PROTOCOL APPLICATION FORM

SOCIAL, BEHAVIORAL, AND EDUCATIONAL EXPEDITED REVIEW HUMAN SUBJECTS IN SOCIAL, BEHAVIORAL, AND EDUCATIONAL RESEARCH

University of Massachusetts Amherst

Protocol ID: 2016-3033

Other Personnel

| Protocol Director | | Degree: | Title | | |
|---|--|--|---------------------------|---|--------|
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| Human Subjects Tr | aining Comp | leted? | | Υ | |
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| Personnel | > Human Subjects Training Completed? |
|--|--|
| | |
| Subject Population(s) Checklist | Yes/No |
| • Minors (under 18) | N |
| Pregnant Women | N |
| Cognitively Impaired or Decisionally Challenged | N |
| Older individuals (75 and over) | N |
| Healthy Volunteers | Y |
| Students/Employees | Y |
| International Populations | N |
| PrisonersOther (i.e., any population that is not specified above) | N N |
| Other (i.e., any population that is not specified above) | IN . |
| Study Location(s) Checklist | Yes/No |
| University of Massachusetts Amherst | Υ |
| Baystate Medical | N |
| University Health Services | N |
| Hartford Hospital | N |
| Other (Specify other Study Locations) | N |
| General Checklist | Yes/No |
| Training Grant? | N |
| • Funded Study (or proposal submitted to sponsor)? | N |
| Cooperating Institution(s)? | N |
| Federally Sponsored Project? | N |
| Human blood, cells, tissues, or body fluids (tissues)? | N |
| Subjects will be paid for participation? | N |
| | ., |
| Funding Checklist | |
| Funding - Grants/Contracts | |
| Funding - Fellowships | |
| NONE | |
| Gift Funding | |

Social, Behavioral & Education Research Expedited Review

A protocol must be no more than minimal risk (i.e., "not greater than those ordinarily encountered in daily life") AND must only involve human subjects in one or more of the following paragraphs.

Select one or more of the following paragraphs:

- 1. N Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - a) Research on drugs for which an investigational new drug application (21 CFR Part 31,32) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b) Research on medical devices for which
 - i) an investigational device exemption application (21 CFR Part 812) is not required;
 or
 - ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- 2. N Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - i) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - ii) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- 3. N Prospective collection of biological specimens for research purposes by non invasive means.
- 4. N Collection of data through non invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:

- i) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy:
- ii) weighing or testing sensory acuity;
- iii) magnetic resonance imaging;
- iv) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- v) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- 5. N Research involving materials (data, documents, records, or specimens) that

have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

- 6. N Collection of data from voice, video, digital, or image recordings made for research purposes.
- 7. Y Research on individual or group characteristics or behavior(including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

1. Purpose of the study

a) Provide a brief lay summary of the purpose of the study.

The proposed study will use a speeded acceptability judgment task to investigate how English speakers understand sentences that contain syntactic ambiguities. The main question in this study is whether listeners create only a single or multiple interpretations for an ambiguous sentence like "I saw the daughter of the actress on the balcony" (which could mean either the daughter, or the actress, is the one on the balcony). At issue is whether listeners subconsciously consider all possible interpretations of ambiguous sentences like this, or if they construct and interpret only one single interpretation.

The study will involve reading sentences that are flashed phrase-by-phrase on a computer screen, and having participants judge whether or not they perceive the sentence as an acceptable or unacceptable sentence of English, as well as their confidence in their decision ("Very confident", "Reasonably confident", "Not at all confident").

b) What does the Investigator(s) hope to learn from the study?

By jointly measuring whether readers perceive ambiguous sentences as unacceptable, and their confidence in these judgments, we hope to find evidence that will distinguish serial (single interpretation) from parallel (multiple interpretation) parsing strategies. In doing so, we hope to learn about the ways that comprehenders negotiate linguistic ambiguity in normal day to day life.

2. Study Procedures

a) Describe all study procedures.

Participants will be seated in a room in the Linguistics department (in the ILC), in front of an iMac computer screen. There may be up to four participants in a room at the same time. Each participant will be seated in front of their own computer. Measures will be taken to ensure that each participant can see only their screen to ensure a measure of privacy, and they may be given noise-cancelling headphones to wear (without any sound) to slightly reduce ambient noise.

After a brief familiarization procedure with the experiment, participants will read sentences that are flashed phrase-by-phrase on a computer screen at approximately 500ms per word or

phrase. After a sentence, participants will hit one of two keys on the keyboard to indicate whether they found the sentence acceptable or not. We will require that their response must be given in under 2 seconds or less. Their response and their reaction time will be recorded. Following the acceptability judgment, participants will be asked to rate their confidence in their decision ("Very confident", "Reasonably confident", "Not at all confident").

In this experiment, participants will read and judge approximately 108 sentences. They will be given up to three brief rest periods during this time to reduce fatigue. We anticipate that the experiment will take no longer than 45 minutes.

b) State if audio or video taping will occur. Describe what will become of the tapes after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the tapes.

None. Although the eye-tracker uses a camera to monitor the position of the participant's eye on the screen, no video data is saved.

c) State if deception will be used. If so, provide a rationale and describe debriefing procedures. Submit a debriefing script in Section #11 (Attachments).

None.

3. Background

a) Describe past findings leading to the formulation of the study.

There is much work in psycholinguistics on the question of whether humans parse sentences serially or in parallel. However, much of the work uses reading time measures to evaluate this question. However, it has been known since Lewis (2000) that reading time measures do not provide unambiguous evidence that distinguishes serial versus parallel parsing. In this project, we hope to use a novel source of evidence (acceptability judgments plus ratings) to distinguish these two models of sentence interpretation, bringing new data to bear on an old theoretical question.

4.(a-f) Subject Population

 State how many subjects you propose to use and state the rationale for the proposed number.

We plan to recruit and record data from approximately 75 subjects in our study. Previous research suggests this is a number that is sufficient to provide adequate statistical power to test our hypotheses. All participants will be run under the same SONA protocol. If the results of a statistical power analysis suggest that fewer participants need to be run, we may run fewer participants.

Of our proposed 75 subjects, we will recruit 50 from the SONA subject pool, and 25 from the Linguistics subject pool (see 4g for details on subject recruitment).

- b) Describe the subject population, including the age range, gender, ethnic background, and type of subjects (e.g. students, professors, subjects with learning disabilities, mental health disorders, etc.). Please incorporate specific inclusion/exclusion criteria (e.g. physical and psychological health, demographic information, or other unique characteristics).
 - UMass undergraduates who are students in Psychology or Linguistics classes. They are presumed normal and competent. We will require that participants be (self-reported) native speakers of American English, have normal or corrected-to-normal vision, and have no (self-reported) history of reading or language disorders.
- c) State the number and rationale for involvement of potentially vulnerable subjects to be entered into the study, including minors, pregnant women, prisoners, economically and educationally disadvantaged, decisionally challenged, and homeless people.

NA

d) If women, minorities, or minors are not included, a clear compelling rationale must be provided. Examples for not including minors: disease does not occur in children; drug or device would interfere with normal growth and development; etc.

With the exception of minors and non-native speakers of American English, we will sample the UMass population randomly.

e) State the number, if any, of subjects who are laboratory personnel, employees, and/or students. They should be presented with the same written informed consent. If compensation is allowed, they should also receive it.

All participants will be students.

f) State the number, if any, of subjects involved in research conducted abroad and describe any unique cultural, economic or political conditions.

None.

4.(g-i) Subject Population

g) Describe your procedures for recruiting subjects, including how potential subjects will be identified for recruitment. Attach all recruitment materials in Section #11 (Attachments). Note: Potential subjects may not be contacted before IRB approval.

We will recruit subjects using EITHER the Psychology Department's SONA system or the Linguistics Department's YouCanBookMe website. The SONA system is available to students taking Psychology classes. The YouCanBookMe website is advertised to students taking Linguistics classes. It may be accessed at this address: https://xlingumass.youcanbook.me/

The SONA study title, for all sub-experiments, will be "Speeded Acceptability Judgments: 2016-2017." The description on SONA/YouCanBookMe will read:

"This study is designed to investigate how acceptable or natural certain sentences of English are. In this experiment, you will be asked to read to a number of sentences in American English and you will be asked to make a judgment about each sentence you read. For example, you may be asked whether a sentence sounds natural to you or not. You may additionally be asked a comprehension question about many of the sentences. The experiment will take approximately 30 to 45 minutes. In order to participate, you must be a native speaker of American English. The experiment will take place in the Linguistics department, which is in the Integrative Learning Center (ILC) near the Student Union and Student Center. The room number is ILC N442."

h) Compensation. Explain the amount and type of compensation (payment, experimental credit, gift card, etc.), if any, that will be given for participation in the study. Include a schedule for compensation and provisions for prorating.

Subjects recruited through the SONA system in Psychology will receive one course credit for being in an experiment lasting an estimated 30 to 45 minutes. We will round course credit received to the nearest half hour. So for a participant who is in the lab 45 minutes or less, they will receive one course credit. We do not anticipate that any participant will be in the lab long enough to merit 2 course credits.

Subjects recruited through the Linguistics system will receive one extra credit point for being in an experiment lasting an estimated 20 minutes. We will round points received to the nearest 20 minutes. So for a participant who is in the lab 45 minutes or less, they will receive two course credits. A participant in the lab between any more than 45 minutes will receive 3 points. We do not anticipate that any participant will be in the lab long enough to merit 4 points.

Note that there is no direct correspondence between 'points' in the Linguistics system and 'credits'

in the SONA system, and so it is not necessarily the case that Linguistics participants are being given 'more' credit than are Psychology participants.

i) Please state: A: The total expected duration of the study, including the time expected for data analysis (e.g., This study is expected to last 1 year) AND B: How much time each subject is expected to be involved in the study (e.g., The involvement of each subject will be 1-session for a total of 90 minutes).

Data will be collected and analyzed during the Spring of 2016 and the fall of 2016. Each subject will participate in a single session estimated to last 30-45 minutes.

5. Risks

HHS Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research..." This also includes risks to subject confidentiality and any discomforts, hazards, or inconveniences.

For the categories below, include a description of risks.

a) Describe the risks related to:

Physical well-being

Minimal risk of discomfort from remaining seated at a computer.

Psychological well-being

Minimal risk. All language materials will be carefully evaluated to ensure that they do not contain offensive or inflammatory content.

Economic well-being

No risk.

Social well-being

Minimal risks. Subjects will be tested in a room with up to four other participants and a single experimenter.

Breach of confidentiality (including audio/video taping)

Data will be stored on a password protected computer, and subjects will be assigned unique identifiers. Subject names and subject identifiers will only be associated on a testing log which will be stored in a locked laboratory room. Signed consents will similarly be stored in a locked laboratory room.

b) For research conducted internationally, describe any political or sociocultural considerations that may affect your research design (for example, in some communities it may not be customary to sign documents, etc.)

NA

 Discuss plans for ensuring necessary medical or professional intervention in the event of a distressed subject.

In case of any event, we will immediately contact the Psychological Services Center in Tobin Hall, and if necessary, the University Health Services. We do not anticipate needing to do this, however. There has not to date been any single instance of a distressed subject in any similar experiments run by the PI in the six years he has been running experiments of this type.

6. Benefits

a) Describe the potential benefit(s) to be gained by the subjects or by the acquisition of important knowledge which may benefit future subjects, etc. (This DOES NOT include compensation or extra credit).

Subjects will learn about the research process and will learn a little bit about the nature of their language. Debriefing forms will be tailored to explain the phenomenon studied in each eye-tracking experiment. As basic research, the proposed study does not provide any direct benefit to the subjects.

7. Procedures to Maintain Confidentiality

a) Describe the procedures in place which protect the privacy of the subjects and maintain the confidentiality of the data, as required by the federal regulations, if applicable.

Data will be stored on a password protected computer, and subjects will be assigned unique identifiers. Subject names and subject identifiers will only be associated on a testing log which will be stored in a locked laboratory room. Signed consents will similarly be stored in a locked laboratory room.

b) If information derived from the study will be provided to a government agency, or any other person or group, describe to whom the information will be given and the nature of the information.

NA

c) Specify where and under what conditions study data will be kept, how specimens will be labeled and stored (if applicable), who has access to the data and specimens, and what will be available to whom.

Data will be stored on a password protected computers housed in the Linguistics department (Integrative Learning Center) that are only accessible to the primary investigator or his assistants (all of whom have received CITI training in human subjects research).

8. Potential Conflict of Interest

| a) | N | Do any of the involved investigators or their immediate family (as described below) have consulting arrangements, management responsibilities or equity holdings in the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)? |
|----|---|---|
| b) | N | Do any investigators or their immediate family have any financial relationship with the Sponsoring company, including the receipt of honoraria, income, or stock/stock options as payment? |
| c) | N | Is any Investigator(s) a member of an advisory board with the Sponsoring company? |
| d) | N | Do any investigators receive gift funds from the Sponsoring company? |
| e) | N | Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property utilized in this protocol? |

"Immediate family" means a spouse, dependent children as defined by the IRS, or a domestic partner.

If one or more of the above relationships exist, please include a statement in the consent form to disclose this relationship. i.e., a paid consultant, a paid member of the Scientific Advisory Board, has stock or stock options, or receives payment for lectures given on behalf of the sponsor. The consent form should disclose what institution(s) or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment.

If you answer yes to any of the questions above, please go to the policies for more information.

9. Informed Consent

You can add different Consent Forms, Alteration Forms, and Waivers. Provide consent process background information, in the table below, for each Consent Form(s), Alteration Form(s), and Waiver(s).

9.1 Consent Form consent form 2016

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.

CITI trained researchers will obtain consent.

How is consent being obtained?

Written consent will be obtained.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?

All participants are undergraduates at UMass Amherst, and are presumed competent.

9.2 Consent Form stamped 03/22/16

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.

How is consent being obtained?

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?

10. Assent Background

All minors must provide an affirmative consent to participate by signing a simplified assent form, unless the Investigator(s) provides evidence to the IRB that the minor subjects are not capable of assenting because of age, maturity, psychological state, or other factors.

11. Attachments

| Document Type | Document Name | Attached Date |
|---------------|--|---------------|
| Other | Dillon, Brian Lab Personnel Form Link - Google Docs | 07/29/2015 |
| Other | Experimental Stimuli | 03/16/2016 |
| Other | ROC_Debrief | 03/19/2016 |

Obligations

Obligations of the Principal Investigator are: Modifications - Changes in any aspect of the study (for example, project design, procedures, consent forms, advertising materials, additional key personnel or subject population) will be submitted to the IRB for approval before instituting the changes; Consent Forms - All subjects will be given a copy of the signed consent form. Investigators will be required to retain signed consent documents for six (6) years after close of the grant or three (3) years if unfunded; Training - Human subject training certificates, including those

for any newly added personnel, will be provided for all key personnel;

Adverse Events - All adverse events occurring in the course of the protocol will be reported to the IRB as soon as possible, but not later than ten (10) working days; Continuing Review - IRB Protocol Report Forms will be submitted annually at least two weeks prior to expiration, six weeks for protocols that require full review; Completion Report - The IRB will be notified when the study is complete. To do this, complete the IRB Protocol Report Form and select "Final Report."

Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel;

Adverse Events/Unanticipated Problems - All events occurring in the course of the protocol will be reported to the IRB as soon as possible, but not later than five (5) working days;

Continuing Review - IRB Protocol Report Forms will be submitted annually at least two weeks prior to expiration, six weeks for protocols that require full review;

Completion Report - The IRB will be notified when the study is complete. To do this, complete the IRB Protocol Report Form and select "Final Report."

Y The Principal Investigator has read and agrees to abide by the above obligations.