Exempt status may be claimed under the following categories. **Please check all that apply.**

☐ **1.** Research is a study of normal educational practices in commonly accepted educational settings.

Note: This exemption does not apply to research with children when the investigator[s] participate in the activities being observed; for example, in classroom situations where the investigator is taking part in the classroom activities being studied, or if activities are introduced for the purpose of the proposed project and are not part of the usual curriculum or activities.

☐ **2.** Research involves:
- **a.** The use of educational tests, surveys, or interviews where identifiers are not recorded by the Investigator or where there is neither a risk of harm to subjects nor information sought concerning sensitive aspects of the subject's own behavior. (**Note:** This exemption does not apply to research involving surveys and interviews with children or to experiments such as computer simulations of decision making or laboratory tests of group interactions or to activities involving deceit or manipulation of beliefs); *or*
- **b.** Observation of public behavior where identifiers are not recorded by the Investigator or there is neither a risk of harm to subjects nor observation of sensitive aspects of the subjects' own behavior

☐ **3.** Research involves the use of educational tests, surveys, interviews, or observation of public behavior that is not exempt under the above category **if:**
- **a.** subjects are elected or appointed public officials or candidates for public office; *or*
- **b.** federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☒ **4.** Research involves only:
- **a.** the collection or study of existing data, documents, records, pathological or diagnostic specimens, where publicly available; *or*
- **b.** the information is private but identifiers are not recorded by the Investigator.

Note: Recent Office of Human Research Protections guidance on types of data that do and do not require review and approval has changed the interpretation of category 4a. Please consult the UCAIHS web site at http://www.nyu.edu/ucaihs/apply/. In addition, Protected Health Information, as defined under the HIPAA Privacy Act, may not have secondary use without review and approval by the organization from which it is derived, as detailed on the following page.

☐ **5**. Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or 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 FDA or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Part 2
Please complete the following Exempt Justification Statement.

I believe my research qualifies for exempt status under one or more categories indicated above, for the following reason(s): (*Enter supporting statement for exemption[s] by number using the space provided by the form.)*

The proposed project is an analyis of previously collected data collected under the auspices of IRB at the University of Michigan, and as such is a secondary data set that is currently available to the general scientific community.

NOTE ON PROTECTED HEALTH INFORMATION

The Health Insurance Portability and Accountability Act (HIPAA) is the Federal legislation that governs all uses and disclosures of Protected Health Information (PHI), also known as individually identifiable health information, in order to protect individual privacy. HIPAA protects PHI for both living individuals and decedents (as opposed to the federal Common Rule which governs research activities with human subjects in the U.S. and pertains only to the living).

New York University is classified as a "hybrid institution" encompassing both a "covered entity" (including the Medical and Dental Schools) involved in the creation and receipt of PHI and an "uncovered entity" (including most other University units). The UCAIHS serves as the IRB for the uncovered entity components of NYU. Specific HIPAA regulations govern the release of PHI for research purposes for or from covered entities and place regulatory responsibilities on investigators at uncovered entities who seek research subjects or information from or though the assistance of covered entities.

Therefore, investigators planning to make use of data obtained from or through other organizations that are covered entities (including the NYU Medical Center), must obtain approval for the use of that data from the covered entity as part of the required UCAIHS and cooperating institution IRB approvals.

PURPOSE OF STUDY

Please describe the purpose of your proposed research, making clear the question the research is attempting to address. Avoid the use of technical terms or discipline specific language. Your explanation must be clear to those unfamiliar with your field. References are unnecessary.

This study examines a new approach to conducting Monte Carlo simulation studies to evaluate the applicability of new statistical methods under conditions where assumptions are violated, designed by the PI. The approach uses large extant data files and creates infinitely large pseudo populations from that data by using sampling with replacement. In the current project, the PI is evaluating the ability of a modified linear probability model (MLPM) that uses Huber-White sandwich estimators to adequately capture population parameters relative to the more commonly used logistic regression methods. The MLPM has many advantages relative to logistic regression and if it performs well, it becomes a distinct alternative to more traditional logistic modeling. I will use the data set to identify a wide range of binary regression models on which I can conduct my Monte Carlo simulations using extant data methodology.

SUBJECT SELECTION AND RECRUITMENT

Part 1
Selection of subjects must be equitable, scientifically justifiable, and, in the case of protected populations such as children, prisoners, pregnant women, or mentally disabled persons, should reflect their special needs. In addition, investigators should be sensitive to the use of educationally and economically disadvantaged persons as subjects. If you are excluding women, children, or minorities or other specific populations from your subject pool, you must include a scientific justification for such exclusion.

Investigators are advised to consult with UCAIHS staff prior to planning studies with regulated access to special populations such as prisoners or the mentally disabled. In addition, investigators are **strongly discouraged** from proposing recruitment that includes their own classes, clients, patients, or similar groups, in order to avoid any potential for coercion.

Please answer the following questions:

a. What is the expected sample size (number of subjects to be included)? **N/A - Secondary Data Analysis**

b. What are your criteria for inclusion of potential subjects (e.g., age range, country of birth or native language, medical status, grade in school, membership in a particular organization, marital or parental status)?
N/A - Secondary Data Analysis

c. What are the criteria for subject exclusion (e.g., age range, country of birth or native language, medical status, grade in school, membership in a particular organization, marital or parental status)?
N/A - Secondary Data Analysis

Part 2
Describe in detail how the subjects will be recruited. Investigators should make every attempt to use indirect recruitment methods (i.e., methods in which the investigator does not make direct contact with potential subjects but rather makes information available on the opportunity to participate and how to contact the investigator if interested).

a. How will investigators identify potential subjects (how will they know whom to recruit)?
N/A - Secondary Data Analysis

b. Where and how will potential subjects be informed of the opportunity to participate? *Include copies of recruitment letters, flyers, or advertisements, and/or a copy of the oral and written statements to be used at the time of recruitment of subjects.*
N/A - Secondary Data Analysis

c. How will subjects be able to let the investigator know they wish to participate?
N/A - Secondary Data Analysis

Please provide any additional information, if relevant.

STATEMENT TO SUBJECTS

What will the investigator tell potential subjects once they indicate interest in participation about the study and how will the investigator tell them (e.g., by letter, phone call, email, presentation to a group)?

The statement to the subject should include information on the purpose of the study, what subjects will be asked to do if they participate, where the study will be carried out, how much of the subjects' time participation may take, and what type of information they might be asked to provide. It should also make clear that participation is voluntary and that subjects may withdraw from the study at any time.

Include a copy of any written statements or verbal scripts to be used. Statements to children should state that written parental permission is required for participation and be in language appropriate to the subjects' age.

N/A - Secondary Data Analysis

HARM OR BENEFIT TO SUBJECTS

Describe any potential harm/risk or benefit to the subjects. If there is no more than minimal risk to subjects (e.g., no greater than that of everyday life), then state that "there is no risk from participation beyond that of everyday life." If there is the possibility of greater than minimal risk, include a discussion of why the additional risk is justifiable. For approval of any study with more than minimal risk, the benefits must clearly be shown to outweigh the risks. If appropriate, include information on how risk might be managed. For example, an investigator could provide a list of community or University counseling services when there is potential for emotional distress.

Detail any direct benefits to subjects. If there are none, so state. Take care not to exaggerate potential benefits; research studies rarely provide direct benefits to subjects and that the results of research are often tenuous.

Note: Gifts or payment of any kind to participants are incentives or reimbursements, not benefits. If any gifts or incentives will be offered to subjects, provide details in the section on procedures. Information on incentives should be made clear in recruitment materials and consent/permission forms.

PROCEDURES TO BE FOLLOWED

Describe the procedures to be followed in carrying out the project, including:,

- **a.** where the study will be conducted;
- **b.** exactly what the participants will be expected to do at each stage of the project;
- **c.** how much time each activity will require and the total time for participation;
- **d.** who will supervise the participation or conduct interviews;
- **e.** how material such as surveys will be distributed and returned.
- **f.** any incentives or reimbursements for participants (describe and explain what participants receive if they withdraw before the study is completed).

N/A - Secondary Data Analysis

*If applicable, attach **one copy** of any survey, questionnaire, testing protocols, and/or proposed interview questions to the **each copy** of the application for review **only.** If longer than 10 pages, attach 1 copy only to the original application*

CONFIDENTIALITY

If the data will not be obtained anonymously, describe the specific methods by which confidentiality will be protected (i.e., use of data coding systems or pseudonyms). **Data** can be anonymous if the investigator does not know the participants' names at all. If the study includes more than one session or instrument, anonymity may be achieved by assigning code names that track participants' data from one session or document to another but are unrelated to participants' true names. **Participants** are not anonymous unless the investigator never learns their names. Describe how anonymity will be assured. If any online surveys or responses are included in the procedures, describe the methods to be used to ensure that identifying material will not be transmitted or recorded electronically (e.g., email address, IP numbers).

In addition, please specify:

- **a.** how and where data will be stored;
- **b.** who will have access to data (faculty sponsors always have access);
- **c.** how long the data will be kept (regulations require that all data, including consent forms, be kept for at least 3 years after the completion of the project;
- **d.** what will happen to data after the study is completed (if it will be retained, state how confidentiality will be maintained; if it will be destroyed, explain how).

The data base will be kept on a secured, encrypted hard drive. The computer as well as the data file will require a password to open. No identifying information appears on the data files. Only the PI will have access to the data for purposes of analysis.

Note: Pay particular attention to the protection of subjects' confidentiality in such settings as open or group situations. While investigators may promise to maintain confidentiality, they cannot guarantee that others in a group situation will do so. *Attach additional pages as needed.*

INFORMED CONSENT AND PERMISSION

Enter description of proposed consent procedure. ***Attach copies of all forms, scripts, etc. to be used to obtain informed consent from adult subject(s) in non-protected populations and, if subjects are under 18 years of age or institutionalized mentally disabled, from their parents or legally authorized representatives****. Explain how participants will be given the consent form, parental or other permission forms and/or assent script (where and when), and how signed forms will be returned to the investigator. Please see the UCAIHS website for Forms and Language for Consent Forms, Permission Forms, & Child Assent.*

Note:
In all cases in which subjects will be minors (under 18 years of age), a parental permission form is required. In addition:

- for minors over age 12, a **separate consent form** is required, and
- for children under age 12, an oral **assent procedure** and **script** appropriate to the age of the subject are required.

In cases in which minors are participants, and it is possible that suggestion of harm to the child or others may be elicited, the parental permission form and the consent form for a minor over age 12 should include a mandated reporting statement.

If video- or audiotapes are involved, the consent/permission form should indicate that the subject has the right to review all or any portion of the tape and request that it be destroyed. Parents may not review audio/videotapes of children.

If it is possible that the investigator might wish to quote or otherwise identify a subject in any publication, an attribution statement must be included and a justification for requesting attribution.
If the study involves focus group participation or other group activities, the consent form must include a statement of the limits of confidentiality in group settings, that is, while the investigator may hold all individual information confidential, he/she cannot guarantee that other members of the group will do so.

Subjects must be given a copy of the unsigned consent form before subjects' participation begins.

Any proposed changes to the standard written informed consent process must be clearly detailed and justified as part of the application. Unless there is a clear justification, consent/permission forms should use the UCAIHS Recommended Language.

If adult participation will be completing surveys of questionnaires anonymously, a Project Summary Statement containing all the information included in a Consent Form without a signature may be used in place of a signed Consent Form.

N/A - Secondary Data Analysis

COOPERATING INSTITUTIONS

Investigators may submit an Application for Review prior to obtaining approvals from all cooperating organizations; however, final approval to conduct research at a particular research site will not be granted until a copy of that institution's written approval has been submitted for the Committee's files. Institutional Review Board approval is required from all organizations which have an IRB. A letter from an appropriate senior official, on letterhead, should be obtained from organizations that do not have an IRB. List all institutions expected to provide access to potential subjects, to data necessary to identify subjects, to data previously collected, or facilities where the research is to be conducted, etc., including:

- hospitals (Institutional Review Board approval is required);
- institutions of higher education (Institutional Review Board approval is required);
- health care providers (e.g., clinics, physicians' offices);
- schools (for New York City public schools, NYC Department of Education approval is also required); and
- agencies, associations, or membership organizations.

Please indicate the status of cooperating institutions' approval (i.e., attached, in process, not yet requested).*Attach originals of IRB approval or approval letters on the cooperating institutions' letterhead, from appropriate authorized officials at each institution listed or submit to the UCAIHS as soon as available.* Investigators should be aware that approval processes at other organizations, particularly school boards and hospitals, may take considerable time. Please take this into account in planning the study.

N/A

INFORMED CONSENT AND PERMISSION

If applicable, provide the following:

- a description of the debriefing procedures to be used (i.e., for studies involving deception);
- a statement describing what actions you will take should the research reveal the possibility of a medical or other potentially troublesome condition, emotional distress in reaction to sensitive questions, or other adverse effects. Such information should also be included in all Consent & Permission forms.

N/A