PENNSTATE

HRP-591 - Protocol for Human Subject Research

Protocol Title:

Economic Experiment on _____

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Version Date:

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Clinicaltrials.gov Registration #:

N/A

If you need help…

University Park and other campuses:

Office for Research Protections Human Research Protection Program
The 330 Building, Suite 205
University Park, PA 16802-7014
Phone: 814-865-1775
Fax: 814-863-8699
Email: irb-orp@psu.edu

College of Medicine and Hershey Medical Center:

Human Subjects Protection Office
90 Hope Drive, Mail Code A115, P.O. Box 855
Hershey, PA 17033
(Physical Office Location: Academic Support Building Room 1140)
Phone: 717-531-5687
Fax number: 717-531-3937
Email: irb-hspo@psu.edu

Instructions for using this protocol template:

1. Add this completed protocol template to your study in CATS IRB (http://irb.psu.edu) in the "Basic Information" section. Links to Penn State's protocol templates are available in the same location where they are uploaded and their use is required.
2. This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB determine whether a study meets all criteria for approval.
3. There may be sections in this template that do not apply. If a section or question does not apply to the research study in question, provide the response "Not Applicable".
4. **DO NOT TYPE IN THE GRAY BOXES.** All guidance language appears in gray boxes and these boxes MUST be deleted from the final version of the protocol prior to upload to CATS IRB.

Table of Contents

1.0 Objectives

1.1 Study Objectives

We aim to study _____

1.2 Primary Study Endpoints

After __ rounds in which subjects make economic decisions, the experiment will end.

1.3 Secondary Study Endpoints

None

2.0 Background

2.1 Scientific Background and Gaps

It is not well-understood how _____. We seek to examine _____.

2.2 Previous Data

None

2.3 Study Rationale

Understanding the effects of _____.

3.0 Inclusion and Exclusion Criteria

3.1 Inclusion Criteria

Subjects will be included on a first-come basis. They can sign up through the Penn State LEMA lab recruitment website.

3.2 Exclusion Criteria

None, other than they must be able to sign up through the website and be available during the time. To sign up on the website you must be a Penn State student and 18 years of age or older

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

Subjects will only be removed if the experiment cannot fit them in due to capacity of the lab, or should an unexpected event occur (broken computer etc..)

3.3.2 Follow-up for withdrawn subjects

Subjects who are removed early will simply be paid a $5 show up fee on the spot. No further contact is needed.

4.0 Recruitment Methods

4.1 Identification of subjects

Participants will be identified through the LEMA lab recruitment website. Those registered with LEMA will have the ability to sign up.

4.2 Recruitment process

The experiment will be listed on the LEMA lab recruitment website, where those registered can sign up. The description will include the game description and the potential payoffs.

4.3 Recruitment materials

The Penn State LEMA website and automated online recruitment system

4.4 Eligibility/screening of subjects

N/A

5.0 Consent Process and Documentation

5.1 Consent Process

5.1.1 Obtaining Informed Consent

5.1.1.1 Timing and Location of Consent

Consent will be at the beginning of the experiment after the subjects have read the instructions and informed consent form.

5.1.1.2 Coercion or Undue Influence during Consent

The experiment is in a secure location and subjects are recruited through a large voluntary database. There are no foreseeable benefits for including or excluding a particular subject. Participants can skip questions or withdraw at any time from the experiment if they are uncomfortable.

5.1.2 Waiver or alteration of the informed consent requirement

N/A

5.2 Consent Documentation

5.2.1 Written Documentation of Consent

N/A

5.2.2 Waiver of Documentation of Consent

Implied consent will be obtained through subject continuation of the experiment. At the beginning, subjects will be able to read the instructions and a consent form on the computer before committing to the experiment. If a subject clicks the "continue" button, consent is implied. The consent document includes that subjects must be at least 18 years old. Participants have the option to print this document at the beginning or end of the experiment.

5.3 Consent – Other Considerations

5.3.1 Non-English Speaking Subjects

It is a requirement to speak English to be a part of the LEMA recruitment website.

5.3.2 Cognitively Impaired Adults

N/A

5.3.2.1 Capability of Providing Consent

N/A

5.3.2.2 Adults Unable To Consent

N/A

5.3.2.3 Assent

N/A

5.3.3 Subjects who are not yet adults (infants, children, teenagers)

5.3.3.1 Parental Permission

N/A

5.3.3.2 Assent

N/A

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

N/A

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

- ☐ Authorization will be obtained and documented as part of the consent process.
- ☐ Partial waiver is requested for recruitment purposes only *(Check this box if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained)*
- ☐ Full waiver is requested for entire research study *(e.g., medical record review studies)*
- ☐ Alteration is requested to waive requirement for written documentation of authorization

6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

6.2.1.1 Plan to protect PHI from improper use or disclosure

N/A

6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers

N/A

6.2.2 Explanation for why the research could not be practicably be conducted without access to and use of PHI

N/A

6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

N/A

6.3 Waiver or alteration of authorization statements of agreement

N/A

7.0 Study Design and Procedures

7.1 Study Design

The experiment will be conducted in the Penn State LEMA lab. Subjects will act anonymously through individual computers running the experiment software. Subjects will (insert abbreviated experiment design here). Subjects repeat this for __ periods. Subjects will be paid out at the end based on their performance.

7.2 Study Procedures

Subjects will be tasked with _____. The experiment ends after __ periods. The instructions subjects will be given are attached in the supplemental section of this review.

From a subject perspective:
1) Sign up via LEMA recruitment website
2) Sign in on the day of the experiment
3) Receive random computer assignment
4) Read instructions and informed consent form
5) Opportunity to ask questions
6) Begin first round of experiment
7) Opportunity to ask questions again at the end of the round
7) Continue on an additional __ rounds
8) Check out and receive payment with proctor

7.3 Duration of Participation

Each subject will be asked to stay for one hour.

8.0 Data and Specimen Banking For Future Undetermined Research

8.1 Data and/or specimens being stored

N/A

8.2 Location of storage

N/A

8.3 Duration of storage

N/A

8.4 Access to data and/or specimens

N/A

8.5 Procedures to release data or specimens

N/A

8.6 Process for returning results

N/A

9.0 Statistical Plan

9.1 Sample size determination

We will collect data for the control as well as 3 treatment experiments. Each treatment may need to be run with 10-30 subjects. That totals 40-120 subjects.

9.2 Statistical methods

Regression analysis

10.0 Confidentiality, Privacy and Data Management

10.1 Confidentiality

No identifiers will be used in the data. The experiment will payout students based on the computer they are randomly sitting at. Therefore, their connection to their performance ends when they leave the room.

10.1.1 Identifiers associated with data and/or specimens

N/A

10.1.1.1 Use of Codes, Master List

N/A

10.1.2 Storage of Data and/or Specimens

The electronic data will be in a secure, locked room, PSU LEMA lab on the head computer. The data will also be password protected by the principal investigator. It will not be on a server.

10.1.3 Access to Data and/or Specimens

Only the experimenter will have access to the anonymous data.

10.1.4 Transferring Data and/or Specimens

N/A

10.2 Privacy

The only potential individual information gathered would be the names of the subjects. This is due to the sign up system. However, there is no need for the experiment to have that information.

If a subject is uncomfortable they may leave at any time. Questions/concerns will be answered by the experiment proctor if needed.

11.0 Data and Safety Monitoring Plan

N/A

11.1 Periodic evaluation of data

N/A

11.2 Data that are reviewed

N/A

11.3 Method of collection of safety information

N/A

11.4 Frequency of data collection

N/A

11.5 Individual's reviewing the data

N/A

11.6 Frequency of review of cumulative data

N/A

11.7 Statistical tests

N/A

11.8 Suspension of research

N/A

12.0 Risks

This experiment has no foreseeable risks for the subjects. Subjects will act anonymously and will understand the payoff potential beforehand, so they will not be misled.

13.0 Potential Benefits to Subjects and Others

13.1 Potential Benefits to Subjects

Economic decision-making skills, monetary pay-off based on decisions

13.2 Potential Benefits to Others

We hope to shed light on _____. This information can help _____.

14.0 Sharing Results with Subjects

Subjects will know how they individually performed due to the compensation plan. However, they will not know how any other specific subject performed. They will be able to view the general-collective results in the published paper if they wish.

15.0 Economic Burden to Subjects

15.1 Costs

None, minus the opportunity cost of spending an hour of their time in the experiment

15.2 Compensation for research-related injury

N/A

16.0 Number of Subjects

40-120

17.0 Resources Available

17.1 Facilities and locations

The experiment will be conducted in the Penn State LEMA laboratory, which is a secure environment that allows subjects to interact through computers.

17.2 Feasibility of recruiting the required number of subjects

The LEMA recruitment website has over 4000 active students signed up. Therefore it is feasible to expect 60 to be available for the experiment.

17.3 PI Time devoted to conducting the research

High priority research for experimenter

17.4 Availability of medical or psychological resources

N/A

17.5 Process for informing Study Team

The researchers will meet periodically to discuss the progress of the research project.

18.0 Other Approvals

N/A

19.0 Subject Stipend (Compensation) and/or Travel Reimbursements

Subjects will be paid $5 for simply showing up. At the end of the experiment, subjects will be paid additional money based on their performance in the game.

20.0 Multi-Site Research

N/A

20.1 Communication Plans

N/A

20.2 Data Submission and Security Plan

N/A

20.3 Subject Enrollment

N/A

20.4 Reporting of Adverse Events and New Information

N/A

20.5 Audit and Monitoring Plans

N/A

21.0 Adverse Event Reporting

21.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

21.2 Auditing and Inspecting

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

22.0 Study Monitoring, Auditing and Inspecting

22.1 Auditing and Inspecting

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

23.0 References

24.0 Appendix