Human Participant Ethics Protocol Submission

CONFIDENTIAL

0 - Identification

RIS Human Protocol Number

Protocol Title
INPUT YOUR TITLE

Protocol Type
Investigator Submission

Applicant Information

Applicant Name
Prof Morgan Barense

Rank / Position	**Department / Faculty**
Assoc Professor	Dept of Psychology - Faculty of Arts & Science
Business Telephone	**Extension**
416-978-5429	

Email Address
barense@psych.utoronto.ca

Collaborators/Co-Investigators

Name	Department	Email	Phone	Designation	Alt Contact

Projected Project Dates

Estimated Start Date

Estimated End Date

1 - History of the Protocol

A Protocol has been recently closed which is similar to this application or this application will replace ☐

2 - Location

Location of the Research: ☒ University of Toronto ☐ Other Locations

Administrative Approval/Consent

Administrative Approval/Consent Needed: ○ Yes ○ No

Community Based Particatory Research Project? ○ Yes ○ No

Other Ethic Boards Approval(s)

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Another Institution or Site involved? ◯ Yes ◯ No

3 - Agreements and Reviews

Funding

Project Funded? ◯ Yes ◯ No

Agreements

Funding/non-funding Agreement in Place? ◯ Yes ◯ No

Any Team Member Declared Conflict of Interest? ◯ Yes ◯ No

Reviews

☐ This research has gone under scholarly review by thesis committee, departmental review committee, peer review committee, or some other equivalent

☐ This research will go under scholarly review prior to funding

☐ This review will not go under a scholarly review

4 - Potential Conflicts

Conflict of Interest

Will researchers, research team members, or immediate family members receive any personal benefit? ◯ Yes ◯ No

Restrictions on Information

Are there any restrictions regarding access to, or disclosure of information (during or after closure)? ◯ Yes ◯ No

Researcher Relationships

Are there any pre-existing relationships between the researchers and the researched? ◯ Yes ◯ No

Collaborative Decision Making

Is this a community based project - i.e.: a collaboration between the university and a community group? ◯ Yes ◯ No

5 - Project Details

Summary

Rationale

Describe the purpose and scholarly rationale for the project

PROVIDE A RATIONALE FOR YOUR PROPOSED RESEARCH.

Methods

Describe formal/informal procedures to be used

INCLUDE A LIST OF EXPERIMENTAL CONDITIONS, AS WELL AS BEHAVIOURAL DATA THAT MAY BE COLLECTED.

ALL PROTOCOLS MUST INCLUDE THE FOLLOWING TEXT:

The subject will be asked to lie on a long narrow table for up to two hours while the MRI system gathers information. During this time, she/he will be exposed to a magnetic field and radiofrequency. She/he will hear repetitive tapping noises and will be required to wear earplugs or earphones to reduce the noise.

Our scans are not clinical and are not intended for diagnostic or therapeutic purposes. There is a possibility, however, that the MRI technologist could observe

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suspicious abnormalities (e.g. cyst, tumour, and tissue damage caused by a stroke) in the structural scans. In this case, the MRI images will be sent to a neuroradiologist for blind review. In the event the neuroradiologist detects an abnormality, the Center staff will contact the participants.

INCLUDE IF YOU WISH TO USE EYETRACKING:

We may monitor subjects' eye fixation/movement during the experiment. The eye tracker uses a small video camera to record an image of the eyes and reports to the experimenter a continuous stream of numbers that indicates eye position. To make the eye visible to the camera in the dark, a small infrared light is used to illuminate the eye. Infrared is invisible to human eyes, so the subject will not see the light. The power of this light is a tenth below the safety standard for chronic exposure for human eyes. However, because infrared light can increase the evaporation rate of tears, it may result in a dryness sensation (the same dryness sensation when you first move to a place with a dry climate). Blinking will eliminate the dryness sensation. Alternatively, the subject may need to use eye drops.

Copies of questionnaires, interview guided and/or other instruments used

Document Title	Document Date
Not Applicable	

Clinical Trials

Is this a clinical trial? ○ Yes ◉ No

6 - Participants and Data

Participants and/or Data

What is the anticipated sample size of number of participants in the study? 0

Describe the participants to be recruited, or the individuals about whom personally identifiable information will be collected. List the inclusion and exclusion criteria. Where the research involves extraction or collection personally identifiable information, please describe where the information will be obtained, what it will include, and how permission to access said information is being sought.

ALL PROTOCOLS MUST INCLUDE THE FOLLOWING TEXT:

Participants will be subjected to MR screening conditions, as defined in the MRI screening form (Appendix B) and Toronto Neuroimaging Facility Protocol (Appendix D). Critically, participants will not have any metal implant or metal object in his or her body and should not be pregnant.

INCLUDE INFORMATION ABOUT YOUR PLANNED ANNUAL SAMPLE SIZE. PROVIDE INFORMATION ABOUT YOUR POPULATION BELOW, FOR EXAMPLE:

"Any healthy adult person (over 19 years old) with no history of neurological or psychiatric disease can participate in this project." OR "Participants will be restricted to right-handed individuals and participants under 35 years of age because handedness and aging have well-established impacts on brain organization."

Is there any group or individual-level vulnerability related to the research that needs to be mitigated (for example, difficulty understanding consent, history of exploitation by researchers, or power differential between the researcher and the potential participant)? ○ Yes ○ No

Recruitment

Is there recruitment of participant? ◉ Yes ○ No

Recruitment details including how, from where, and by whom

EXAMPLE TEXT:

We will be recruiting healthy adults from the UofT community. Potential participants will be recruited either in answer to the enclosed flyer (Appendix C), or through research participant pools for which potential participants have registered [list the pools you use, including ToNI's participant database, lab specific databases, subject pools, the adult volunteer pool, child's study center pool, and student participants pools]. Recruitment flyers will be posted around the University of Toronto St. George Campus on public bulletin boards.

ATTACH A COPY OF ALL POSTERS, ADVERTISEMENTS, FLYERS, LETTERS, E-MAIL TEXT, OR TELEPHONE SCRIPTS TO BE USED FOR RECRUITMENT AS APPENDICES.

Is participant observation used? ○ Yes ◉ No

Will translation materials be used/required? ○ Yes ○ No

Attach copies of all recruitment posters, flyers, letters, email text, or telephone scripts

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Document Title	Document Date
Not Applicable	

Compensation

Will the participants receive compensation? (•) Yes ( ) No

Type of Compensation

☒ Financial

☐ In-kind

☒ Other

Compensation Justification Details

EXAMPLE TEXT:

Participants will receive $20 per hour for their participation. This is a standard compensation for participation in fMRI studies.

Some participants may be laboratory personnel who freely volunteer to participate in the design phase of their own or other team members' experiments, specifically in the adaptation of cognitive tasks for the MRI environment. The total number of sessions will vary by experiment, but we anticipate that each experiment may require 2-3 pilot sessions. Each session would not need to be performed by the same lab member. We anticipate that advanced lab members (e.g. graduate students and postdocs) may pilot an experiment every 1-2 years. Lab members who volunteer may thus be involved in piloting roughly 0-3 sessions per year. Opportunities to participate in this fashion will be broadly communicated within the lab and no individual will be asked directly. Opportunities will only be communicated laterally (e.g. amongst graduate students or amongst postdocs) or from trainees at earlier stages in their career to later stages (e.g. grad student to postdocs). The principal investigator will never request that individuals take part in this process.

Is there a withdrawal clause in the research procedure? (•) Yes ( ) No

Is compensation affected when a participant withdraws?

Compensation will not be affected if participants choose to withdraw from the study at any point after arriving for the study.

7 - Investigator Experience

Investigator Experience with this type of research

Please provide a brief description of the previous experience for this type of research by the applicant, the research team, and any persons who will have direct contact with the applicants. If there is no previous experience, how will the applicant and research team be prepared?

INCLUDE DETAILS ABOUT PI AND RESEARCH TEAM EXPERIENCE WITH MR RESEARCH. IF INEXPERIENCED PERSONNEL WILL BE INVOLVED IN THE RESEARCH (E.G. NEW GRADUATE STUDENTS) INCLUDE THIS TEXT:

For those individuals who have not had previous experience (e.g. graduate students or research assistants), training will be provided by the principal investigator and/or experienced researchers and personnel. This will involve going through the relevant testing procedures, initial assistance in participant recruitment, and sitting in on neuroimaging sessions until the inexperienced research team member is sufficiently confident and skilled to conduct data acquisition sessions.

Are community members collecting and/or analyzing data? ( ) Yes ( ) No

8 - Possible Risks and Benefits

Possible Risks

Potential Risk Details:

Physical Risks	(•) Yes	( ) No
Psychological/emotional Risks	( ) Yes	(•) No
Social Risk	( ) Yes	(•) No
Legal Risk	( ) Yes	(•) No

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Risk Description

There are risks associated with MRI scanners if metal objects enter the scanner room. This includes biomedical devices such as pacemakers and aneurysm clips, prostheses, and other metallic objects embedded in the body such as bullets, shrapnel, and any metal fragments from working around metal. All other metallic objects must also be removed from the subject prior to entering the magnet room to prevent them from becoming a projectile or being pulled by the magnet. Full subject screening and removal of metal objects prior to scanning will alleviate these risks.
The effects of the scan on a fetus are unknown and, therefore, we will not perform the examination during pregnancy.

The magnitude of temperature increase during MRI scanning is minimal and within FDA guidelines. The MRI scanner has in place a means to ensure that energy deposition is sufficiently low to stay well within these guidelines for temperature increases. Additionally, in rare cases, contact with the conductive materials such as wires or other metallic objects, or skin-to-skin contact that forms conductive loops may result in excessive heating and burns during the experiment. The operators of the MRI scanner will take steps, such as using foam pads when necessary, to minimize this risk. Tattoos with metallic inks can also potentially cause burns. The risk of these burns will be minimized by instructing participants to immediately report any heating or burning sensations during a scan in progress. The experimenters will terminate the session if participants report any of these sensations.

Other potential discomforts (claustrophobia due to the confined MRI environment, back pain due to the need for participants to lie still, loud noise from the scanner) will be minimized using standard procedures: (1) appropriate subject screening; (2) maintaining constant contact with the participant during scanning in order to make them more comfortable or to stop the scan if required in the event of significant discomfort; (3) the use of ear plugs and noise attenuating headphones.

INCLUDE ONLY IF YOU PLAN ON USING EYE TRACKING IN YOUR RESEARCH:

When the eye-tracker system is used, another concern is associated with the infrared light. The infrared light is emitted from the eye tracker at very low amperage (class 1 laser) and causes no damage to the eye. However, it might cause discomfort due to creating dryness sensation in the eyes. We will instruct the participant to blink to eliminate the dryness sensation. If the participant still feels uncomfortable, the usage of the eye-tracking system will be terminated.

Potential Benefits

Benefit Description

There are no guaranteed benefits from participation.

9 - Consent

Consent Process Details

A copy of the consent form will be provided to the participant. During the consent process, every section of the consent form will be carefully reviewed with the participant of the study by one of the study personnel. The risks and benefits will be explained and an emphasis will be placed that the study is STRICTLY voluntary and they may withdraw at any time without further explanation. Upon completion of the review, the study personnel will then ask the participant if they need any clarification, or have any questions. If the participant requires further discussion with others, a copy of the consent form will be provided to the participant whereby they are allowed to take it with them and review it with others prior to signing.

All personnel involved in the project have substantial experience acquiring MRI data from participants. All testers will be well-trained by the time they begin collecting data.

Uploaded letter/consent form(s)

Document Title	Document Date
Not Applicable	

Is there additional documentation regarding consent such as screening materials, introductory letters etc.: ◯ Yes ◯ No

Uploaded letter/consent form(s)

Will any information collected in the screening process - prior to full informed consent to participate in the study - be retained for those who are later excluded or refuse to participate in the study? ◯ Yes ◯ No

Is the research taking place within a community or organization which requires formal consent be sought prior to the involvement of the individual participants ◯ Yes ◯ No

Are any participants not capable (e.g.: children) of giving competent consent? ◯ Yes ◯ No

10 - Debriefing and Dissemination

DeBrief

Will deception or intentional non disclosure be used? ◯ Yes ◯ No

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Will a written debrief be used? ◯ Yes ◯ No

Do participants/communities have the right to withdraw their data following the debrief? ◯ Yes ◯ No

Information Feed Back Details following completion of a participants participation in the project

Participants will be told that that they can contact XXXXX if they wish to be informed of the results of the study after its completion. On doing so, participants will be provided with a brief summary of the results. XXXXX contact information will be on the consent form.

Procedural details which allow participants to withdraw from the project

Prior to beginning the experiment, participants will be informed both verbally and in writing that they have the right to withdraw from the study at any time with no penalty whatsoever. If a participant chooses to withdraw, he or she may immediately discontinue the task. The participant will then be fully compensated and given a complete debriefing.

☐ Not Applicable

What happens to a participants data and any known consequences related to the removal of said participant

Incomplete data from a participant who withdraws will be destroyed. There will be no consequences from withdrawing for the participant.

☐ Not Applicable

List reasons why a participant can not withdraw from the project (either at all or after a certain period of time)

☒ Not Applicable

11 - Confidentiality and Privacy

Confidentiality

Is the data confidential? ◉ Yes ◯ No

Will the confidentiality of the participants and/or informants be protected? ◉ Yes ◯ No

List confidentiality protection procedures

Each participant will be assigned to a unique ID number. All data will be identified by the ID numbers only, and stored digitally. Only the individual investigators can link subject name and ID. For all scientific uses, the data will be displayed without identifying information. Further, the data will only be viewable using special purpose computer hardware and software, so that unauthorized viewing of the data will be complicated. Data will be archived in digital form and stored in a locked office and on a password protected and encrypted file server. Consent forms will be kept confidentially in a secured cabinet in a locked office. Paper score sheets will not identify participants by name, only by participant ID number.

INCLUDE ADDITIONAL DETAILS IF NEEDED.

Are there any limitations on the protection of participant confidentiality? ◯ Yes ◯ No

Is participant anonymity/confidentiality not applicable to this research project? ◯ Yes ◯ No

Data Protection

Describe how the data (including written records, video/audio recordings, artifacts and questionnaires) will be protected during the conduct of the research and subsequent dissemination of results

Imaging data and digitally transcribed behavioral data will be archived on a password protected secure file system and kept indefinitely. Consent forms and MRI screening forms will be stored securely in a locked filing cabinet for up to three years beyond the completion of the study.

INCLUDE DETAILS ABOUT BEHAVIOURAL DATA AND HOW IT WILL BE STORED.

DESCRIBE HOW PAPERWORK WITH IDENTIFYING INFORMATION WILL BE STORED, FOR EXAMPLE:

Any other physical paperwork containing identifying information, demographic information and/or pre-screening information will be converted to an anonymized and secure digital format, and original sheets will be destroyed within 3 days of original data capture.

Explain for how long, where and what format (identifiable, de-identified) data will be retained. Provide details of their destruction and/or continued storage. Provide a justification if you intend to store identifiable data for an indefinite length of time. If regulatory requirements for data retention exists, please explain.

EXAMPLE STORAGE POLICY:

Imaging data and digitally transcribed behavioral data will be kept indefinitely in anonymized form. This time will allow the researchers to revisit the data in the

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future if necessary should future research necessitate a reanalysis of the data. All participants will be informed that any data collected from them will be anonymized and stored securely. Consent forms and MRI screening forms will be securely maintained in physical form for up to three years beyond the date of the completion of the study, for compliance with Canadian and US research regulations. Physical paper containing identifying information, demographic information and/or pre-screening information will be converted to an anonymized and secure digital format, and original sheets will be destroyed within 3 days of original data capture.

Will the data be shared with other researchers or users? (•) Yes ( ) No

Please describe how and where the data will be stored and any restrictions that will be made regarding access.How will participant consent be obtained? If data is to be made open access, please describe how and where they will be maintained.

Participants will be asked if they authorize the MRI facility to use their data in future research within the MRI research facility in the Department of Psychology. If they consent to this data sharing, de-identified MRI data files (files that are anonymous and which cannot be linked back to the participant in any way) will be made available to other researchers within the facility. These files will only be made available to researchers who are affiliated with the scanning facility and the files will be stored on password protected secure files systems.

12 - Level of Risk and Research Ethics Board

Level of Risk for the Project

Group Vulnerability: Low

Research Risk: Low

Risk Level: 1

Explanation/Justification

Explanation/Justification detail for the group vulnerabilty and research risk listed above

The group vulnerability is low because participants will be healthy adults from the UofT community, and this group is not considered to be vulnerable.

We will ensure that research risk is low by following MRI safety protocols. These protocols are described in detail in Appendix D. To briefly summarize:

1. We will screen the participant before the MRI scan to guarantee there are no metal objects within the participant and that the participant is not claustrophobic or pregnant. This screening process will mitigate the risk of physical harm that could be caused by metal implants or metal projectiles, as well as discomfort caused by claustrophobia and the unknown consequences of MRI on the unborn fetus.

2. We will maintain constant contact with the participant during the MRI scan and will terminate the session in the event of significant discomfort. This will minimize the chance of physical discomfort and tissue heating.

3. We will use ear protection to reduce the MRI acoustic noise.

4. We will use foam pads and cushions to make the participant more comfortable and minimize the risk of burning.

Research Ethics Board

REB Associated with this project: Social Sciences, Humanities & Education

13 - Application Documents Summary

Uploaded Documents

Document Title	Document Date

14 - Applicant Undertaking

I confirm that I am aware of, understand, and will comply with all relevant laws governing the collection and use of personal identifiable information is research. I understand that for research involving extraction or collection of personally identifiable information, provincial, federal, and/or international laws may apply and that any apparent mishandling of said personally identifiable information, must be reported to the office of research ethics.

As the Principal Investigator of the project, I confirm that I will ensure that all procedures performed in accordance with all relevant university, provincial, national, and/or international policies and regulations that govern research with human participants. I understand that if there is any significant deviation in the project as originally approved, I must submit an amendment to the Research Ethics Board for approval prior to implementing any change.

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☐ I have read and agree to the above conditions

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